Reference Manual

BECKMAN COULTER DxC 700 AU

For *In Vitro* Diagnostic Use

CE

B71496AE
April 2021

Beckman Coulter, Inc.
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BECKMAN COULTER

Reference Manual
BECKMAN COULTER DxC 700 AU
PN B71496AE (April 2021)

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EC REP

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Rx Only
Original Instructions

Revision History

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.

B71496AE, 04/2021

Software version 1.0

This document was created to:

- Update the Test Volume and Methods: General Tab section.

B71496AD, 04/2019

Software version 1.0

This document was created to:

- Update Key Sub-Processes section.
- Update Common Test Parameters Menu section.
- Update Misc. Menu section.
- Update Lipemia, Icterus, and Hemolysis (LIH) section.
- Update Cautions with Cups or Tubes Specifications section.
- Update Display Reaction Monitor section.

B71496AC, 06/2018

Software version 1.0

- This document was created to document the changes in the software that enable the whole blood HbA1c testing function.
- Updated the minimum test volume only for Japan in System Monitoring and Results > Display Reaction Monitor. Changed it to a footnote:
- Replaced the following terms:
  - *[Test Order STAT]* with *[STAT Test Order]*
  - *alarm* with *event*
  - *STAT Start* with *Start STAT*
  - *Addition of User* with *Add User*
  - *Register user list* with *List of Registered Users*
  - *Send to LIS Stop* with *Stop Sending to LIS*
  - *Result Transfer* with *Analysis Results Transfer Mode*
  - *Data Not Transferred to LIS, Data Not Printed with Data Not Yet Transferred* with *LIS, Data Not Yet Printed*
  - *QC materials* with *control materials*

- Updated the Bar Code Operation, Input Notes in Table 2.19 Calibrators Tab Description.

B71496AB, 03/2017

Software version 1.0

This document was created to add the CE mark to the title page.

Initial Issue, B71496AA, 12/2016

Software version 1.0

Warranty

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter, and at the customer's expense.

Warranty

Contents

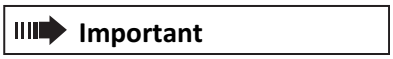
Safety Notice

Read all product manuals and consult with Beckman Coulter-trained personnel before you operate the system. Do not perform any procedure before you carefully read all instructions. Always follow the product labels and the recommendation from the manufacturer. For more information, contact Beckman Coulter.

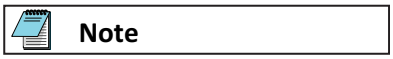
Alerts for Warning, Caution, Important, Note, and Tip

Warning indicates a potentially hazardous situation which, if not avoided, could cause death or serious injury. Warning can indicate the possibility of erroneous data that could cause an incorrect diagnosis.

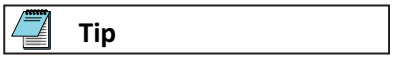
Caution indicates a potentially hazardous situation which, if not avoided, can cause minor or moderate injury. Caution can also alert against unsafe practices, or indicate the possibility of erroneous data that could cause an incorrect diagnosis.



Important indicates important information to follow.



Note indicates notable information to follow.



Tip indicates information to consider.

Use Statement

- The system is for indoor use only.
- Use the system in a manner specified by Beckman Coulter, as the protection provided by the system can be impaired and incorrect results or system failure can occur.

Notice to Users

- In the unlikely event that a serious incident occurs with this product, we will notify the users and the administrative authorities of the country in writing.
- If a user discovers a serious incident, the user should contact a Beckman Coulter Representative.

Symbols Glossary

Table 1 Symbols Glossary

Symbol	Description
CE	**CE Marking** This symbol indicates conformity with the provisions of the applicable EU directives.
C SA® US	**cNRTLus Certification Mark** This symbol indicates recognition by a Nationally Recognized Testing Laboratory (NRTL) that the system has met the relevant product safety standards for the United States and Canada. *OSHA, CEC*
Made in *Country of Origin*	**Country of Origin Symbol** This symbol indicates the country that the product was manufactured in.
	**Moving Parts Symbol** This symbol indicates that there are moving parts in the area. Only operate the system when all covers are in position and use caution to reduce the risk of personal injury. While the system is operating, do not touch the moving parts of the system. Do not insert fingers or hands into any system opening.
	**Warning; Crushing of hands** This symbol indicates a warning of a closing motion of mechanical parts of equipment. *ISO 7010. Graphical Symbols for electrical equipment in medical practices. #W024* **Supplemental Product-Specific Manufacturer Information** Use caution to avoid injury to hands when close to equipment with moving mechanical parts.
	**RCM Symbol** This symbol indicates compliance with the Australian Communications Media Authority (ACMA) requirements (safety and EMC) for Australia and New Zealand.

Table 1 Symbols Glossary (Continued)

Symbol	Description
	**RoHS Caution Symbol** This symbol indicates that this electronic information product contains certain toxic or hazardous elements, and can be used safely during its environmental protection use period. The number in the middle of the logo indicates the environmental protection use period (in years) for the product. The outer circle indicates that the product can be recycled. The logo also signifies that the product should be recycled immediately after its environmental protection use period has expired. The date on the label indicates the date of manufacture. These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 *Marking for Control of Pollution Caused by Electronic Information Products* requirements.
	**RoHS Environmental Symbol** This symbol indicates that the product does not contain any toxic or hazardous substances or elements. The *e* stands for electrical, electronic, and environmental electronic information products. This symbol indicates that this electronic information product does not contain any toxic or hazardous substances or elements, and is green and is environmental. The outer circle indicates that the product can be recycled. The symbol also indicates that the product can be recycled after being discarded, and should not be casually discarded.
	**RxOnly Symbol** This symbol is recognized by the US FDA as an alternative to the following statement: Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner. *21 CFR 801.109(b)(1)*

Table 1 Symbols Glossary (Continued)

Symbol	Description
	**Recycling Symbol** This symbol is required by the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. This symbol indicates that: 1. The device was put on the European Market after August 13, 2005. 2. The device is not to be disposed of via the municipal waste collection system of any member state of the European Union. Customers must understand and follow all laws regarding the correct decontamination and safe disposal of electrical equipment. For Beckman Coulter products bearing this label, contact your dealer or your local Beckman Coulter Representative for more information on the take-back program that facilitates the correct collection, treatment, recovery, recycling, and safe disposal of these products. *EU Directive 2002-96-EC: waste electrical and electronic equipment (WEEE)* For the Japan market: This system is considered an industrial waste, subject to special controls for infectious waste. Before disposal of the system, refer to the *Waste Disposal and Public Cleaning Law* for compliance procedures.
	**"ON" (power)** This symbol indicates connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5007* **Supplemental Product-Specific Manufacturer Information** This symbol indicates the on position.
	**"ON"/"OFF" (push-push)** This symbol indicates connection to or disconnection from the mains. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5010* **Supplemental Product-Specific Manufacturer Information** This symbol can also indicate a switch that is used as an on and off switch, without disconnecting power.

Table 1 Symbols Glossary (Continued)

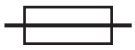
Symbol	Description
	**"ON" for a part of equipment** This symbol indicates the On condition for a part of equipment. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5264* **Supplemental Product-Specific Manufacturer Information** This symbol can also indicate on or reset conditions.
	**Stop** This symbol indicates the control or the indicator to stop the active function. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5110A* **Supplemental Product-Specific Manufacturer Information** This symbol indicates a stop button.
	**"OFF" (power)** This symbol indicates disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5008* **Supplemental Product-Specific Manufacturer Information** This symbol indicates the off position.
	**Fuse** This symbol indicates fuse boxes or their location. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5016* **Supplemental Product-Specific Manufacturer Information** This symbol can also indicate a fuse location and rating.
	**Dangerous voltage** This symbol indicates hazards arising from dangerous voltages. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5036* **Supplemental Product-Specific Manufacturer Information** This symbol can also indicate an area of the system to not access under any circumstances, due to possibility of high voltages and the risk of electrical shock.

Table 1 Symbols Glossary (Continued)

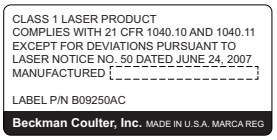
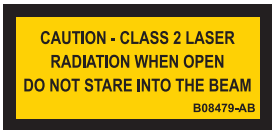
Symbol	Description
	**Protective earth; protective ground** This symbol indicates a terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode. *IEC 60417: Graphical symbols for use on equipment - Overview and application, #5019*
	**Warning, Hot Surface** This symbol indicates a warning of a hot surface. *ISO 7010. Graphical Symbols – Safety colors and safety signs. #W017* **Supplemental Product-Specific Manufacturer Information** This symbol indicates that there is a hot surface or component (such as a lamp) in the area that, if touched, can cause a burn.
	**Laser Compliance** This symbol indicates that the product is a Class 1 Laser Product and is in compliance with international standard and US requirements. *21 CFR 1040*
	**Laser Class 2 Panel Label** This symbol on a panel indicates that there is Class 2 laser light radiation beyond the panel it is placed on. Use caution and do not stare into the beam when laser light is in the area. *IEC 60825: Safety of laser products - Part 1: Equipment classification and requirements, clause 7.4*
	**Manufacturer** This symbol indicates the medical device manufacturer. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.1* **Supplemental Product-Specific Manufacturer Information** This symbol indicates who the legal manufacturer of the product is.
	**Authorised representative in the European Community** This symbol indicates the authorized representative in the European community. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.2*

Table 1 Symbols Glossary (Continued)

Symbol	Description
	**Catalogue Number** This symbol indicates the manufacturer's catalogue number so that the medical device can be identified. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.6*
	**In vitro diagnostic medical device** This symbol indicates a medical device that is intended to be used as an in vitro diagnostic medical device. *ISO 15223-1: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements, clause 5.5.1*
	**Caution** This symbol indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.4.4*
	**Warning; Biological hazard** This symbol indicates a warning of a biological hazard. *ISO 7010. Graphical Symbols - Safety colors and safety signs. #W009* **Supplemental Product-Specific Manufacturer Information** This symbol indicates a caution to operate only with all covers in position to decrease risk of personal injury or biohazard. This symbol indicates the use of biohazardous materials in the area. Use caution when working with possible infectious samples. Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats. Handle and dispose of biohazardous materials according to your laboratory procedures.
	**Consult instructions for use** This symbol indicates the need for the user to consult the instructions for use. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.4.3*

Table 1 Symbols Glossary (Continued)

Symbol	Description
	**Date of Manufacture** This symbol indicates the date when the medical device was manufactured. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.3*
	**Serial number** This symbol indicates the manufacturer's serial number so that a specific medical device can be identified. *ISO 15223-1. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements. #5.1.7*
	**Warning; Laser Beam** This symbol indicates a warning of a laser beam. *ISO 7010. Graphical Symbols - Safety colors and safety signs. #W004* **Supplemental Product-Specific Manufacturer Information** This symbol indicates that there can be laser light radiation in the area. Take precautions to prevent exposure.
	**California Proposition 65** This symbol indicates that this product can expose you to chemicals known to the State of California to cause Cancer and Reproductive Harm. For more information go to https://www.P65Warnings.ca.gov.

Summary of Hazards

This section describes the possible hazards of the system. The hazards of individual procedures in this manual are included in the warnings or cautions within the instructions. Read this section before you operate this system.

Follow the power requirements in the system specifications. Follow the procedures and safety warnings throughout this manual.

If you use the system in a manner not specified by Beckman Coulter, the protection provided by the system can be impaired and incorrect results or system failure can occur.

Bar Code Reader

Do not adjust or remove the housing of any bar code reader. The bar code readers use lasers and looking directly at the laser light can be hazardous. Assume that the laser is always on.

Use of control or adjustments or performance of procedures other than these specified herein may result in hazardous radiation exposure.

Biohazardous and Chemical Materials

Observe all biohazard precautions when doing maintenance, service, or troubleshooting on the system. Biohazard precautions include, but are not limited to, wearing gloves, eye shields, and lab coats, and washing hands after working on contaminated portions of the system.

Follow all laboratory procedures and policies for handling infectious and pathogenic materials.

Avoid skin contact with reagents and other chemical preparations. Wear Personal Protective Equipment (PPE) to work with reagents and other chemical preparations used with the system. For more information, refer to the related SDS (Safety Data Sheet).

Clean spills of biohazardous or other potentially hazardous substances on the system immediately. If the system must be decontaminated, contact Beckman Coulter.

Follow your laboratory procedure for biohazardous and hazardous material disposal.

Electric Shock

Do not replace or service any components where you can contact hazardous parts that can cause electric shock. Beckman Coulter must perform this maintenance. To completely power off the system, turn off the main breaker that is located on the left side of the analyzer module.

Electrical Ground

Never operate the system until the power cord is connected correctly to an electrical ground.

Electromagnetic Wave and Noise

The system generates, uses, and can radiate radio frequency energy. If the system is not installed and operated correctly, this energy can cause interference with other equipment. In addition, other equipment can radiate radio frequency energy to which the system is sensitive. If you suspect interference between the system and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- This IVD medical equipment complies with the emission and immunity requirements described in this part of the EN/IEC 61326 series.
- As to emission, this system has been designed and tested to CISPR 11 Class A, so in a domestic environment, it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
- It is recommended to evaluate the electromagnetic environment prior to operation of the system.
- Do not use this system in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources), as these can interfere with the proper operation.

- Do not use mobile or cordless telephones and transceivers in the same room as the system.
- Do not use medical equipment that can be susceptible to malfunctions caused by Electric Magnetic Field (EMF) near the system.

Flammable Materials

Do not use this system near flammable materials.

Moving Parts

While the system is in operation, do not touch or go close to any moving parts. Close protective guards and covers during operation. Failure to close covers correctly can cause injury or incorrect results.

Noise Level Generated by the Analyzer

60 dB

Liquid Waste

Handle all liquid waste as potentially infectious.

Some liquid waste can require special treatment before disposal. Follow your laboratory procedure.

Some substances in the reagents, control samples, calibrators, and wash solutions have disposal regulations. Follow your laboratory procedure.

Solid Waste

Handle all solid waste as potentially infectious.

Some solid waste can require special treatment before disposal. Follow your laboratory procedure.

Handle any used or replaced parts (such as tubing, mix bars, probes, cuvettes, and wash nozzles) as infectious waste materials. Follow your laboratory procedure.

DxC 700 AU Hazards

- A Beckman Coulter representative installs the system. If the system installation needs modification, contact Beckman Coulter.
- If the system malfunctions, power off the system completely using the main breaker located on the left side of the analyzer module before any repair service.
- If fluid is spilled on the system, turn off the main breaker located on the left side of the analyzer module immediately. Wipe up the spill only after turning off the main system breaker. If fluid enters the system after a spill, contact Beckman Coulter before restarting the system.

- Before transferring the analysis results to a Laboratory Information System, confirm that the sample numbers and sample IDs are correct.
- Substances such as Lipemia, Icterus, and Hemolysis can interfere with results. Refer to the reagent *Instructions for Use* (reagent IFU) for specific substance interference information.
- To be sure the analytical data is accurate:
  - Confirm the quality of deionized (DI) water is within specifications.
  - Confirm that all tests have passed calibration, and calibration is not expired.
  - Inspect the quality control data.
- Use the correct reagent, calibrator, and control to analyze samples.
- Avoid excessive reagent agitation, which can cause bubbles. If bubbles are visible on the surface of the reagent, remove them. Confirm that the reagent bottles are placed securely on the reagent tray with the correct adapters and partitions. If the bottles are tilted, incorrect results can occur, or you can damage the reagent probe.
- Prepare reagents, wash solutions, calibrators, and control samples according to the reagent IFU, paying particular attention to any reconstitution, mixing, and pretreatment instructions.
- Handling samples:
  - Precautions when using whole blood (HbA1c)
    - Use the HbA1c tab with the HbA1c reagent (for automated sample preparation) delivered from Beckman Coulter. Use of any other reagent can cause incorrect diagnostic results. Operation of the three tests 100.HbA1c, 101.T-Hb, and 102.A1c, and some of the specific test parameters are pre-programmed and you cannot change them.
    - If the blood has coagulated, obtain a new sample.
    - If the blood cells have precipitated, mix the whole blood by inverting gently.
  - Sample to sample carryover is one potential source of analytical error in the clinical laboratory. Do not use the same sample run on an AU Chemistry system for analysis of analytes for which a small quantity of carryover could cause problems with the results.
  - This system analyzes serum, urine, plasma, other sample types, and whole blood (for HbA1c only). Other refers to other body fluids such as cerebrospinal fluid (CSF). Some samples cannot be analyzed depending on the analysis test, reagent, and sample tubes used. For questions regarding reagent and sample tube type, contact Beckman Coulter.
  - Use serum or plasma that is clot free, or urine that is free from suspended matter. If serum or urine contains clots or suspended matter, the probe can clog and cause problems with the analysis results.
  - Chemicals present in the sample (medicine, anticoagulant, preservative, and so on) can significantly interfere with the results.
  - Highly viscous samples can interfere with the testing of the samples and the reliability of data.
  - Refer to the IFU for each test for correct sample collection and storage. Incorrect storage of samples can alter the analyte in a sample.
  - Use only sample containers and sample tubes specified by Beckman Coulter.
  - To reduce the risk of interference, centrifuge and then separate serum and plasma samples adequately from blood cells immediately. Before analysis, confirm that samples are free from suspended matter, such as fibrin. While the system has a sophisticated clot detection mechanism, this mechanism is not able to detect all clots. Carefully inspect the samples.

  - — Collect urine samples using correct preservatives and remove any suspended matter using centrifugation before analysis (CLSI GP16-A2).
  - — Confirm that any anticoagulants or collection devices that employ a barrier are compatible with the test reagent being used. Refer to the reagent *Instructions for Use* for suitable and validated sample types. Use caution when using sample tubes containing barriers or gels. Confirm the suitability of all collection devices in use.
  - — For information about whether a serum separating agent is correct or not, contact the chemical reagent manufacturer or distributor.
  - — When using sample containers or tubes containing a separating medium, confirm that there is enough serum to avoid contaminating or blocking the sample probe with the separating medium.
  - — Confirm that there is enough sample for correct sampling to occur. The small amount of wash water left on the sample probe can dilute the volume of sample left in the sample tube.
- To prevent water leaks, confirm that Beckman Coulter has fitted water supply and drainage hoses according to local guidelines.
- To confirm system performance, maintain and inspect the system periodically by replacing the parts according to the instructions in this guide.
  - — Have and follow a maintenance schedule for this system.
  - — Create a maintenance routine for the computer software and hardware, including frequent backing up of data containing analysis settings, results history, and the event log list file.
  - — Do not store backups onsite. Keep one copy on-site for reference and one copy offsite.
- Before using the system for the first time, set parameters for the reagent and sample quantity, measurement wavelength, calibrator values, and so on. Enter test specific parameters from the reagent setting sheet to have optimum system performance. Enter any updates to these settings into the system immediately.
- Dedicate the computer hardware to only running the system software. Do not connect the computer hardware to the Internet, unless instructed to do so by Beckman Coulter.
- Keep the analyzer covers closed except for startup procedures and maintenance. If the covers are open for extended periods of time, excess condensation can be generated in the reagent refrigerators and cause errors.
- Be sure all consumables are unopened before use. If the consumables appear to be opened or contaminated, contact Beckman Coulter.

Labels

- Stripes - Orange stripes affixed to the system surface indicate the movement areas of the hardware components. Avoid these areas during operation.
- Warning Labels - Identify areas of the system where hazards exist and where caution should be taken to avoid serious injury or death.
- Instruction Labels - Instruction labels are affixed on the system at relevant locations to alert the operator to operate the system correctly.

Fluorocarbons Recovery and Destruction Law Label

This system uses a Hydro FluoroCarbon (HFC) cooling medium.

HFC chemicals cannot be discharged indiscriminately. When the system is discarded, recover HFC chemicals.

The type, pressure, and volume of the HFC chemicals are described on the label.

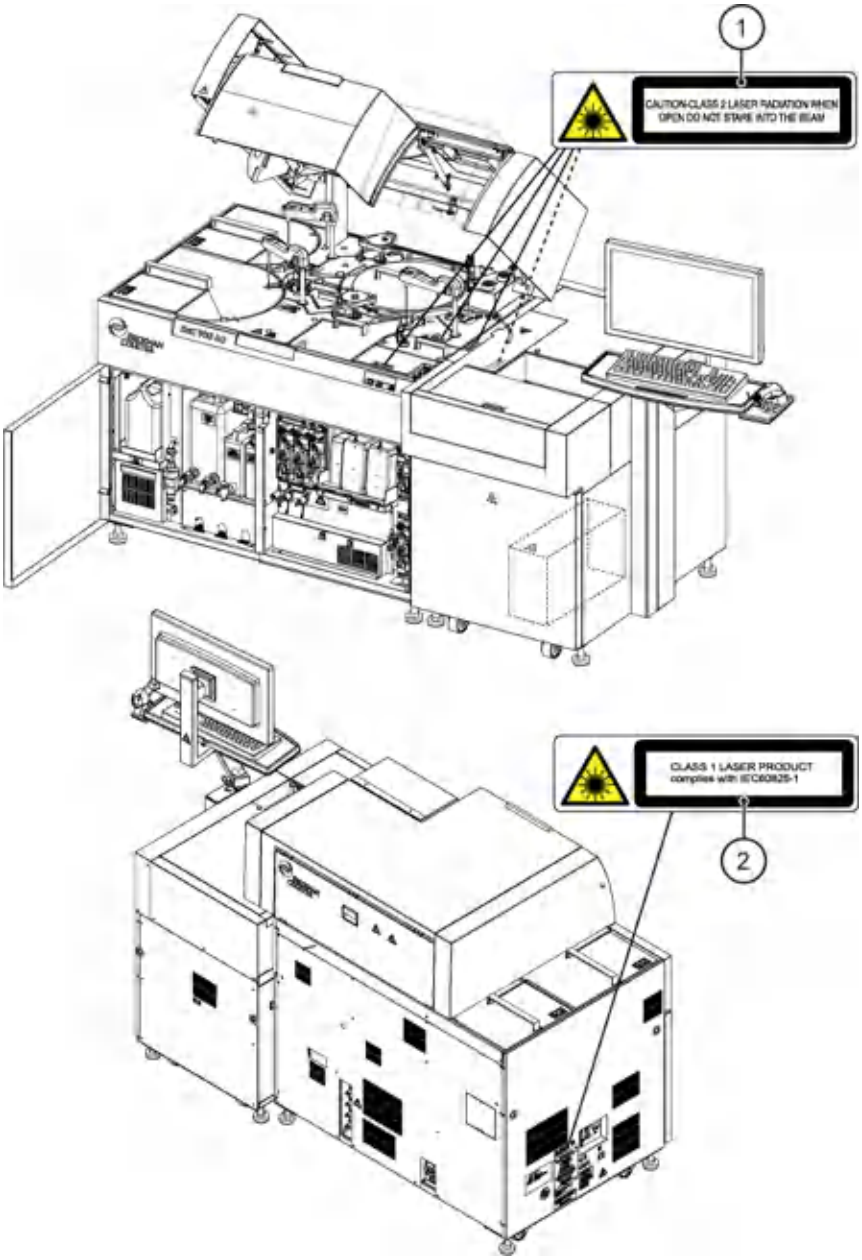
Restricted Use

- Samples and reagents: Refer to the reagent Instructions for Use used for measurement.
- Consumables: Refer to Chapter 6 *Maintenance* in this IFU.
- Computer Connectivity (LIS, Automation, Pro Services): Refer to *System Overview* > *Hardware Overview* > *Computers* section.

DxC 700 AU Laser Labels

This system complies with IEC60825-1 and is classified as a Class 1 laser product.

Figure 1 Laser Labels



1. CAUTION-CLASS 2 LASER RADIATION WHEN OPEN DO NOT STARE INTO THE BEAM
2. CLASS 1 LASER PRODUCT complies with IEC60825-1

CHAPTER 1

System Overview

Software Overview

Software Paths

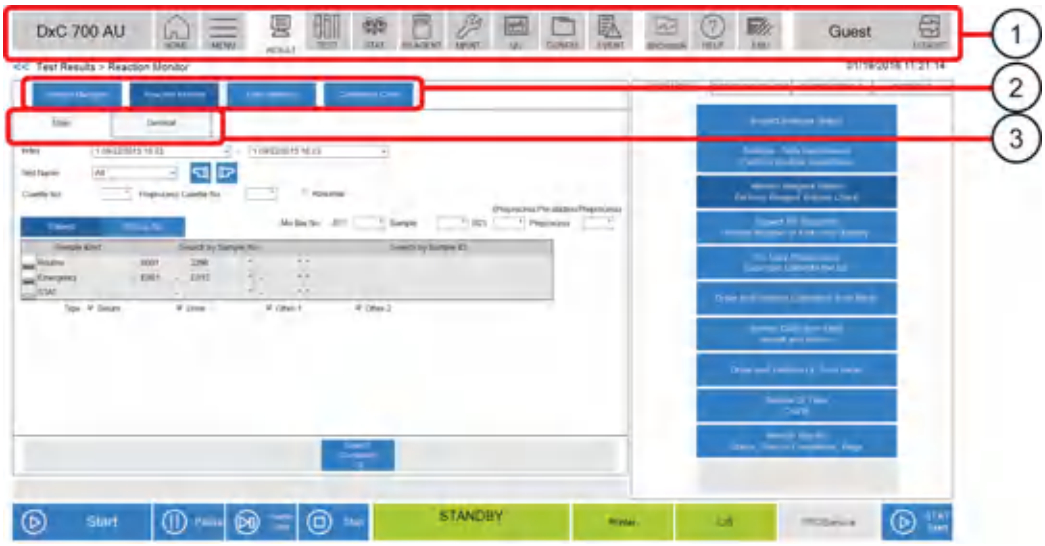
A software path signifies a sequence of options that you select in the software interface in the indicated order.

This manual expresses software paths in the following format:

Select **Navigation Button** > **Screen** > **Tab**.

For example, Figure 1.1 Software Paths shows the path **Test Results** > **Reaction Monitor** > **Main**.

Figure 1.1 Software Paths



1. Navigation buttons
2. Screen buttons
3. Tab buttons

Organization and Functional Outline of Test Results Menu

Use this menu to manage the test results.

Table 1.1 Test Results Menu Options

Navigation Button	Screen
RESULT	**Sample Status** View the status of the last 1,000 samples processed in the current index. Refer to the topic on the Sample Status screen in the *DxC 700 AU Instructions for Use*. Refer to Sample Status Screen.
	Detail View the results of the sample analysis in detail. Refer to the topic on the Sample Status screen in the *DxC 700 AU Instructions for Use*. Refer to Detail Screen.
	Realtime Display View the results of the sample analysis in real time. Refer to the topic on the Sample Status screen in the *DxC 700 AU Instructions for Use*. Refer to Realtime Display Screen.
	Sample Manager Display the Sample Manager screen. Refer to Sample Manager Screen.
	ISE Calibration Display the ISE Maintenance: Calibration tab (**MAINT.** > **ISE Maintenance** > **Calibration**). Refer to Organization and Functional Outline of Maintenance Menu.
RESULT > Sample Manager	**Sample Manager** Display analysis results, perform data correction, print data lists, and batch transfer data online. Refer to Sample Management.
	Reaction Monitor View information about reaction processes of analysis results. Refer to Display Reaction Monitor.

Table 1.1 Test Results Menu Options (Continued)

Navigation Button	Screen
	Data Statistics View key statistics of patient sample results and the results of a test within one index as bar charts. Refer to View Data Statistics.
	Correlation Chart View a correlation chart. Refer to Create a Correlation Chart.

Organization and Functional Outline of Sample Program Menu

Use this menu to order tests for samples from racks.

Table 1.2 Sample Program Menu Options

Navigation Button	Screen
TEST	**Rack (patient)** Order tests and demographics for patient samples manually. Refer to the topic on ordering for routine and emergency samples in the *DxC 700 AU Instructions for Use*. Refer to Rack (Patient) Screen.
	Rack (Calibration) Order tests for calibrators. Refer to the topic on ordering and performing calibration from the racks in *DxC 700 AU Instructions for Use*. Refer to Rack (Calibration) Screen.
	Rack (QC) Order tests for control samples. Refer to the topic on ordering and performing quality control (QC) from the racks in *DxC 700 AU Instructions for Use*. Refer to Rack (QC) Screen.

Organization and Functional Outline of STAT Menu

Use this menu to view the STAT status, order tests from the STAT table, and program the parameters for STAT table analysis.

Table 1.3 STAT Menu Options

Navigation Button	Screen
STAT	**STAT Status** View the status of the STAT table and start STAT sample analysis. Refer to the topic on priority STAT samples in the *DxC 700 AU Instructions for Use*. Refer to STAT Status Screen.
	STAT (Patient) Order tests and demographics manually for patient samples for STAT table analysis. Refer to the topic on entering manual orders for priority STAT samples in the *DxC 700 AU Instructions for Use*. Refer to STAT (Patient) Screen.
	STAT (Calibration) Order tests for calibrators for STAT table analysis. Refer to the topic on ordering and performing calibration from the STAT table in the *DxC 700 AU Instructions for Use*. Refer to STAT (Calibration) Screen.
	STAT (QC) Order tests for control samples for STAT table analysis. Refer to the topic on ordering and performing quality control (QC) from the STAT table in the *DxC 700 AU Instructions for Use*. Refer to STAT (QC) Screen.
	AUTO ACAL/QC Setup Program the parameters for automatic ACAL and QC on the STAT table. Refer to AUTO ACAL/QC Setup Screen.

Organization and Functional Outline of Reagent Menu

Use this menu to view the quantity of photometric and ISE tests onboard, monitor the status of photometric and ISE reagents onboard, confirm reagent volumes, and load reagents in *MEASURE* mode.

Table 1.4 Reagent Menu Options

Navigation Button	Screen
REAGENT	**Reagent Management** Inspect the quantity of reagent and the quantity of tests available in a bottle. Refer to Reagent Management.
	Reagent Inventory A calculation of the volume or tests of R1 and R2 (for each reagent) used for each day of the week for a specified timeframe. Refer to Reagent Inventory.
	Reagent Consumption A breakdown of reagent used for a specified timeframe by volume or tests of R1 and R2 by each rack type. Refer to Reagent Consumption.
	Rack (Calibration) Perform calibration orders for calibration analysis from racks. Refer to the topic on ordering and performing calibration from the racks in the *DxC 700 AU Instructions for Use*. Refer to Rack (Calibration) Screen.
	STAT (Calibration) Perform calibration orders for calibration analysis from the STAT table. Refer to the topic on ordering and performing calibration from the STAT table in the *DxC 700 AU Instructions for Use*. Refer to STAT (Calibration) Screen.

Organization and Functional Outline of Maintenance Menu

Use this menu to monitor and perform analyzer and ISE maintenance, save and load parameters, review the system software versions, and perform diagnostic functions.

Table 1.5 Maintenance Menu Options

Navigation Button	Screen
MAINT.	**Analyzer Maintenance** View the maintenance schedule and perform maintenance procedures. Refer to the topic on accessing maintenance operations in the *DxC 700 AU Instructions for Use*. Refer to Analyzer Maintenance Screen.
	ISE Maintenance View the maintenance schedule of the ISE module and perform ISE maintenance procedures. Refer to the topics on ISE maintenance in the *DxC 700 AU Instructions for Use*. Refer to ISE Maintenance Screen.
	File Management Save and load parameters to internal hard disk or external memory media. For more information, refer to Save or Load Parameters.
	Version Information View the system software versions. Refer to Version Information Screen.

Organization and Functional Outline of Quality Control Menu

Use this menu to display and edit the results and history for quality control.

Table 1.6 Quality Control Menu Options

Navigation Button	Screen
QC	**Chart** View the QC data variation within the same or between index dates as a daily chart or a day-to-day chart. Refer to Monitor the QC Using the Daily Variation Chart.
	Twin Plot Chart View the QC data variation of two control samples as a twin plot chart. Refer to Monitor the QC Using the Twin Plot Chart.

Table 1.6 Quality Control Menu Options (Continued)

Navigation Button	Screen
	QC Setup Program the control materials and QC check protocols. Refer to QC Setup Menu.

Organization and Functional Outline of Calibration Menu

Use this menu to display a history of calibration information and perform calibration verification.

Table 1.7 Calibration Menu Options

Navigation Button	Screen
MENU > Calibration	**Calibration Monitor** View the current reagent blank and calibration status and a history of the reagent blank and calibration data on a graph. Refer to Monitor the Reagent Blank and Calibration.
	ISE Calibration Confirm the ISE calibration results. Refer to the topic on calibrating the ISE in the *DxC 700 AU Instructions for Use*. Refer to Calibrate the ISE Screen.
	Calibration Setup Program calibrators, calibration parameters, and ISE parameters. Refer to Calibration Setup Menu.

Organization and Functional Outline of Configuration Parameters Menu

Use this menu to program test parameters, calibration parameters, quality control parameters, system condition parameters, online conditions, sample program format, and list formats.

Table 1.8 Configuration Parameters Menu Options

Navigation Button	Screen
CONFIG.	**Test Name Parameters** Program basic parameters such as test name and reagent ID. Refer to Test Name Parameters Screen.
	Panel Program panels for patient samples, reagent blank, calibration, and QC. Refer to Panel Screen.
	Group of Tests Assign tests to a Group. You can program a maximum of three Groups of tests. You can program a maximum of 60 photometric tests and 3 ISE tests in a Group. Refer to Group of Tests Screen.

Table 1.8 Configuration Parameters Menu Options (Continued)

Navigation Button	Screen
CONFIG.	**Test Volume and Methods** Program detailed parameters for tests (in the General, LIH, ISE, HbA1c, Calculated Tests, and Range tabs). • **General** Program detailed parameters for general test items. Refer to Test Volume and Methods: General Tab. • **LIH (Serum Index)** Program detailed parameters for the Lipemia/Icterus/Hemolysis test. Refer to LIH Tab. • **ISE** Program detailed parameters for the ISE tests. Refer to Test Volume and Methods: ISE Tab. • **HbA1c** Program detailed parameters for the Whole Blood HbA1c test. Refer to HbA1c Tab. • **Calculated Tests** Program detailed parameters for calculated tests. Refer to Calculated Tests Tab. • **Range** Program parameters for the reference interval. Refer to Range Tab.
CONFIG.	**Rerun Test Parameters** Program the rerun decision limits, reflex limits, and the rerun dilution rate for individual tests. Refer to Rerun Test Parameters Screen.
	Rerun Check Parameters Program the common parameters for a rerun analysis (in the Flag and Reflex tabs). Refer to Rerun Check Parameters Screen.

Table 1.8 Configuration Parameters Menu Options (Continued)

Navigation Button	Screen
	Calibration Setup Program calibrators, calibration parameters, and ISE parameters. Refer to Calibration Setup Menu.
	QC Setup Program the control materials and QC check protocols. Refer to QC Setup Menu.
	Checked Tests Program parameters for logic checked tests. Refer to Checked Tests Screen.
	Contamination Parameters Program parameters to prevent contamination of tests. Refer to Contamination Parameters Screen.
	Data Check Parameters Program parameters for data check, such as diagnosis of prozone. For more information, contact Beckman Coulter. Refer to Prozone Check Tab.
	Analysis Mode Program the sample identification mode, bar code definition, auto or manual rerun, and other system parameters. Refer to Analysis Mode Screen.
CONFIG.	**System Setup** Program the language, offline format, sample type name, date format, date and time, and other type name. Refer to System Setup Screen.
	Program the Logon Program the logon conditions (in the User Setting, Security, and Access Level tabs). Refer to Program the Logon.

Table 1.8 Configuration Parameters Menu Options (Continued)

Navigation Button	Screen
	Comment Master Program the comments and symbols of unit. Refer to Comment Master Screen.
	User Menu Beckman Coulter pre-programs **USER MENU** in order of a typical operating workflow. Select **CONFIG.** > **User Menu** to edit pre-programmed menus. Refer to the topic on Program a User Menu in the *DxC 700 AU Instructions for Use*. Refer to User Menu Screen.
	Online Program the parameters for online communication between a Laboratory Information System (LIS) and the DxC 700 AU. Refer to Online Menu.
	Sample Program Format Program the sample order format, patient information format, and data output at analytical measuring range error. Refer to Sample Program Format Screen.
	List Format Program the common format parameters for printing the pending list, test summary, and reports. Refer to List Format Screen.

Note

If the DxC 700 AU connects to the Laboratory Automation System, the system uses rerun parameters from the LIS, not the parameters set in the Rerun Test Parameters or Rerun Check Parameters screens.

Principles of Analysis

This system performs automated analysis of serum, urine, plasma, other sample types, and whole blood (for HbA1c only). It measures sample components and automatically generates results.

This section provides an overview of how the DxC 700 AU tests samples. It also describes the ISE measuring method.

Reagent Blank

To calculate a measurement value (reaction OD), the system subtracts the reagent blank OD (reagent OD at each photometric point of P0 to P27) and the Deionized (DI) water blank OD values (photocal data) from the measured OD of a sample reacted with a reagent.

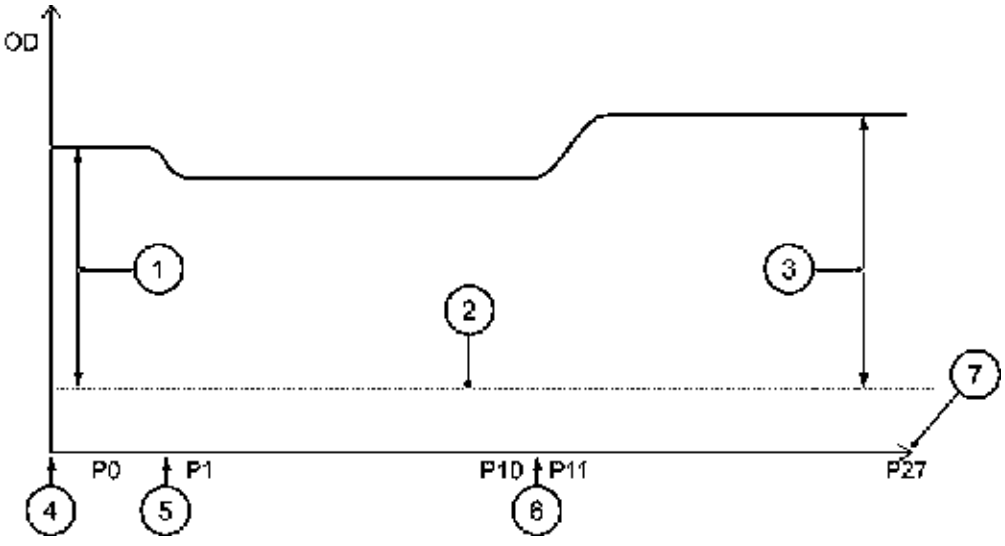
By performing a reagent blank measurement, the system obtains reagent blank OD values (RB) at all photometric points shown in the following chart.

You measure reagent blanks in blue racks. You can program position 1 and position 2 of the blue racks for serum, urine, other-1, other-2, and whole blood in the Calibration Setup: Calibrators tab (**CONFIG.** > Calibration Setup > Calibrators). Typically, you program position 1 for serum, urine, other-1, other-2, and whole blood, and you do not use position 2. Place the sample (deionized water) in position 1 of the blue rack.

The system measures up to four replicates of the sample and determines the reagent blank data (reagent blank OD value).

1 replicate: the OD value.
2 replicates: the mean value of two OD values.
3 replicates: the mean value of the two closest OD values.
4 replicates: discard the highest and lowest OD values and average the two remaining OD values.

Figure 1.2 Reagent Blank (Compared with Water Blank; Example of 2-step Analysis)



1. Reagent OD value at the first point (first data)
2. Deionized water blank (photocal data)
3. Reagent OD value at the last point (second data)
4. R1 (first reagent) dispensing
5. Sample (water) dispensing
6. R2 (second reagent) dispensing
7. Photometric point

First-point Reagent OD Value (First Data)

- First-point reagent OD value (RB) = {first point measured OD value} -{DI water blank (photocal data)}.
- If the first-point reagent OD value is outside the reagent OD range that you have programmed in **Reagent OD Limit 1st** of the Test Volume and Methods: General tab (**CONFIG.** > **Test Volume and Methods** > **General**), the system adds a flag y (for over range) or u (for under range) to the data.

Last-point Reagent OD Value (Second Data)

- Last-point reagent OD value (RB) = {last point measured OD value} - {DI water blank (photocal data)}.
- If the last-point reagent OD value is out of the reagent OD range that you have programmed in **Reagent OD Limit Last** of the Test Volume and Methods: General tab (**CONFIG.** > **Test Volume and Methods** > **General**), the system adds a flag Y (for over range) or U (for under range) to the data.

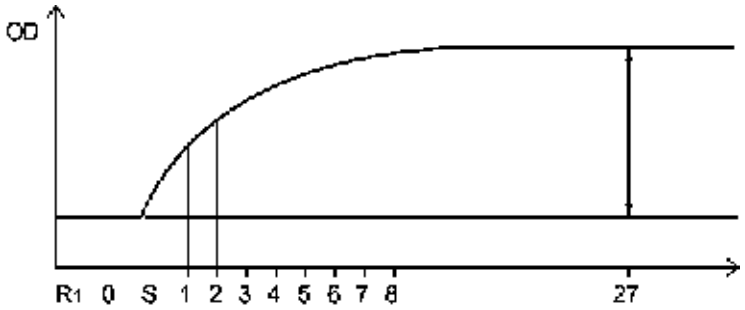
End Point Assays

1-Point Assay

This general end point assay determines the reaction mixture OD from the OD measured at a specified photometric position.

Reaction mixture OD = OD (at specified position) - OD0 (at position 0)

Figure 1.3 Reaction Curve for 1-Point End-Point Assay



2-Point Assay (Self-Blank Method)

This end point assay requires a sample blank adjustment. Eliminate the OD values before dispensing the reagent 2 as the blank channel. To obtain correct data without influences from turbidity or color of the serum, the OD values of the blank channel are subtracted from the OD values measured after dispensing the reagent 2.

The following expression represents the OD value in this assay:

K2 = {R1. V / (R1.V + R2.V + S.V)}

K3 = {(R1.V + S.V) / (R1.V + R2.V + S.V)}

Reaction OD value = (Px - K2 × P0) - (K3 × Pz - K2 × P0).

This calculation result is defined as the reaction OD value.

Figure 1.4 Reaction Curve for 2-Point End Point Assay (Self-Blank Method)

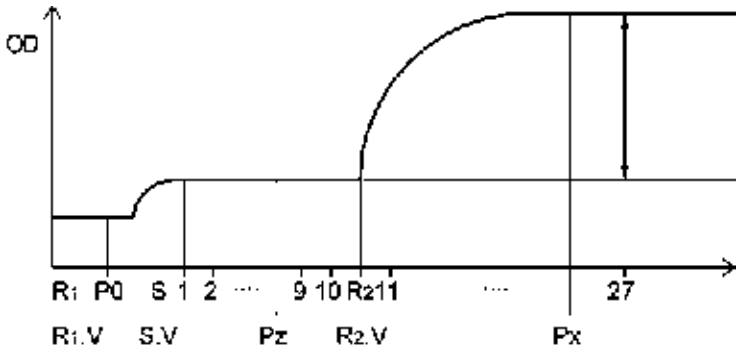


Table 1.9 2-Point Assay (Self-Blank Method)

Item	Description
R1.V:	Reagent 1 dispense volume
R2.V:	Reagent 2 dispense volume
S.V:	Sample dispense volume
P0:	OD value at the first point
Pz:	OD value before dispensing reagent 2
Px:	OD value after dispensing reagent 2

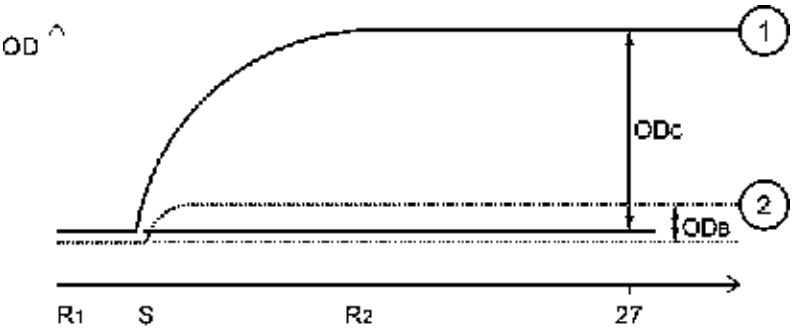
End Assay (Sample Blank Correction)

This type of assay uses two cuvettes, a cuvette for the color reaction and a cuvette for the sample blank. The system measures blank item OD values, which include serum quality issues, first. Then, the system subtracts the blank item value from the measured OD value of the actual sample (OD value of the color item).

With this end assay (sample blank correction), you can obtain higher accuracy data than the 2-point assay even when you cannot avoid serum quality issues (dotted line in Figure 1.5 Reaction Curve for End Point Assay (Sample Blank Correction)).

Reaction OD value = [Color item OD value (OD_C)] - [Blank item OD value (OD_B)]

Figure 1.5 Reaction Curve for End Point Assay (Sample Blank Correction)



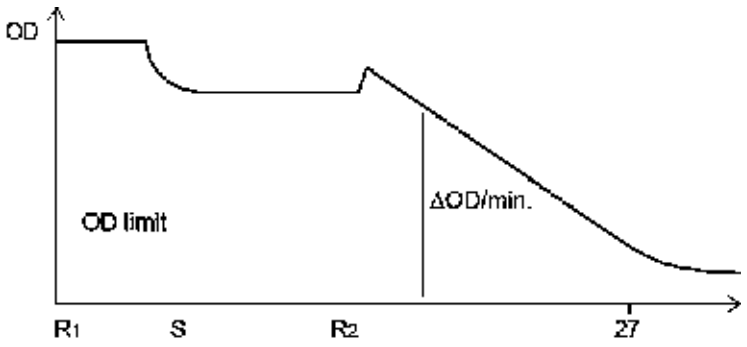
1. Color reaction channel
2. Sample blank channel

Rate Assays

Rate Assay

This assay determines the rate of absorbance variation per minute by calculating the average of the absorbance variations (ΔOD) between photometric points using the least squares method.

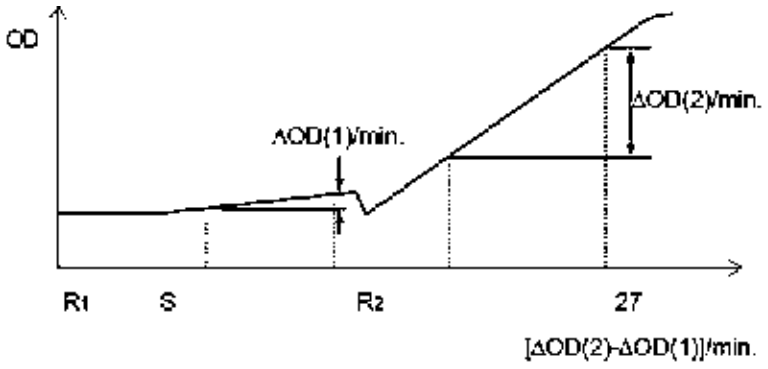
Figure 1.6 Reaction Curve for Rate Assay



Double Rate Assay

This assay determines the rate of absorbance variation per minute by calculating the average of the absorbance variations (ΔOD) between photometric points using the least squares method. Next, the system obtains the OD rate of the objective substance from the calculation expression.

Figure 1.7 Reaction Curve for Double Rate Assay

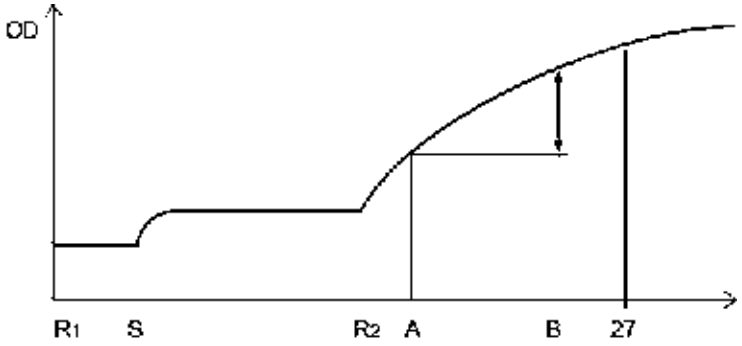


Fixed Point Assay

A fixed point assay measures the OD value at two specified photometry points. The system measures the two photometry points after the beginning of reaction between sample and reagent.

Reaction OD value = OD_B - OD_A

Figure 1.8 Reaction Curve for Fixed Point Assay



Quality Control

You can use many quality control techniques to monitor analyzer accuracy.

The analyzer software uses single rule, multi-rule, and twin plot QC evaluation.

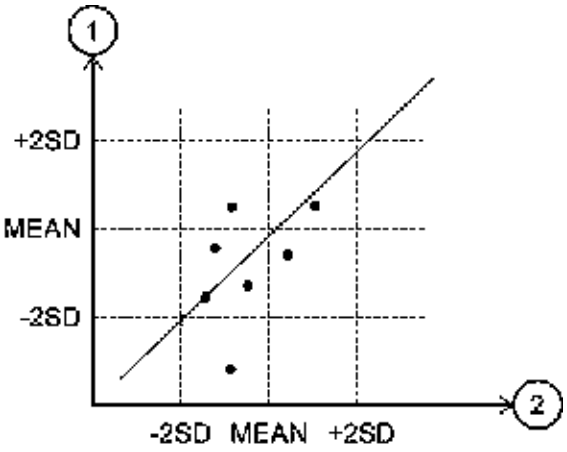
- Single rule is the most common technique.
- Use multi-rule to prevent notification of insignificant errors.
- Use twin plot for easier classification of systematic and random errors.

For more information, refer to Monitor QC.

Twin Plot Control

Evaluate quality controls with normal level expected values and abnormal level expected values together.

Figure 1.9 Twin Plot Chart



1. Abnormal control
2. Normal control

If both the normal and abnormal level samples fall below their lower control limits or both exceed their upper control limits, confirm the calibration system to determine systematic errors.

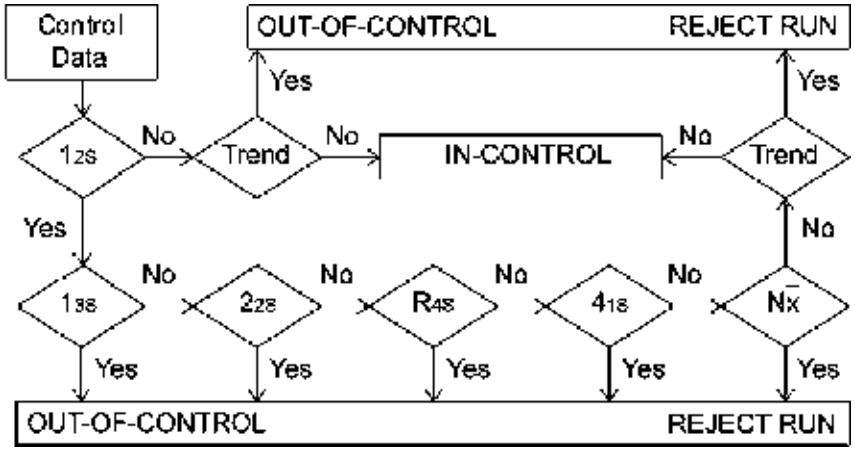
If only the abnormal level sample falls below the lower control limit, you can suspect a reagent problem. The twin plot control technique offers the advantage of classification of a systematic error or a random error.

Multi-Rule Control

In the day-to-day control, you confirm a control error by examining the control chart, but it is difficult to do confirmation of numerous tests on a real-time basis. With the multi-rule control technique, you can speedily cope with an error real-time, as this control technique identifies the rule out of range from a specific flag.

With this control technique, you must prepare a normal and abnormal level control.

Figure 1.10 Standard of Judgment from the Multi-Rule Shewhart Technique (Logic Diagram Applicable to Control Rules)



Symbols for Multi-Rule Control and Logic

The following describes the symbols for multi-rule control and logic:

- 1_{2S} is a judgment level for determining if one piece of control exceeds the control limit determined as 'MEAN ±2 SD'. If they do not exceed the control limit, the system makes an inquiry to 1_{3S} for the next judgment level. If one piece of control exceeds the control limit, it is judged that the system has not correctly attained quality control.
- 1_{3S} is a judgment level for determining if one piece of control exceeds the control limit determined as 'MEAN ±3 SD'. If they do not exceed the control limit, the system makes an inquiry to 2_{2S} for the next judgment level. If one piece of control exceeds the control limit, it is judged that the system has not correctly attained quality control.
- 2_{2S} is a criteria level for judging whether the two continuous pieces of control data exceed the control limit determined as 'MEAN ±2 SD' in one direction. If they do not exceed the control limit, the system makes an inquiry to R_{4S} for the next judgment level. If they exceed the control limit, it is judged that the system has not correctly attained quality control.

Note

The term *continuous* can have the following meanings:

  - To be continuous in both directions for one identical control substance.
  - To have continuity of high concentration and low concentration between control substances.

- R_{4S} is a judgment level for determining whether either of two continuous pieces of data with high and low concentrations exceeds the control limit specified as 'MEAN + 2SD' and whether the other exceeds the control limit of 'MEAN –2SD'. In other words, it judges whether the two continuous pieces of data exceed 4SD in the same range. If the data is within the control limit, judgment advances to the next judgment level, 4_{1S}. If the data is outside of the control limit, the system has not correctly attained quality control.
- 4_{1S} is a judgment level for determining whether four continuous pieces of control data exceed the control limit of either 'MEAN +1 SD' or 'MEAN -1 SD'. If they do not exceed either control limit, the system makes an inquiry to the next judgment standard N_x for necessary judgment, but if they exceed the limit, the system has not correctly attained quality control.
- N_x is a judgment level for determining whether continuous N (7 to 10) pieces of control data are above or below the control mean. If the controls do not exceed the control limit, quality control has been correctly attained. If the controls exceed the control limit, quality control has not been correctly attained. The N_x rule uses a maximum of 10 pieces of previous data for judgment.
- Trend evaluates if 4 to 10 sequential results of measurement of the same control material are increasing or decreasing.

If exceeding one of the six multi-rule controls generates an error, the system attaches a flag to the control data.

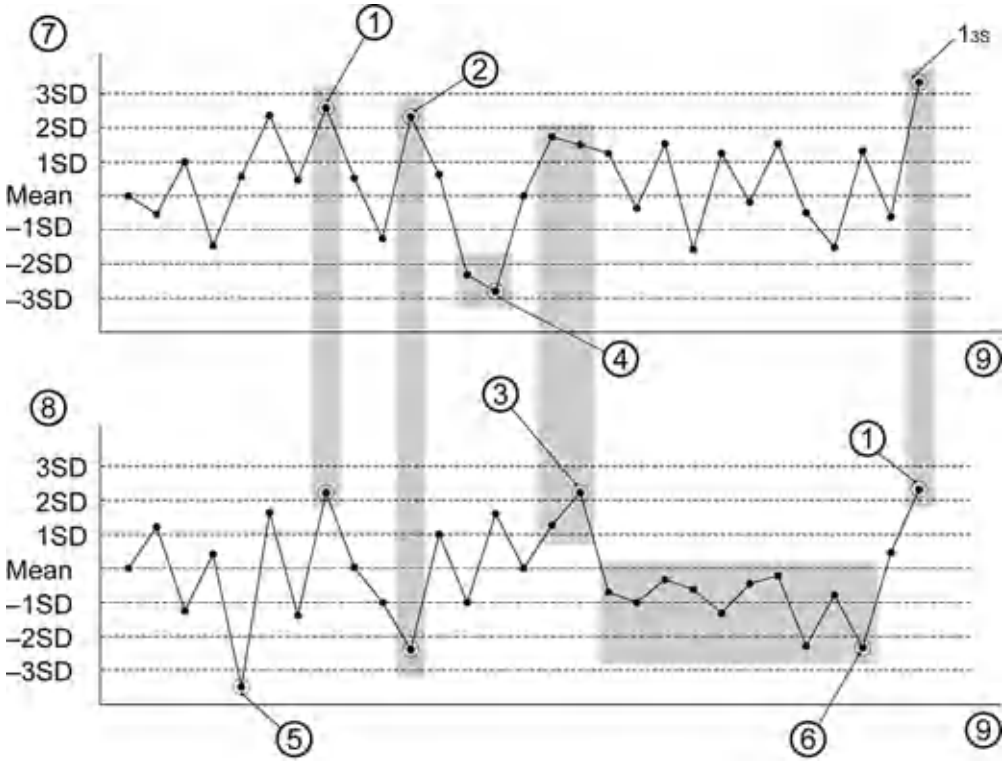
Table 1.10 Multi-Rule Control Limit, Flag, and Cause of Error

Control Limit	Flag	Cause of Error
Exceeds 1_{3S}	2Q	Random error
Exceeds 2_{2S}	3Q	Systematic error
Exceeds R_{4S}	4Q	Random error
Exceeds 4_{1S}	5Q	Systematic error
Exceeds N_x	6Q	Systematic error
Trend abnormality	7Q	Increase or decrease in continuous quality control data

Control Errors Example

The following charts show control errors according to the multi-rule control:

Figure 1.11 Control Errors Example



1. 2_{2S}: Systemic error. The high and low value controls both exceed the 2 SD level in one direction. The system generates a 3Q flag.
2. R_{4S}: Random error. The high value control exceeds the 2 SD level and the low value control exceeds the -2 SD level. The system generates a 4Q flag.
3. 4_{1S}: Systemic error. Four continuous QC results exceed the 1 SD level in one direction. The system generates a 5Q flag.
4. 2_{2S}: Systemic error. The high value control had two continuous results over 2 SD or under -2 SD in one direction. The system generates a 3Q flag.
5. 1_{3S}: Random error. One result is either over 3 SD or under -3 SD. The system generates a 2Q flag.
6. N_X: Systemic error. Ten continuous results are below the mean. The system generates a 6Q flag.
7. High value control
8. Low value control
9. Day

The following text describes the possible errors and causes for the random errors and systematic errors shown in Figure 1.11 Control Errors Example. To troubleshoot the errors, refer to the following information:

For the random errors:

- Dispensing accuracy error (sample or reagent): Poor syringe (sample, reagent) dispensing accuracy because of syringe integrity problems or incorrect installation, air introduced into the plumbing system, dirty probes, empty reagents, and so on.
- Poor photometer accuracy: Lamp deterioration.
- Reagent degeneration: Incorrect reagent storage or contamination.
- Poor quality control sample: Incorrect sample, different lot, and so on.
- Insufficient cleaning: Mix bar cleaning incorrect or insufficient.

- Poor mixing: Mix bar component defective, incorrect mix bar used, cuvette wheel defective.

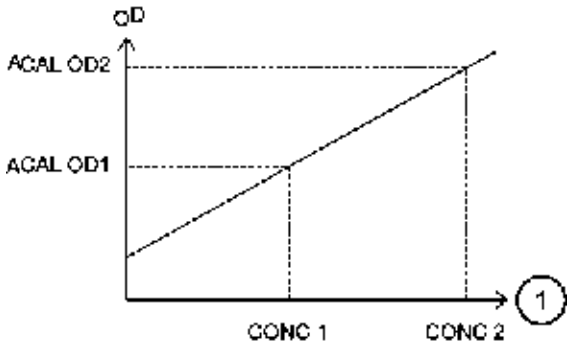
For the systematic errors:

- Incorrect calibration: Incorrect reconstitution of calibrators.
- Deteriorated reagent: Reagent degeneration, different lot, and so on.
- Temperature: Incorrect temperature control.

Summary of Calibration Types

You can generate a maximum of 15 types of calibration curves. The following information describes the six major types of calibration curves.

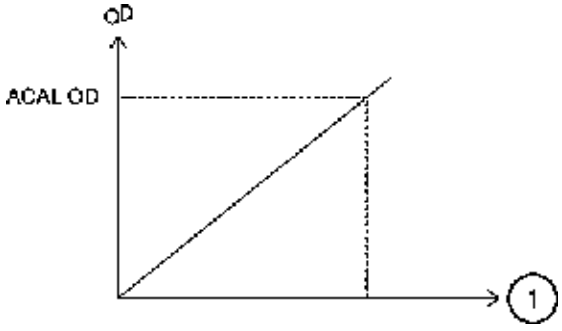
Figure 1.12 ACAL AA



1. CONC: Calibrator Concentration value

- Generate this calibration curve using two different calibrators. The Y intercept is above or below 0 but does not pass through 0 (reagent blank).
- Use this type of calibration curve for fixed point assays.

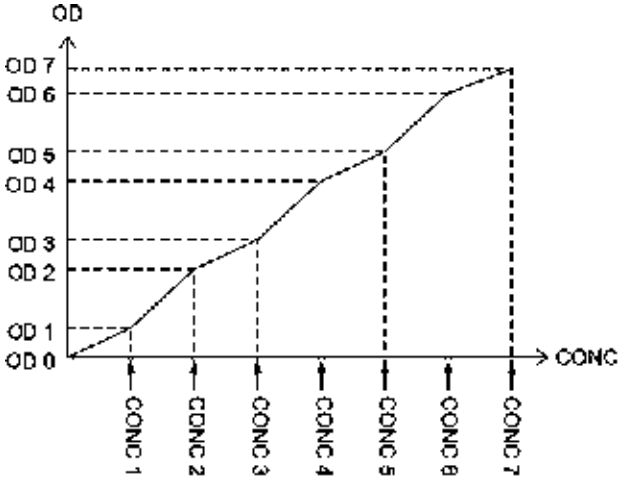
Figure 1.13 ACAL AB



1. CONC: Calibrator Concentration value

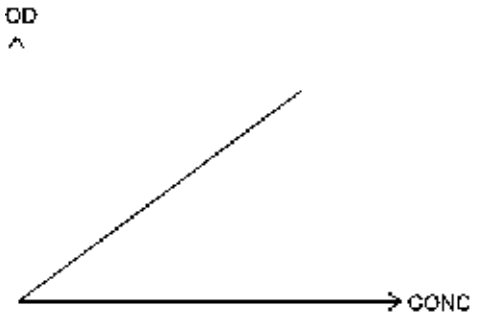
- Generate this calibration curve using a single calibrator and the reagent blank. The Y intercept passes through 0.
- Use this type of calibration curve for end point assays. An example of a test using this type of calibration is Glucose.

Figure 1.14 ACAL 7AB



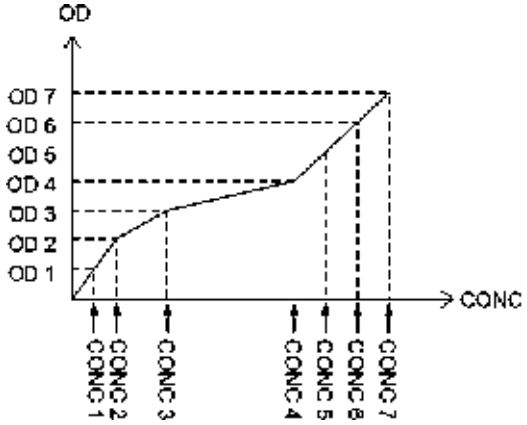
- Generate this calibration curve using a minimum of two calibrators up to a maximum of 7 calibrators. The Y intercept passes through 0.
- Use this type of calibration curve for immunoturbidimetric assays. An example of a test using this type of calibration is C-Reactive Protein.

Figure 1.15 MCAL MB



- Set the calibration coefficient with a theoretical or traceable reference method.
- MB factor derived from extinction coefficient or IFCC reference labs that is a derived factor.
- An example of a test using this type of calibration is Lactate Dehydrogenase.

Figure 1.16 MCAL 7 MB



- Generate this calibration curve by entering the OD and concentration for a maximum of 7 calibrators.
- Use this type of calibration curve for immunoturbidimetric tests with constantly curving characteristics.

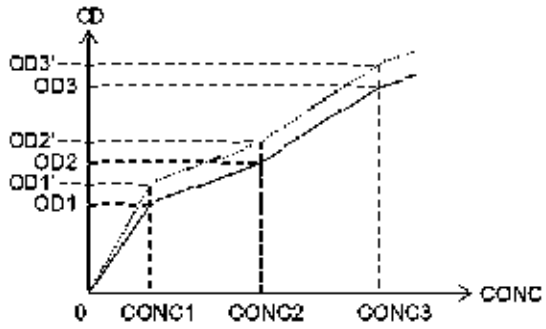
ACAL nAB (single-point correction)

First, analyze one of multiple standard solutions for 2AB to 7AB. By using the ratio between the reaction OD values of this standard solution and the previously measured standard solution, correct the reaction OD values of other standard solutions, and then recreate the calibration chart.

You can correct the calibration chart with two points of OD0 and another OD value, if the standard solution with a concentration of 0 is available.

Example 1: If none of multiple standard solutions has a concentration of 0.

Figure 1.17 Single-point Correction without a Standard Solution Concentration of Zero



You can perform a single point update to the calibration curve for calibrations defined as 2AB to 7AB. A single calibrator is used to obtain a new reaction OD. The ratio between the previously obtained OD and the current OD causes the OD of the other calibrators to be adjusted, and the new calibration curve is calculated.

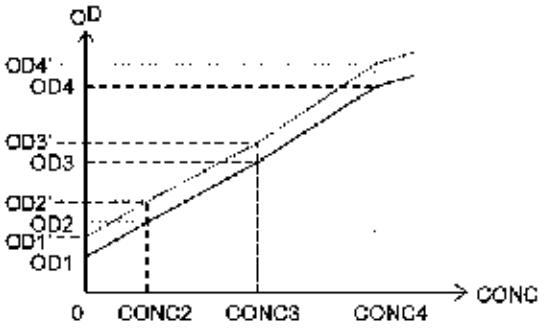
1. Perform the single-point correction.

$$ODn' = ODn \times \frac{OD2'}{OD2}$$

2. Recalculate for the calibration curve.

Example 2: If any standard solution has a concentration of 0.

Figure 1.18 Single-point Correction with a Standard Solution Concentration of Zero



ODn: previous OD value ODn': OD value after correction

If you perform a correction with two points of CONC1 and another (CONC3), execute the following calculation.

1. Use the reaction OD values of CONC1 and CONC3 (OD1' and OD3') as they are.
2. Correct each point:

$$ODn' = \alpha \times (ODn - OD1) + \beta$$

$$\alpha = \frac{OD3' - OD1'}{OD3 - OD1}$$

$$\beta = OD1'$$

Principles of the Real-time Water Blank Check

The real-time water blank check method compares the water blank reading obtained during analysis to the previous water blank reading. If the deviation in the water blank reading on a cuvette exceeds a tolerance level, the system generates a `PHOTOMETRY ERROR DURING CUVETTE WASH` event.

The system generates a `PHOTOMETRY ERROR DURING CUVETTE WASH` event when it detects a cuvette overflow or unstable photometry. The following conditions can cause unstable photometry:

- Incorrectly placed cuvettes in the cuvette wheel
- Dirty cuvettes
- Insufficient amount of wash solution being supplied to clean the cuvettes
- A deteriorating lamp

When the system generates a `PHOTOMETRY ERROR DURING CUVETTE WASH` event, check to see if a cuvette overflow has occurred. Refer to the topic on recovering from a photometry error during a cuvette wash event in *DxC 700 AU Instructions for Use*.

- If a cuvette overflow has occurred, refer to the topic on recovering from a cuvette wheel overflow in the *DxC 700 AU Instructions for Use*. It is necessary to identify and reanalyze all samples affected by the cuvette overflow.
- If a cuvette overflow has not occurred, the system might have generated the `PHOTOMETRY ERROR DURING CUVETTE WASH` event because of unstable photometry. Refer to the topic on recovering from an unstable photometry error in the *DxC 700 AU Instructions for Use* to determine the cause of the error and perform corrective actions.

Principles of the ISE Measuring Method

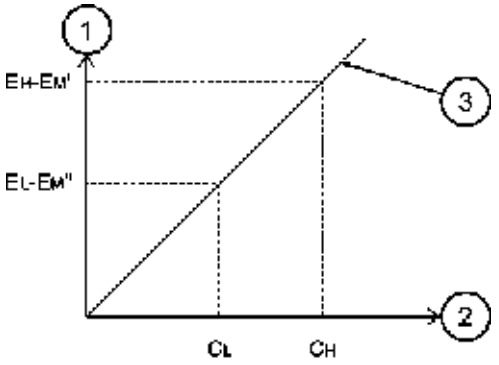
The system mixes sample and ISE Buffer Solution using a specified sample ratio in the sample pot of the ISE module (optional). The system aspirates the mixture and passes it to the Na, K, and Cl electrodes. The system measures the potential generated at the electrodes. The system cycles ISE MID Standard Solution between samples to measure the reference potential and to prevent carryover.

Calibration Processing on the ISE

During calibration of the ISE, the system measures both ISE MID Standard Solution and Standard Solution H and L, which have a known concentration. The system obtains the relationship between the electrode potential and ion concentration then, and calculates the Na, K, and Cl calibration setup coefficient S (slope).

Calibration

Figure 1.19 Calculation of Slope



1. Potential difference (mV)
2. CONC (logarithm) mmol/L
3. Calibration

C_H	A known concentration of Standard Solution H used for calibration
C_L	A known concentration of Standard Solution L used for calibration
E_H-E_M'	A potential difference between Standard Solution H and ISE MID Standard Solution
E_L-E_M''	A potential difference between Standard Solution L and ISE MID Standard Solution

The system creates a calibration using a potential difference between the two points of known concentration.

Correction by M-CAL

M-CAL at the ISE is data correction using a calculation formula, Y = AX + B.

Y: corrected value, X: measured value.

Coefficients A and B are obtained in the following way.

Correlation regression with a measurement (y) obtained from the system before correction and value (x) obtained from any conventional method or standard method.

You can obtain coefficients A and B by a 3-point regression calibration or Manual calculation.

y = ax + b

gives

x= (1/a)y - (b/a)

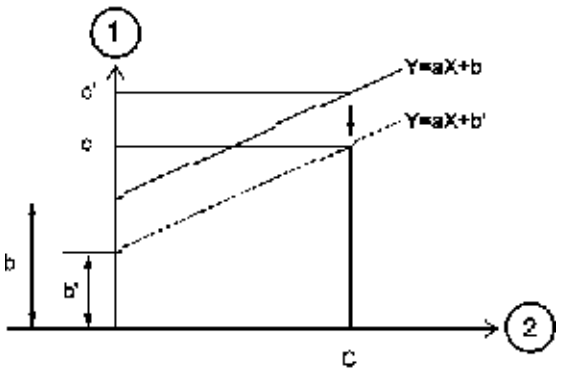
Therefore, A =-1/a, B = -b/a

The two methods to perform M-CAL are:

- Manual: Obtain A and B with the previously listed equations and enter them as the factors.
- CRS (3-point regression CAL): Optional.

Correction by A-CAL

Figure 1.20 Correction by A-CAL



1. Y (measured value)
2. X (known concentration of a sample subject to A-CAL)

- Corrected value: c' - c
- b'=b-(c'-c)

  a = factor

  b = offset

Let a known concentration of a sample for A-CAL be c, and let the measurement obtained by this system from a sample for A-CAL after an M-CAL correction be c´. To make the

known concentration of the sample for A-CAL and a measurement obtained by this system consistent, correct the difference between c and c´ using A-CAL. Here, Y = aX + b is Y = aX + b´.

You can apply this A-CAL correction to values that have been subject to an M-CAL correction.

Key Sub-Processes

This section describes some important analysis steps.

Sample Identification

A test order is an instruction to perform specified tests on a sample. When you place a sample onto the system, it uses the test order information to link the sample to the required tests. The system must be able to identify samples correctly. The system can also use sample bar codes to link test order information to each sample to be tested.

The system recognizes samples on racks by three sample identification modes.

Bar Code (Sample ID) Mode

The system reads the sample bar code label on each sample cup and then links this information to a corresponding order to perform analysis. You can place samples in any order, and the system allows empty spaces on the racks. It is critical to test that sample bar codes match sample orders.

Sequential Mode

The system analyzes the first sample on the first rack presented, using the information in the first test order. It uses the second test order for the second sample on the rack, and so on. In sequential mode, the system does not read the sample bar code label, unless you select **Sequential Sample ID Read** in the Analysis Mode screen (**CONFIG.** > **Analysis Mode**). When you select **Sequential Sample ID Read**, the system reads a sample bar code label, but does not use the sample ID for test orders. For more information, refer to Analysis Mode Screen.

Place samples on the racks in numerical order, without empty spaces on the rack.

Warning

Running the system in sequential mode is not recommended because of the possibility of sample and result mismatch. If you must run a sample in sequential mode, be careful and use extra cross checks.

To be sure of correct sample analysis in sequential mode, confirm that there are no empty spaces in the racks.

If a Beckman Coulter Representative has programmed the system during installation to analyze only the same sample type in the same rack, never mix different sample types in one rack.

Note

If the DxC 700 AU connects to a Laboratory Automation System, sequential mode is not available.

Rack ID Mode

The system reads the rack ID and assigns the sample No. according to the cup position in the rack. Set the samples in the rack in the order entered for the samples at the time of sample order. The system does not read sample bar code labels in Rack ID mode.

For example, when the samples from No. 1 to No. 10 are set on rack ID 0001 and the samples from No. 11 to No. 20 are set on rack ID 0002, you can find sample No. 14 in position 4 on rack ID 0002 and sample No. 57 in position 7 on rack ID 0006. In Rack ID mode, you can place the racks in any order into the rack input area. The maximum rack ID for Rack ID mode is 999.

Warning

In Rack ID mode, use extreme caution when placing samples in the rack to avoid concordance errors (incorrect sample and result). Take time to perform cross checks on racks and samples.

Note

If the DxC 700 AU connects to a Laboratory Automation System, Rack ID mode is not available.

Sample Transfer

Sample tubes or cups containing sample are placed on the system using sample racks or placed on the STAT table. Select **Start** to start the analysis from a rack. Select **Start STAT** to start the analysis from the STAT table. The system determines the test order information and the sample probe aspirates the sample.

Program the sample volume and diluent volume for each test in **CONFIG.** > **Test Volume and Methods** > **General**.

After dispensing, the sample probe is washed in the wash well with deionized water internally and externally.

Reagent Transfer

The system has two reagent transfer probes. Any required reagent is aspirated from the corresponding reagent bottle in the reagent refrigerator and dispensed into the cuvette in the incubation bath. The system uses information programmed in **CONFIG.** > **Test Volume**

and Methods > **General** to determine the quantity of reagent to use. A mixture of sample and reagent which has been dispensed into one cuvette is called a reaction mixture.

The reagent probes are washed internally and externally with deionized water, between each reagent dispense, to ensure minimal reagent carryover. In addition, you can program contamination avoidance parameters. For more information, refer to Contamination Parameters Screen.

Reaction Mixture Mixing

The mix bar component uses fluororesin-coated mix bars to mix the reaction mixture in the cuvette to uniformity. Two mix bar components are provided. Each of the two mix bar components has three sets of mix bars. While one of the three sets mixes, the other two are washed in the wash well with diluted wash solution and rinsed with deionized water.

Reaction Mixture Incubation and Washing

The cuvette wheel is set in an incubation bath to keep the reaction temperature in the cuvette at a constant level.

When the photometer readings complete, the wash nozzle component aspirates the reaction mixture in a cuvette, and the cuvette is washed with diluted wash solution, rinsed with deionized water, and then dried.

Photometric Measurement

Various chemical components in the sample and the reagents produce a color reaction in the cuvette. Light from a halogen lamp passes through the reaction mixture, and separates into specific wavelengths by a diffraction grating. A photodetector measures the optical density of the reaction mixture. The system performs measurements at 18-second intervals throughout the reaction period. The system uses the measured values for the reaction period and wavelengths that are defined in the Test Volume and Methods: General tab (**CONFIG.** > **Test Volume and Methods** > **General**) for concentration calculation.

Online Test Orders and Test Orders Using Keyboard Entries

LIS Direction Online

An LIS direction online order is possible when you set **Test Order Information Receive** in the Online: Setup tab (**CONFIG.** > **Online** > **Setup**) to **LIS Direction**, and the DxC 700 AU connects to a Laboratory Information System (LIS) over a TCP/IP connection. The LIS sends test order information to the DxC 700 AU, and the DxC 700 AU saves the information without an inquiry from the DxC 700 AU at any time.

If LIS direction online connects an LIS and a DxC 700 AU, the operator does not have to perform test orders from the DxC 700 AU.

Real-time Online

A real-time online test order is possible when you set **Test Order Information Receive** in the Online: Setup tab (**CONFIG.** > **Online** > **Setup**) to **Realtime**, and the DxC 700 AU connects to

an LIS. In responding to any inquiry from the analyzer to the LIS, the system processes everything automatically.

If an LIS and the DxC 700 AU connect real-time online, the operator does not have to perform test orders from the DxC 700 AU.

Batch Online

A batch online test order is possible when you set **Test Order Information Receive** in the Online: Setup tab (**CONFIG.** > **Online** > **Setup**) to **Batch**, and the DxC 700 AU connects to an LIS over an RS-232C connection. The DxC 700 AU sends batch inquiries to the LIS for sample information (such as test item) for multiple samples.

Keyboard Entry

You can perform manual sample ordering by sample number at the DxC 700 AU.

You can perform manual sample ordering at the DxC 700 AU with or without an LIS.

Sample Identification and Date and Time

Sample Number

This value is a 4-digit number used to identify each sample. Sample number assignment methods vary with sample identification modes.

Sample ID

A sample ID used to identify each sample.

In sample ID (Bar code) mode, the system reads the bar code label attached to each sample cup and uses it as the sample ID.

Rack ID

A rack ID is used for identifying each rack. In Rack ID mode, the sample number of each sample is automatically assigned using the rack ID and the position on the rack. When the DxC 700 AU is connected to a Laboratory Automation System, racks are not used on the system.

System date and time

This value is the system date and time under the management of the internal clock of the system.

Index date and time

An index, created by setting the date and time, is a data file used as the main search key for sample data.

The current date and time is automatically set as the index date and time on starting up the system; however, this option is an operator-defined option.

Understanding and Handling Reagents, Calibrators, and Controls

This section describes the reagents used on the DxC 700 AU.

Reagents

Beckman Coulter reagents are highly concentrated, and most reagents are ready to use.

The system can use reagents, calibrators, and control materials supplied by manufacturers other than Beckman Coulter. Confirm usability with the reagent manufacturer or distributor.

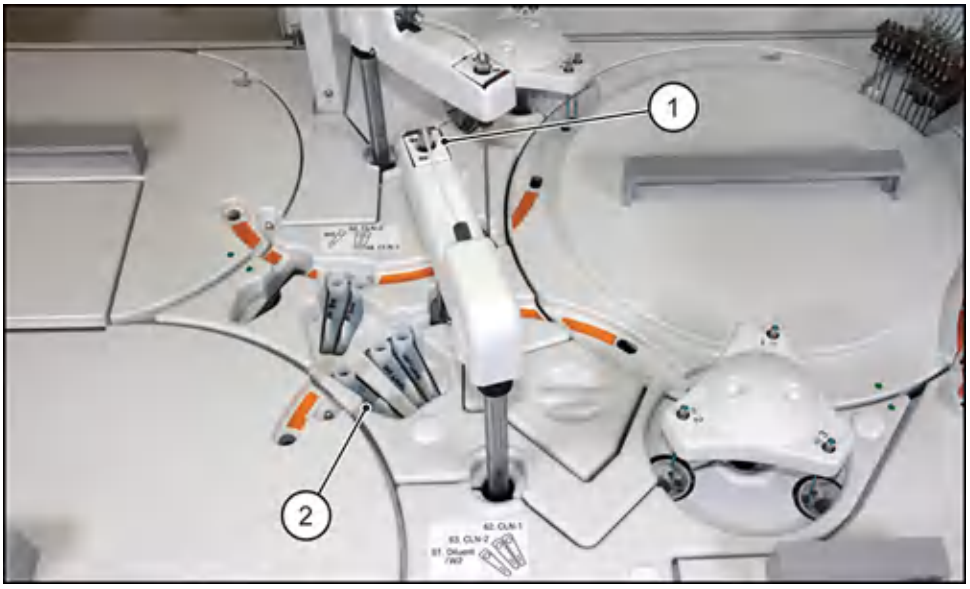
Reagents are supplied in bottles of 15 mL, 30 mL, 60 mL, or 120 mL. Set reagent bottles containing reagents in the reagent refrigerator fixed by adapters and partitions, depending on the size.

The system reads the bar code label on a reagent bottle and registers it.

Sample Diluents

For samples with a high concentration, the system uses deionized water or other diluent for automatic dilution analysis. The diluent is in a 60 mL bottle placed in a designated diluent bottle position labeled 61. The following figure shows the Diluent/W2 position close to the reagent (R1) refrigerator.

Figure 1.21 Sample Diluent Bottle Position



1. Reagent probe
2. Sample diluent bottle

Calibrators

You can program a maximum of 200 different calibrators on the system.

Calibrate in the following situations:

- When a reagent bottle has changed, and you have programmed the system to calibrate new bottles in **Advanced Calibration** in the Calibration setup: General tab (**CONFIG.** > **Calibration setup** > **General**).
- When a reagent lot has changed.
- When you have used the same lot on the system for a predefined number of days.
- QC results fell outside the specified control limits.
- There has been major preventive maintenance, or critical part replacement, and QC performance is affected.

For more information on test-specific calibration, refer to the reagent *Instructions for Use*.

For more information on operation precautions, refer to the topic on calibrating tests in the *DxC 700 AU Instructions for Use*.

Quality Control Samples

Perform Quality Control (QC) analysis after calibration and as directed after particular maintenance procedures to confirm that the system is working correctly. Perform QC analysis at regular intervals for verification of system stability. Perform this check using a control sample from the QC supplier.

For more information on operation precautions, refer to the topic on processing quality control (QC) in the *DxC 700 AU Instructions for Use*.

ISE Quality Control Materials

Commercial Control Materials for the ISE

Beckman Coulter advises using the most widely accepted, reliable ISE control materials available locally. Substances in control serum can affect ISE tests.

Commercial control materials contain additives for regulating the density of components, and they contain various preservatives. If you measure this type of control material using an ion selective electrode, the added materials can cause problems with the electrode, and could cause measurement errors, including abnormal data.

⚠ Caution

The following items affect measurement:

- **Samples that contain antibiotics or other drugs can cause errors.**
- **Bilirubin does not affect the K and Cl electrodes, but small positive errors occur in the Na electrode.**
- **Positive errors occur in the Cl electrode caused by halogen ions (Br, I).**
- **A positive error is recognized in the K electrode for samples where the hematocrit value is 65% or more. If a hemolytic sample is used, K shows an excessively positive error.**
- **Use the anticoagulant Lithium Heparin. Any other anticoagulants can cause an error in measured values. Use the anticoagulant immediately after collecting blood.**

- **To prevent fluctuations caused by sample evaporation, keep serum and plasma samples tightly closed in a refrigerator. Also, measure samples stored in a refrigerator after the temperature of the sample has returned to room temperature.**

CHAPTER 2

Parameters

Common Test Parameters Menu

Test Name Parameters Screen

Use the Test Name Parameters screen (**CONFIG.** > **Test Name Parameters**) to program test parameters, including the test name, reagent ID, and alarm tests.

Test numbers 1 to 120 are pre-programmed as closed or open test numbers.

- Closed Test Numbers - During installation, Beckman Coulter Representative loads a CD containing Beckman Coulter test parameters, which occupy a set of closed test numbers. Closed test numbers reduce manual programming time and possible programming errors.
- Open Test Numbers - The system supports the ability to add tests that are not from Beckman Coulter. Tests that use reagents that are not from Beckman Coulter use open test numbers.

The system allows a maximum of 120 programmed tests. You can print the contents of the Test Name Parameters screen.

Table 2.1 Test Number Programming Options and Descriptions

Test Number	Programming Options	Description
1 to 90	Closed or Open	Customer specific
91 to 95	None	FSE Troubleshooting
96 to 99	None	LIH, Na, K, Cl
100 to 102	None	HbA1c
103 to 120	Closed or Open	Customer specific

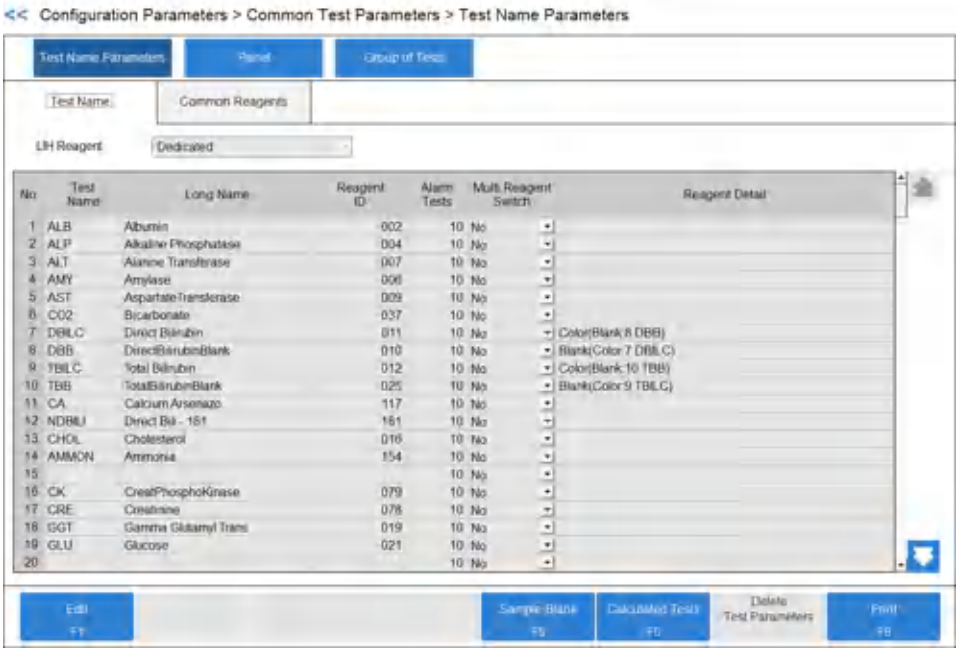
For closed test numbers, you cannot program some fields in the Test Volume and Methods: General tab (**CONFIG.** > **Test Volume and Methods** > **General**). For detailed information, refer to Test Volume and Methods: General Tab.

You can program all other fields on the Configuration Parameters menu, including the fields that are in the tabs on the Test Name Parameters screen (Test Name, Long Name, Reagent ID, Alarm Tests, and Multi Reagent Switch), for closed or open test numbers.

Test Name Tab

Select **CONFIG. > Test Name Parameters > Test Name**.

Figure 2.1 Test Name Parameters: Test Name Tab



Program the following items as required.

Table 2.2 Test Name Tab Description

Item	Contents	Input Notes
LIH Reagent	Dedicated or Non Dedicated	If you select **Dedicated** the system uses test number 96. LIH with LIH Reagent (OSR62166) as the reagent. LIH Reagent has a reagent ID and you can place it in any open position in the R1 refrigerator. If you select **Non Dedicated** the system uses an existing (on-board) test and reagent for LIH testing. You can program a maximum of three tests to the Group for LIH analysis.
No.	1 to 120	You can program a maximum of 120 tests. Closed test numbers are pre-programmed; you manually program open test numbers. The system processes tests on a sample in the order (1 to 120) that is displayed. The system reserves test numbers 91 to 95 for FSE Troubleshooting, 96 for LIH, 97 for Na, 98 for K, 99 for Cl, 100 for HbA1c, 101 for T-Hb, 102 for A1c, and you cannot change them.
Test Name	An abbreviated test name.	A maximum of 6 characters. The system pre-programs test names for test numbers 96 to 102 and you cannot change them.
Long Name	A complete test name.	A maximum of 20 characters.

Table 2.2 Test Name Tab Description (Continued)

Item	Contents	Input Notes
Reagent ID (for all countries and regions except Japan)	3 digits (000 to 999)	The 3-digit Reagent ID located on the top, right side of the reagent IFU, or the first 3 digits from the reagent ID label. For two tests to use the same bottle of reagent, enter the same reagent ID. Available for reagent ID or fixed reagents. In **Reagent Management**, both test names display for the bottle.
Manufacturer ID (for Japan only)	3 digits (000 to 999)	The first three digits of the reagent ID. The reagent manufacturer defines the Manufacturer ID. Refer to the reagent *Instructions for Use*.
Test Code (for Japan Only)	2 digits (00 to 99)	The 2 digits of the reagent ID following the first 3 digits. Refer to the reagent *Instructions for Use*.
Alarm Tests	1 to 200 The default is 32.	The quantity of tests remaining when the system generates a `Reagent Insufficient` event.
Multi Reagent Switch	Yes or No	**Yes**: When the system is using multiple sets of an R1/R2, and the R1 or R2 becomes empty in the first set, the analyzer switches to the second set of R1/R2 at the same time. One indicator bar displays for R1 and R2 in **Reagent Management**. **No**: The default setting. If an R1 or R2 becomes empty, the analyzer does not switch to the second set of R1/R2 at the same time. An indicator bar displays for R1 and R2 in **Reagent Management**. **Caution** **Beckman Coulter recommends selecting Yes for Multi Reagent Switch for all Beckman Coulter reagents.**
Reagent Detail	Displays a comment indicating the test is a sample blank test or a calculated test.	Display only and not enterable.

Caution

Changing the test name affects all results associated with that test number. The system assigns the new test name to any previously reported results (with the old test name). Use extreme caution when you change the test name.

Do not change the test name without noting the time and date of the change and then confirming any results printed before this time and date.

Important

The system processes tests on a sample in the order (1 to 120) that is displayed, with some exceptions. For information on contamination prevention, refer to Contamination Parameters Screen.

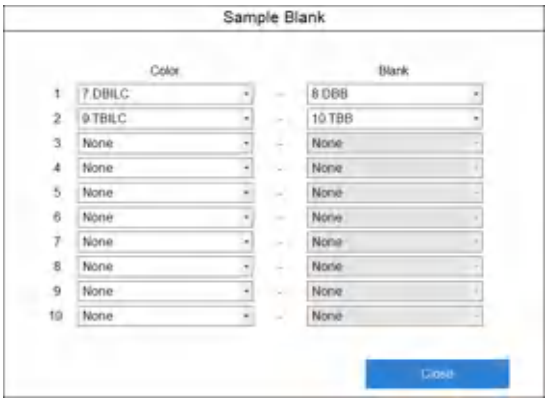
Sample Blank [F5]

Interference from other substances in the serum might affect the measured optical density. To correct this interference, the system performs a sample blank correction. Sample blank correction uses the terms color and blank, which refer to the active reagent (color) and the inert reagent (blank). The system multiplies the OD value of Y obtained from the formula Y = X - B (X is the OD value of a color item and B is the OD value of a blank item) with a factor. You can program a maximum of 10 sample blank tests.

Sample Blank tests include total and direct bilirubin. These tests contain an R1 color reagent and an R1 blank reagent.

- Select **CONFIG.** > **Test Name Parameters** > **Test Name** > **Sample Blank** [F5]. The Sample Blank dialog displays.

Figure 2.2 Sample Blank Dialog



- In **Color**, select the test to assign a color item.
- In **Blank**, select the test to assign a blank item.
- Select **Close** to save the programming.

Note

You cannot program calculated tests as color Items or blank Items.

Calculated Tests [F6]

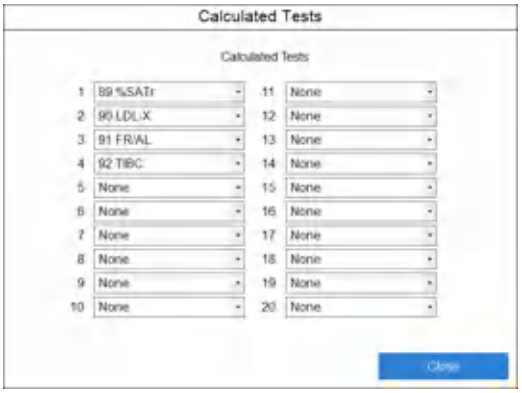
You can program a maximum of 20 tests as a calculated test. Refer to Calculated Tests Tab to program the specific tests and formula for the calculation.

Note

Program a calculated test name in the Test Name tab before you select it in the Calculated Tests dialog.

- Select **CONFIG.** > **Test Name Parameters** > **Test Name** > **Calculated Tests** [F6]. The Calculated Tests dialog opens.

Figure 2.3 Calculated Tests Dialog



- Select the calculated test name.
- Select **Close** to save the programming.

Common Reagents Tab

You can program common reagents for the R1-2 of a 3-part reagent that you use for more than one test. Assign the common reagent to the test in the General tab (**CONFIG.** > **Test Volume and Methods** > **General**). You can program a maximum of 10 common reagents.

Select **CONFIG.** > **Test Name Parameters** > **Common Reagents**.

Figure 2.4 Test Name Parameters: Common Reagents Tab

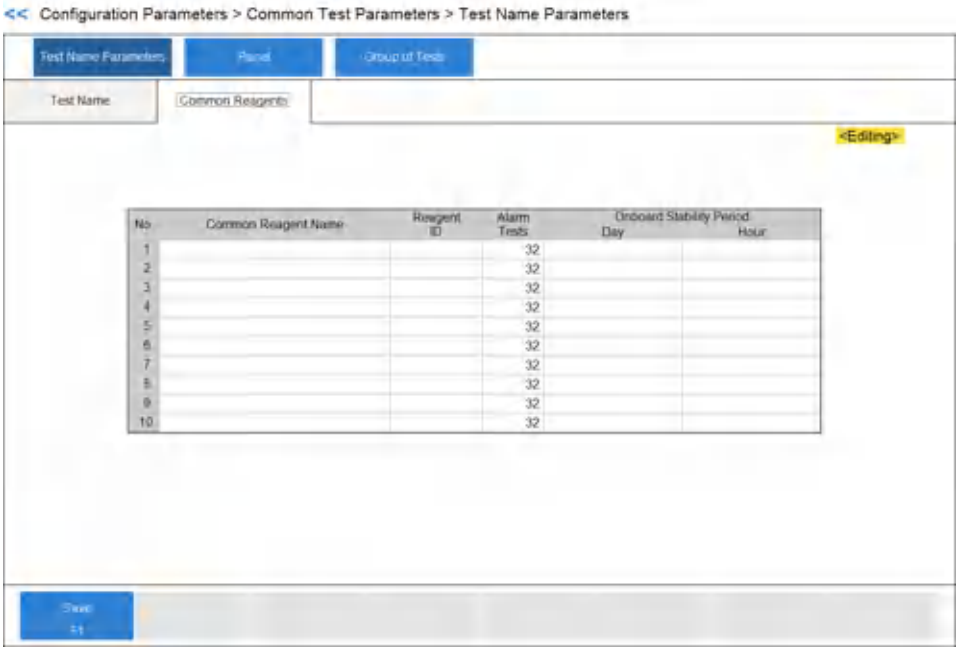


Table 2.3 Common Reagents Tab Description

Item	Contents	Input Notes
Common Reagent Name	Reagent name	A maximum of 6 characters.
Reagent ID (for all countries and regions except Japan)	3 digits (000 to 999)	The 3-digit Reagent ID located on the top, right side of the reagent IFU, or the first 3 digits from the reagent ID label.
Manufacturer ID (for Japan only)	3 digits (000 to 999)	The first three digits of the reagent ID. The reagent manufacturer defines the Manufacturer ID. Refer to the reagent *Instructions for Use*.
Test Code (for Japan Only)	2 digits (00 to 99)	The 2 digits of the reagent ID following the first 3 digits. Refer to the reagent *Instructions for Use*.
Alarm Tests	1 to 200. The default is 32.	Quantity of tests remaining before the system generates a `Reagent Insufficient` event.
Onboard Stability Period	Day (0 to 999) Hour (0 to 23)	Hours or days until the reagent onboard stability expires.

Panel Screen

A panel is a group of tests that you typically order at the same time. Using a panel reduces the quantity of selections needed, because a single panel is selected instead of multiple tests. You can program a maximum of 100 panels (Number 0 to Number 99) for samples, reagent blank, calibration, and QC. You can program a maximum of 99 tests in a panel. The

quantity of sample blank tests, LIH, and sample type limits the quantity of tests that you can program in a panel.

Assign each panel a name.

You cannot select unavailable tests.

You can only select ISE tests when the sample type is Serum or Urine.

For more information, contact Beckman Coulter.

Panel: Patient Sample Tab

Select **CONFIG.** > **Panel** > **Patient Sample**.

Figure 2.5 Panel: Patient Sample Tab

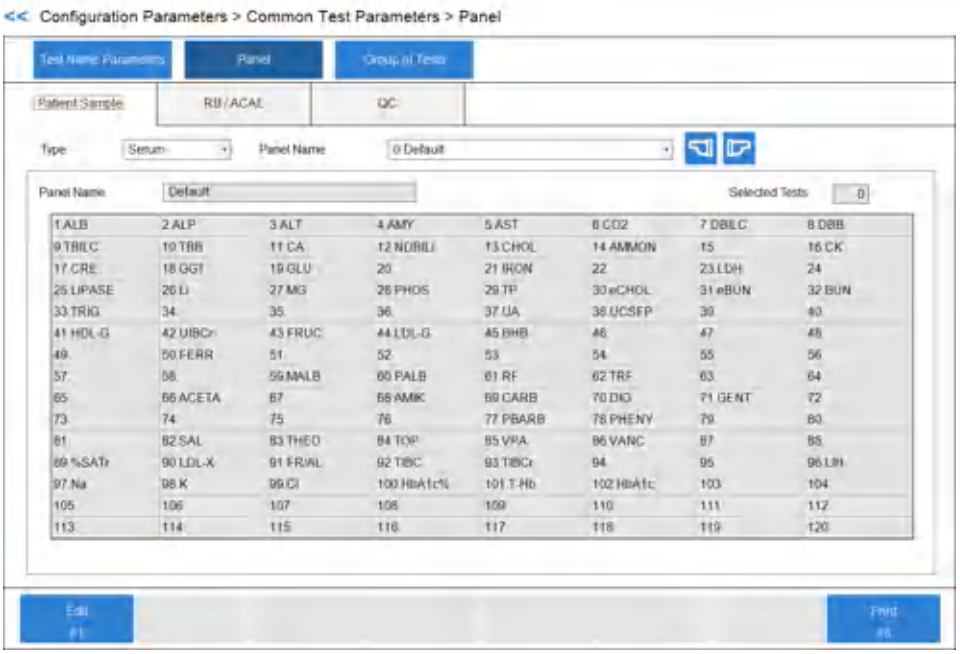


Table 2.4 Patient Sample Tab Description

Item	Contents	Input Notes
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Panel Name (option)	0 to 99	
Panel Name (selected option)	Panel name	A maximum of 20 characters.
Selected Tests	Displays the quantity of tests selected (highlighted in blue) in the panel.	

Note

You cannot select tests that are not available.

You can select ISE tests only when the sample type is Serum or Urine.

The system displays 100. HbA1c, 101.T-Hb and 102. A1c, but the fields are unavailable, and you cannot select them.

Panel: RB/ACAL Tab

Select **CONFIG.** > **Panel** > **RB/ACAL**.

Figure 2.6 Panel: RB/ACAL Tab

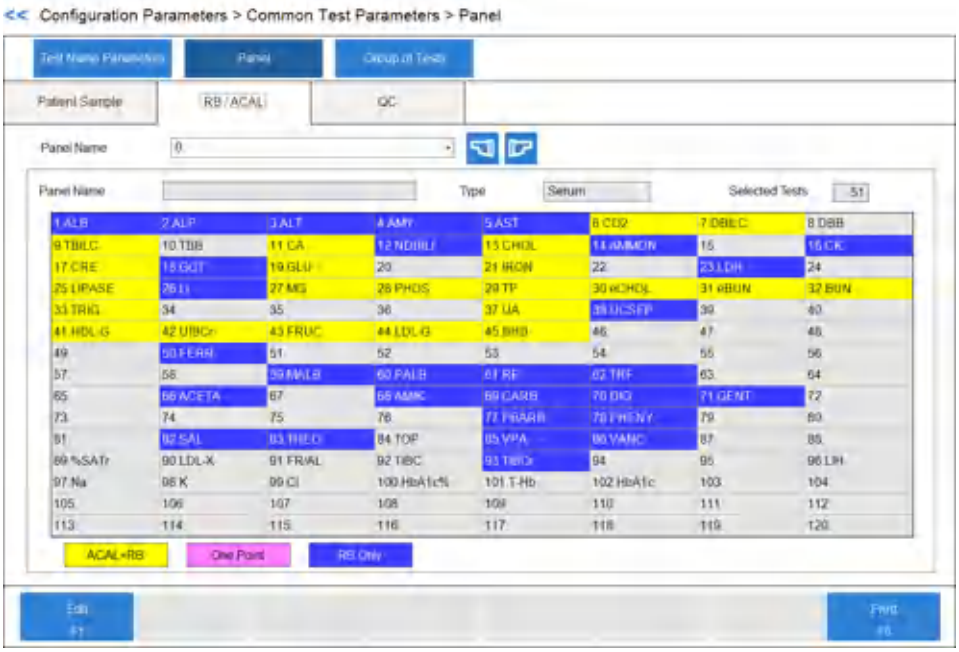


Table 2.5 RB/ACAL Tab Description

Item	Contents	Input Notes
Panel Name (option)	0 to 99	
Panel Name (selected option)	Panel name	A maximum of 20 characters.
Type	Serum, Urine, Other-1 or Other-2	
Selected Tests	Displays the quantity of tests selected (highlighted in yellow, pink, or blue) in the panel.	Select **Edit** [F1], and then select **Calibration Options** [F5] to change between the available calibration options: ACAL + RB (yellow) One Point (pink) RB Only (blue) Refer to Summary of Calibration Types and Calibration Setup: General Tab for more information.

Note

The programming in the General tab (**Calibration Setup** > **General**) determines the calibration options available from **Calibration Options** [F5].

You cannot select tests that are not available.

You can select ISE tests only when the sample type is Serum or Urine.

Panel: QC Tab

Select **CONFIG.** > **Panel** > **QC**.

Figure 2.7 Panel: QC Tab

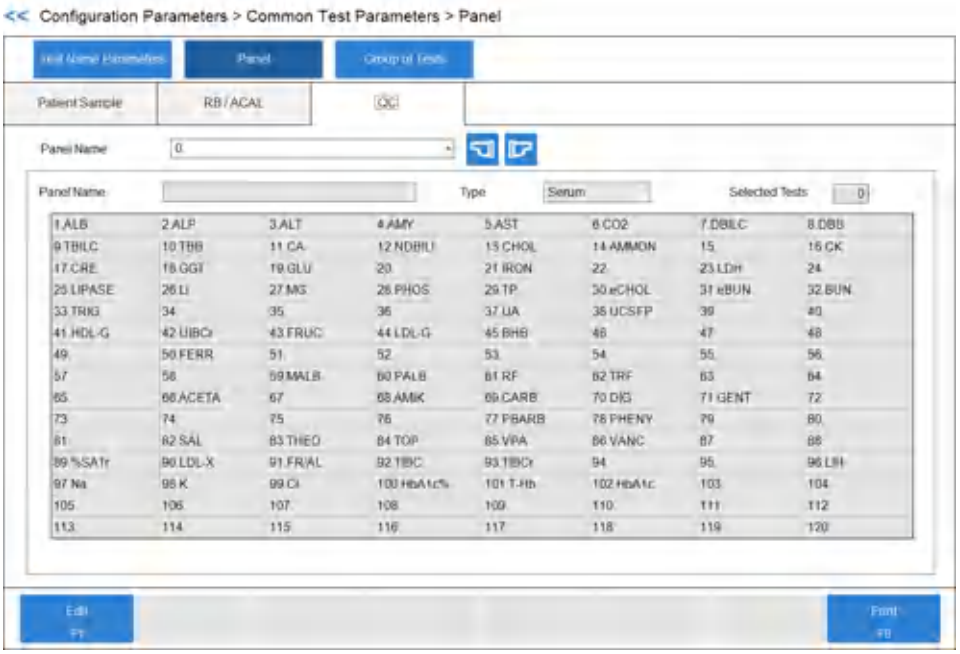


Table 2.6 QC Tab Description

Item	Contents	Input Notes
Panel Name (option)	0 to 99	Panel numbers 87 to 99 are default QC panels and correspond to a specific group and sample type. Refer to the following note.
Panel Name (selected option)	Panel name	A maximum of 20 characters.
Type	Serum, Urine, Other-1 or Other-2	
Selected Tests	Displays the quantity of tests selected (highlighted in blue) in the panel.	

Note

QC panels 87 to 99 are the default QC panels that the system automatically orders in the Rack (QC) screen (**TEST** > **Rack (QC)**). The QC panel numbers 87 to 99 correspond to a specific group and sample type:

- Number 87: Serum: For Group 1
- Number 88: Serum: For Group 2
- Number 89: Serum: For Group 3
- Number 90: Urine: For Group 1
- Number 91: Urine: For Group 2
- Number 92: Urine: For Group 3
- Number 93: Other-1: For Group 1
- Number 94: Other-1: For Group 2
- Number 95: Other-1: For Group 3
- Number 96: Other-2: For Group 1
- Number 97: Other-2: For Group 2
- Number 98: Other-2: For Group 3
- Number 99: Whole Blood: For Groups 1, 2, and 3

Note

You cannot select tests that are not available.

Group of Tests Screen

A Group is a collection of tests that you can program as the tests on board the analyzer. You can program three Groups of tests. Specify the Group in the Create Index dialog (**HOME** > **Create Index** [F1]). The system confirms that the reagents required for the Group are in the reagent refrigerators during the reagent check.

Program a maximum of 60 photometric tests plus the 3 ISE tests (63 total) in each Group.

Tests print in the order that you assign them to the Group. To change the test print order, select **CONFIG.** > **Group of Tests** > **Edit** [F1]. Select the test to move, then select **Forward** [F2] or **Backward** [F3]. LIH and calculated tests print last.

Select **CONFIG.** > **Group of Tests**.

Figure 2.8 Group of Tests Screen

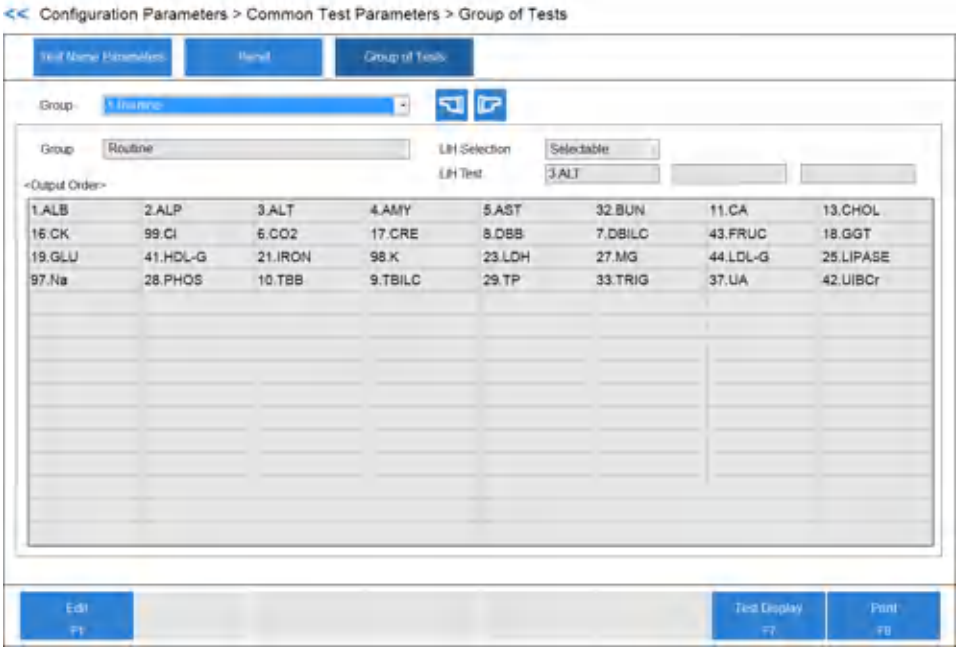


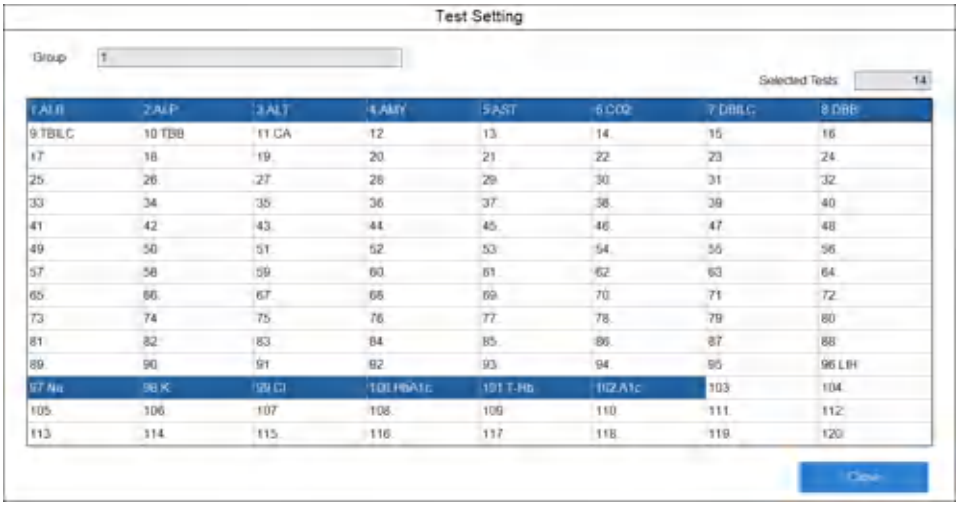
Table 2.7 Group of Tests Screen Description

Item	Contents	Input Notes
Group (option)	1, 2, or 3	
Group (selected option)	The Group name	A maximum of 20 characters.
LIH Selection	Select All or Selectable	**Select All**: Order LIH automatically on every sample. If you do not add `test 96. LIH` to any Group (1, 2, or 3) that has tests programmed, a red `Incorrect Parameter` message displays, and analysis cannot start. **Selectable**: Order LIH as needed on samples.
LIH Test Setting [F6]	A maximum of 3 tests for LIH analysis.	This option is only available if you set **LIH Reagent** to **Non Dedicated** in the Test Name Parameters: Test Name tab (**CONFIG.** > **Test Name Parameters** > **Test Name**). The system uses an existing (on board) test and reagent for LIH testing. You can select a maximum of 3 tests from the Group for LIH analysis.

Table 2.7 Group of Tests Screen Description (Continued)

Item	Contents	Input Notes
Test Setting [F5]	Select (highlight in blue) the tests to include in the Group.	Select tests in the order to display and print. The **<Output Order>** section displays the print order of the tests. You cannot select calculated tests to include in the Group because the system performs calculated tests automatically when you order all tests on a sample that are part of the calculated test.
Forward [F2] and Backward [F3]	Change the display and print order (output order) of the tests.	Select **Edit** [F1], then select the test to move, then select **Forward** [F2] and **Backward** [F3]. LIH and calculated tests print last.

Figure 2.9 Test Setting Dialog



Specific Test Parameters Menu

Program parameters in the Test Volume and Methods (**CONFIG.** > **Test Volume and Methods**), Rerun Test Parameters (**CONFIG.** > **Rerun Test Parameters**), and Rerun Check Parameters (**CONFIG.** > **Rerun Check Parameters**) screens.

Test Volume and Methods Screen

Program specific test parameters, LIH parameters, ISE parameters, HbA1c parameters, calculated tests, and reference intervals for tests.

Caution

Incorrect test parameters cause errors in analysis results, and can cause an incorrect diagnosis. Visually confirm test volume and methods settings against published settings, and analyze with materials with known concentrations.

For more information on displaying a list of programmed values, refer to Table 2.19 Test Volume and Methods: General Tab Description.

Test Volume and Methods: General Tab

Program the specific analysis parameters for each test. Program the test name before programming specific tests parameters. For more information, refer to Test Name Tab.

Pre-programming of test numbers 1 to 90 and 103 to 120 as either closed or open depends on the specific requirements for your laboratory.

The programmable parameters in the Test Volume and Methods screen (**CONFIG.** > **Test Volume and Methods**) determine whether to program a closed or open test number.

- Closed test numbers have fixed parameters (not programmable) and programmable parameters. After selecting **Edit** [F1], the background color becomes gray for fixed parameters and white for programmable parameters.
  - — Fixed parameters (not editable)
    - — Sample Volume and Dilution
    - — Pre-Dilution Rate and Diluent Bottle
    - — Reagent Volume R1 (R1-1) and Dilution
    - — Reagent Volume R1-2 and Dilution
    - — Reagent Volume R2 (R2-1) and Dilution
    - — Common Reagent Type and Name
    - — Wavelength (Primary and Secondary)
    - — Method
    - — Reaction Slope
    - — Measuring Point-1 (First and Last)
    - — Measuring Point-2 (First and Last)
    - — Analytical Measuring Range (High)
    - — Onboard Stability Period
  - — Editable parameters
    - — Reagent OD Limit First (Low and High)
    - — Reagent OD Limit Last (Low and High)
    - — Analytical Measuring Range (Low)
    - — Correlation Factor (A and B)
    - — LIH Influence Check
- For open test numbers, you can program all parameters.
- You can program all other parameters in the Configuration Parameters menus, including in the Test Name Parameters screen (Test Name, Long Name, Reagent ID, Alarm Tests, and Multi Reagent Switch), for closed or open test numbers.

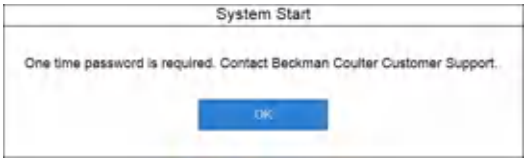
Caution

When Saving or Loading Parameters:

Follow all cautions in the *DxC 700 AU Instructions for Use* when using external media to save or load parameters. To save parameters for each DxC 700 AU, you need one CD-R or USB external memory device.

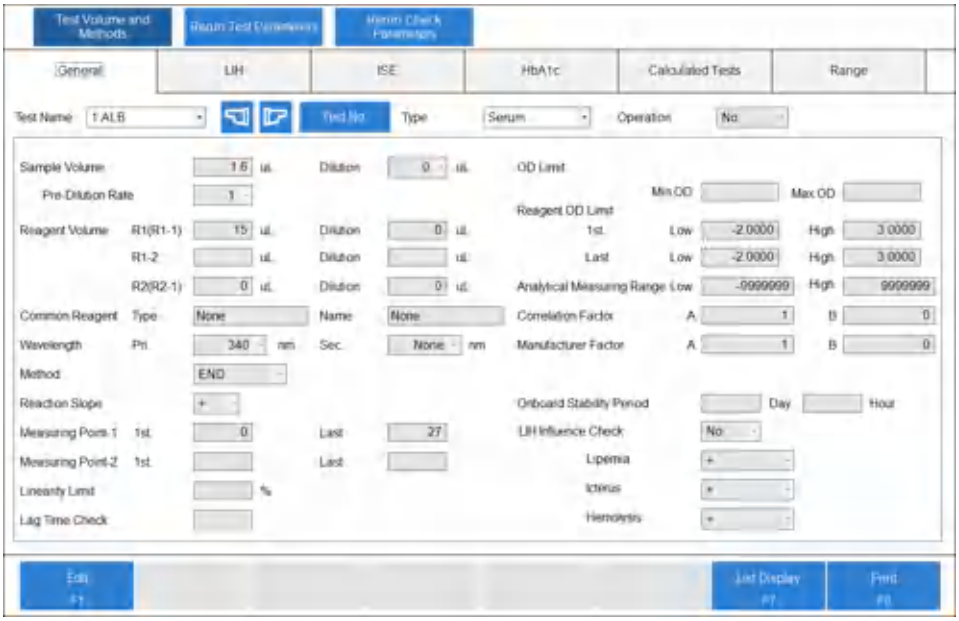
You save pre-programming of test numbers 1 to 90 and 103 to 120 as either closed or open along with other parameters on the external media. If you load the parameters from one DxC 700 AU onto another DxC 700 AU with a different configuration of closed and open test numbers, the following message displays after 30 days when you turn on the DxC 700 AU. If the following System Start message displays, contact Beckman Coulter.

Figure 2.10 System Start Dialog



Select **CONFIG.** > **Test Volume and Methods** > **General**.

Figure 2.11 Test Volume and Methods: General Tab



Enter test parameters from the reagent setting sheet. You cannot program a field that is not available.

Table 2.8 Test Volume and Methods: General Tab Description

Item	Contents	Input Notes
Test Name	Abbreviated test name in a list.	Select the Test Name to program the parameters.
Type	Serum, Urine, Other-1, or Other-2	The sample type.
Operation	Yes or No	**Yes**: the test is operational for the type displayed. **No**: the test is not operational for the type displayed. If you program a test as **No**, it is not available to order or run. The test displays grayed out and is inaccessible in the list of tests.
Sample Volume and Dilution	If Dilution is 0 µL, then you can set the sample volume between 1.0 µL and 25.0 µL. If Dilution is 10 µL, then you can set the sample volume between 1.0 µL and 20.0 µL. The minimum sample volume is 1.0 µL.	You can set **Sample Volume** in increments of 0.1 µL. The system uses deionized water (0 or 10 µL) dispensed for a sample dilution following the sample dispense. If you set **Dilution** to 0 µL, then the system aliquots an extra 2.9µL of sample for dispensing accuracy.
Pre-Dilution Rate	1, 3, 5, 10, 15, 20, 25, 50, 75, or 100	Defines the automatic pre-dilution rate. The system uses two cuvettes for dilution and reaction for a test. First the analyzer performs sample dilution with deionized water or other diluent in a dilution cuvette, then dispenses the test sample volume from the dilution cuvette into a reaction cuvette. Refer to Pre-Dilution Rate Volumes for the sample volumes required for each pre-dilution rate.
Reagent Volume	R1(R1-1): 10 to 250 µL R1-2: 0, 5, 10 to 20 µL R2(R2-1): 0, 10 to 250 µL	You can set reagent volumes in increments of 1.0 µL. The total maximum reagent volume and dilution is 250 µL.
Dilution	(R1-1): 0, 10 to 240 µL R1-2: 0, 10 to 20 µL R2(R2-1): 0, 10 to 240 µL	
Wave Length Pri.	340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750, and 800 nm	

Table 2.8 Test Volume and Methods: General Tab Description (Continued)

Item	Contents	Input Notes
Wave Length Sec.	None, 340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750, and 800 nm	
Method	END, RATE, FIXED, END1, RATE1, FIXED1	The 1 at the end of a method name indicates a method not using a reagent blank correction. The system does not subtract the reagent blank from the measuring points.
Reaction Slope	+, -	Select **+** for an increasing reaction curve. Select **-** for a decreasing reaction curve.
Measuring Point-1 Measuring Point-2	END method, FIXED method • First: 0 to 26 • Last: 1 to 27 RATE method • First: 0 to 25 • Last: 1 to 27	Self blank: The system subtracts absorbance of Measuring Point-2 data (caused by sample) from Measuring Point-1 data (reaction data).
Linearity Limit	0 to 100	A check for Rate Methods to confirm if the reaction is non-linear caused by exceeding the defined % variance or OD limits between photometer read points. If the limits are exceeded, the system generates a * flag. Refer to Linearity Limit.
Lag Time Check	YES or NO	You can set **Yes** for only Rate Methods. *Lag time* is the time after the system adds all reagents to the sample and before it takes any read points to determine the reaction rate. Refer to Lag Time Check.
OD Limit	-2.0000 to 3.0000	You can program this field for only Rate and Fixed methods. Generates a B flag for less than the minimum OD and a D flag for greater than the maximum OD.
Reagent OD Limit	-2.0000 to 3.0000	Reagent blank OD limits at the first and last read points. Generates a u flag or U flag for less than the minimum reagent OD. Generates a y flag or Y flag for greater than the maximum reagent OD.

Table 2.8 Test Volume and Methods: General Tab Description (Continued)

Item	Contents	Input Notes
Analytical Measuring Range	Low: -9999999 to 9999999 High: Low value to 9999999	The range the analyzer can measure for a reagent. Enter a 7-digit numerical value, not including a minus sign or decimal point. Generates an F flag (over) or G flag (under) flag. If the system cannot calculate a concentration value, it uses the OD value to determine measurements outside of the analytical measuring range. Generates a Fx flag for an OD value greater than the OD of the upper limit of the analytical measuring range. Generates a Gx flag for an OD value less than the OD of the lower limit of the analytical measuring range. Set the number of decimal places in the Range tab.
Correlation Factor	A: -9999999 to 9999999 B: -9999999 to 9999999	Corrects the concentration value with the equation Y = AX + B. The system performs the correlation correction after checking the analytical measuring range.
Manufacturer Factor	Display only	This coefficient corrects the concentration value with the equation of Y=AX+B. The system corrects the value before checking the analytical measuring range.
Onboard Stability Period	Days (0 to 999) and hours (0 to 23)	The onboard stability period starts when the system performs the reagent check, even if the system does not use the reagent.
LIH Influence Check	Yes or No	Only displays if Beckman Coulter enables the optional Test Specific LIH in System Maintenance. **Yes**: Flags the result with l, i, or h if the level of LIH exceeds the specific limits of the test. If the system does not perform LIH testing on the sample, the system generates an n flag. **No**: Does not perform test specific LIH evaluation for the test.
Lipemia	+, ++, +++, ++++, +++++	If you program **Yes** in **LIH Influence Check**, program test-specific LIH criteria from the test-specific reagent setting sheet.
Icterus		
Hemolysis		
Change Reagent Type [F5]	Function button	Select **R1-2** to program a 3-part reagent.
Set Common Reagent [F6]	Function button	Program the R1-2 of a 3-part reagent to use for two tests.

Table 2.8 Test Volume and Methods: General Tab Description (Continued)

Item	Contents	Input Notes
List Display [F7]	Function button	Displays a list of all test parameters. Use the list to confirm parameters. Six tests display at a time. Select the sample type to display in **Type**.

Pre-Dilution Rate Volumes

Table 2.9 Pre-Dilution Rate Volumes

Pre-Dilution Rate	Sample Volume (µL)	Dilution Volume (µL)	Volume in Cuvette
3	50	100	150
5	30	120	150
10	20	180	200
15	15	210	225
20	10	190	200
25	8	192	200
50	4	196	200
75	3	222	225
100	2	198	200

Linearity Limit

Linearity Calculation Method:

(|a-b|/(|c|* 0.5))*100 = Linearity limit value (parameter)

a: OD value change quantity of the first half of the reaction curve

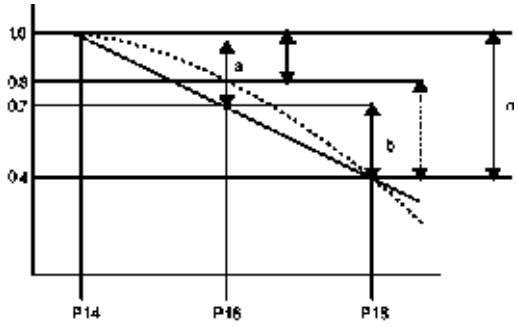
b: OD value change quantity of the last half of the reaction curve

c: OD value change quantity of the reaction curve (between photometry start point and end point)

| |: Absolute value

- For a straight line (like the solid line shown in Figure 2.12 Linearity Calculation Method), the values of a and b become almost the same and linearity becomes 0%.
- For a curved line (like the dotted line shown in Figure 2.12 Linearity Calculation Method), a becomes smaller and b becomes larger, and linearity becomes 67% approximately.

Figure 2.12 Linearity Calculation Method



Lag Time Check

If you select **Yes** in **Lag Time Check**, the system performs the following check:

- The Predicted maximum reaction OD (delta OD) is calculated to the concentration.
- Checks the converted concentration against the analytical measuring range.

  If more than two points of the measurements fall within the analytical measuring range, the lag time check occurs using the measurement results. The system generates an E flag when the measurement results fail the lag time check.

  If only two points or less of the measurements fall within the analytical measuring range, the system calculates the OD using the measurement results obtained before the measuring points programmed in the General tab, for example P11.

LIH Tab

If you assign LIH to Test 96, LIH using Dedicated LIH Reagent or saline, program the LIH parameters. Refer to Test Name Tab.

Select **CONFIG.** > **Test Volume and Methods** > **LIH**.

Figure 2.13 Test Volume and Methods: LIH Tab

Note

LIH Judgement Level

The system observes OD limits to flag samples for lipemia, icterus, and hemolysis. Each sample prints with LIP (lipemia), ICT (icterus), and HEM (hemolysis) tests with normal, +, ++, +++, ++++, +++++.

Note

LIH Reagent (OSR62166) is the only validated reagent for sample and test-specific LIH testing.

Table 2.10 LIH Tab Description

Item	Contents	Input Notes
LIH Reagent	Dedicated or Non Dedicated	Displays what you select in the Test Name tab (**CONFIG.** > **Test Name Parameters** > **Test Name**). You can enter values in Sample Volume, Dilution, Reagent Volume, and Onboard Stability Period only if you set LIH Reagent to **Dedicated**. If you set LIH Reagent to **Non Dedicated**, the system uses the parameters from the on-board test.

Table 2.10 LIH Tab Description (Continued)

Item	Contents	Input Notes
Sample Volume and Dilution	Sample volume and dilution volume in µL	Set in increments of 0.1 µL. • If Dilution is 0 µL, you can set the sample volume from 1.0 to 25.0 µL. • If Dilution is 10 µL, you can set the sample volume from 1.0 to 20.0 µL. • The minimum sample volume is 1.0 µL.
Reagent R1 (R1-1) Volume and Dilution	Reagent volume and dilution volume in µL	Set in increments of 0.1 µL. The total reagent volume and dilution is a maximum of 250 µL. • If Dilution is 0 µL, you can set the reagent volume from 10 to 250 µL. • If Dilution is 10 µL, you can set the reagent volume to 0, or from 10 to 240 µL.
Onboard Stability Period	Days (0 to 999) and Hours (0 to 23)	
LIH Judgement Level	Program the judgment level separately for Lipemia, Icterus, and Hemolysis. + : 0.0 to 3.0 ++ : + value to 3.0 +++ : ++ value to 3.0 ++++ : +++ value to 3.0 +++++ : ++++ value to 3.0	Refer to the LIH reagent setting sheet or enter values established by the facility. LIH Reagent with LIH parameters from the reagent setting sheet is the only validated option for test-specific LIH.

Test Volume and Methods: ISE Tab

If you use the ISE option, program the operation, analytical measuring range, and correlation factor for the serum and urine sample types.

Select **CONFIG.** > **Test Volume and Methods** > **ISE**.

Figure 2.14 Test Volume and Methods: ISE Tab

Note

Sample Volume, Dilution, MID CONC, STD CONC Low, and STD CONC High display the pre-programmed values and you cannot change them.

Program the Operation, LIH Influence Check, Analytical Measuring Range, and Correlation Factor for Serum and Urine.

Table 2.11 Test Volume and Methods: ISE Tab Description

Item	Contents	Input Notes
Operation	Yes or No	Select **Yes** to enable operation for Na, K, and Cl testing for Serum or Urine.
LIH Influence Check	Yes or No	LIH Influence Check only displays if Beckman Coulter enables the optional Test Specific LIH in System Maintenance. **Yes**: Flags the result with l, i, or h if the level of LIH exceeds the specific limits of the test. If the system does not perform LIH testing on the sample, the system generates an n flag. **No**: Does not perform test-specific LIH evaluation for the test.
Lipemia	+, ++, +++, ++++, +++++	If you program **Yes** in **LIH Influence Check**, program test-specific LIH criteria from the test-specific reagent IFU.
Icterus		
Hemolysis		

Table 2.11 Test Volume and Methods: ISE Tab Description (Continued)

Item	Contents	Input Notes
Analytical Measuring Range	Low: -9999999 to 9999999 High: Low value to 9999999	Refer to *ISE Reagents Instructions for Use*. Enter a 7-digit numerical value, not including a minus sign and decimal point. Set the number of decimal places in the Range tab.
Correlation Factor	A: -9999999 to 9999999 B: -9999999 to 9999999	Correlation value = A x (measuring value) + B. Enter a 7-digit numerical value, not including a minus sign and decimal point.

HbA1c Tab

⚠ Caution

Use this function with the HbA1c reagent (for automated sample preparation) delivered from Beckman Coulter. Use of any other reagent can cause incorrect diagnostic results.

Operation of the three tests 100. HbA1c, 101. T-Hb, and 102. A1c, and some of the specific test parameters are pre-programmed and you cannot change them.

Program HbA1c Tests

Select **CONFIG.** > **Test Volume and Methods** > **HbA1c**.

Figure 2.15 Test Volume and Methods: HbA1c Tab

Table 2.12 HbA1c Tab Description

Item	Contents	Input Notes
Operation	Yes or No	Select **Yes** to enable operation for HbA1c analysis. This selection enables operation for tests 100. HbA1c, 101. T-Hb, and 102. A1c. You cannot enable 100. HbA1c, 101. T-Hb, or 102. A1c individually.
Reagent OD Limit	First Low:-2.0000 to 3.0000 High:-2.0000 to 3.0000 Last Low:-2.0000 to 3.0000 High:-2.0000 to 3.0000	
Dynamic Range	Low: -9999999 to 9999999 High: Low value to 9999999	
Correlation Factor	A: -9999999 to 9999999 B: -9999999 to 9999999	Corrects the concentration value with the equation Y = AX + B. The system performs the correlation correction after checking the dynamic range.
Manufacturer Factor	Display only	This coefficient corrects the concentration value with the equation of Y=AX+B. The system corrects the value before checking the dynamic range. If you program **Correlation Factor** and **Manufacturer Factor**, the system calculates the results with both factors. Onboard Stability Period Days (0 to 999) and Hours (0 to 23)

Calculated Tests Tab

Program the calculation parameters for a maximum of 20 calculated tests. Define the calculated test name in the Calculated Tests dialog (**CONFIG.** > **Test Name Parameters** > **Test Name** > **Calculated Tests** [F6]) before it becomes available to enter parameters. When you program, order, and run all the tests in the calculation simultaneously, the system performs the calculated tests and prints them automatically. You can assign a reference interval to the calculated test in the Range screen.

To program the calculated test name, refer to Test Name Parameters Screen.

Select **CONFIG.** > **Test Volume and Methods** > **Calculated Tests**.

Figure 2.16 Test Volume and Methods: Calculated Tests Tab

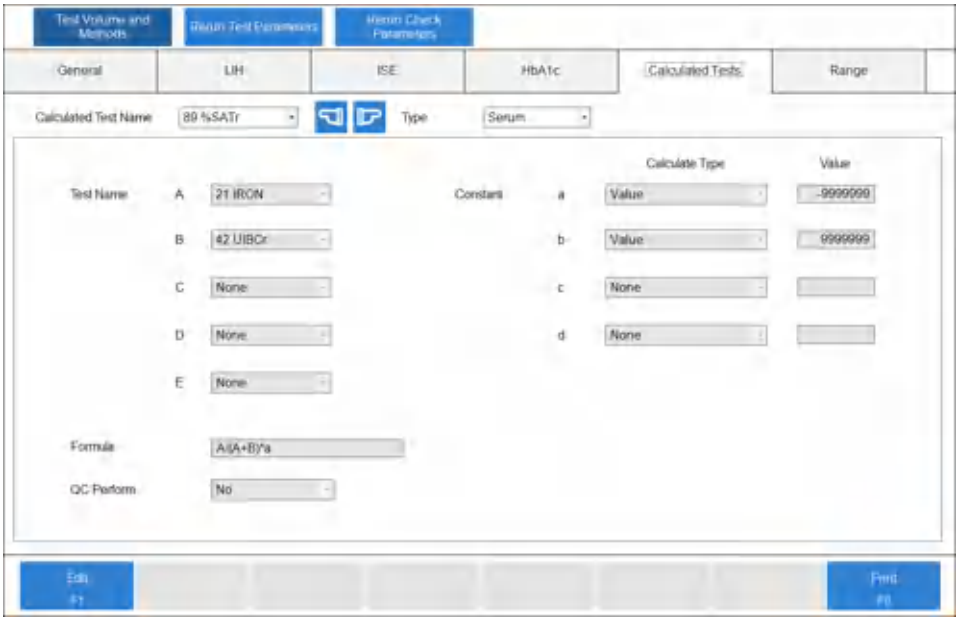


Table 2.13 Calculated Tests Tab Description

Item	Contents	Input Notes
Calculated Test Name	Calculated test number 1 to 20	Assign a calculated test name to a calculated test number in the Calculated Tests dialog (**CONFIG.** > **Test Name Parameters** > **Test Name** > **Calculated Tests** [F6]) before it becomes available.
Type	Serum, Urine, Other-1, or Other-2	The sample type.
Test Name	Select the tests involved in the calculation at A, B, C, D, and E.	You can set a maximum of 5 tests.
Constant	If you select **Value** for **Calculate Type**, enter a numerical constant (-9999999 to 9999999) in **Value** for a through d. If you select one of the items from **Patient Info.-1** through **Patient Info.-6** for **Calculate Type**, then you can use Patient Information 1 to 6 defined as a Numeric Attribute.	You can set a maximum of 4 constants. Enter a 7-digit numerical value, not including a minus sign and decimal point. You can program patient information in the Sample Program Format screen (**CONFIG.** > **Sample Program Format**). Select **Numeric Attribute** in **Attribute** to allow entering a numerical value as a patient demographic used as a constant a through d in the calculated test.

Table 2.13 Calculated Tests Tab Description (Continued)

Item	Contents	Input Notes
Formula	Calculated test formula	A maximum of 20 characters. A combination of the characters in +-*/ ()ABCDEabcd
QC Perform	Yes or No	If you select **Yes**, you can program a QC range for the calculated test in the Check tab (**CONFIG.** > **QC Setup** > **Check**).

Note

The calculation formula uses A to E, arithmetic calculation, and the coefficients a to e. The coefficients can use numerical patient information (for example, weight).

If you select **Yes** for **QC Perform**, you can program a QC range for the calculated test in the Check tab (**CONFIG.** > **QC Setup** > **Check**). For example, the QC might be in range for TP and ALB. But if the system performs an albumin and globulin ratio calculation with a QC range programmed, the calculated test QC can be out of range.

If a calculated test generates a rerun flag, or if all tests in the calculated test generate a rerun flag, the system reruns the calculated test. You can program a calculated test to generate ph, pl, P, N, H, L, J, and K flags.

You cannot use color Items, blank Items, LIH, calculated tests, and test numbers of 100, 101, and 102 in the formula.

Range Tab

Program the reference interval values for tests.

The system performs data judgment with the use of numerical values (quantitative method) or flags (qualitative method).

Select **CONFIG.** > **Test Volume and Methods** > **Range**.

Figure 2.17 Test Volume and Methods: Range Tab

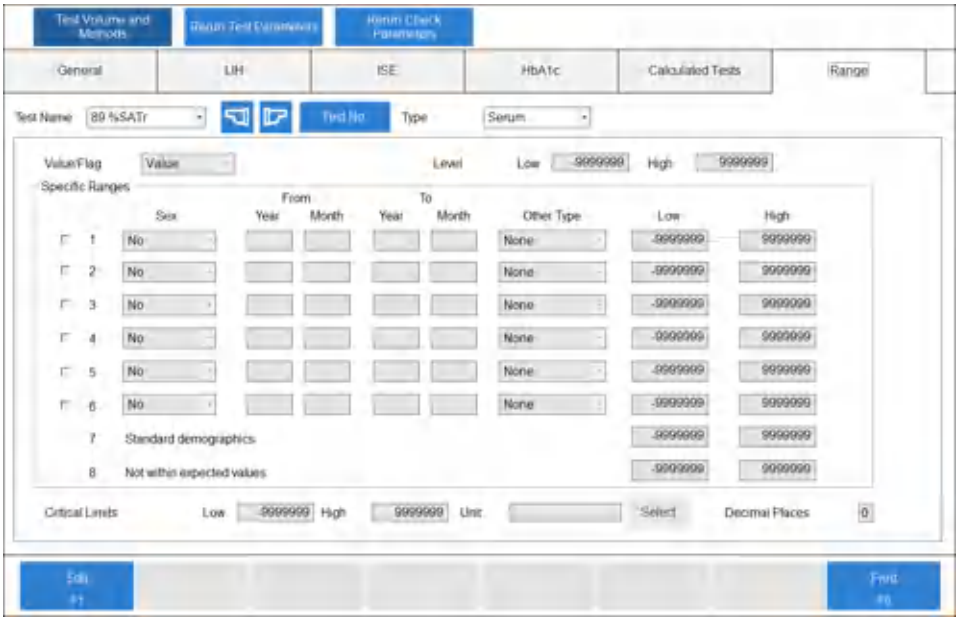


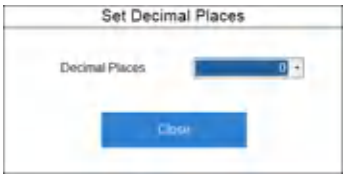
Table 2.14 Range Tab Description

Item	Contents	Input Notes
Test Name	A test name	
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Value/Flag	Value or Flag. For Flag, enter a number (-9999999 to 9999999) for Level: Low and Level: High.	**Value**: Program a normal reference interval in **Specific Ranges** (1 to 8) to generate L (low) or H (high) flag on tests. You can program specific reference intervals by sex and age. **Flag**: Program a range in **Low** and **High** of the **Level** section to generate a P (positive) flag if over the high limit, or N (negative) flag if below the low limit. Typically you program this range for qualitative drugs-of-abuse testing.
Critical Limits	Enter a number (-9999999 to 9999999) for Low and High.	Enter operator-defined critical limits. The system generates a pl flag if the result falls below the low limit, and a ph flag if the result falls above the high limit. It generates an audible alarm if the critical limit is exceeded.
Unit	The units to print on a report.	

Table 2.14 Range Tab Description (Continued)

Item	Contents	Input Notes
Specific Ranges 1 to 8	Low: -9999999 to 9999999 High: Low value to 9999999	A 7-digit numerical value, not including a minus sign and decimal point. Program the number of decimal places in the Decimal Places dialog (**Decimal Places** [F5]). Program ranges to generate L flags for data less than the low limit or H flags for data greater than the high limit. **1** to **6**: Enter a reference interval for age, sex, or other type. Program patient demographics to use this feature. **Note** Other Type provides the option to program a reference interval other than age and sex. For more information, refer to Other Type. **7. Standard demographics:** Enter a generic reference interval. Use this range for a sample without patient demographic information (age or sex). **8. Not within expected values:** Use this range for a sample with patient demographic information (age or sex), but the age or gender information does not satisfy the age and sex defined in **1** to **6**.
Decimal Places [F5] displays after selecting Edit [F1].	0 to 4	The decimal places entered affect software prompts and printed results.

Figure 2.18 Set Decimal Places Dialog



Other Type

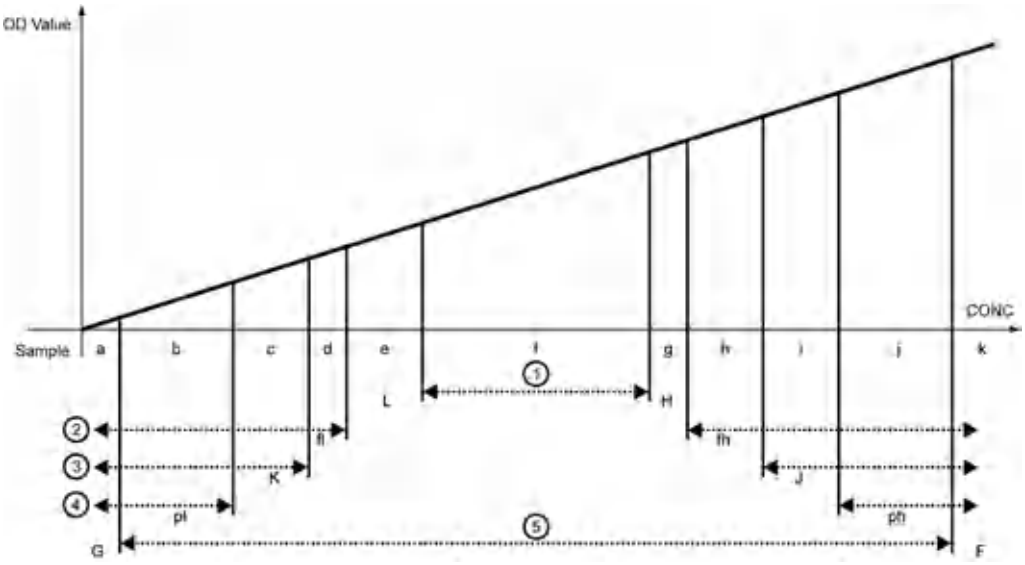
Other Type provides the option to program a reference interval other than age and sex when using patient demographics.

Other Type has six classifications (1 to 6) that can be named in **Other Type** in the Range tab. Refer to Table 2.13 Range Tab Description for more information.

To activate the Other Type as a reference interval for patient demographics, select **Other Type** in the Sample Program Format screen. For more information, refer to Sample Program Format Screen. You can select the Other Type reference interval when ordering in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics**, or **STAT** > **STAT (Patient)** > **Demographics**).

Programmable Ranges and Limits in the General, ISE, and Range Tabs, and the Rerun Test Parameters Screens to Generate Flags

Figure 2.19 Possible Flags in Order of Increasing OD



1. Reference interval
2. Reflex values
3. Rerun decision values
4. Critical values
5. Analytical measuring range

- Up to 4 flags can be attached to abnormal data according to priority.

Sample	a	b	c	d	e	f	g	h	i	j	k
Flag	G,pl, L,K, (fl)	pl,L, K,fl	L,K, fl	L,fl	L	none	H	H,fh	H,J, fh	ph,H, J,fh	F,ph, H,J,(fh)

- As sample f is within the reference interval, it has no flag.
- The four flags with the highest priorities are displayed on the monitor and are printed on the report next to the result.
- Online parameters can be programmed to transmit two or four result flags. Refer to Online Menu for more information.
- The rerun decision limits and reflex limits are programmed within the analytical measuring range.

Table 2.16 Screen or Tab to Program Each Range

Contents	Screen or Tab
Reference interval	**CONFIG.** > **Test Volume and Methods** > **Range**
Critical limits	**CONFIG.** > **Test Volume and Methods** > **Range**

Table 2.16 Screen or Tab to Program Each Range (Continued)

Contents	Screen or Tab
Analytical measuring range	**CONFIG.** > **Test Volume and Methods** > **General and ISE**
Rerun Decision limits	**CONFIG.** > **Rerun Test Parameters**
Reflex limits	**CONFIG.** > **Rerun Test Parameters**

Rerun Test Parameters Screen

The DxC 700 AU allows either manual or automatic rerun sample analysis. This section describes how to program the rerun tests.

Normal rerun:

The analyzer performs analysis with the same parameters used for the first-run analysis.

Rerun with dilution:

The analyzer performs analysis with a pre-dilution or a smaller sample volume than the first run. Pre-dilution means that the system makes a dilution cuvette of sample and diluent on-board the analyzer. The system dispenses the sample from the dilution cuvette into the reaction cuvette.

1. Reduce the sample dispense volume.
2. Increase the dilution ratio.

Rerun with concentration:

The analyzer performs analysis with a larger sample volume than the first-run analysis.

1. Increase the sample dispense volume.
2. Reduce the dilution ratio.

Warning

- **With operator-defined parameters, the operator must confirm that the results satisfy the requirements for test performance, including reproducibility and accuracy.**
- **For best performance, confirm that the measured value with the rerun dilute or condense sample volume and dilution ratio is well within the analytical measuring range of the test.**
- **When possible, change either the sample volume or the dilution ratio and avoid changing both for dilution or condense.**

Note

If the DxC 700 AU is connected to a Laboratory Automation System:

- For samples transported from the Laboratory Automation System, the system queries the Laboratory Information System for the test order and required dilution. The analyzer processes the sample as a first-run sample.
- The system processes samples on the STAT table as rerun samples and can query the Laboratory Information System or use rerun parameters for the rerun order.

Program the sample volume, diluent volume, and pre-dilution rate for a normal rerun, rerun with dilution, and rerun with concentration.

Select **CONFIG.** > **Rerun Test Parameters**.

Figure 2.20 Rerun Test Parameters Screen

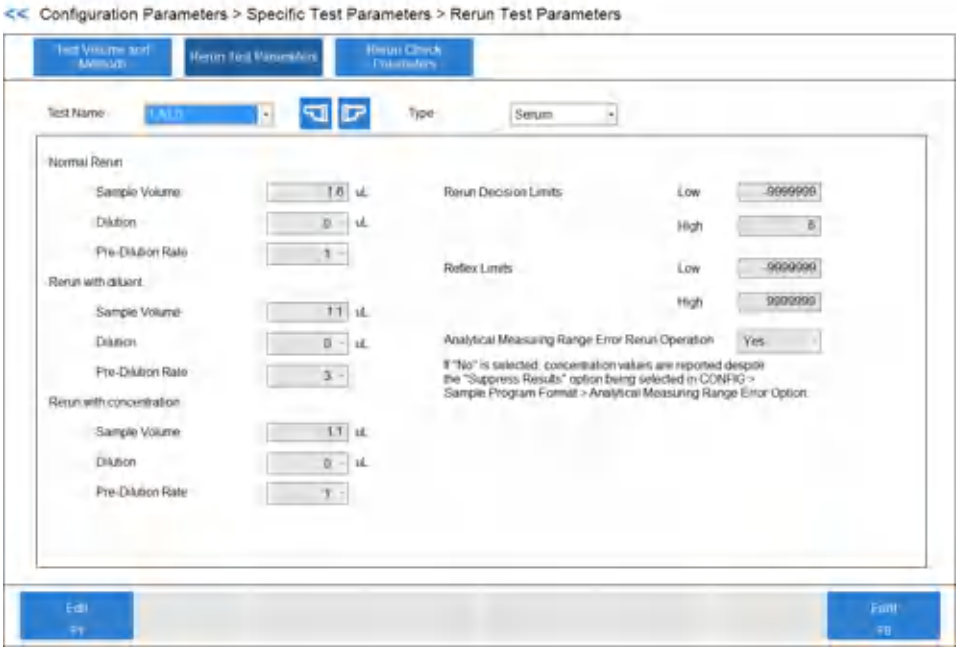


Table 2.17 Rerun Test Parameters Screen Description

Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Normal Rerun • Sample Volume • Dilution • Pre-Dilution Rate	Sample Volume, Dilution, and Pre-Dilution Rate display from the General tab (**CONFIG.** > **Test Volume and Methods** > **General**).	

Table 2.17 Rerun Test Parameters Screen Description (Continued)

Item	Contents	Input Notes
Rerun with diluent and Rerun with concentration • Sample Volume • Dilution	• If Dilution is 0 µL, then you can set the sample volume between 1.0 µL and 25.0 µL. • If Dilution is 10 µL, then you can set the sample volume between 1.0 µL and 20.0 µL. • The minimum sample volume is 1.0 µL.	You can set **Sample Volume** in increments of 0.1 µL. The system uses deionized water (0 or 10 µL) dispensed for a sample dilution following the sample dispense.
Pre-Dilution Rate	1, 3, 5, 10, 15, 20, 25, 50, 75, 100	Defines the automatic pre-dilution rate. The system uses two cuvettes for dilution and reaction for a test. First the analyzer performs sample dilution with deionized water or other diluent in a dilution cuvette, then dispenses the test sample volume from the dilution cuvette into a reaction cuvette. Refer to Pre-Dilution Rate Volumes for the sample volumes required for each pre-dilution rate.
Rerun Decision Limits Low and High	A number (-9999999 to 9999999)	Operator-defined limits to generate a rerun order. Results below the low limit generate a K flag. Results above the high limit generate a J flag.
Reflex Limits Low and High	A number (-9999999 to 9999999)	Operator-defined limits to generate the reflex testing. Results below the low limit generate an fl flag. Results above the high limit generate an fh flag. The system uses these limits to automatically order related tests when the deciding test results in either of these flags. Program the deciding test and related tests in the Reflex tab (**CONFIG.** > **Rerun Check Parameters** > **Reflex**).

Table 2.17 Rerun Test Parameters Screen Description (Continued)

Item	Contents	Input Notes
Analytical Measuring Range Error Rerun Operation	Yes or No	If you select **Yes**, a test generates a F, G, Fx, or Gx flag, and you select the corresponding flag in the Flag tab (**CONFIG.** > **Rerun Check Parameters** > **Flag**), the system reruns the test. If you select **No**, a test generates a F, G, Fx, or Gx flag, and you select the corresponding flag in the Flag tab (**CONFIG.** > **Rerun Check Parameters** > **Flag**), the system does not rerun the test and always reports concentration values, even if they are above the analytical measuring range. The default setting is **Yes**.

Rerun Check Parameters Screen

Flag Tab

Select **CONFIG.** > **Rerun Check Parameters** > **Flag**.

Figure 2.21 Rerun Check Parameters: Flag Tab

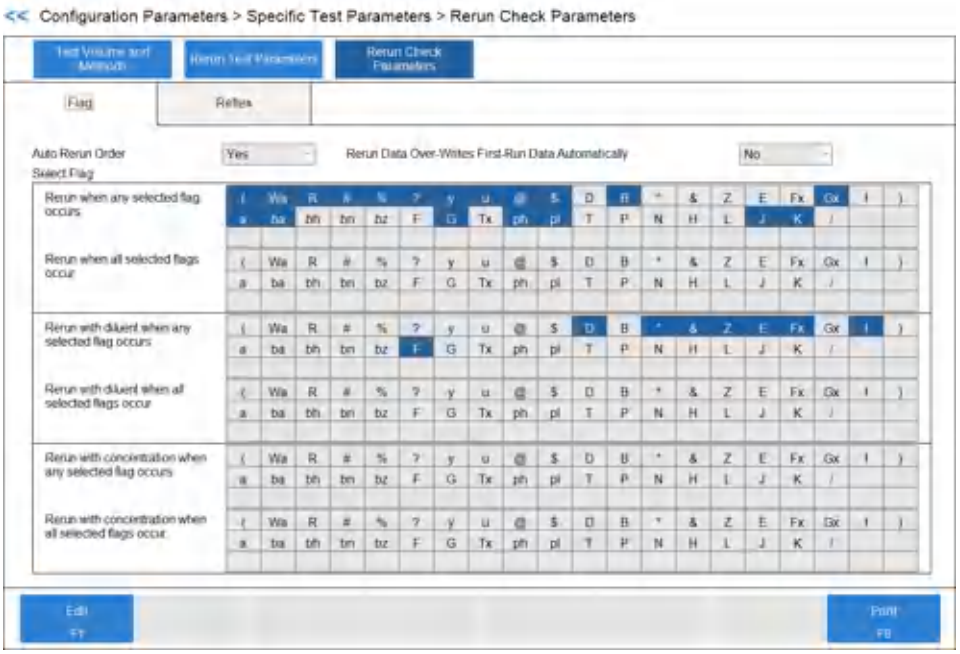


Table 2.18 Flag Tab Description

Item	Contents	Input Notes
Auto Rerun Order	Yes or No	Select **Yes** to generate automatic rerun orders. If you select **No**, you must retrieve the rerun orders in the Rerun dialog (**TEST** > **Rack (Patient)** > **Test Order** > **Rerun** [F3]) or (**STAT** > **STAT (Patient)** > **Test Order** > **Rerun** [F3]).
Rerun Data Over-Writes First-Run Data Automatically	Yes or No	Select **Yes** to automatically over-write first-run data with rerun data. Select **No** to review the first-run data and rerun data before over-writing.
Rerun when any selected flag occurs.	Select the flags to generate a rerun order.	The system issues a rerun order when it generates any of the highlighted flags.
Rerun when all selected flags occur.	Select a flag to generate a rerun order.	The system issues a rerun order only when it generates all highlighted flags.
Rerun with diluent when any selected flag occurs.	Select a flag to generate a rerun order.	The system issues a rerun dilution order when it generates any of the highlighted flags.
Rerun with diluent when all selected flags occur.	Select a flag to generate a rerun order.	The system issues a rerun dilution order only when it generates all highlighted flags.
Rerun with concentration when any selected flag occurs.	Select a flag to generate a rerun order.	The system issues a rerun condense order when it generates any of the highlighted flags.
Rerun with concentration when all selected flags occur.	Select a flag to generate a rerun order.	The system issues a rerun condense order only when it generates all highlighted flags.

You can select the same flag for only one of the following options. The last option selected is programmed.

- Rerun when any selected flag occurs
- Rerun with diluent when any selected flag occurs
- Rerun with concentration when any selected flag occurs

Selecting the same combination of flags in these three options generates an error message when you select **Save** [F1]:

- Rerun when all selected flags occur
- Rerun with diluent when all selected flags occur
- Rerun with concentration when all selected flags occur

Select **Cancel** to resolve the error. If you select **OK** with the error unresolved, the analyzer cannot start analysis.

For more information on flags, refer to the *DxC 700 AU Instructions for Use*.

If any test in the calculation generates a rerun flag, the system reruns all tests programmed as part of the calculated test. If you program the flag to rerun with a dilution, then the system dilutes that test. Other tests in the calculation without rerun flags rerun with first-run sample volumes.

Reflex Tab

Program a deciding test and a maximum of five related tests as a group for reflex testing. When the deciding test causes a rerun, fl, or fh flag, the system automatically orders the related tests for rerun analysis. The system also orders the deciding test with a rerun flag, but not with a fl or fh flag.

For example, if you program ALB as the Deciding Test and TP as the Related Test, the system orders both ALB and TP for rerun analysis when the system generates a rerun flag on ALB. However, when the system generates a fl or fh flag on ALB, the system orders only TP, and not ALB.

You can program a maximum of 10 reflex groups.

Note

If a result does not fall within the Reflex Range programmed in the Rerun Test Parameters screen (**CONFIG.** > **Rerun Test Parameters**), the system generates a fh or fl flag.

Select **CONFIG.** > **Rerun Check Parameters** > **Reflex**.

Figure 2.22 Rerun Check Parameters: Reflex Tab

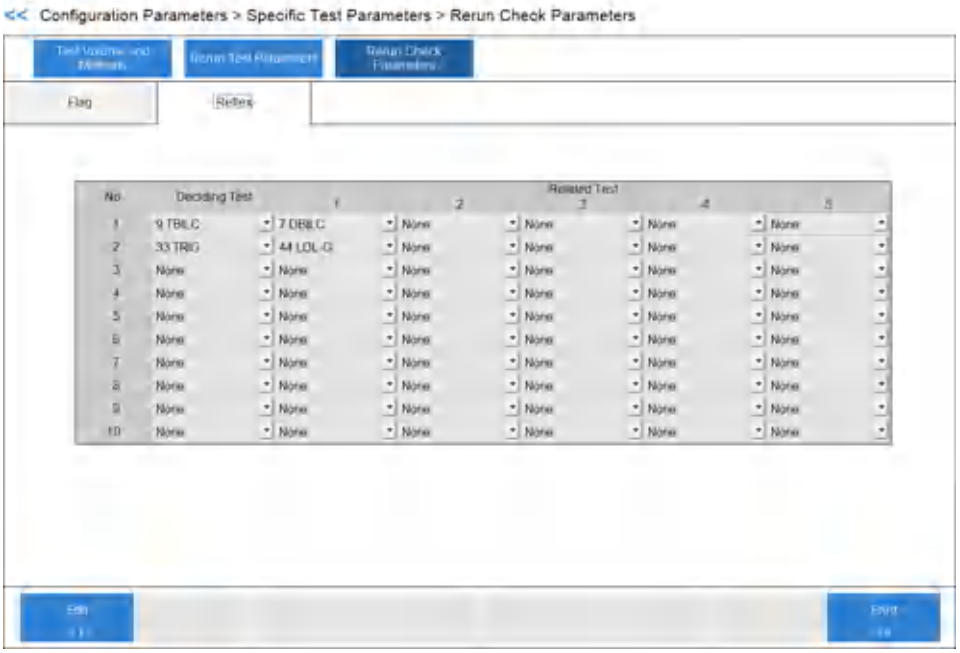


Table 2.19 Reflex Tab Description

Item	Contents	Input Notes
Deciding Test	Name of test	Generates an automatic rerun order for the related tests when it causes fl, fh, or other rerun flags on the deciding test. The system generates the rerun order for the deciding test when the rerun flag is generated, but does not generate the rerun order for the deciding test when the fl or fh flag is generated.
Related Test	Name of test	Generates an automatic rerun order for the related test when it causes a rerun, fl, or fh flag on the deciding test.

Calibration Setup Menu

Program the calibrators used for calibration analysis and the calibration parameters.

You typically assign calibrators to positions in the yellow rack, or you enable calibrator bar code operation and place the calibrators in any position in the yellow rack.

You can assign calibrators to positions on the STAT table, or you can enable calibrator bar code operation and place the calibrators in any Free position on the STAT table.

Note

If the DxC 700 AU connects to a Laboratory Automation System, you must enable calibrator bar code operation and perform calibration from the STAT table.

Caution

Incorrect calibration parameters cause errors in analysis results, and can cause misdiagnosis. Visually confirm specific test calibration parameter settings against the published settings, and through analysis using Quality Control materials.

For more information on displaying a list of set values, refer to Calibration Setup: General Tab.

Calibrators Tab

Program a maximum of 200 calibrators required for specific tests programmed on the system. Beckman Coulter programs calibrators to a type (Serum, Urine, Other-1, Other-2, or Whole Blood), as determined by laboratory requirements.

Select **CONFIG.** > **Calibration Setup** > **Calibrators**.

Figure 2.23 Calibration Setup: Calibrators Tab

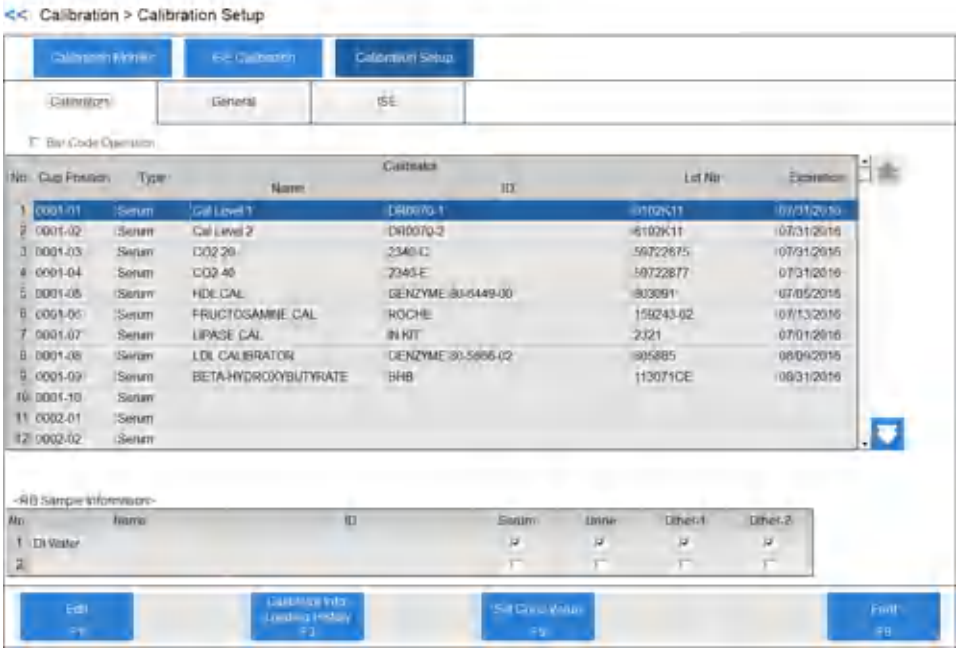


Table 2.20 Calibrators Tab Description

Item	Contents	Input Notes
Bar Code Operation	Selected or Cleared	To use a calibrator bar code, select **Bar Code Operation**. Enter a calibrator ID or scan the calibrator bar code ID into the ID field. In bar code operation, you can place calibrators in any position in the yellow rack. If **Bar Code Operation** is cleared, you assign calibrators to positions in the yellow rack.
Cup Position	Cup Position	Display only. If you select **Bar Code Operation**, nothing displays. If **Bar Code Operation** is cleared, the system displays the cup positions on the rack.
Type	Sample Type	Display only. The system displays the sample type (Serum, Urine, Other-1, Other-2, or Whole Blood).
Name	Calibrator name	A maximum of 20 characters.
ID	Calibrator ID (bar code)	When you select **Bar Code Operation**, a maximum of 26 alphanumeric characters for the calibrator ID. You can enter a calibrator ID or scan the calibrator bar code ID.
Lot No.	Calibrator lot number	A maximum of 15 alphanumeric characters.
Expiration	Calibrator expiration date	Enter a date, for example YYYY/MM/DD.

Table 2.20 Calibrators Tab Description (Continued)

Item	Contents	Input Notes
RB Sample Information	Reagent blank number, name, ID, and sample type	You can define two types of reagent blank material (No. 1 and No. 2). All tests use deionized water, typically assigned to position 1. Select **Serum**, **Urine**, **Other-1**, **Other-2**, or **Whole Blood**, for **No. 1**. Enter a reagent blank name (a maximum of 20 characters), typically deionized water. Enter a reagent blank ID (a maximum of 26 characters) if you select **Bar Code Operation**.
Calibrator Info Loading History [F3]	History records of the calibrator measured on the system.	Display only. You can confirm the calibrator that was used on the system in the past.
Set Conc Value [F5]	Calibrator concentration	Use it to enter calibrator concentrations for a new lot number. For tests with a multi-point calibration curve, confirm the concentration of all calibrator levels.

Note

You can set the reagent blank for each sample type.

When you select **No. 1**, set the cup in the first cup position of the blue rack or the RB1 position on the STAT table.

When you select **No. 2**, set the cup in the second cup position of the blue rack or the RB2 position on the STAT table.

If the DxC 700 AU connects to a Laboratory Automation System, you must perform reagent blanks from the STAT table. Set the reagent blank No. 1 in position RB1 and reagent blank No. 2 in position RB2 on the STAT table.

Calibration Setup: General Tab

Program all specific calibration parameters for each test. Program and confirm the information from the reagent setting sheet for the test.

Select **CONFIG.** > **Calibration Setup** > **General**.

Figure 2.24 Calibration Setup: General Tab

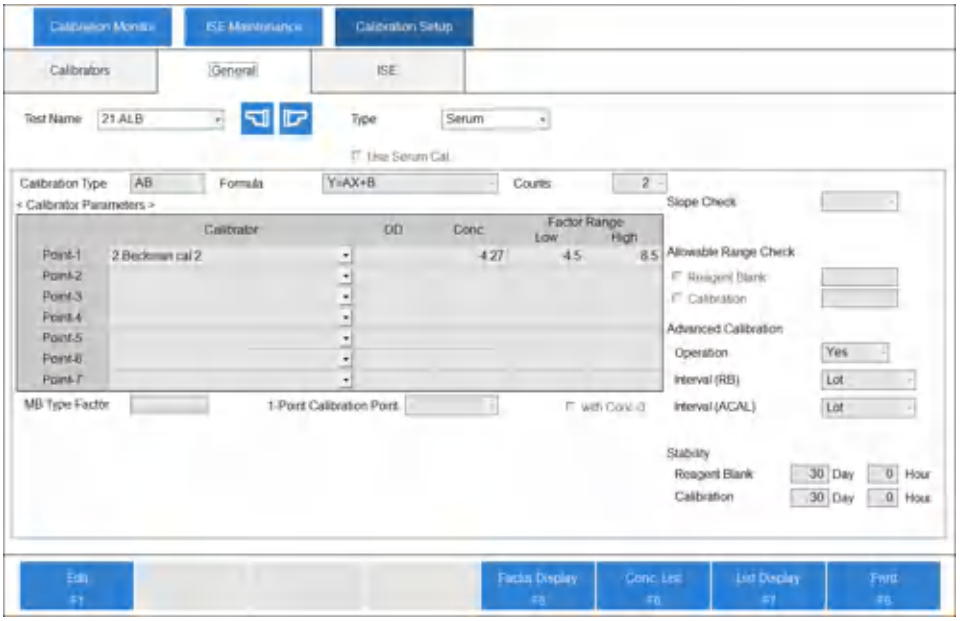


Table 2.21 Calibration Setup: General Tab Description

Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Use Serum Cal.	Selected or Cleared	Select this option to use the Serum calibration curve for the Urine, Other-1, or Other-2 test. The system does not calibrate Urine, Other-1, or Other-2 test.
Calibration Type	MB to 7 MB, AA, AB to 7 AB, 4 MC to 10 MC	Enter the calibration type from the reagent setting sheet. For a description of the different calibration types, refer to Summary of Calibration Types.
Formula	Interpolation formula for the calibration curve.	Select the formula from the reagent setting sheet. The calibration type limits the formulas that you can select for a test.
Counts	1, 2, 3, or 4	The quantity of reagent blank and calibration replicates used for calculation. If you select **1**, the system uses the reagent blank or calibrator OD for calculation. If you select **2**, the system uses the mean value of the replicates. If you select **3**, the system use the mean value of the two closest replicates. If you select **4**, the system uses the highest and lowest replicate values, and it uses the mean value of the two replicates.

Table 2.21 Calibration Setup: General Tab Description (Continued)

Item	Contents	Input Notes
Slope Check	+ or -	Refer to the reagent setting sheet. For multi-point calibrations (AA and 2 AB to 7 AB) the software checks to confirm that all OD values are increasing (+) or decreasing (-).
Allowable Range Check: Reagent Blank	OD value (0.0000 to 3.0000)	Refer to the reagent setting sheet. An acceptable dispersion of OD values (OD delta check) for the reagent blank for AA, AB to 7AB, and 4MC to 10MC.
Allowable Range Check: Calibration	OD value (0.0000 to 3.0000)	Refer to the reagent setting sheet. An acceptable dispersion of OD values (OD delta check) for the calibration for AA, AB to 7AB, and 4MC to 10MC.
Advanced Calibration: Operation	Yes or No	Refer to the reagent setting sheet. Advanced calibration allows reagent blank and calibration for up to 5 bottles or lot numbers of the same test.
Advanced Calibration: Interval (RB)	Bottle or Lot	
Advanced Calibration: Interval (ACAL)	Bottle, Lot, or None	
Stability: Reagent Blank and Calibration	0 to 999 (Day) and 0 to 23 (Hour)	
MB Type Factor	Factor value (-9999999 to 9999999)	For MB calibration type, enter the factor value. Refer to the reagent setting sheet.
1-Point Calibration Point	Calibrator Point-1 to Point-7	For a multi-point calibration, enter the calibrator number to adjust the multi-point calibration curve by a single point.
with Conc-0	Selected or Cleared	Select this option for a multi-point calibration to include the zero concentration. If 1-Point Calibration Point is used and zero concentration is the origin, select **Conc-0** and enter the calibrator number in **1-Point Calibration Point**.
Calibrator	Calibrator name	To display the calibrator name, program the calibrator in the Calibrators tab (**CONFIG.** > **Calibration Setup** > **Calibrators**).
OD	OD value	Enter the OD (-2.0000 to 3.0000) for calibration types 2 MB to 7 MB.
Conc	Calibrator concentration	A maximum of 9 digits including the decimal point and minus sign, from -9999999 to 9999999.

Table 2.21 Calibration Setup: General Tab Description (Continued)

Item	Contents	Input Notes
Factor Range or OD Range	OD range: -2.0000 to 3.0000 Factor range: -9999999 to 9999999	Refer to the reagent setting sheet. When the calibration type is 2AB to 7AB, you can program an OD Range. When the calibration type is AB or AA, you can program a Factor Range. Exceeding the range generates a Calibration Factor/OD Range event.
Factor Display [F5]	Calibration factor and curve	Display only. You can confirm that the calibration factor and the calibration curve for the Calibration type are 2 MB to 7 MB.
Conc. List [F6]		
List Display [F7]	Displays a list of all test parameters configured in **Calibration Setup** > **General**.	Use the list to confirm parameters. Select the sample type, and a maximum of six tests to display at a time.
Print [F8]		

Advanced Calibration

Advanced Calibration allows calibration of up to 5 bottles or lot numbers of the same reagent before the patient run. When the system switches to a new bottle or lot number for a reagent, the system uses the correct calibration curve. You can use Advanced Calibration for reagent ID positions, or fixed (assigned) positions. For more information, contact Beckman Coulter.

Calibration Setup: ISE Tab

Program specific calibration parameters for the ISE tests (Na, K, and Cl).

Select **CONFIG.** > **Calibration Setup** > **ISE**.

Figure 2.25 Calibration Setup: ISE Tab

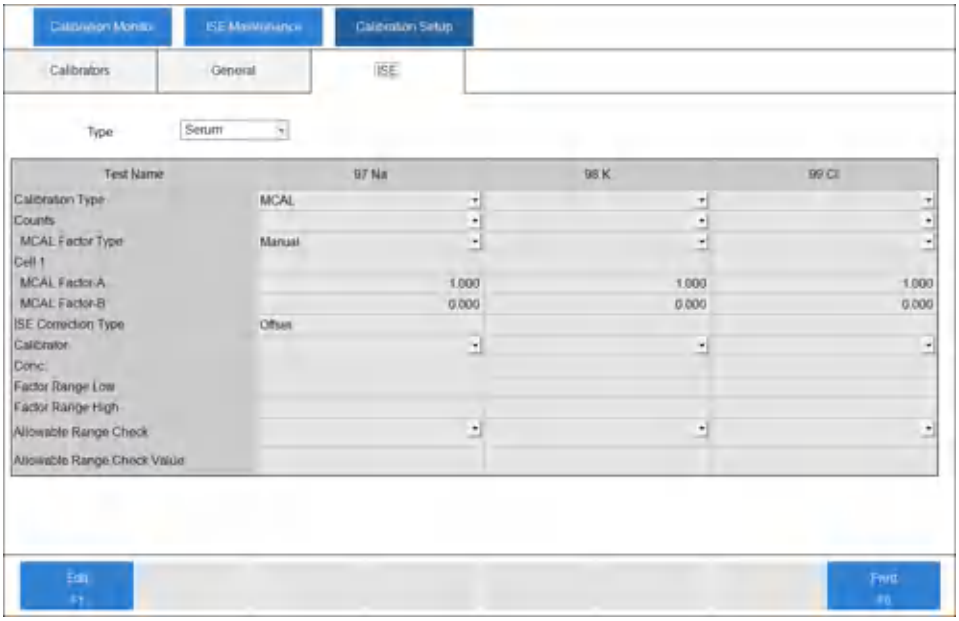


Table 2.22 Calibration Setup: ISE Tab Description

Item	Contents	Input Notes
Type	Serum or Urine	
Calibration Type	MCAL or ACAL	Selecting MCAL means that the system performs ISE calibration using the Serum or Urine Standard Solution H and L and the calibration is monitored from the Calibration tab (**MAINT.** > **ISE Maintenance** > **Calibration**). Selecting **ACAL** means that the system calibrates from calibrator in the yellow rack or STAT table. Programming MCAL or ACAL applies to all three ISE tests (Na, K, and Cl).
Counts	1 to 4	If you select **ACAL**, select the quantity of calibration replicates.
MCAL Factor Type	Manual or CRS Calibration	CRS calibration is only available in Japan.

Note

It is only possible to select **Calibrator**, **Conc**, **Factor Range Low**, **Factor Range High**, **Allowable Range Check**, and **Allowable Range Check Value** if you program the calibration type to **ACAL**.

Table 2.23 Calibration Setup: ISE Tab Description for ACAL

Item	Contents	Input Notes
Calibrator	Calibrator for Na, K, and Cl	Select the calibrator to use for Na, K, and Cl.

Table 2.23 Calibration Setup: ISE Tab Description for ACAL (Continued)

Item	Contents	Input Notes
Conc	Calibrator concentration	Enter the calibrator concentration for Na, K, and Cl (-9999999 to 9999999).
Factor Range Low and Factor Range High	Factor range	Enter the calibration low factor limit (-9999999) to high factor limit (9999999) for Na, K, and Cl.
Allowable Range Check	Yes or No	Select **Yes** to perform an OD delta check on the calibrator OD values.
Allowable Range Check Value	OD value	If you select **Yes** in **Allowable Range Check**, enter the OD value for the OD delta check.

QC Setup Menu

Program the controls used for QC analysis, and all specific QC parameters.

Quality control (QC) samples, necessary for any diagnostic device, confirm system performance.

Check the performance of the DxC 700 AU regularly by analyzing control samples. Establish a control frequency for your laboratory. If feasible, test control samples each time you test patient samples and calibrate. If you detect any trends or sudden shifts in values, review all operating parameters.

Establish guidelines for your laboratory to take corrective action in case controls do not fall within the specified control limits.

You can perform QC analysis in the green racks or the STAT table. When you enable QC Bar Code Operation, you can place controls in any position in the green racks or STAT table.

If the DxC 700 AU connects to a Laboratory Automation System, you must enable QC bar code operation and perform QC analysis from the STAT table.

Caution

Erroneous analysis data can cause erroneous diagnosis results. Always perform QC analysis at the same time as analysis of general patient samples to confirm normal analysis.

Controls Tab

Program a maximum of 100 controls required for specific tests. Beckman Coulter programs control numbers to a type (Serum, Urine, Other-1, Other-2, or Whole Blood), as determined by laboratory requirements.

Select **CONFIG.** > **QC Setup** > **Controls**.

Figure 2.26 QC Setup: Controls Tab

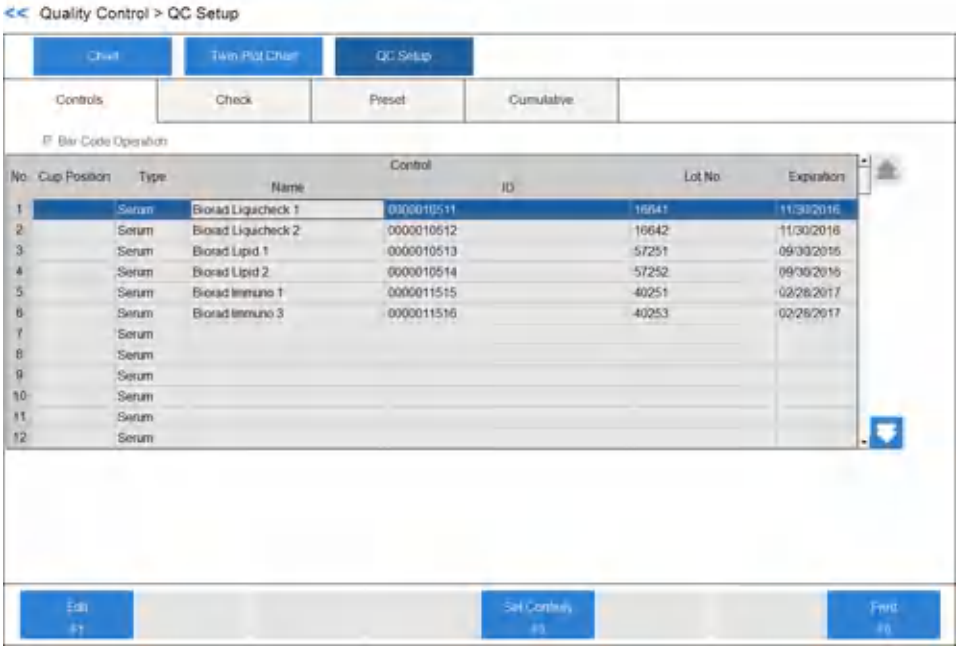


Table 2.24 Controls Tab Description

Item	Contents	Input Notes
Bar Code Operation	Selected or Cleared	If you select **Bar Code Operation**, the system assigns control IDs to control materials, and you can place controls in any position in the green rack or STAT table. If **Bar Code Operation** is cleared, you assign controls to positions in the green rack or STAT table.
Cup Position	Cup Position	Display only. If you select **Bar Code Operation**, nothing displays. If **Bar Code Operation** is cleared, the system displays the cup positions on the rack.
Type	Sample Type	Display only. The system displays the sample type (Serum, Urine, Other-1, Other-2, or Whole Blood).
Name	Control name	A maximum of 20 characters.
ID	Control ID (bar code)	When you select **Bar Code Operation**, a maximum of 26 alphanumeric characters for the control ID.
Lot No.	Control lot number	A maximum of 15 alphanumeric characters.
Expiration	Control expiration date	Enter a date.

Check Tab

Program the specific control parameters for each test.

Two quality control methods are:

- Single check, which uses the mean value and the standard deviation of the control
- Multi check, with multiple rules, including the tendencies of past results in the control

You can evaluate QC using Preset mode or Cumulative mode. In Preset mode, you enter the QC mean, SD, and range in the Preset tab. In Cumulative mode, the system calculates the QC mean, SD, and range from QC run on the analyzer.

For more information, refer to Quality Control.

Select **CONFIG.** > **QC Setup** > **Check**.

Figure 2.27 QC Setup: Check Tab

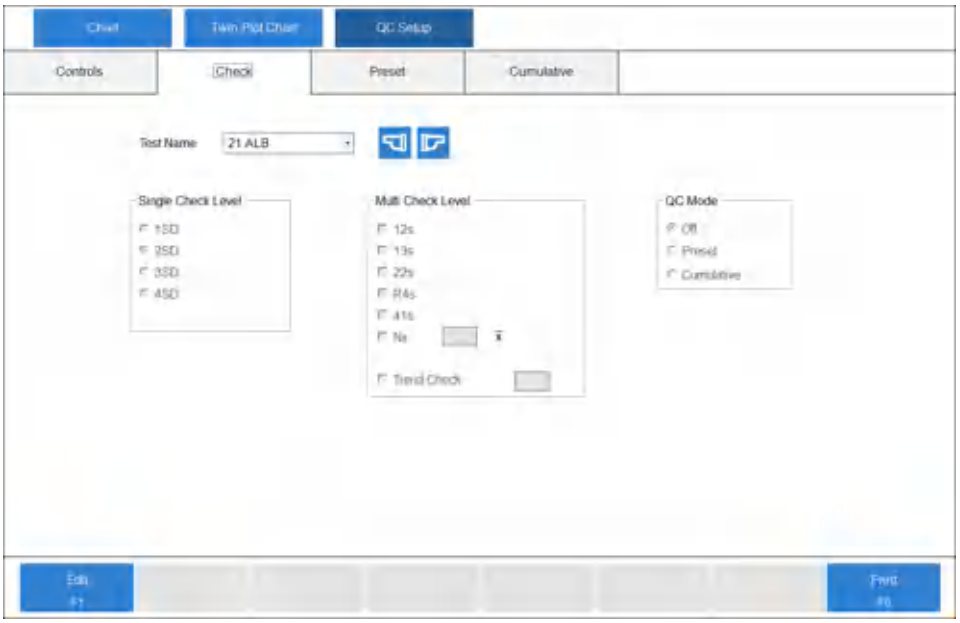


Table 2.25 Check Tab Description

Item	Contents	Input Notes
Test Name	Test name	
Single Check Level	1SD, 2SD, 3SD, or 4SD	The system checks the standard deviation as the control limit. Set the deviation level (1SD to 4SD). The flag is 1Q for any QC value that exceeds the SD level selected.

Table 2.25 Check Tab Description (Continued)

Item	Contents	Input Notes
Multi Check Level	Check 1_{2s}, 1_{3s}, 2_{2s}, R_{4s}, 4_{1s}, Nx, and/or Trend Check	• If you select 1_{2s} and the control data on one side exceeds +/- 2SD, the system generates a 1Q flag is generated. • If you select 1_{3s} and the control data on one side exceeds +/- 3SD, the system generates a 2Q flag. • If you select 2_{2s} and two consecutive control data exceed +/- 2SD in the same direction, the system generates a 3Q flag. • If you select R_{4s} and consecutive high and low control data exceeds + 2SD and - 2SD, the system generates a 4Q flag. • If you select 4_{1s} and four consecutive control data exceed +/- 1SD in any direction, the system generates a 5Q flag. • If you select Nx, program from 7 to 10 points to check if consecutive control data is above or below the mean value. The system generates a 6Q flag. • If you select Trend Check, program from 4 to 10 points to check for consecutively increasing or decreasing values. The system generates a 7Q flag. When using Multi Check, select 1_{2s} to initiate the process to implement the following checks when the data exceeds 1_{2s}.
QC Mode	Off, Preset, or Cumulative	• If you select **Off**, the system does not perform a QC check and does not generate QC events and flags. • If you select **Preset**, the system generates QC events and flags from the values programmed in the Preset tab. • If you select **Cumulative**, the system generates QC events and flags from the calculated QC values obtained from the analyzer. You can calculate the QC mean, standard deviation, and range in the Cumulative tab. The system does not calculate the QC value automatically.

Preset Tab

When you use Preset mode, enter known values for the mean, SD, and range. You can program a maximum of 10 controls for each test and sample type.

Select **CONFIG.** > **QC Setup** > **Preset**.

Figure 2.28 QC Setup: Preset Tab

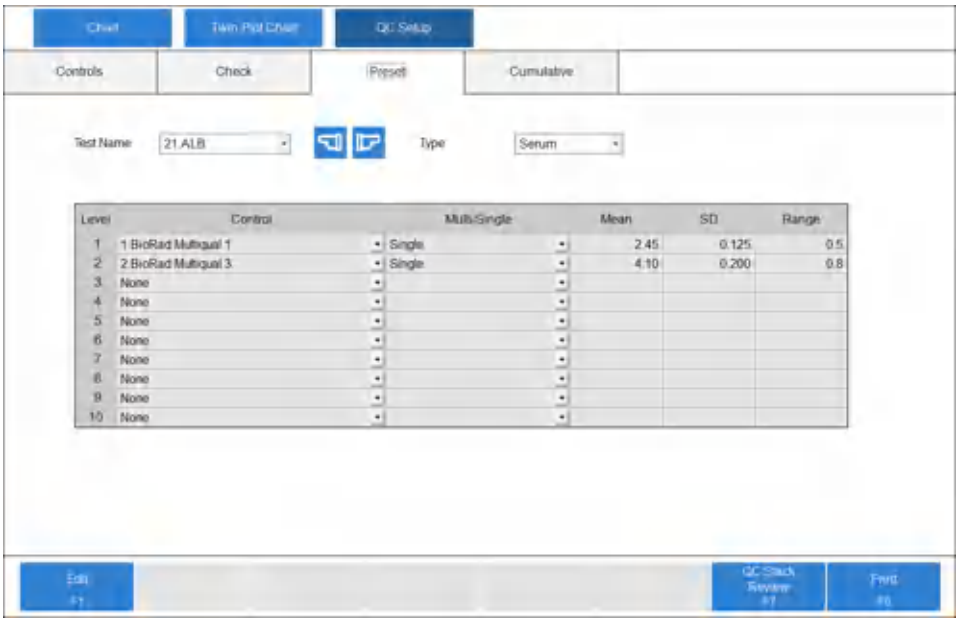


Table 2.26 Preset Tab Description

Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Control	Control material	Select the control material from the available control materials programmed in the Controls tab (**CONFIG.** > **QC Setup** > **Controls**).
Multi/Single	Multi or Single	Program each control to use Single Check or Multi Check rules. For Multi Check rules to evaluate QC data correctly, program two control materials for the test.
Mean	QC mean value	
SD	Standard deviation	Enter the value of one standard deviation.
Range	Range value	Enter the value of the range for acceptable QC.
QC Stack Review [F7]	Displays the last 10 QC results for the low and high control for the test.	QC data only displays if you select **Multi** to program the test. Select **Close** to close the dialog.

Figure 2.29 QC Stack Review Dialog

Note

You can program for QC on calculated tests only controls that are common to all tests in the calculation.

If you select **Multi** for two controls, you can display the Twin Plot chart in the Twin Plot Chart screen (**QC** > **Twin Plot Chart**).

Cumulative Tab

When you select **Cumulative** for **QC Mode** in the Check tab, the system calculates QC mean, standard deviation, and range from QC data run on the analyzer.

Select **CONFIG.** > **QC Setup** > **Cumulative**.

Figure 2.30 QC Setup: Cumulative Tab

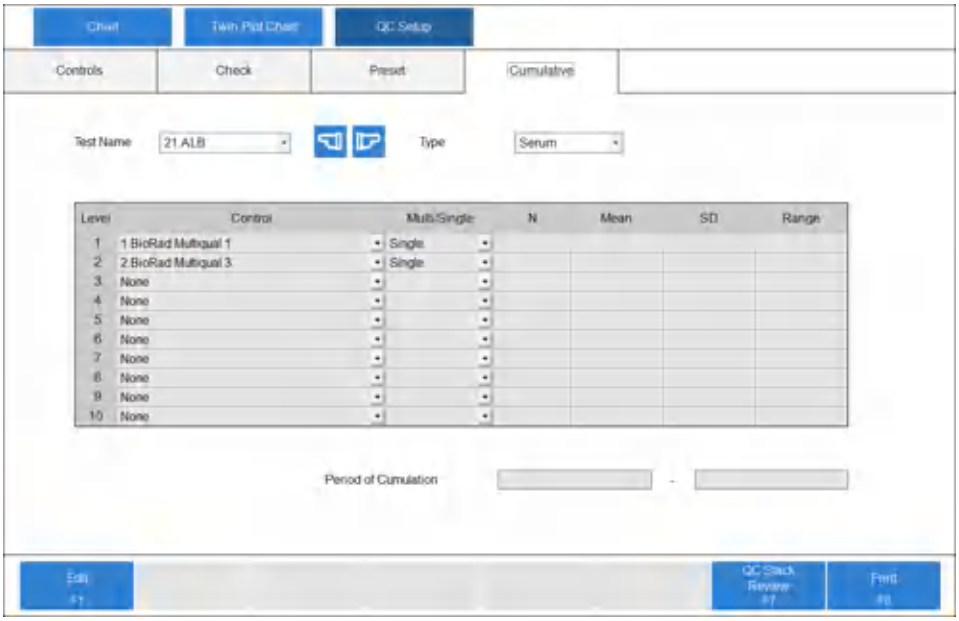
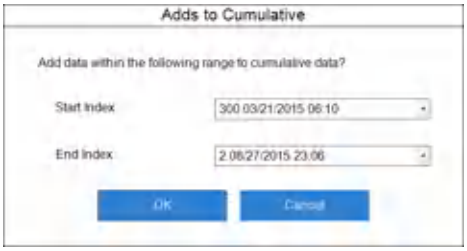


Table 2.27 Cumulative Tab Description

Item	Contents	Input Notes
Test Name	Test name	
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Control	Control material	Select the control material. Program the available control materials in the Controls screen.
Multi/Single	Multi or Single	Program each Control to use Single Check or Multi Check rules. For Multi Check rules to properly evaluate QC data, program two control materials for the test.
Period of Cumulation	Displays the values that you select for **Start Index** and **End Index** for the calculation of QC statistics in the Adds to Cumulative dialog.	
Adds to Cumulative [F5]	Displays the Adds to Cumulative dialog to set the start index and end index to calculate QC statistics.	Adds QC data from the selected start index and end index to any existing QC statistics, and calculates a new QC mean, SD, and range. When you select **OK**, the system calculates and displays the number of QC data points (N), QC mean, SD, and range.
New Cumulative [F6]	Start index and end index to calculate QC statistics.	Calculates a new QC mean, SD, and range using data between the start index and end index. When you select **OK**, the system calculates and displays the number of QC data points (N), QC mean, SD, and range.
QC Stack Review [F7]	Displays the last 10 QC results for the low and high control for the test.	QC data only displays if you select **Multi** to program the test. Select **Close** to close the dialog.

Figure 2.31 New Cumulative Dialog

Figure 2.32 Adds to Cumulative Dialog



Note

You can program for QC on calculated tests only the controls that are common to all tests in the calculation.

If you select **Multi** for two controls, you can display the Twin Plot chart in the Twin Plot Chart screen (**QC** > **Twin Plot Chart**).

STAT Table Setup

STAT Table Setting Dialog

When you perform patient sample analysis, calibration, or QC from the STAT table, program the STAT table settings beforehand.

Important

With Multiple Loads STAT Table operation, the system selects **Bar Code** for all sample kinds in the **[STAT Test Order]** section and **Free** for all positions in the STAT table position settings.

The setting is not programmable.

Select **STAT** > **STAT Status** > **STAT Table Setting** [F6]. The system displays the STAT Table Setting dialog.

Figure 2.33 STAT Table Setting Dialog

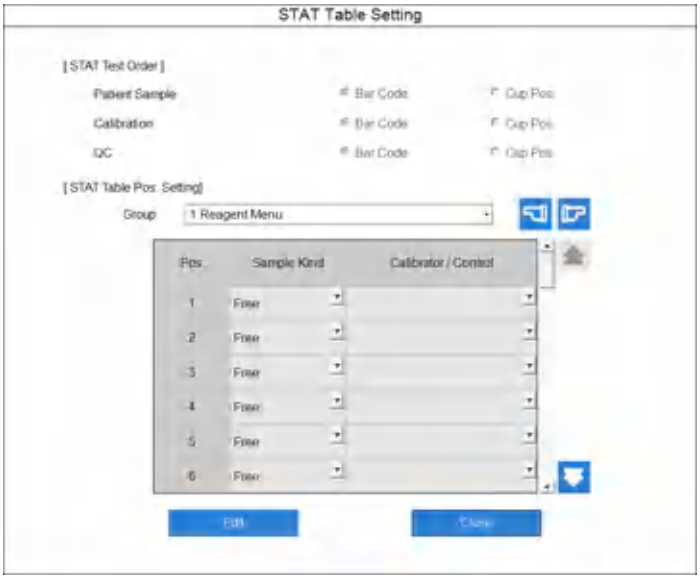


Table 2.28 STAT Table Setting Dialog: STAT Test Order Description

Item	Contents	Input Notes
Patient Sample	Bar Code or Cup Pos.	
Calibration	Bar Code or Cup Pos.	
QC	Bar Code or Cup Pos.	

Table 2.29 STAT Table Setting Dialog: STAT Table Pos. Setting Description

Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select **1**, **2**, or **3** to program the STAT Table position for the Group.
Pos.	STAT position number	Not programmable.
Sample Kind	Free, Patient, Cal., or QC	Select **Free** when you select **Bar Code** in the **[STAT Test Order]** section of the STAT Table Setting dialog. You can place all bar-coded sample kinds in a position assigned as Free. Select **Patient**, **Cal.**, or **QC** when you select **Cup Pos.** in the **[STAT Test Order]** section of the STAT Table Setting dialog. You can place patient samples only in positions for which you select **Patient**, calibrators only in positions for which you select **Cal.**, and control samples only in positions for which you select **QC**.

Table 2.29 STAT Table Setting Dialog: STAT Table Pos. Setting Description (Continued)

Item	Contents	Input Notes
Calibrator/Control	Free or the name of a calibrator	Programmable when the sample kind is calibrator. Select **Free** or a specific calibrator. If you select **Free**, the system automatically assigns a calibrator when you order the calibration in the STAT (Calibration) tab. If you select a calibrator, the system reserves the position for the selected calibrator.
	Free or the name of a control	Programmable when the sample kind is QC. Select **Free** or a specific control. If you select **Free**, the system automatically assigns a control when you order the QC in the STAT (QC) tab. If you select a control, the system reserves the position for the selected control.

Auto ACAL/QC Setup Screen

Auto ACAL/QC Setup: ACAL Tab

Programming **Yes** in the ACAL tab makes automatic STAT calibration available. When the event programmed for **Execution Type** occurs during sample analysis, and the STAT table contains all necessary calibrators, the system performs automatic STAT calibration.

If you program automatic STAT calibration, the amber STAT TABLE ROTATION LED continuously blinks slowly during analysis.

If you use Quick STAT analysis, or Multi STAT table operation, program **No** for all items in the Auto ACAL/RB column.

Select **CONFIG.** > **Auto ACAL/QC Setup** > **ACAL**.

Figure 2.34 Auto ACAL/QC Setup: ACAL Tab

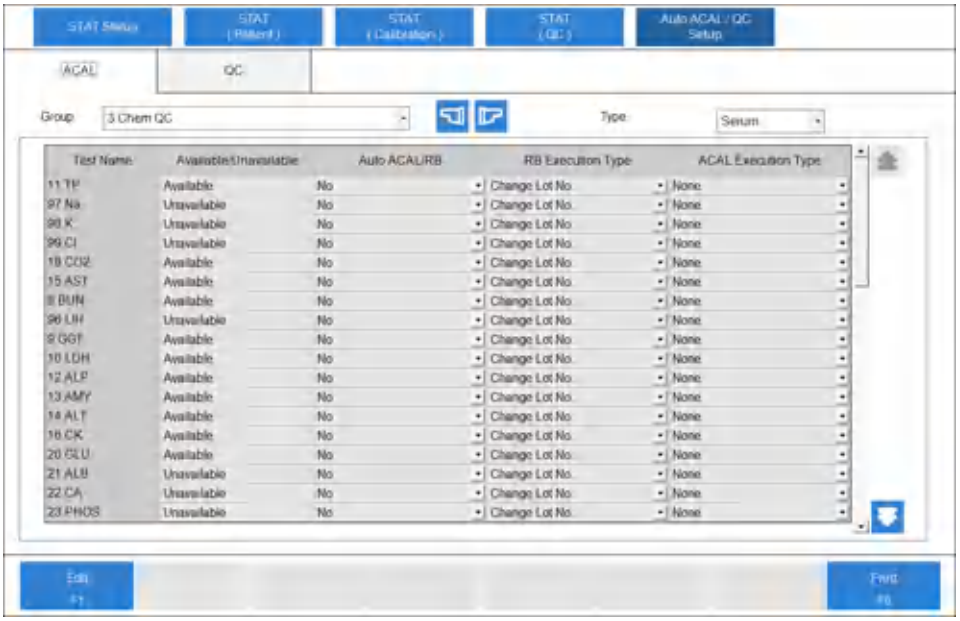


Table 2.30 ACAL Tab Description

Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select **1**, **2**, or **3** to program automatic STAT calibration for the Group.
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Test Name	Test Name	Displays the test names assigned to Group.
Available/Unavailable	Available or Unavailable	Displays `Available` if the Position tab lists all of the necessary calibrators.
Auto ACAL/RB	Yes or No	**Yes**: The system performs automatic STAT calibration according to the execution type. **No**: The system does not perform automatic STAT calibration.
RB Execution Type	Change Bottle No.	The system performs reagent blank when it switches to the second sequenced reagent bottle because the first sequenced reagent bottle becomes empty during sample analysis. Each sequenced reagent bottle owns a unique bottle number. Bottles have the same reagent lot number.
	Change Lot No.	The system performs reagent blank when it switches to a reagent bottle with a new lot number during analysis because all sequenced reagent bottles with the same lot number become empty during sample analysis.

Table 2.30 ACAL Tab Description (Continued)

Item	Contents	Input Notes
ACAL Execution Type	Change Bottle No.	The system calibrates when it switches to the second sequenced reagent bottle because the first sequenced reagent bottle becomes empty during sample analysis. Each sequenced reagent bottle owns a unique bottle number. All reagent bottles have the same reagent lot number.
	Change Lot No.	The system calibrates when it switches to a reagent bottle with a new lot number during analysis because all sequenced reagent bottles with the same lot number become empty during sample analysis.
	None	The system does not calibrate.

Note

Automatic STAT calibration occurs during sample analysis. You can use advanced calibration by bottle number or lot number to calibrate before QC and sample analysis. Refer to Calibration Setup: General Tab.

Auto ACAL/QC Setup: QC Tab

You can program the automatic STAT QC in the QC tab (**CONFIG.** > **Auto ACAL/QC Setup** > **QC**) when you select the STAT Test Order for QC to Cup Pos. For information on programming STAT table positions, refer to STAT Table Setup.

To make automatic STAT QC available, select **Test** or **Sample** in **Cyclic Type**, or **Yes** in **Execute after Calibration**.

Automatic STAT QC occurs during sample analysis after calibration, or a specified number of samples or tests have processed and the STAT table contains the necessary controls.

When you program automatic STAT QC, the amber STAT TABLE ROTATION LED continuously blinks slowly during analysis.

If you do not require cyclic automatic STAT QC, program **None** for all items in **Cyclic Type**.

If you do not require automatic STAT QC after calibration, program **No** for **Execute after Calibration**.

To perform Quick STAT operation, program **None** for all items in **Cyclic Type** and **No** for **Execute after Calibration**.

Select **CONFIG.** > **Auto ACAL/QC Setup** > **QC**.

Figure 2.35 Auto ACAL/QC Setup: QC Tab

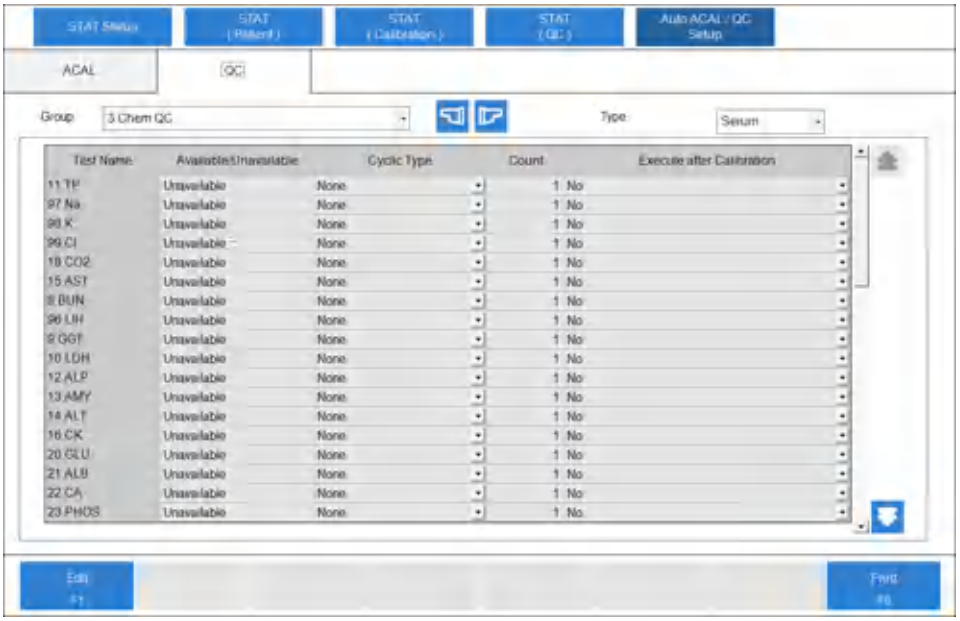


Table 2.31 QC Tab Description

Item	Contents	Input Notes
Group	Group 1, 2, or 3	Select **1**, **2**, or **3** to program automatic STAT QC for the Group.
Type	Serum, Urine, Other-1, Other-2, or Whole Blood	
Test Name	Test name	Displays the test names assigned to **Group**.
Available/Unavailable	Available or Unavailable	Displays `Available` if the Position tab lists all of the necessary controls.
Cyclic Type	None	The system does not perform QC analysis automatically from the STAT table.
	Test	The system performs QC automatically from the STAT table after analysis of the programmed number of tests (displayed in **Count**).
	Sample	The system performs QC automatically from the STAT table after analysis of the programmed number of samples (displayed in **Count**).
Count	1 to 999	The test or sample number interval before the system performs QC automatically from the STAT table.
Execute after Calibration	Yes or No	Select **Yes** to perform QC automatically from the STAT table after reagent blank or calibration.

Misc. Menu

Checked Tests Screen

Obtain a value with optional checked tests using multiple tests and confirm that this value lies within a pre-programmed range. If the result is out of range, the system adds a T flag to the result.

For each sample type, you can program a maximum of 20 checked tests.

Program the calculations for the tests to be checked.

Select **CONFIG.** > **Checked Tests**.

Figure 2.36 Misc.: Checked Tests Screen

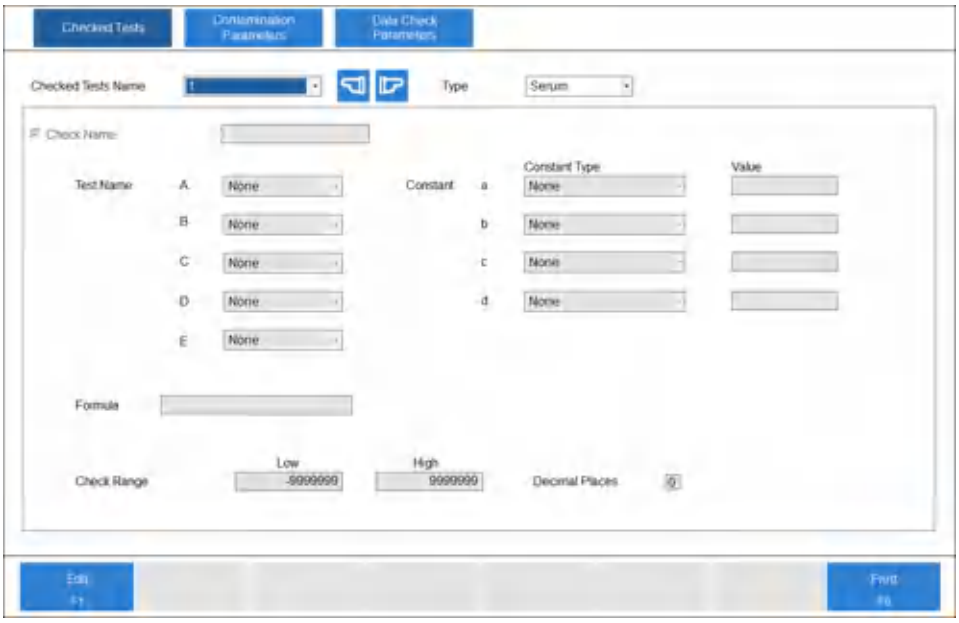


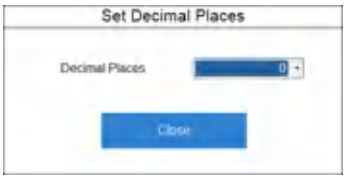
Table 2.32 Checked Tests Screen Description

Item	Contents	Input Notes
Checked Tests Name	Checked test number (1 to 20)	Select the number to program.
Type	Serum, Urine, Other-1, or Other-2	
Check Name box	Selected or Cleared	Select if the checked test is programmed. Keep cleared if the checked test is not used. The system clears all programmed contents when you clear the box.
Check Name field	8 or less characters	Enter the checked test name.
Test Name: A, B, C, D, and E	Test name	

Table 2.32 Checked Tests Screen Description (Continued)

Item	Contents	Input Notes
Constant: a, b, c, and d	Value or Patient Info.-1 to Patient Info.-6	If you select **Value**, enter a numerical value (maximum of 7 digits) in **Value**. If you select **Patient Info.-1** to **Patient Info.-6**, the system uses a value entered in patient demographics in the order for the constant.
Formula	Check calculation formula	Enter the formula with the characters +, -, *, /, (,), A, B, C, D, E, a, b, c, d Enter a maximum of 20 characters.
Check Range	Low and high limit for the check range	If the check exceeds the range, generates a T flag.
Set Decimal Places [F5]	Displays the Set Decimal Places dialog, where you select **0** to **4**	Select the number of decimal places for **Check Range**.

Figure 2.37 Set Decimal Places Dialog



Contamination Parameters Screen

Although the system has sufficient washing capability, cross contamination can occur in readily affected samples or in analysis tests with high sensitivity. You can program extra washing conditions and avoidance parameters to prevent such contamination.

Caution

When you program contamination prevention conditions, the analysis processing speed can decrease. Consult the reagent *Instructions for Use* or the reagent manufacturer.

Contamination Prevention Tab

Program reagent, mix-bar, and cuvette contamination avoidance conditions for readily affected items.

Caution

When you change contamination prevention conditions, perform W2 with the cleaning solutions to prevent the cuvette contamination. The required cleaning solutions depend on what you programmed for cuvette before.

- **If you programmed Yes (CLN-1) for cuvette before change the condition, W2 with CLN-1 is needed.**
- **If you programmed Yes (CLN-2) for cuvette before change the condition, W2 with CLN-2 is needed.**
- **If you programmed both of Yes (CLN-1) and Yes (CLN-2) for cuvette before change the condition, both of W2 with CLN-1 and W2 with CLN-2 are needed.**
- **If you did not program neither Yes (CLN-1) nor Yes (CLN-2) for cuvette before change the condition, W2 is not needed.**

Select **CONFIG.** > **Contamination Parameters** > **Contamination Prevention**.

Figure 2.38 Contamination Parameters: Contamination Prevention Tab

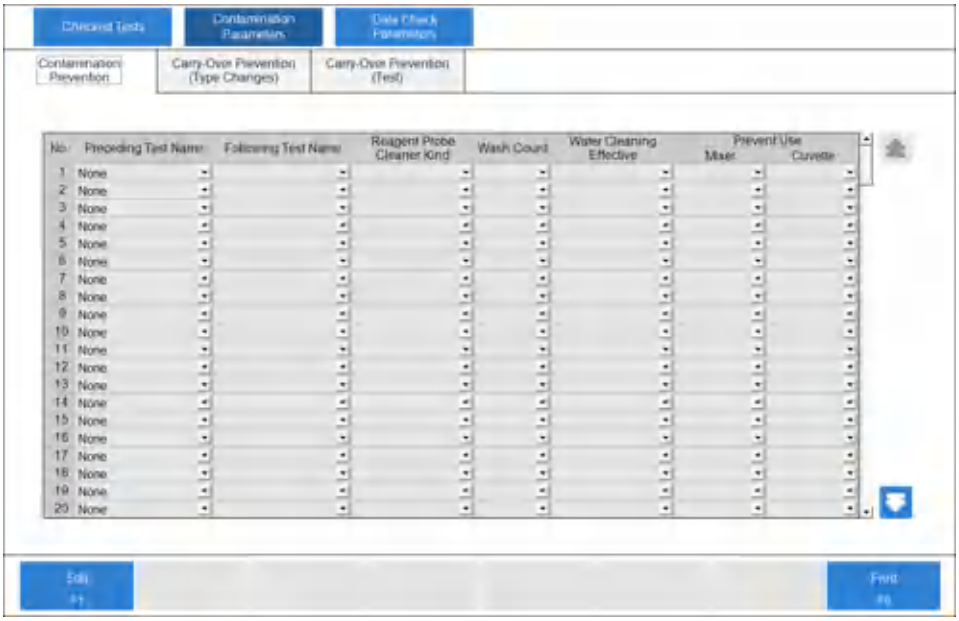


Table 2.33 Contamination Prevention Tab Description

Item	Contents	Description
Preceding Test Name	Test name	Select the test and type to perform extra washing before the test analysis. You can also select the cleaning solution (**CLN-1**, **CLN-2**), or **All** for the preceding test. **Note** User cannot select the following combinations of settings. • **Preceding Test** is **All** and **Following Test** is **DENAT**. • **Preceding Test** is **DENAT** and Following Test is **All**.
Following Test Name	Test name	Select the test that the preceding test affects, or select **All**.

Table 2.33 Contamination Prevention Tab Description (Continued)

Item	Contents	Description
Reagent Probe Cleaner Kind	Water, CLN-1 or CLN-2	The system cleans the reagent probe with water, cleaning solution 1, or cleaning solution 2. Place the required cleaning solution on the analyzer. The CLN-1 positions are 62. CLN-1 and 49. CLN-1, and the CLN-2 positions are 63. CLN-2 and 50. CLN-2 next to the refrigerators. There is an option to place CLN-1 into the refrigerators. For more detailed information, refer to Assign Reagent Probe Cleaning Solution-1 Positions in the Refrigerators.
Wash Count	0 to 5	Enter the number of times that the system washes the reagent probe in water or cleaning solution.
Water Cleaning Effective	Yes or No	**Yes**: The normal rinsing of the reagent probe with deionized water between tests has the same cleaning effect as the programmed contamination avoidance cleaning. If you select **5** for **Wash Count** for cleaning solution 1, and you run 5 or more tests between the two affected tests, the system does not perform the additional cleaning with cleaning solution 1. **No**: Cleaning 5 times with cleaning solution 1 always occurs before the affected test, even if you run 5 or more tests between the two affected tests.
Mixer	Yes or No	**Yes**: The system does not use the mix bar for the following test immediately after the preceding test. **No**: The system uses the mix bar for processing of the following test immediately after the preceding test.
Cuvette	Yes, Yes (CLN-1), Yes (CLN-2) or No	**Yes**: The system does not use the cuvette or uses it for a test other than the following test after the preceding test. **Yes (CLN-1)** or **Yes (CLN-2)**: The system washes the cuvette with cleaning solution 1 or cleaning solution 2 after the preceding test or uses it for a test other than the following test after the preceding test. **No**: The system can use the cuvette for processing the following test.

This example shows the difference between selecting **Yes** and selecting **No** for **Water Cleaning Effective**.

Other settings:

- Preceding Test Name: A
- Following Test Name: B

- Reagent Probe Cleaner Kind: CLN-1 or CLN-2
- Wash Count: 5

  With these settings, the test sequences of the two samples that require seven tests (A, B, C, D, E, F and G) differ. In this sequence, w is a cycle of cleaner washing.
- **Yes**: First sample: B, A, C, D, E, F, G Second sample: B, A, C, D, E, F, G
- **No**: First sample: B, A, C, D, E, F, G Second sample: A, C, D, E, F, G, w, w, w, w, w, B

Assign Reagent Probe Cleaning Solution-1 Positions in the Refrigerators

When you select the reagent probe cleaning solution-1 position option in the refrigerator, assign the reagent probe cleaning solution-1 positions in the refrigerators. You can assign up to 5 CLN-1 bottles. After performing a reagent check, the system assigns a 1 to 5 bottle sequence determined by the number of bottles you assign. Bottle sequence 1 has the least volume and bottle sequence 5 has the most volume. When multiple CLN-1 bottles are in use, the system uses bottle sequence 1 until the volume is insufficient. The system then automatically switches to bottle sequence 2. An event message about the bottle switch displays in the event display area.

Caution

When you select a position option, the designated 62.CLN-1 and 50.CLN-1 become unusable. A minimum of one bottle of CLN-1 must always be assigned to a fixed position in the R1 and R2 refrigerators before you perform the reagent check. If a minimum of one CLN-1 bottle is not assigned, the reagent check cannot be completed. The reagent status remains Unchecked in red, and you cannot start analysis or routine operations.

Caution

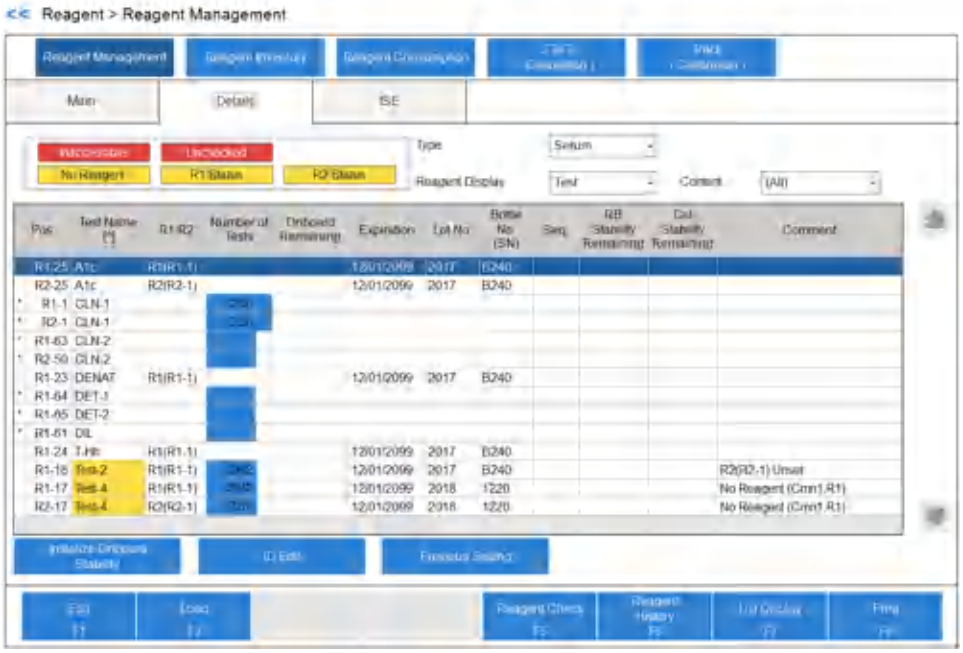
Use only an alkaline cleaning solution for CLN-1. Acidic cleaning solutions have the potential of affecting other reagents in the refrigerators or the refrigerator components.

---

1 Select **Reagent** > **Reagent Management** > **Details**.

The system displays the Reagent Management: Details tab. The system indicates assigned (fixed) positions with an asterisk highlighted in blue in the column to the left of the Pos. column.

Figure 2.39 Reagent Management: Details Tab



2 In **Reagent Display**, select **Position**.

3 In **Content**, select **R1** to assign a position in the R1 refrigerator.

4 Select an open position to assign to the reagent probe cleaning solution-1.

5 Select **Edit** [F1].
The system displays the Edit dialog for the selected position.

Figure 2.40 Edit Dialog (Fixed Reagent)

6 Select **Fixed Reagent**.

a. In **Test Name**, select **CLN-1**.

b. In **Bottle Size**, select **60 mL**.

Note

The **Type**, **Lot No.**, and **Bottle No. (SN)** fields become unusable. You cannot select them.

7 If you assign multiple reagent probe cleaning solution-1 positions, select another position by selecting the forward or back button. Then repeat Step 6.

8 Select **OK**.
The system closes the Edit dialog.

9 Confirm that the system indicates assigned (fixed) positions with an asterisk in the column to the left of the Pos. column.

10 In **Content**, select **R2** to assign a position in the R2 refrigerator.

11 Select an open position to assign the reagent probe cleaning solution-1.

12 Select **Edit** [F1].
The system displays the Edit dialog for the selected position.

Figure 2.41 Edit Dialog (Fixed Reagent)

13 Select **Fixed Reagent**.

a. In **Test Name**, select **CLN-1**.

b. In **Bottle Size**, select **60 mL**.

Note

The **Type**, **Lot No.**, and **Bottle No. (SN)** fields become unusable. You cannot select them.

14 If you assign multiple reagent probe cleaning solution-1 positions, select another position by selecting the forward or back button. Then repeat step 13.

15 Select **OK**.
The system closes the Edit dialog.

16 Confirm that the system indicates assigned (fixed) positions with an asterisk in the column to the left of the Pos. column.

Carry-over Prevention (Type Changes) Tab

Program extra cleaning of the sample probe between different sample types.

Select **CONFIG.** > **Contamination Parameters** > **Carry-over Prevention (Type Changes)**.

Contact Beckman Coulter for detailed information about contamination parameters.

Figure 2.42 Contamination Parameters: Carry-over Prevention (Type Changes) Tab

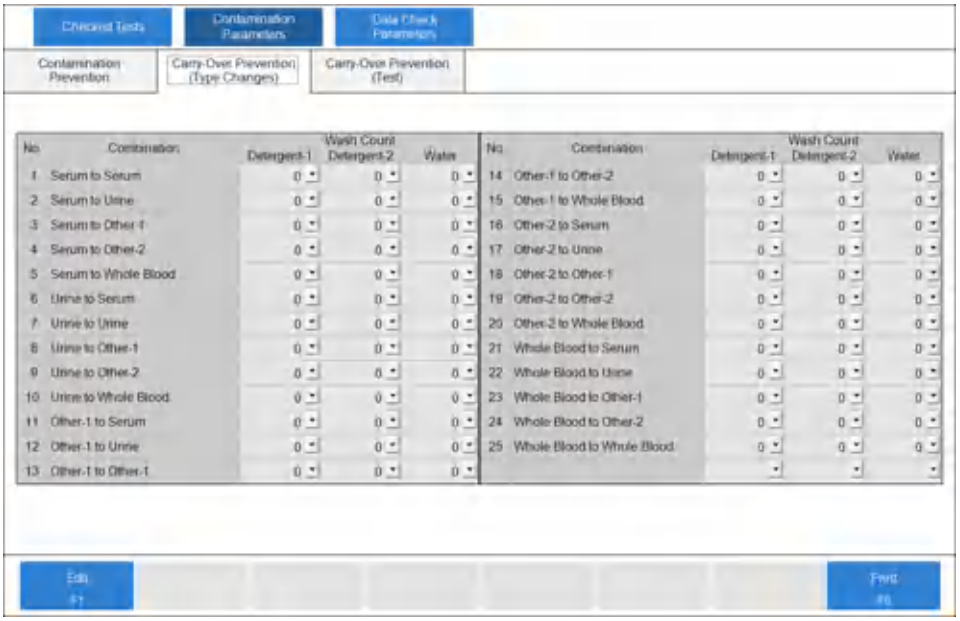


Table 2.34 Carry-over Prevention (Type Changes) Tab Description

Item	Contents	Input Notes
Wash Count: Detergent-1, Detergent-2, Water	0 to 6	Select the number of times that the system cleans the sample probe with water, detergent 1, and detergent 2 when changing between sample types. Place cleaning solutions detergent 1 and detergent 2 in positions 64. Det-1/W2 and 65. Det-2 on the analyzer by the sample probe.

Carry-over Prevention (Test) Tab

Program extra sample probe washes before or after highly sensitive tests.

Program the washing count after analysis for tests affecting other tests. Program the washing count before analysis for tests that other tests readily affect.

Contact Beckman Coulter for more information about contamination parameters.

Select **CONFIG.** > **Contamination Parameters** > **Carry-over Prevention (Test)**.

Figure 2.43 Contamination Parameters: Carry-over Prevention (Test) Tab

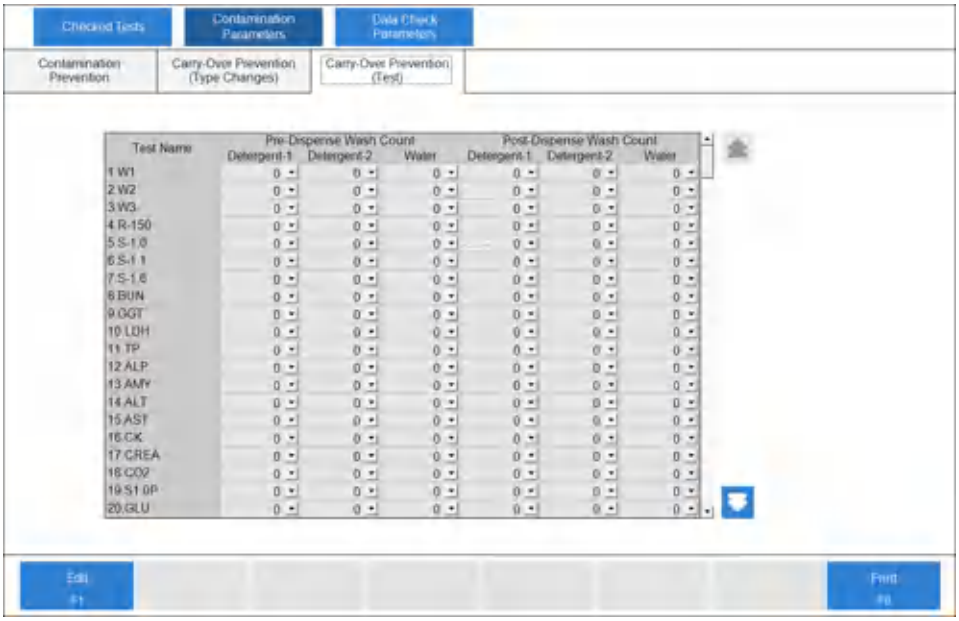


Table 2.35 Carry-over Prevention (Test) Tab Description

Item	Contents	Input Notes
Pre-Dispense Wash Count: Detergent-1, Detergent-2, Water	0 to 6	Select the number of times that the system cleans the sample probe with water, detergent 1, and detergent 2 before dispensing the test. Place cleaning solutions detergent 1 and detergent 2 in positions 64. Det-1/W2 and 65. Det-2 on the analyzer by the sample probe.
Post-Dispense Wash Count: Detergent-1, Detergent-2, Water	0 to 6	Select the number of times that the system cleans the sample probe with water, detergent 1, and detergent 2 after dispensing the test. Place cleaning solutions detergent 1 and detergent 2 in positions 64. Det-1/W2 and 65. Det-2 on the analyzer by the sample probe.

Data Check Parameters Screen

Prozone Check Tab

Program check points and decision limits to detect 1 of 4 different abnormal reaction types for Prozone effects in an increasing turbidimetric test. If necessary, the reagent setting sheet provides data check parameters. For more information, contact Beckman Coulter.

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1 Select **CONFIG.** > **Data Check Parameters** > **Prozone Check**.

Figure 2.44 Data Check Parameter: Prozone Check Tab

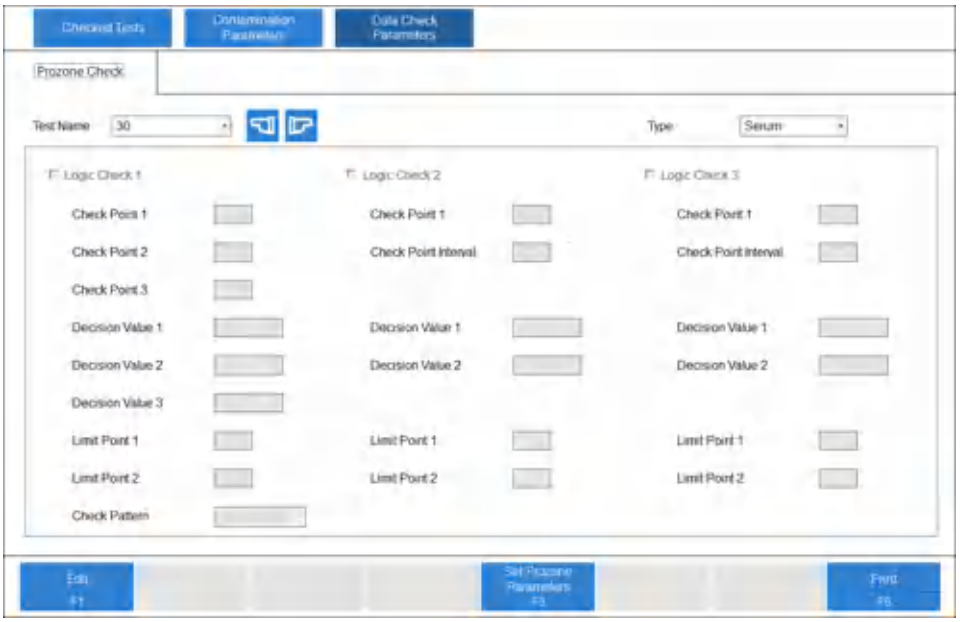


Table 2.36 Prozone Check Tab Description

Item	Description
Check Point 1 to Check Point 3	Enter the photometric measuring point for evaluation or the photometric measuring point for start of evaluation.
Check Point Interval	Enter the point interval from the evaluation start point for the check. No input is possible for logic check 1.
Decision Value 1 to Decision Value 3	Enter the OD to use for evaluation.
Limit Point 1, 2	Set evaluation points other than check points. When the low concentration reaction and Prozone draw similar curves, this can be used to cancel low concentration.
Check Pattern (only with Logic Check 1)	— **Pattern 1**: application of both evaluation formulas 1 and 2 — **Pattern 2**: application of only evaluation formula 1 — **Pattern 3**: application of only evaluation formula 2 — **Pattern 4**: neither evaluation formula 1 nor 2 applied

2 Select **Edit** [F1].

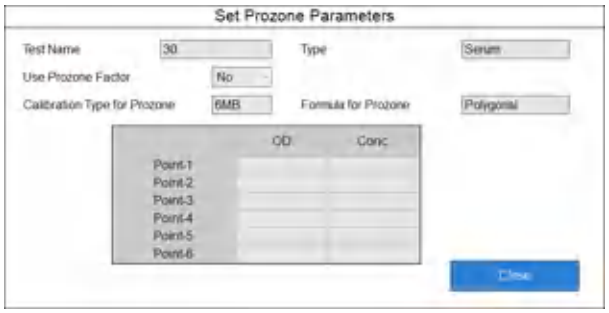
3 Enter a check for one of the data check items 1 through 3, and program the data check tests.

You can check multiple data checks.

4 Select **Set Prozone Parameters** [F5].

The Set Prozone Parameters dialog displays.

Figure 2.45 Set Prozone Parameters Dialog



The system can perform data calculation using a dedicated calibration type. The Set Prozone Parameters dialog displays a polygonal line of the 6-MB formula type, and the concentration value for OD is set.

5 Select **Close** to close the Set Prozone Parameters dialog.

6 Confirm that the information is correct, and then select **Save** [F1].

System Condition Menu

System parameter options affect system operations and software.

Analysis Mode Screen

Program the sample identification mode, auto rerun option, rack number limit for sample type, and alarm sound options in the Analysis Mode screen.

1 Select **CONFIG.** > **Analysis Mode**.

Figure 2.46 System Condition: Analysis Mode Screen

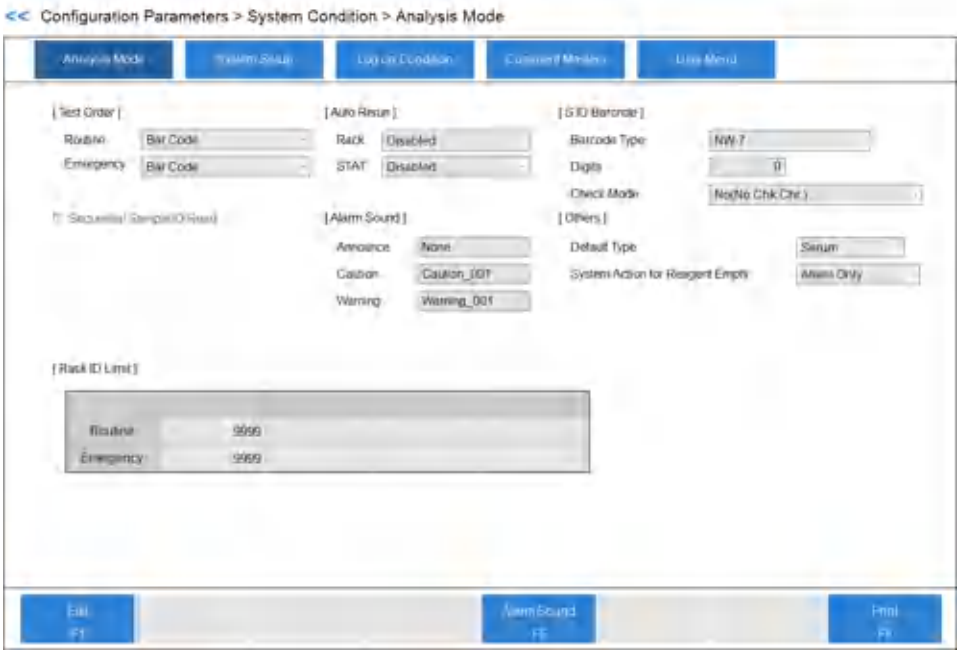


Table 2.37 Analysis Mode Screen Overview

Option	Description
Test Order	Program the sample identification mode.
Auto Rerun	Program the auto rerun option.
S.ID Bar Code	Program the bar code type to use for sample identification. Select from five types of bar codes. You can use multiple bar code types. If you want to use Multicode, contact Beckman Coulter.
Alarm Sound	Program the alarm sound that the system generates. If you use multiple systems, you can identify each system with a different alarm sound.
Others	Program other system conditions.
Rack ID Limit	Sample kind mixed (default): The system displays 9999. Sample kind sorted (option): Program the rack ID limit for each sample type. The FSE programs this option at the system installation.

2 Select **Edit** [F1].

3 Program the system parameters for each item in the table:

Table 2.38 Analysis Mode Screen Description

Item	Contents	Input Notes
Test Order		
Routine Emergency	Sequential Rack ID Bar Code	— **Sequential**: Performs an item inquiry in the order of sample tube detection. — **Rack ID**: Performs an item inquiry in the order of rack ID number and sample position in the rack. — **Bar Code**: Performs an item inquiry according to the bar code ID attached to the sample cups.
Sequential Sample ID Read	Selected or Cleared	Selected: If you select **Sequential** or **Rack ID** as the sample identification mode in the **Test Order** and the sample has a bar code label, the analyzer can read the bar code but does not use this information for the test order. In Sequential and Rack ID modes, the system stores the bar code as the sample ID.
Auto Rerun		
Rack STAT	Disabled Enabled	— **Disabled**: The system generates a rerun list after the first run. The operator determines the samples to rerun, and manually performs the rerun from the white or red racks, or the STAT table. — **Enabled**: The system automatically performs the rerun using the rerun parameters.
S. ID Bar Code		
Bar Code Type	Select from 7 types	Refer to Sample Bar Code Label Specifications for available bar code types.
Digits	0 to 26 digits	Do not include the check digit. 0 means the number of digits is not specified.

Table 2.38 Analysis Mode Screen Description (Continued)

Item	Contents	Input Notes
Check Mode	No (No Chk. Chr.) No (With Chk. Chr.) Yes	— **No (No Chk. Chr.)**: Use bar codes without check characters. The system does not perform a check. — **No (With Chk. Chr.)**: Use bar codes with check characters, but the system does not perform a check. — **Yes**: Use bar codes with check characters. The system performs the check. For more information, refer to Bar Code Check Methods.
Others		
Default type	Serum, Urine, Other-1, Other-2, or Whole Blood	Select the default sample type to display in **Type** in all screens.
System Action for Reagent Empty	Event Only or With Pause	— **Event Only**: Analysis continues, except for the empty reagent. — **With Pause**: Analysis stops for all tests and the system shifts to *PAUSE* mode.
— Select Bar Code analysis if the DxC 700 AU connects to a Laboratory Automation System. — The sample ID does not include the Check Character as a component of it. The system does not display it or store it. — Refer to the Laboratory Automation System manual for available bar code types. — The bar code digits are 0 to 17 if the DxC 700 AU connects to a Laboratory Automation System. — Check Mode is not applicable when the system reads the bar code label on the Laboratory Automation System.		

Caution

When you enter 0 for the number of digits (no setting) for interleaved 2 of 5, the system can interpret a reading with missing digits as a correct reading. For example, when the system cannot read digits at the edge of the label because of an incorrectly attached label, correct analysis is impossible. The same also applies when interleaved 2 of 5 is included in Multicode.

Caution

Use of sequential mode is not recommended for samples, as positive patient identification cannot be guaranteed. Analysis without a sample ID can cause incorrect patient results.

4 Select **Alarm Sound** [F5]. The Alarm Sound dialog opens.

Figure 2.47 Alarm Sound Dialog

5 Select the alarm sound to be used for **Announce** (none or seven options), **Caution** (five options), and **Warning** (six options).

If you select **None**, no alarm sounds when the event occurs.

Note

Select **Play** to hear the alarm sound. The alarm sound stops after a specified time or when you select **Stop**, **OK**, or **Cancel**.

6 Select **OK**.

7 Confirm that the information is correct, and then select **Save** [F1].

Program the Rack ID Limit (Option)

Two options are available to place the samples in the rack:

1. The system analyzes different sample types (serum, urine, Other-1, Other-2, and Whole Blood) in one rack. The system recognizes the sample type with the test order information. This is the default setting.
2. The system analyzes only the same sample type in one rack. The system recognizes the sample type by the rack ID range that you assign to each sample type. This is an optional setting that you can request.

By default, the system analyzes different sample types in one rack, but you can request for a Beckman Coulter Representative to program the system during installation to analyze only the same sample type in one rack. To determine if your system has the default setting, look at the **Rack ID Limit** section of the Analysis Mode screen (**CONFIG.** > **Analysis Mode**). You cannot edit the values in the **Rack ID Limit** section if it is in default mode. For more information, contact Beckman Coulter.

When you select the second option (the same sample type in one rack), program the rack ID limit for each sample type.

1 Select **CONFIG.** > **Analysis Mode**.

Figure 2.48 System Condition: Analysis Mode Screen

2 Select **Edit** [F1].

3 Enter the upper limit value for the rack ID number according to the following input value limitations for **Rack ID Limit**. Refer to Figure 2.48 System Condition: Analysis Mode Screen.

	Serum	Urine	Other-1	Other-2	Whole Blood
Routine	0 to 9999	0 or Serum column + 1 to 9999	0 or Urine column + 1 to 9999	0 or Other-1 column + 1 to 9999	0 or 9999 (non-editable)
Emergency					

The number of digits of the rack ID number is four or five digits according to the programming at installation. The standard is four digits. The explanations apply for four digits.

The corresponding racks are white racks for routine samples, red racks for emergency samples.

The number entered for each sample type is the rack ID upper limit. Starting with the Serum column, then Urine, Other-1, Other-2, and Whole Blood, the number you enter must be higher than any numbers for the previous sample type (up to 9999) or 0.

The system does not process sample types programmed to 0.

The system assigns 0 or 9999 to the last columns automatically.

4 Confirm that the information is correct, and then select **Save** [F1]. If there is a discrepancy, the system highlights the setting with the discrepancy, and the display stays in edit mode.

System Setup Screen

Program the system language, offline format, sample type name, date format, date and time, other type name, log on password, and auto power on options in the System Setup screen.

Select **CONFIG.** > **System Setup**.

Figure 2.49 System Setup Screen

Table 2.40 System Setup Screen Description

Item		Contents	Input Notes
Language			
	Screen	Languages	Select the language to display on the screen.
	Help	Help languages	Select the system help language.
Instrument Serial Number		A 10-digit number	Display only. The Beckman Coulter System ID
Offline Format			
	Field Delimiter	, space tab . : ; - / |	Select the delimiter to be added between each item of data.
	Decimal Point Character	.	Display only.
Sample Type Name			
	Type 1	Serum	Display only.
	Type 2	Urine	Display only.
	Type 3	Other-1	Enter the operator-defined name.

Table 2.40 System Setup Screen Description (Continued)

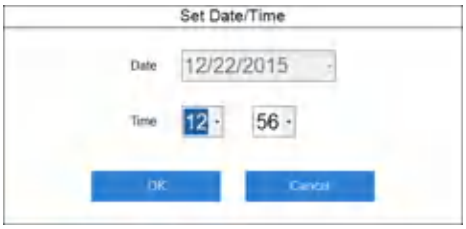
Item		Contents	Input Notes
	Type 4	Other-2	Enter the operator-defined name.
	Type 5	Whole Blood	Display only.
Date Format		Date format	Select the date format.
Date/Time Setting		System date and time	Select **Set Date/Time** [F5] to change the date and time.
Other Type Name		Type 1 to Type 6	Enter the operator-defined name. Other Type is an additional demographic criteria to classify the patient sample. For more information, refer to Other Type. Used in **Specific Range** as user demographics criteria. Refer to Range Tab.

Set Date and Time

The system displays the current date and time in the top right corner under the navigation bar. The system updates the current date and time for daylight savings time from regional settings.

1 Select **Set Date/Time** [F5].
The system displays the Set Date/Time dialog.

Figure 2.50 Set Date/Time Dialog



2 Set the current date in **Date**.

3 Set the current time as a 24-hour display in **Time**.

4 Select **OK**.
The system updates the current date and time.

Change the Password for the User Currently Logged On

1 Select **Password Setup** [F6].

Figure 2.51 Password Setup Dialog

2 In **Current Password**, enter the current password.

3 In **New Password**, enter the new password.

You can use up to 20 uppercase and lowercase characters.

Note

Using a password is optional. If you do not enter a password, the user name entered for logon has access to the assigned user level.

4 In **Confirm**, reenter the password entered in step 3.

5 Select **OK**.

Auto Power On Setup

The lamp requires approximately 20 minutes after pressing **ON** to warm up so that the system can start analysis.

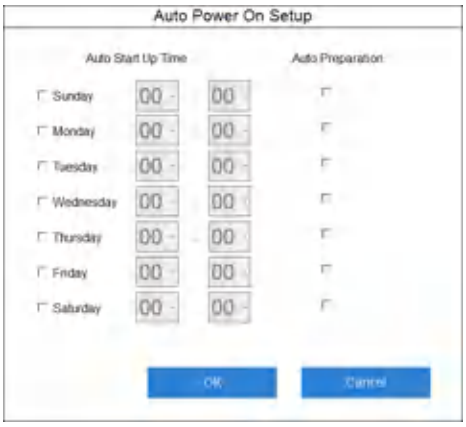
You can program the system to turn on automatically at a specified time of each day of the week.

Caution

The Auto Power On option does not open and close the main water valve, so you must leave it open. Follow laboratory standard operating procedures for inspecting the deionized water system and main water valve.

1 Select **Auto Power On Setup** [F7].

Figure 2.52 Auto Power On Setup Dialog



2 Select the desired day to start the Auto Power On function.

3 Set the hours and minutes.

4 If the Auto Preparation button is enabled, select **Auto Preparation** to perform Auto Preparation.

Note

In System Maintenance, Beckman Coulter enables Auto Preparation for each day of the week. The three auto preparation options are:

— W1
— Photocal
— W1 + Photocal

5 Repeat steps 2 to 4 for each day to be set.

6 Select **OK**.

Program the Logon

Program user names and passwords for the system. Select **LOGOUT** in the navigation button area to log on or out for each operator. The system registers such information.

Each user name belongs to an access level. Assign access levels to menus, submenus, and functions such as Specific Test Parameters or Quality Control.

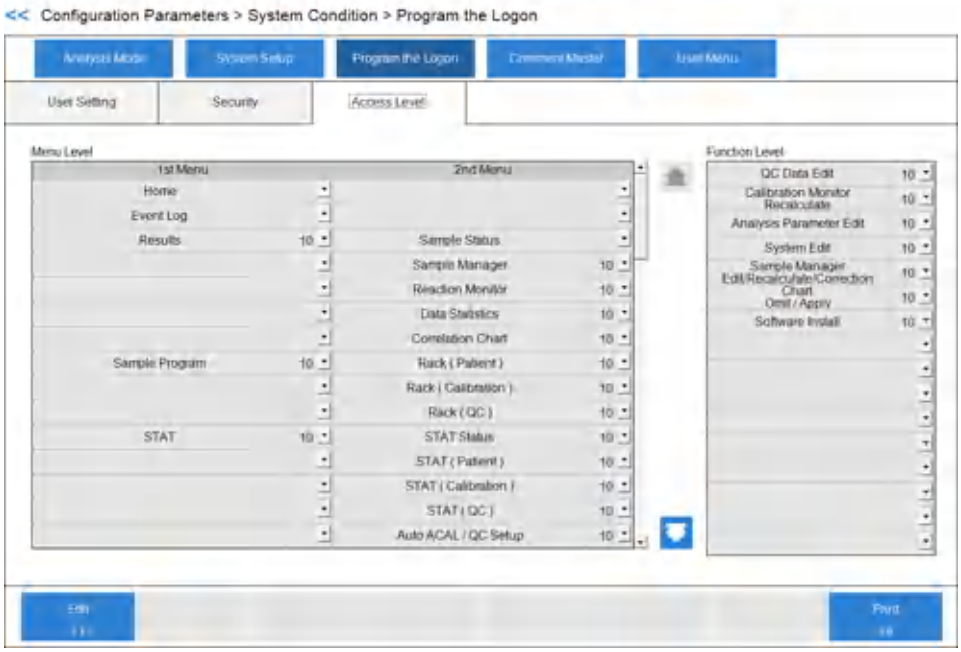
You can program a maximum of 30 user names with passwords. You can change user names, passwords, and access levels, and delete users. For detailed information, refer to User Setting Tab.

Access Level Tab

You can program access levels from 1 to 10 for each user name. The initial access level is 10, so all users assigned to 1 through 10 have access to menus. The most secure menu access level is 1, as only users assigned as a 1 have access. A user assigned to a 5 for example, has access to menus assigned from 5 to 10. Confirm that a user is programmed to have full access to all menus. For more information, refer to User Setting Tab.

1 Select **CONFIG.** > **Program the Logon** > **Access Level**.

Figure 2.53 Program the Logon: Access Level Tab



2 Select **Edit** [F1].

3 Program the menu level within the range from 1 to 10.

Note

Set the level for the 1st Menu to the same or higher number than the number for the 2nd Menu.

4 Repeat step 3 for all of the items for 1st Menu, 2nd Menu, and Function Level.

5 Select **Save** [F1]. The Program the Logon dialog opens.

Note

If there is any conflict in access levels between the first Menu and the second Menu, the Logon Condition dialog displays for notification of a programming conflict. Select **Cancel** to resolve the conflict, or **OK** to close the dialog. If you select **OK**, the system assigns the same level from first Menu to second Menu.

6 Select **OK** to save the settings.

Caution

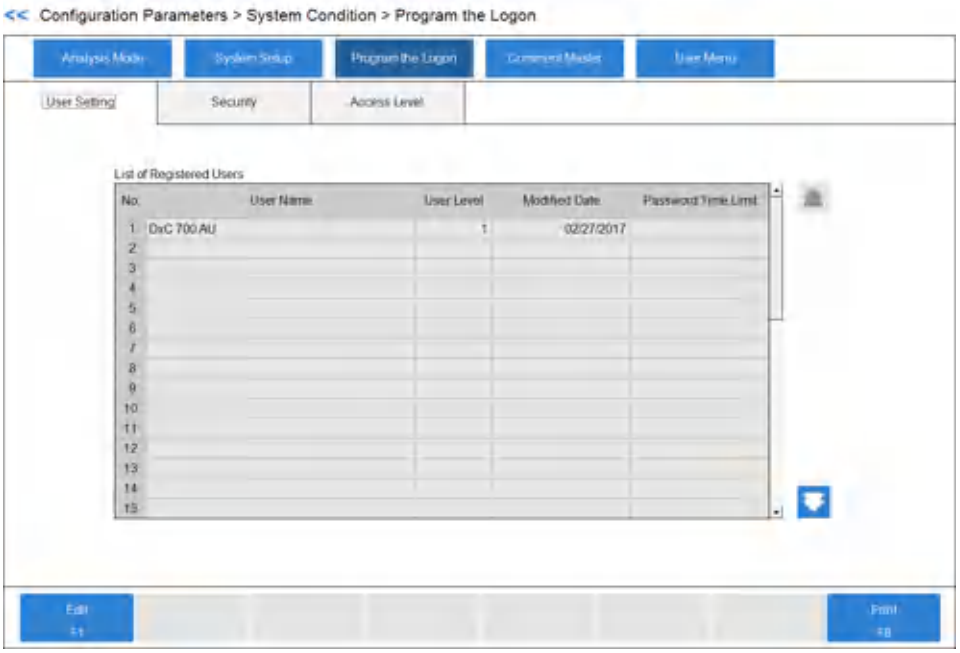
You cannot program an item from second Menu with a higher number than an item from first Menu.

User Setting Tab

Program a New User Name and Password

1 Select **CONFIG.** > **Program the Logon** > **User Setting**.

Figure 2.54 Program the Logon: User Setting Tab



2 Select **Edit** [F1].

3 Select an available number in No. (from 1 to 30).

4 Select **Add User** [F2]. The Add User dialog opens.

Figure 2.55 Add User Dialog

5 Enter the **User Name**. Upper and lower case characters can be used for up to 20 characters.

6 Enter the password for the new user in **Password**. Upper and lower case characters can be used for up to 20 characters. Use of a password is optional. If a password is not entered, the user name entered for logon has access to the assigned user level.

7 For confirmation, reenter the password entered in step 6 in **Confirm**.

8 If it is necessary to change the user access level, select 1 to 10 in the User Level column. A smaller number means a higher level of access to menus and functions.

9 Select **OK**.

10 Repeat steps 3 to 9 for each user.

11 Select **Save** [F1]. The Program the Logon dialog opens.

12 Select **OK** to save the settings.

Note

Functions and menus that are not accessible mean that the User Level for the user does not allow them to access these items. If you need access to these items, ask an administrator to change the User Level. For more information, refer to Access Level Tab.

Change the User Name Password or User Level

1 Select **CONFIG.** > **Program the Logon** > **User Setting**.

2 Select **Edit** [F1].

3 From **List of Registered Users**, select the user name to be changed.

4 Select **Modify** [F3]. The Modify dialog opens.

Figure 2.56 Modify Dialog

5 Change the **User Name** if necessary.

6 Select **Change** to change the password if necessary.

7 Enter the **Current Password**.

8 Enter the **New Password**.

9 For confirmation, reenter the password entered in step 8 in **Confirm**.

10 If it is necessary to change the user access level, select 1 to 10 in the User Level column. A smaller number means a higher level of access to menus and functions.

11 Select **OK**.

12 Select **Save** [F1]. The Program the Logon dialog opens.

13 Select **OK** to save the settings.

Delete Users

1 Select **CONFIG.** > **Program the Logon** > **User Setting**.

2 Select **Edit** [F1].

3 Select the user name to be deleted and select **Delete** [F4]. The system displays the delete message.

4 Select **OK**. The user name is deleted.

5 Select **Save** [F1].

Security Tab

Security options include programming a password expiration date, an auto lock of the console, and an auto logon feature.

1 Select **CONFIG.** > **Program the Logon** > **Security**.

Figure 2.57 Program the Logon: Security Tab

2 Select **Edit** [F1].

3 To set an expiration date for a password, select **Enable** next to **Password Expiration Date**. Enter the number of days that the password is effective before you must change it.

You can set a number between 1 and 60 days as an expiration date for the password.

4 To auto lock the screen, select **Enable** next to **Auto Lock**. In **Wait time**, select a time from 5 to 60 minutes for the system to wait to activate the auto lock.

5 To enable the auto log on function without inputting a user name and password at system startup, select **Enable** next to **Auto Log on**. Select the user name to set up for auto log on in **Auto Log on User**.

6 Select **Save** [F1]. The Confirmation dialog opens.

7 Select **OK** to save the settings.

Note

The password expiration date is effective for all user names.

Note

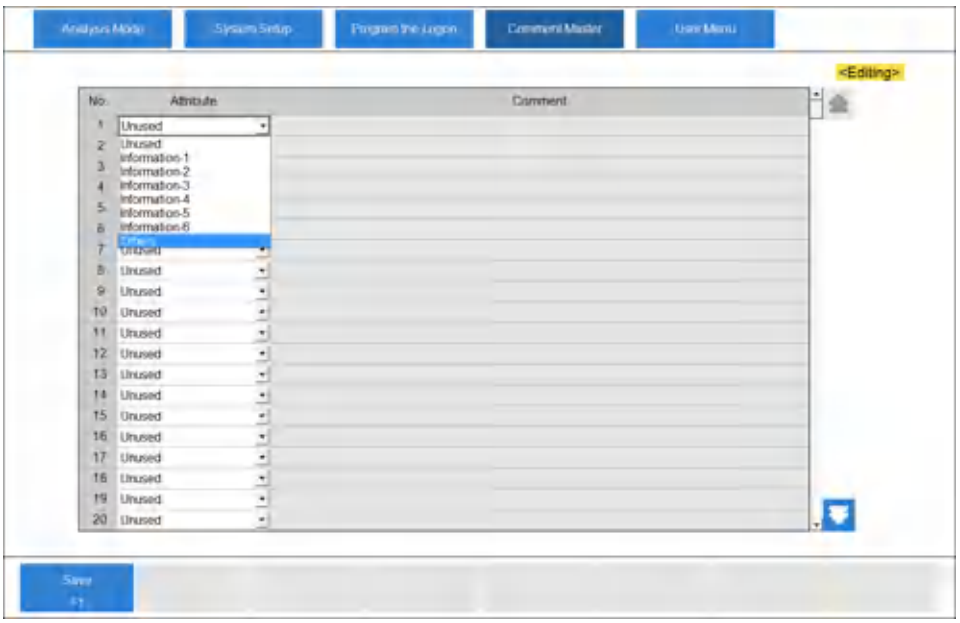
You cannot use auto log on when you enable auto lock.

Comment Master Screen

Program a list of standard comments for the system to insert when you select **Comment Master**, as an alternative to reentering the comments manually. You can program up to 220 comments. You can program up to 20 comments for Unit.

1 Select **CONFIG.** > **Comment Masters**.

Figure 2.58 System Condition: Comment Masters Screen



2 Select **Edit** [F1].

3 In **Attribute**, select the comment attribute.

- For comments number 1 to 220:
  - **Unused**: The comment is not used (no comment).
  - **Information 1** to **Information 6**: You can select the comments in demographic fields 1 to 6 in the Demographics tabs (**TEST** > **Rack (Patient)** > **Demographics** and **STAT** > **STAT (Patient)** > **Demographics**).
  - **Others**: You can select the comment in **Operator Name** in the Change Operator dialog (**HOME** > **Change Operator** [F2]), or **Comments** in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics** or **STAT** > **STAT (Patient)** > **Demographics**), and the Calibration Monitor tab (**MENU** > **Calibration** > **Calibration Monitor**).
- For comments number 221 to 240:
  - **Unused**: The comment is not used (no comment).
  - **Unit**: You can select the comment in **Unit** in the Range tab (**CONFIG.** > **Test Volume and Methods** > **Range**).

4 Enter the comment in **Comment**.

- For comments number 1 to 220:

— **Unused**: You cannot edit the comment. If you change the attribute of an entered comment to **Unused**, the system retains the entered comment.
— **Information 1** to **Information 6**: You can enter up to 20 characters.
— **Others**: You can enter up to 50 characters.

- For comments number 221 to 240:

— **Unused**: You cannot edit the comment. If you change the attribute of an entered comment to **Unused**, the system retains the entered comment.
— **Unit**: You can enter up to 50 characters.

Note

Program the 1 to 6 patient demographic titles in **<Patient Information>** in the Sample Program Format screen (**CONFIG.** > **Sample Program Format**). The patient demographic titles display in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics** or **STAT** > **STAT (Patient)** > **Demographics**). Refer to Sample Program Format Screen.

5 Confirm that the information is correct, and then select **Save** [F1].

Online Menu

Set the input and output conditions for online connections for this system with a clinical Laboratory Information System. Beckman Coulter typically programs online parameters.

Two methods to connect online:

- RS232C (the default)
- TCP/IP

For changing methods, contact Beckman Coulter. This section describes how to configure each connection.

Program Online Parameters with RS232C Connection

Setup Tab for RS232C

You can select from several communication methods:

- Realtime: Test order inquiries and analysis result output are performed during analysis.
- Batch: Test order inquiries and analysis result output require operator intervention.
- None: No online input or output occurs.

1 Select **CONFIG.** > **Online** > **Setup**.

Figure 2.59 Online: Setup Tab (RS232C)

Note

— **Test Order Information Receive**: Program the test order inquiry mode. Select from three inquiry modes for routine first-run, routine rerun, emergency first-run, emergency rerun, STAT first-run, and STAT rerun.

  — Realtime
  — Batch
  — None (default)

— **Analysis Results Transfer Mode**: Program the output method for analysis results. Select from three output options for routine first-run, routine rerun, emergency first-run, emergency rerun, STAT first-run, STAT rerun, reagent blank, calibration, and QC.

  — Realtime
  — Batch
  — None (default)

  If the DxC 700 AU connects to a Laboratory Automation System, you cannot set the output method for routine rerun, emergency first-run, and emergency rerun.

2 Select **Edit** [F1].

3 Select the communication method for each sample kind.

4 Confirm that the information is correct, and then select **Save** [F1].

Protocol Tab for RS232C

Program the online communication protocol.

1 Select **CONFIG.** > **Online** > **Protocol**.

Figure 2.60 Online: Protocol Tab (RS232C)

2 Select **Edit** [F1].

3 Program the parameters.

Table 2.41 Protocol Tab for RS232C Description

Setting	Values	Initial Value
Upper Protocol		
T.R.I Receive Error Control	— **Stop**: When a communication error occurs, communication stops after the sample with the communication error. — **Continue**: Even when a communication error occurs, the system executes T.R.I. for the next sample.	Stop

Table 2.41 Protocol Tab for RS232C Description (Continued)

Setting	Values	Initial Value
Results Transfer Error Control	— **Stop**: When a communication error occurs, communication stops after the sample with the communication error. — **Continue**: Even when a communication error occurs, the system executes T.R.I. for the next sample.	Stop
Lower Protocol		
<Character Format>		
Character Length	7 and 8	7
Parity Bit	None, Even, and Odd	None
Stop Bit	1 and 2	1
<Basic Data Format>		
Start Code (1st)	01h:SOH to 1Fh:US	02h:STX
Start Code (2nd)	None, 01h:SOH to 1Fh:US	None
End Code (1st)	01h:SOH to 1Fh:US	03h:ETX
End Code (2nd)	None, 01h:SOH to 1Fh:US	None
Text Length	256, 512, and 1024	1024
Device No.	Unchecked and Checked	Unchecked
Device No. (checked)	00 to 99	00
ETB Control	Unchecked and Checked	Unchecked
<Communication Control>		
Bit/Sec.	4800 and 9600	9600
Class	Class A (No ACK/NACK) Class B (With ACK/NACK)	Class A
Retry	0 to 3	1
BCC Check	Unchecked and Checked	Unchecked
<Time Out [x 100msec.]>		
T1	1 to 99 msec.	20
T2	1 to 99 msec.	15

Table 2.41 Protocol Tab for RS232C Description (Continued)

Setting	Values	Initial Value
T3	1 to 99 msec.	15
T4	1 to 99 msec.	20
T5	1 to 99 msec.	20
T6	1 to 99 msec.	10
T7	1 to 99 msec.	20

4 Confirm that the information is correct, and then select **Save** [F1].

Note

Beckman Coulter typically programs online parameters.

Note

Program the protocol after confirmation with the system administrator of the Laboratory Information System. A discrepancy with the settings on the Laboratory Information System might prevent correct communication.

Format Configuration Tab for RS232C

Program the additional information and number of digits for data for online communication.

1 Select **CONFIG.** > **Online** > **Format Configuration**.

Figure 2.61 Online: Format Configuration Tab (RS232C)

— **Used/Unused**: Selected items to be added to online communication messages.
— **Others**:

— **Rack ID Digit**: Four or five digits
— **Online Test No. Digit**: Two or three digits for the test number programmed in the Online Test No. tab (**CONFIG.** > **Online** > **Online Test No.**).
— **Result Digit**: Six or nine digits for the data to be added to the message.
— **No. of Flags**: Two or four flags to be added to the message.
— **Cal. No./Control No. Digit**: Two or three digits

Caution

After confirmation, the system administrator must set the data format on the Laboratory Information System. A discrepancy with the settings on the Laboratory Information System might prevent correct communication.

2 Select **Edit** [F1].

3 Select the items to be used for online communication in **Used/Unused**.

4 Select the digits for each item in **Others**.

5 Confirm the information, and then select **Save** [F1].

Online Test No. Tab for RS232C

Assign each test name to an online test number for online communication.

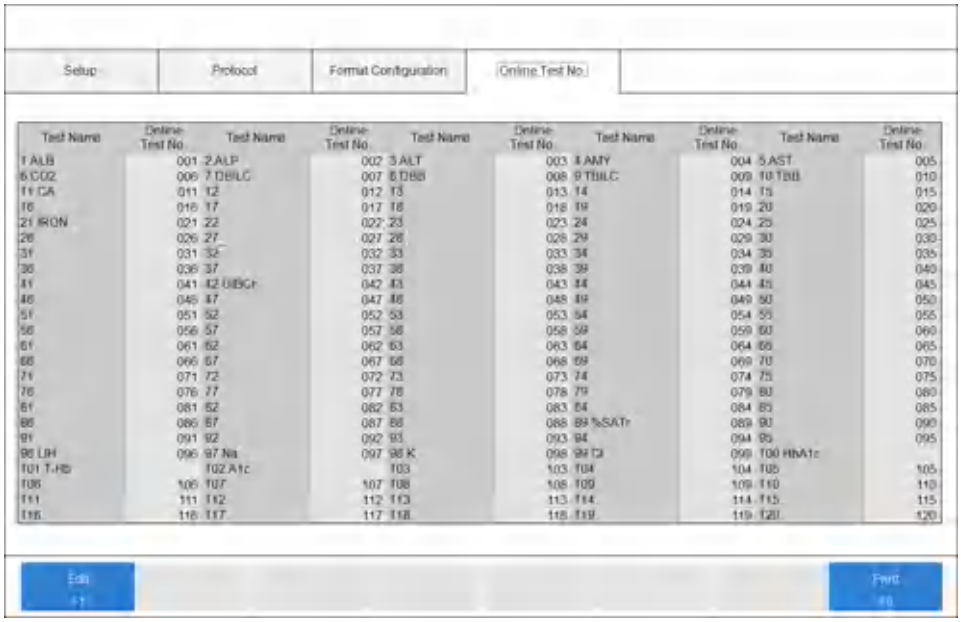
Note

Total and direct bilirubin are programmed as sample blank tests. For more information, refer to Test Name Parameters Screen.

For a blank test in sample blank tests, you cannot program an online test number because the system uses the blank test result only for the calculation and is not a reported result.

1 Select **CONFIG.** > **Online** > **Online Test No.**

Figure 2.62 Online: Online Test No. Tab (RS232C)



2 Select **Edit** [F1].

3 Select the test name to be programmed.

4 Enter the number in **Online Test No.** The combination of the online test number and test must agree with what is in the Laboratory Information System. Set the number as a blank when you do not require online communication.

Note

A discrepancy with the settings on the Laboratory Information System might prevent correct communication.

5 Repeat steps 3 and 4 for each test to be programmed.

6 Confirm that the information is correct, and then select **Save** [F1].

7 If you entered duplicate numbers, the Parameter Error(s) dialog displays. Select **Cancel** and make corrections.

Program Online Parameters with TCP/IP Connection

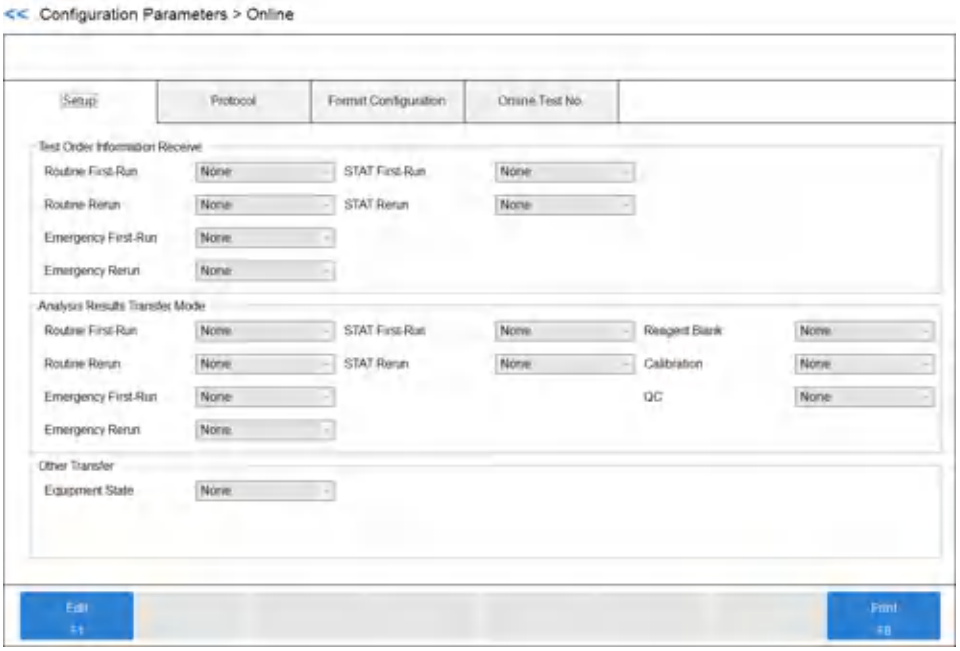
Setup Tab for TCP/IP

You can select from four communication methods:

- Realtime: Test order inquiries and analysis result output are performed during analysis.
- LIS Direction: The Laboratory Information System sends test order information to the DxC 700 AU, and the DxC 700 AU saves the information (without an inquiry process from the DxC 700 AU) during analysis and other modes.
- Batch: Test order inquiries and analysis result output require operator intervention.
- None: No online input or output occurs.

1 Select **CONFIG.** > **Online** > **Setup**.

Figure 2.63 Online: Setup Tab (TCP/IP)



— **Test Order Information Receive**: Program the test order inquiry mode. Select from three inquiry modes for routine first-run, routine rerun, emergency first-run, emergency rerun, STAT first-run, and STAT rerun.

  — Realtime
  — LIS Direction
  — None (default)

— **Analysis Results Transfer Mode**: Program the output method for analysis results. Select from three output options for routine first-run, routine rerun, emergency

first-run, emergency rerun, STAT first-run, STAT rerun, reagent blank, calibration, and QC.

— Realtime
— Batch
— None (default)

— **Other Transfer**: Program the system for output to LIS. When the test order is received with LIS Direction, select **Enable** in **Equipment State**.

— Enable
— None (default)

2 Select **Edit** [F1].

3 Select the communication method for each sample kind.

4 Confirm the information, and then select **Save** [F1].

Protocol Tab for TCP/IP

Program the online communication protocol.

1 Select **CONFIG.** > **Online** > **Protocol**.

Figure 2.64 Online: Protocol Tab (TCP/IP)

2 Select **Edit** [F1].

3 Program the parameters.

Table 2.42 Protocol Tab for TCP/IP Description

Setting Item	Setting Range	Default
T.R.I Receive Error Control	— **Stop**: When a communication error occurs, communication stops after the sample with the communication error. — **Continue**: Even when a communication error occurs, the system executes T.R.I. for the next sample.	Stop
Results Transfer Error Control	— **Stop**: When a communication error occurs, communication stops after the sample with the communication error. — **Continue**: Even when a communication error occurs, the system executes T.R.I. for the next sample.	Stop
Start Code (1st)	None, 01h to 1Fh	None
Start Code (2nd)	None, 01h to 1Fh	None
End Code (1st)	None, 01h to 1Fh	None
End Code (2nd)	None, 01h to 1Fh	None
Device ID box	Selected or Cleared	Cleared
Device No.	32 characters	-
LIS ID box	Selected or Cleared	Cleared
LIS ID	32 characters	-
<Time Out [×100msec.]> T1	00 to 99 msec.	50
<Time Out [×100msec.]> T2	00 to 99 msec.	60
<Time Out [×100msec.]> T3	00 to 99 msec.	20
<Time Out [×100msec.]> T4	00 to 99 msec.	50
Retry	0 to 3	3

4 Confirm the information, and then select **Save** [F1].

Format Configuration Tab for TCP/IP

Program the additional information for online communications.

1 Select **CONFIG.** > **Online** > **Format Configuration**.

Figure 2.65 Online: Format Configuration Tab (TCP/IP)

Caution

After confirmation, the system administrator must set the data format on the Laboratory Information System. A discrepancy with the settings on the Laboratory Information System might prevent correct communication.

2 Select **Edit** [F1].

3 Select the additional items to be used for online communication in **Used/Unused**.

4 Confirm the information, and then select **Save** [F1].

Online Test No. Tab for TCP/IP

Assign each test name to an online test number for online communication.

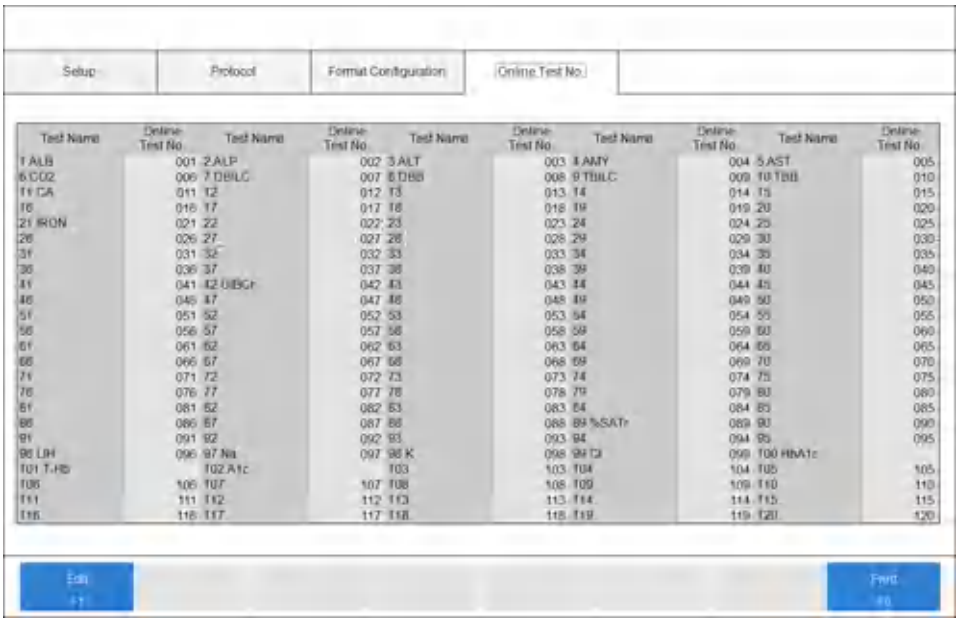
Note

Total and direct bilirubin are programmed as sample blank tests. For more information, refer to Test Name Parameters Screen.

For a blank test in sample blank tests, you cannot program an online test number because the system uses the blank test result only for the calculation and is not a reported result.

1 Select **CONFIG.** > **Online** > **Online Test No.**

Figure 2.66 Online: Online Test No. Tab (TCP/IP)



2 Select **Edit** [F1].

3 Select the test name to be programmed.

4 Enter the number in **Online Test No.** The combination of the online test number and test must agree with what is in the Laboratory Information System. Set the number as a blank when you do not require online communication.

Note

A discrepancy with the settings on the Laboratory Information System might prevent correct communication.

5 Repeat steps 3 and 4 for each test to be programmed.

6 Confirm that the information is correct, and then select **Save** [F1].

7 If you entered duplicate numbers, the Parameter Error(s) dialog displays. Select **Cancel** and make corrections.

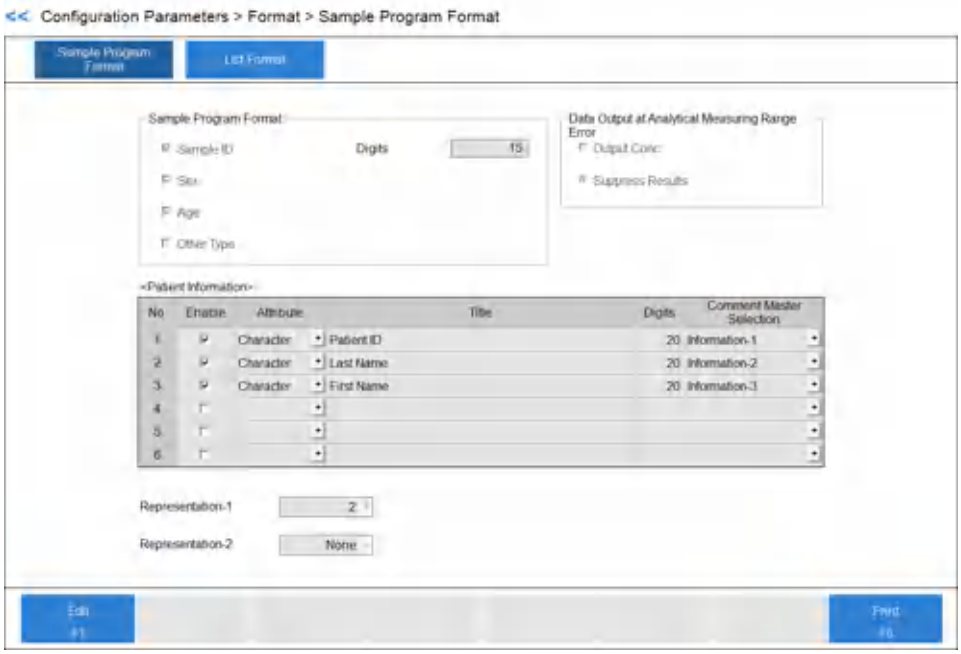
Sample Program Format Screen

Program the test order format, including sample ID and demographic information.

Information programmed in the Sample Program Format screen is part of the data communication protocol, and impacts LIS communication.

1 Select **CONFIG.** > **Sample Program Format**.

Figure 2.67 Sample Program Format Screen



2 Program the sample program format for each item in the table.

Table 2.43 Sample Program Format Screen Description

Item	Contents	Input Notes
Sample ID	Selected or Cleared	Select to enable Sample ID in the Test Order tab (**TEST** > **Rack (Patient)** > **Test Order**) or **STAT** > **STAT (Patient)** > **Test Order**).

Table 2.43 Sample Program Format Screen Description (Continued)

Item	Contents	Input Notes
Digits	4 to 26	Affects how many digits you can enter for the Sample ID in the Test Order tab (**TEST** > **Rack (Patient)** > **Test Order**) or **STAT** > **STAT (Patient)** > **Test Order**). Affects the sample ID field length for the Laboratory Information System online records. Program the number of sample ID digits and bar code parameters in the Analysis Mode screen (**CONFIG.** > **Analysis Mode**). Program the number of digits to be greater than or equal to the digits in the Analysis Mode screen.
Sex	Selected or Cleared	Select **Sex** to enable sex as a demographic in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics** or **STAT** > **STAT (Patient)** > **Demographics**), or receive the information from the LIS. Affects the Laboratory Information System online records.
Age	Selected or Cleared	Select **Age** to enable age as a demographic in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics** or **STAT** > **STAT (Patient)** > **Demographics**), or receive the information from the LIS. Affects the Laboratory Information System online records.
Other Type	Selected or Cleared	Select **Other Type** to enable Other Type as a demographic in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics** or **STAT** > **STAT (Patient)** > **Demographics**), or receive the information from the LIS. Affects the Laboratory Information System online records. For more information, refer to Other Type.

Table 2.43 Sample Program Format Screen Description (Continued)

Item	Contents	Input Notes
Data Output at Analytical Measuring Range Error	Output Conc. or Suppress Result	If you require the concentration value to be output when the result is out of analytical measuring range, select **Output Conc.** If you do not want the concentration value to be output when the result is out of analytical measuring range, select **Suppress Result**. **Note** If you select **No** for **Analytical Measuring Range Error Rerun** in the Rerun Test Parameters screen (**CONFIG.** > **Rerun Test Parameters**), the system outputs the concentration value, even if you select **Suppress Result**.
Patient Information		You can program a maximum of 6 patient demographics for entry in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics** or **STAT** > **STAT (Patient)** > **Demographics**). Affects Laboratory Information System online records.
Enable	Selected or Cleared	Select to enable programming for patient demographics numbers 1 to 6.
Attribute	Character or Numeric	Program if you require letters or numbers for entry in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics** or **STAT** > **STAT (Patient)** > **Demographics**) for patient information. Select **Character** to enter letters. Select **Numeric** to enter numbers for calculated tests and checked tests.
Title	A title name	Enter a maximum of 20 characters that display as the title for the patient information in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics** or **STAT** > **STAT (Patient)** > **Demographics**).
Digits	1 to 20	Affects how many digits can be displayed in **Patient Information** in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics** or **STAT** > **STAT (Patient)** > **Demographics**).

Table 2.43 Sample Program Format Screen Description (Continued)

Item	Contents	Input Notes
Comment Master Selection	Information-1 to Information-6	Program the attribute in the Comment Master screen (**CONFIG.** > **Comment Master**) with **Information-1** to **Information-6**. You can then select the master comment in the Demographics tab (**TEST** > **Rack (Patient)** > **Demographics** or **STAT** > **STAT (Patient)** > **Demographics**).
Representation-1 and Representation-2	Patient Information No. 1 to Patient Information No. 6	Select from **Patient Information No. 1** to **Patient Information No. 6** for the text in **Title** to display in the following screens or tabs: — As a column heading in the Sample Status screen (**RESULT** > **Sample Status**) — As a column heading in the Sample Manager: Main tab (**RESULT** > **Sample Manager** > **Main**) — As a column heading in the Sample Manager: By Patient Test tab (**RESULT** > **Sample Manager** > **By Patient Test**) — As a field heading in the Sample Manager: By Patient Sample tab (**RESULT** > **Sample Manager** > **By Patient Sample**) — As information in the **Cup Information** column in the STAT Status screen (**STAT** > **STAT Status**)

List Format Screen

You must program the list format to print the test summary from the **Test Order** tab, the result from **Sample Manager** > **Main** tab, and the realtime printing. The following five list types are available:

1. Table Type
2. Enumeration Type
3. Data List
4. Results (Fix) Type
5. Result (Seq.) Type

Table 2.44 List Types shows the list types available in each menu.

Table 2.45 Output Settings for Each List Type shows the possible output contents for each list type and the layout available for each list type.

List Types Available in Specific Menus

Table 2.44 List Types

Menu	Table Type	Enumeration Type	Data List	Result (Fix) Type	Result (Seq.) Type
Test Order > Print [F8]	o				
Sample Manager > Main > Print [F8] > Patient	o	o		o	o
Sample Manager > Main > Print [F8] > RB/CAL/QC			o		
List Format > Realtime List [F5]Patient		o		o	o
List Format > Realtime List [F5] > Calibration, RB, QC			o		

Format Parameters for Each List Type

Table 2.45 Output Settings for Each List Type includes possible output settings for each list type.

- : Required output item

o: Optional item

x: Item is not available

Table 2.45 Output Settings for Each List Type

	Title	List Type									
		Table Type		Enumeration Type		Data List		Result (Fix) Type		Result (Seq.) Type	
		Title	Data	Title	Data	Title	Data	Title	Data	Title	Data
Basic Condition	List Name	Within 20 single-byte characters									
	Data Format	6/9		6/9		6/9		6/9		6/9	
	Data Justify	Right/ Left		Right/ Left		Right/ Left		Right/ Left		Right/ Left	
	Patient	o		o		x		x		x	
	Calibration	x		x		o		x		x	
	RB	x		x		o		x		x	
	QC	x		x		o		x		x	
	Print Direction	Portrait/Landscape									
	Paper Size	A4/Letter/Legal/Tabloid									
	Sheet Number[1, 4]	x		x		x		1 to 4		1 to 4	
	Character in sheet[2, 4]	x		x		o		o		o	
	Form Method of Test Name[3, 4]	x		x		x		o		o	
	Number of Flags	x		x		1 to 4		1 to 4		1 to 4	
	Form Method of Data not analyzed	x		x		x		o		x	

Table 2.45 Output Settings for Each List Type (Continued)

	Title	List Type									
		Table Type		Enumeration Type		Data List		Result (Fix) Type		Result (Seq.) Type	
		Title	Data	Title	Data	Title	Data	Title	Data	Title	Data
	Change Page	x		x		x		o		o	
	Line	x		x		o		o		o	
	Fixed Comment	x		x		o		o		o	
Page Header	Header Width[4]	1 to 10 lines									
	Device No.	•	•	•	•	•	•	o	o	o	o
	List Name	o	o	o	o	o	o	o	o	o	o
	Page	o	o	o	o	o	o	o	o	o	o
	Index	o	o	o	o	o	o	o	o	o	o
	Group	o	o	o	o	o	o	o	o	o	o
	Print time	o	o	o	o	o	o	o	o	o	o
	Operator	o	o	o	o	o	o	o	o	o	o
	Reporter	o	o	o	o	o	o	o	o	o	o
Sample Information	Sample Width[4]	1 to 10 lines									
	Sample No.	o	o	o	o	o	o	o	o	o	o
	Rack ID - Cup Pos.	o	o	o	o	o	o	o	o	o	o
	Sample ID	o	o	o	o	o	o	o	o	o	o
	Sex	o	o	o	o	x	x	o	o	o	o
	Age	o	o	o	o	x	x	o	o	o	o
	Month	o	o	o	o	x	x	o	o	o	o
	Other Type	o	o	o	o	x	x	o	o	o	o
	Type	o	o	o	o	o	o	o	o	o	o

Table 2.45 Output Settings for Each List Type (Continued)

	Title	List Type									
		Table Type		Enumeration Type		Data List		Result (Fix) Type		Result (Seq.) Type	
		Title	Data	Title	Data	Title	Data	Title	Data	Title	Data
	Sample Vol.	o	o	o	o	o	o	o	o	o	o
	Sample Dilution Rate	o	o	o	o	x	x	o	o	o	o
	Patient Info. 1 to 6	o	o	o	o	x	x	o	o	o	o
	Patient Comment	x	x	x	x	x	x	o	o	o	o
	Sample Name	x	x	x	x	o	o	x	x	x	x
	Kind No.-Seq. No.	x	x	x	x	o	o	x	x	x	x
	Lot No.	x	x	x	x	o	o	x	x	x	x
	Run Date/Time	o	o	o	o	o	o	o	o	o	o
Test Information		1 to 10 lines									
	Test Name	x	•	x	o	x	•	x	o	x	o
	Test Dilution	x	o	x	o	x	x	x	o	x	o
	Pre-Dilution Rate	x	o	x	o	x	x	x	o	x	o
	Result	x	o	x	•	x	•	x	•	x	•
	Flags	x	o	x	o	x	o	x	o	x	o
	R. Bottle Info.	x	o	x	o	x	o	x	o	x	o
	ISE Info.	x	o	x	o	x	o	x	o	x	o
	Unit	x	x	x	x	x	x	x	o	x	o
	Reference Interval	x	x	x	x	x	o	x	o	x	o
	Output	o	o	o	o	x	x	x	x	x	x
Tail Information	Total Tests	o		o		x		x		x	
	Total Samples	o		o		x		x		x	

Table 2.45 Output Settings for Each List Type (Continued)

	Title	List Type									
		Table Type		Enumeration Type		Data List		Result (Fix) Type		Result (Seq.) Type	
		Title	Data	Title	Data	Title	Data	Title	Data	Title	Data
	Reagent Consumption	o		o		x		x		x	
	Tail name	o		o		x		x		x	

1. Set the number of samples to print on one form sheet.
2. The maximum number of characters per line differs according to the print direction, the paper size, and the sheet number.
   - — Portrait, A4, 1 sheet: 136 characters per line
   - — Landscape, A4, 1 sheet: 168 characters per line
   - — Portrait, A3, 1 sheet: 192 characters per line
   - — Landscape, A3, 1 sheet: 240 characters per line
   - — Portrait, Letter, 1 sheet: 136 characters per line
   - — Landscape, Letter, 1 sheet: 156 characters per line
   - — Portrait, Tabloid, 1 sheet: 180 characters per line
   - — Landscape, Tabloid, 1 sheet: 240 characters per line
   - — Portrait, Legal, 1 sheet: 136 characters per line
   - — Landscape, Legal, 1 sheet: 192 characters per line
   - — For two sheets or more, the number of lines in this list is the number of lines divided by the sheet number.
3. Program whether to use the abbreviated name or long name as the test name.
4. The system cancels the layout setting when the print direction, the paper size, sheet number, character in sheet , header width, or sample width changes. Program the layout again.

Layout Setting Parameters

Table 2.46 Layout Setting Parameters

	Menu	Table Type	Enumeration Type	Data List	Result (Fix) Type	Result (Seq.) Type
Layout	Page Header	o	o	o	o	o
	Sample Information	o	o	o	o	o
	Test Information	x	x	x	o	o

For the Result (Fix) type, the system formats the test information print position to a specific column and line for each test.

For the Result (Seq.) type, the start position for printing test information is set. The specific tests ordered on a sample start printing in consecutive lines at the formatted start print position.

For types other than Result (Fix) and Result (Seq.), you cannot set the test information print position.

Copy Format Parameters

The following eight templates are available from **Manufacturer made**:

1. Patient Data List (Result (Seq.) Type)
2. Patient Data List 2 (Result (Seq.) Type)
3. Patient Report (Result (Seq.) Type)
4. Patient Report 2 (Result (Seq.) Type)
5. Calibration Report (Data List)
6. QC Report (Data List)
7. RB/CAL/QC Data List (Data List)
8. Test Summary (Table Type)
9. (Empty)
10. (Empty)
11. (Empty)
12. (Empty)
13. (Empty)
14. (Empty)
15. (Empty)

You can use these templates by copying them to **User made**, or you can copy the format parameters from one of list formats in **User made**.

1 Select **CONFIG.** > **List Format** > **Basic Condition**.

2 Select **Edit** [F1].

3 Select an available list number (location to copy another list) in **List Name**.

4 Select **Copy** [F7]
The Copy dialog opens.

5 Select **Manufacturer made** or **User made**.

Note

If you want to clear the settings of the list number, in **Copy from**, select the empty list number (9 through 15) from **Manufacturer made** and copy it into the list number that you want to delete. Rename the list with a blank space in **List Name**.

6 Select the list to copy in **Copy from**.

7 Confirm the list number in **Copy to** is the list number you selected in step 3. Select another number if necessary.

8 Select **OK**.
The system copies the list parameters.

9 Enter a list name for the copied list in **List Name**.

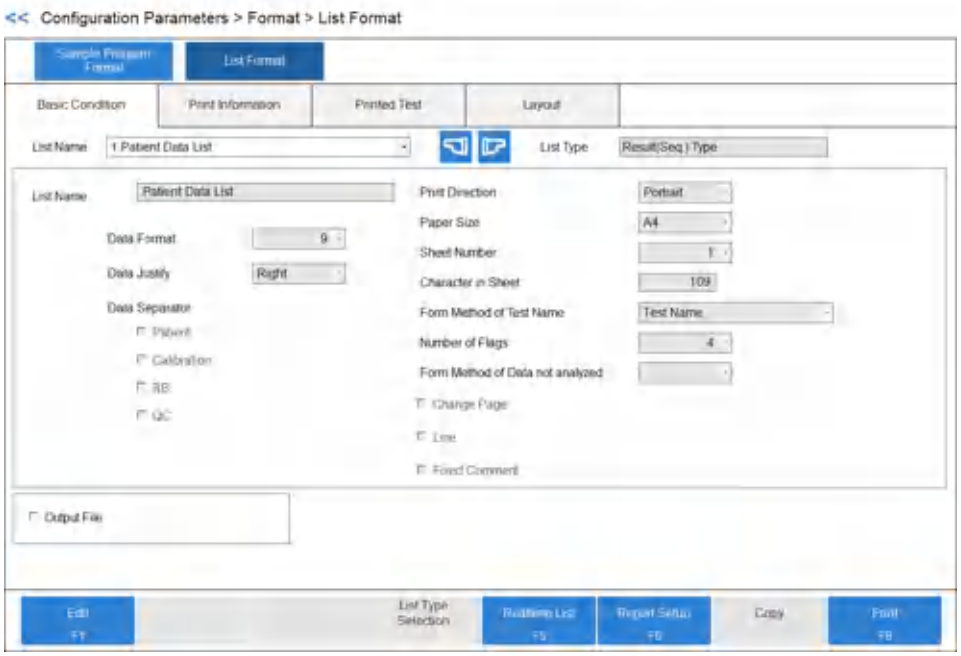
10 Select **Save** [F1].

Program List Formats

Program the format parameters for reports and lists. Five templates that are copied from **Manufacturer made** appear in No. 1 to No. 5 in **List Name** by default.

1 Select **CONFIG.** > **List Format** > **Basic Condition**.

Figure 2.68 List Format: Basic Condition Tab



2 Select **Edit** [F1].

3 Select the list number to be formatted in **List Name**.

4 In **List Name**, enter a list name with a maximum of 20 characters.

5 Select **List Type Selection** [F4] to change the list type. The List Type Selection dialog opens.

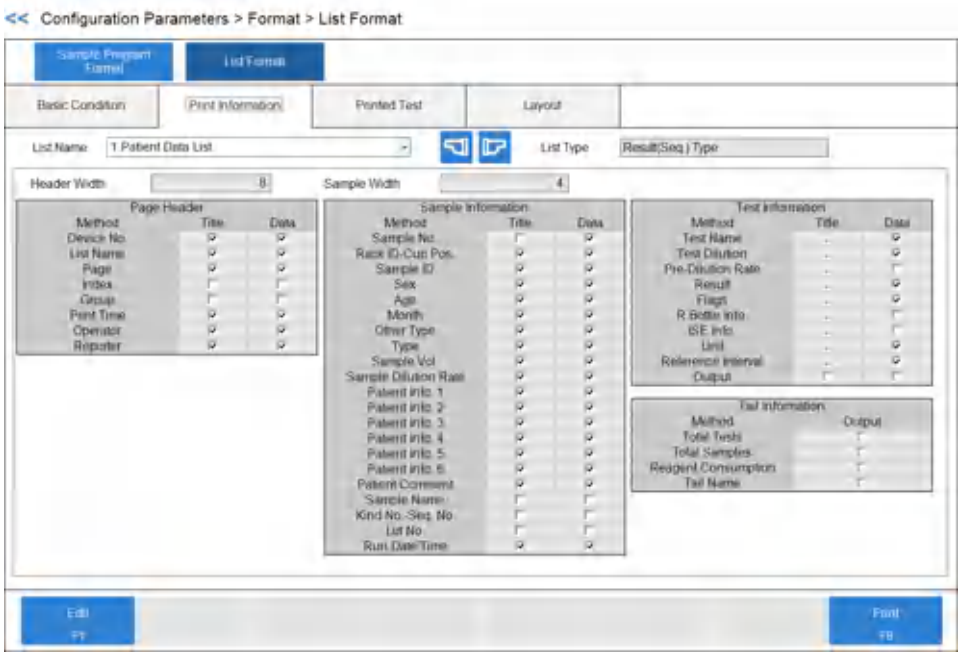
6 Select the list type in **List Type**.

7 Select **OK**.

8 Select or enter settings for the list format.

9 Select **Print Information**.

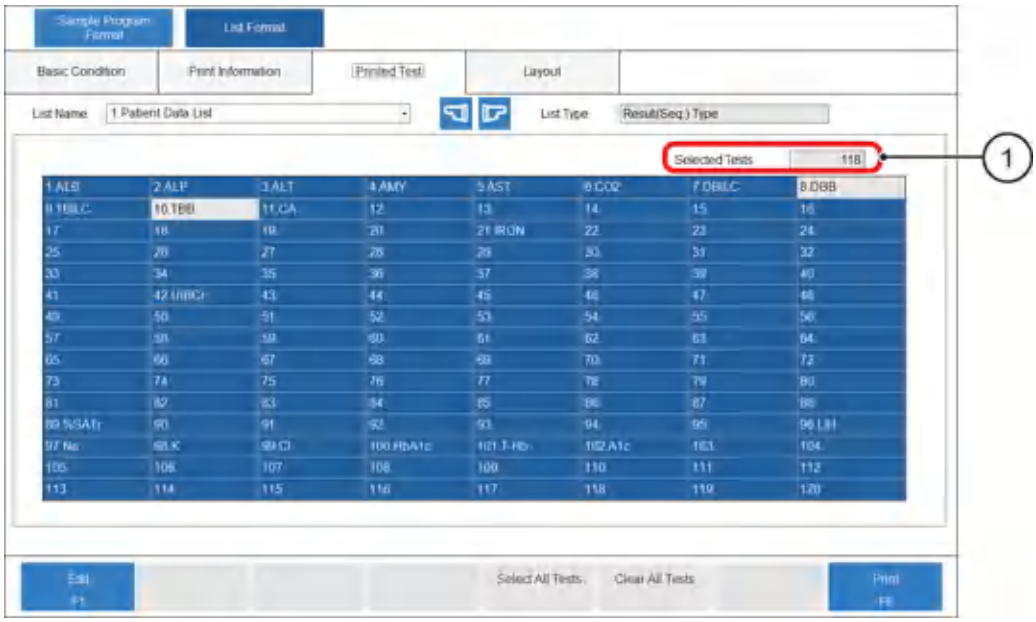
Figure 2.69 List Format: Print Information Tab



10 Select the information to print on the list.

11 Select **Printed Test**.

Figure 2.70 List Format: Printed Test Tab



1. Selected Tests

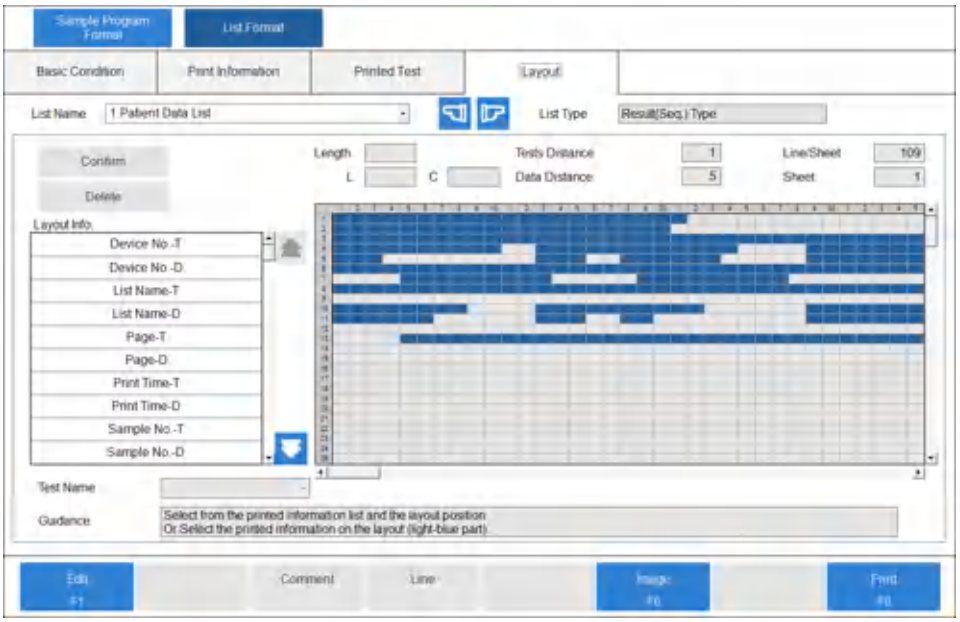
12 Select the tests to print.

The selected tests change to blue. The number of selected tests displays in **Selected Tests**.

13 Select **Select All Tests** [F5] and **Clear All Tests** [F6], as required.

14 Select **Layout**.

Figure 2.71 List Format: Layout Tab



15 Select the item to print from **Layout Info.**

You can select an item only if you have programmed it to print in the Print Information tab. This requirement includes the options for page headers, sample information, test information, comments, and line options.

16 Select the column and line on the grid to start printing the selected item.

17 Select **Confirm**.
The system displays the allocated boxes in blue.

18 Repeat steps 15 and 16 for all layout information.

19 Confirm the information, and then select **Save** [F1].

Save Data to a File

The system saves data to a DxC 700 AU_List_Image.txt file, and does not print realtime when you select **Output File**.

1 Select **CONFIG.** > **List Format** > **Basic Condition**.

2 Select **Output File**.

Add or Change a Comment

Select **Fixed Comment** in the Basic Condition tab (**CONFIG.** > **List Format** > **Basic Condition**) before accessing the Comment dialog (**CONFIG.** > **List Format** > **Layout** > **Comment** [F3]).

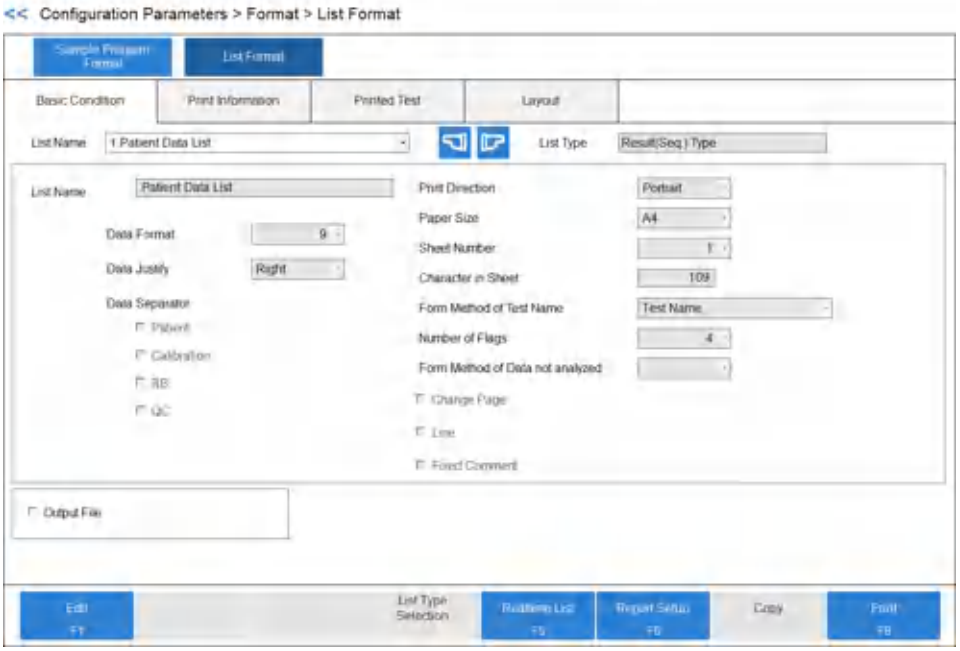
1. Select **CONFIG.** > **List Format** > **Layout**.
2. Select **Edit** [F1].
3. Select **Comment** [F3].
4. Enter a comment (maximum of 20 characters) in **Comment**.
5. Select **Horizontal** or **Vertical** in **Direction**.
6. Select **OK**.
7. Select the comment in **Layout Info.** The squares available to format the selected item display in white.
8. Select the position on the grid to start printing the selected item. Select **Confirm**. The system displays the allocated boxes in blue.
9. Confirm the information, and then select **Save** [F1].

Program Realtime Print Options

You must select a list format for patient samples, reagent blank, calibration, and QC to enable realtime printing.

1. Select **CONFIG.** > **List Format** > **Basic Condition**.

Figure 2.72 List Format: Basic Condition Tab



2 Select **Edit** [F1].

3 Select **Realtime List** [F5].
The Realtime List dialog opens.

Figure 2.73 Realtime List Dialog

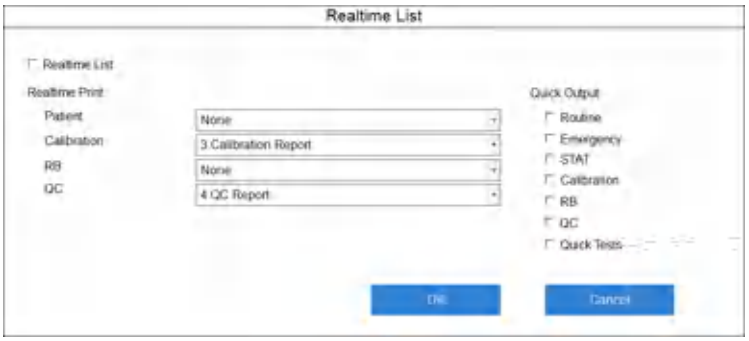


Table 2.47 Realtime List Dialog Description

Option	Description
Realtime List	Select to enable realtime printing.
Realtime Print	Select the list format for **Patient**, **Calibration**, **RB**, and **QC**.
Quick Output	When selected, one sample prints when it is complete per page.

Table 2.47 Realtime List Dialog Description (Continued)

Option	Description
Quick Tests	When selected, the system prints quick test results from samples processed on the STAT table before the normal print time for all tests on a sample. Quick test results are those test results with R1 only (read points before P10) and ISE tests.

4 Select **Realtime List**.

5 Select a list format for **Patient**, **Calibration**, **RB**, and **QC**.

6 If you want a printout for each sample of each applicable sample type, select sample types in **Quick Output**.

7 Select **OK**.
The Realtime List dialog is closed.

8 Select **Save** [F1].

Lipemia, Icterus, and Hemolysis (LIH)

LIH Reagent OSR62166 is a photometric test for the semi-quantitative assessment of lipemia/turbidity , icterus, and hemolysis (LIH) in human serum and plasma on the analyzer.

Several diseases and pre-analytical conditions can cause increased concentrations of chromogens like bilirubin, hemoglobin, and lipids/turbidity in body fluids. Chromogens can interfere with photometric tests.

The system dilutes patient samples with the LIH reagent and measures the absorbance at six wavelengths. If one or more chromogens in a potentially interfering concentration is present in a sample, the system generates and reports applicable flags along with the results of the sample. These flags characterize the type of chromatic substance (LIP: lipemia/turbidity, ICT: bilirubin, HEM: hemoglobin) and the approximate concentration of the interferents.

The following table shows the approximate concentration of chromatic substance.

Warning

The concentrations listed in the table are for reference only. Depending on the matrix effect with an individual serum sample, some results might not meet the listed concentrations.

Table 2.48 Approximate Concentration of Chromatic Substance

Flag	LIP (mg/dL Intralipid)	ICT (mg/dL Bilirubin)	HEM (mg/dL Hemoglobin)
N	<40	<2.5	<50
+	40 to 99	2.5 - 4.9	50 to 99
++	100 to 199	5.0 - 9.9	100 to 199
+++	200 to 299	10.0 - 19.9	200 to 299
++++	300 to 500	20 to 40	300 to 500
+++++	>500	>40	>500

If a sample has one or more flags from the table, refer to the information on interfering substance in the reagent setting sheet to confirm the accuracy of the test results of that sample.

You can program the DxC 700 AU for sample-specific LIH and test-specific LIH. Sample-specific LIH tests the level of LIH in the sample. Test-specific LIH determines the effect this level of LIH has on individual tests.

1. Sample-specific LIH: The system optically identifies the level of lipemia, icterus, or hemolysis by measuring the sample and LIH reagent in the cuvette. Based on the programmed absorbance limits for lipemia, icterus, and hemolysis in the LIH test, the system generates a flag for each interfering substance as N (normal), +, ++, +++, ++++, + ++++, ABN-L (abnormal low), or ABN-H (abnormal high).

   Each sample displays the results of the LIH Test. For example:

   — LIP +
   — ICT N
   — HEM ++
2. Test-specific LIH: The level of lipemia, icterus, or hemolysis in the sample determines the effect on individual tests. Each specific test generates l, i, or h flags if it exceeds the lipemia, icterus, or hemolysis limit. For example, the result of a DBIL affected by the level of hemolysis in the sample:

   — DBIL 0.3 h

LIH Reagent

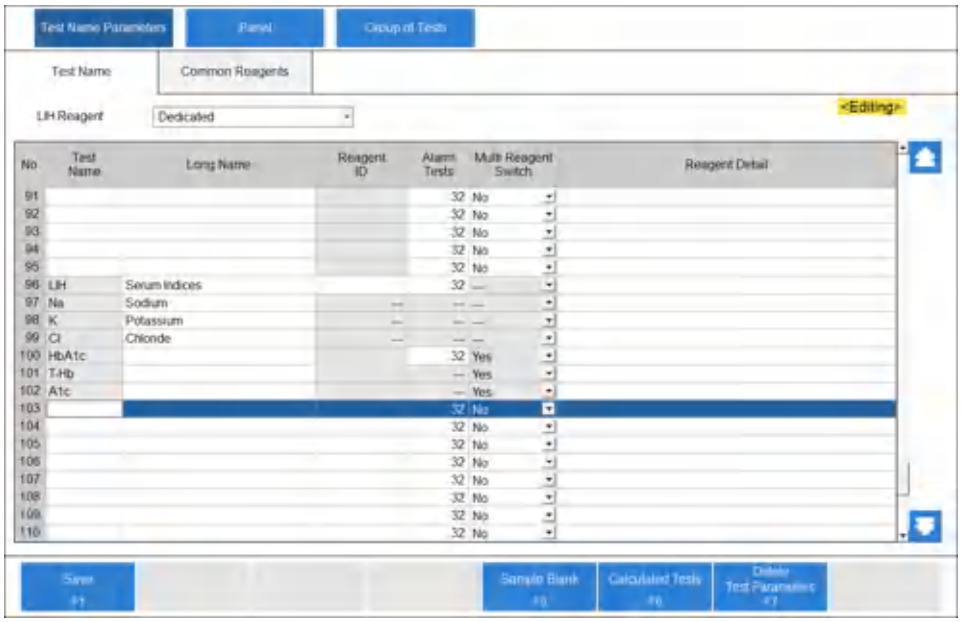
LIH Reagent (OSR62166) is the only reagent validated for test-specific LIH testing.

The LIH Reagent kit contains 16 bottles, and 2,400 tests can be processed per bottle. The LIH Reagent functions as R1. The Onboard Stability is 90 days.

Program LIH

1 Select **CONFIG.** > **Test Name Parameters** > **Test Name**.

Figure 2.74 Test Name Parameters: Test Name Tab



a. Select **Edit** [F1].

b. Select No. **96**.

c. In **Reagent ID**, enter 166.

d. In **Alarm Tests**, enter the number of tests that the system generates a `Reagent Insufficient` event. The default is 32.

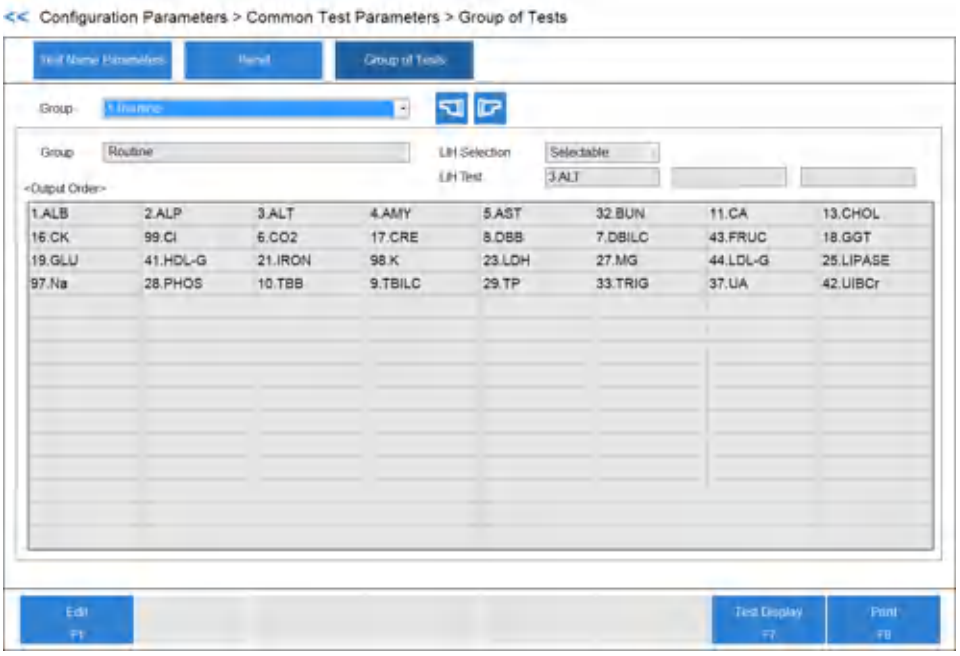
e. In **LIH Reagent**, select **Dedicated**.

f. Confirm the information, and then select **Save** [F1].

---

2 Select **CONFIG.** > **Group of Tests**.

Figure 2.75 Group of Tests Screen



a. Select Group 1, 2, or 3 in **Group** to add LIH.

b. Select **Edit** [F1].

c. Select **Select ALL** or **Selectable** in **LIH Selection**.

— Select **Select ALL** to order LIH automatically on every sample.
— Select **Selectable** to order LIH as needed on each sample.

d. Select **Test Setting** [F5].

e. Select **Test 96. LIH** and then select **Close**.

f. Confirm that LIH displays under **<Output Order>**.

g. Repeat for multiple Groups if needed.

h. Confirm the information, and then select **Save** [F1].

---

3 Select **CONFIG.** > **Test Volume and Methods** > **LIH**.

Note

Use the LIH reagent setting sheet to program 96. LIH Test. LIH test parameters entered in this LIH screen determine sample-specific LIH limits.

Parameter values in the LIH reagent setting sheet are valid only for LIH Reagent OSR62166.

Figure 2.76 Test Volume and Methods: LIH Tab

a. Select **Edit** [F1].

b. Enter the parameters from the LIH reagent setting sheet.

c. Confirm the information, and then select **Save** [F1].

---

4 Select **CONFIG.** > **Test Volume and Methods** > **General**.

Note

You can program **LIH Influence Check** only for the Serum sample type. If Beckman Coulter enables the System Maintenance menu for Other-1 and Other-2, all programmed LIH values affect Other-1 and Other-2 sample types.

Figure 2.77 Test Volume and Methods: General Tab

a. Select **Edit** [F1].

b. In **Test Name**, select a test to program test-specific LIH parameters.

For example, in Figure 2.74 Test Name Parameters: Test Name Tab, **GLU** is selected in **Test Name**.

c. Select **Yes** in **LIH Influence Check** to perform test-specific LIH analysis. Select **No** in **LIH Influence Check** if test-specific LIH analysis is not required for a test.

Refer to the reagent setting sheet for each specific test for the test-specific LIH parameters. For example, for Figure 2.74 Test Name Parameters: Test Name Tab, refer to the Glucose (GLU) reagent setting sheet.

d. Repeat for all tests in the Groups.

e. Confirm the information, and then select **Save** [F1].

5 Select **CONFIG.** > **List Format** > **Printed Test**.

a. Select **Edit** [F1].

b. Select LIH to add it to all required printouts and lists.

Select **List Name** to refer to a list of all the realtime printouts and lists available.

c. Confirm the information, and then select **Save** [F1].

Running the LIH Test

- The system requires one extra cycle time (4.5 seconds) per sample to run the LIH test.
- Place the bar coded LIH reagent bottle in the R1 refrigerator and follow procedures for checking reagents.
- You can program LIH for automatic orders on all samples or you can order it for individual samples as needed. If you program LIH for automatic orders on all samples, LIH is highlighted in blue in the Test Order tab (**TEST** > **Rack (Patient)** > **Test Order**).

Order LIH using normal procedures. You can order LIH by realtime query with the LIS, or manually.

- LIH results print automatically.
- LIH criteria only apply to Serum, Other-1, and Other-2 sample types. For Urine sample types, the LIH test is unavailable and is not operational.

CHAPTER 3

Sample Programming and Processing

Cautions with Cups or Tubes Specifications

Warning

Use only sample cups and tubes listed in the specifications and validated by Beckman Coulter. If other cups or tubes are used, analysis cannot be performed or errors can result.

Note

BD indicates a Becton Dickinson PN. You can use the BD tube or its equivalent.

Cup or Tube Available for Racks or STAT Table

Table 3.1 Cup or Tube Available for Racks or STAT Table

Cup or Tube	Size	PN	Dead Volume (µL)	Dead Volume (µL) for 3 and 5 Pre-Dilution Rate	Dead Volume (µL) when Connected to Laboratory Automation System
Hitachi cup	2.5 mL	MU853200	50	80	N/A for samples from automation line
					50 (or 80) for samples on the STAT table
Auto aliquot tube	13 mm	2910034	80	80	300
Serum Separator Tube	13 x 100 mm	BD 367986	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer
Serum Separator Tube	16 x 100 mm	BD 367988	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer
Lithium heparin with gel separator (light green top)	13 x 75 mm	BD 367960	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer

Table 3.1 Cup or Tube Available for Racks or STAT Table (Continued)

Cup or Tube	Size	PN	Dead Volume (µL)	Dead Volume (µL) for 3 and 5 Pre-Dilution Rate	Dead Volume (µL) when Connected to Laboratory Automation System
Lithium heparin with gel separator (light green top)	13 x 100 mm	BD 367962	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer
Lithium heparin (green top)	13 x 75 mm	BD 367884	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer
Lithium heparin (green top)	13 x 100 mm	BD 367886	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer	4 mm above the non-sample (cells or gel) layer
Primary tube (red top)	13 x 75 mm	BD 366668	140	140	300
Primary tube (red top)	13 x 100 mm	BD 367815	140	140	300

Cup Nested (Inserted) in Tube Available for Racks

Table 3.2 Cup Nested (Inserted) in Tube Available for Racks

Cup, Size	PN	Tube	PN	Dead Volume (µL)	Dead Volume (µL) for 3 and 5 Pre-Dilution Rate
DxC cup, 2.0 mL	652730	DxC transfer	979272	50	200
Access 2 cup, 2.0 mL	81902	DxC transfer	979272	50	200
Access 2 cup, 1.0 mL	81915	13 x 75 mm	BD 367960 BD 367884 BD 366668	140	140
Access 2 cup, 1.0 mL	81915	13 x 100 mm	BD 367962 BD 367886 BD 367815	140	140

Table 3.2 Cup Nested (Inserted) in Tube Available for Racks (Continued)

Cup, Size	PN	Tube	PN	Dead Volume (µL)	Dead Volume (µL) for 3 and 5 Pre-Dilution Rate
Hitachi cup • Sample Cup 2.5 mL	MU853200	SST 16x100 mm	BD 367988	50	80
EZ Nest cup	1270013000	13 x 75 mm	BD 367960 BD 367884 BD 366668	50	150
EZ Nest cup	1270013000	13 x 100 mm	BD 367962 BD 367886 BD 367815	50	150
EZ Nest cup	1270016000	16 x 75 mm	BD 364976	50	120
EZ Nest cup	1270016000	16 x 100 mm	BD 367988	50	120

Cup Nested (Inserted) in Tube Available for STAT Table

Table 3.3 Cup Nested (Inserted) in Tube Available for STAT Table

Cup, Size	PN	Tube	PN	Dead Volume (µL)	Dead Volume (µL) for 3 and 5 Pre-Dilution Rate
DxC cup, 2.0 mL	652730	DxC transfer	979272	50	200
Access 2 cup, 2.0 mL	81902	DxC transfer	979272	50	200
Access 2 cup, 1.0 mL	81915	13 x 75 mm	BD 367960 BD 367884 BD 366668	140	140
EZ Nest cup	1270013000	13 x 75 mm	BD 367960 BD 367884 BD 366668	50	150

Table 3.3 Cup Nested (Inserted) in Tube Available for STAT Table (Continued)

Cup, Size	PN	Tube	PN	Dead Volume (µL)	Dead Volume (µL) for 3 and 5 Pre-Dilution Rate
EZ Nest cup	1270016000	16 x 75 mm	BD 364976	50	120

Cup or Tube Restrictions for Racks

The analyzer has five sensors to detect the height of the cup or tube in a rack. The following restrictions apply when using more than one cup or tube simultaneously:

1. One type of cup or tube can be selected for each sensor.
2. More than one type of cup or tube can be selected for each sensor only if the cup or tube is the same Level: A, B, C, D, E, or F.

Warning

If more than one type of cup or tube is in use for a sensor, and the cup or tube is a different level (A, B, C, D, E, or F):

- **If the maximum probe stroke is programmed to the shortest cup or tube, it is possible that the system cannot aspirate the sample in the longest cup or tube even though there is sufficient volume of sample, and generates a `Sample Empty` event.**
- **If the maximum probe stroke is programmed to the longest cup or tube, the shortest cup or tube must contain sufficient sample to avoid a probe crash.**
- **If the DxC 700 AU connects to a Laboratory Automation System, the probe can have only one probe downward stroke programmed, and you can use only one type of sample tube or cup.**

Table 3.4 Cup or Tube Restrictions for Racks

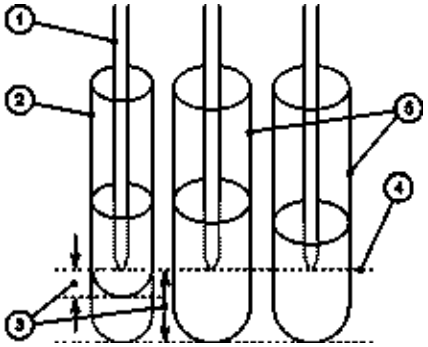
Sensor	Level	Cup or Tube		Tube
1	A	Hitachi cup	MU853200	
2	A	Lithium heparin with gel separator (light green top)	BD 367960	
	A	Lithium heparin (green top)	BD 367884	
	A	Primary tube (red top)	BD 366668	
	B	DxC cup	652730	DxC transfer tube (979272)
	B	Access 2 cup	81902	
	C	Access 2 cup	81915	13 x 75 mm tube
	D	EZ Nest cup	1270013000	
	E	EZ Nest cup	1270016000	16 x 75 mm tube
3	A	Hitachi cup	MU853200	16 x 75 mm tube
4	A	Serum Separator Tube	BD 367986	

Table 3.4 Cup or Tube Restrictions for Racks (Continued)

Sensor	Level	Cup or Tube		Tube
	A	Lithium heparin with gel separator (light green top)	BD 367962	
	A	Lithium heparin (green top)	BD 367886	
	B	Auto aliquot tube	2910034	
	C	Access 2 cup	81915	13 x 100 mm tube
	D	EZ Nest cup	1270013000	
	E	EZ Nest cup	1270016000	16 x 100 mm tube
5	A	Hitachi cup	MU853200	16 x 100 mm tube

The default probe setting in the software for each cup and tube is Level A. If using a cup or tube other than Level A, contact Beckman Coulter. Beckman Coulter must make probe setting changes.

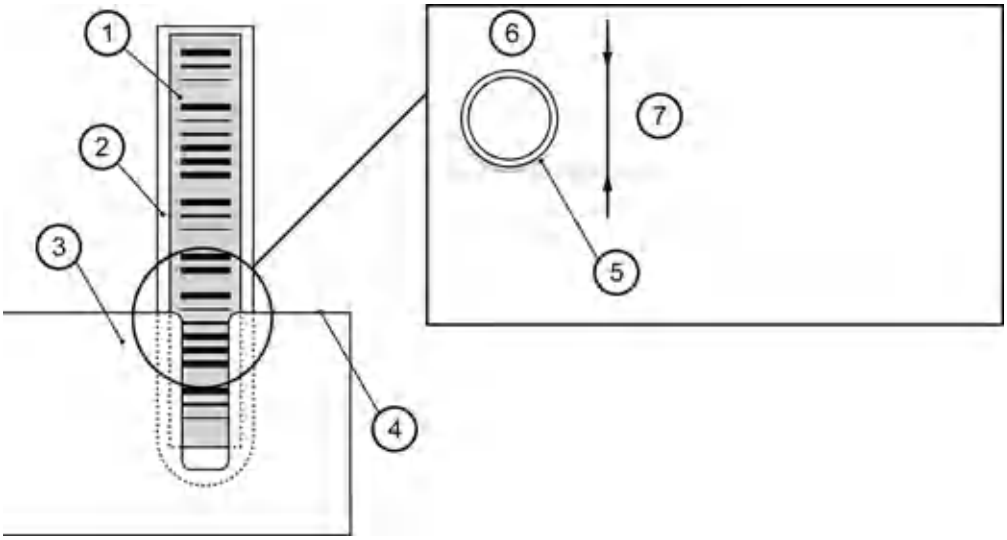
Figure 3.1 Sample Probe Stroke and Cup or Tube Height



1. Sample probe
2. Shortest cup or tube
3. Dead volume
4. Maximum probe downward stroke
5. Longest cup or tube

The maximum outer tube or cup diameter is 16 mm, including the thickness of a sample bar code label. If the tube or cup has a protrusion or lip at the top, the maximum outer diameter is 17.5 mm. If the diameter is greater than 17.5 mm, the tubes do not fit correctly when placed next to each other in the rack.

Figure 3.2 Maximum Outer Cup or Tube Diameter



1. Bar code label
2. Sample tube
3. Rack
4. Rack top
5. Bar code label
6. Top view
7. 16.0 mm or less (outside diameter, including the thickness of a bar code label)

Cup or Tube Restrictions for the STAT Table

Table 3.5 Cup or Tube Restrictions for STAT Table

Sensor	Level	Cup or Tube		Tube
1	A	Hitachi cup	MU853200	
2	A	Lithium heparin with gel separator (light green top)	BD 367960	
	A	Lithium heparin (green top)	BD 367884	
	A	Primary tube (red top)	BD 366668	
	B	DxC cup	652730	DxC transfer tube (979272)
	B	Access 2 cup	81902	
	C	Access 2 cup	81915	13 x 75 mm tube
	D	EZ Nest cup	1270013000	
	E	EZ Nest cup	1270016000	16 x 75 mm tube
3	A	Hitachi cup	MU853200	16 x 75 mm tube
4	A	Serum Separator Tube	BD 367986	
	A	Lithium heparin with gel separator (light green top)	BD 367962	
	A	Lithium heparin (green top)	BD 367886	

Table 3.5 Cup or Tube Restrictions for STAT Table (Continued)

Sensor	Level	Cup or Tube		Tube
	B	Auto aliquot tube	2910034	

Apply Bar Code Labels to Sample Tubes

Warning

The bar code reader might not identify long or short bar code labels.

Bar code labels must not protrude from the top of a sample cup or tube. Position the label perpendicularly. The inclination angle must be 5° or less.

For more information on bar code label specifications, refer to Sample Bar Code Label Specifications.

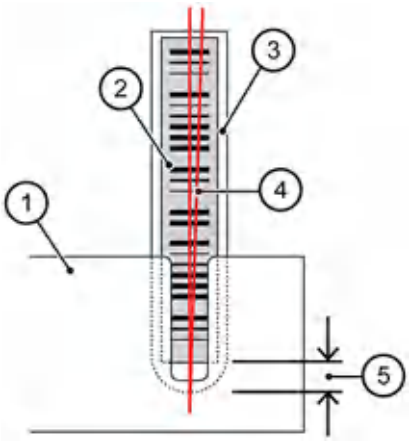
Note

Refer to the Laboratory Automation System manual for applying bar code labels to sample cups when the DxC 700 AU is connected to a Laboratory Automation System.

1 Affix the bar code labels to the outside of the sample tube so that the end of each label is a minimum of 7 mm from the bottom of the cup, and the angle is within a maximum of 5°.

2 Using your finger, rub the label gently to attach it firmly so that it does not peel off.

Figure 3.3 Sample ID Bar Code Label Application

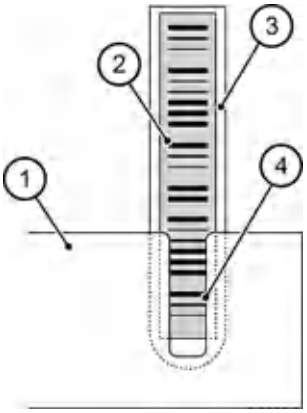


1. NE rack
2. Bar code label
3. Sample tube
4. The inclination angle must be 5° or less
5. 7 mm minimum

NE Racks

An NE rack has a slit that allows you to place the bar code label below the top surface of the rack. The NE rack allows for various tube diameters to be used with or without adapters. Use only NE racks on the DxC 700 AU.

Figure 3.4 NE Rack with Tube

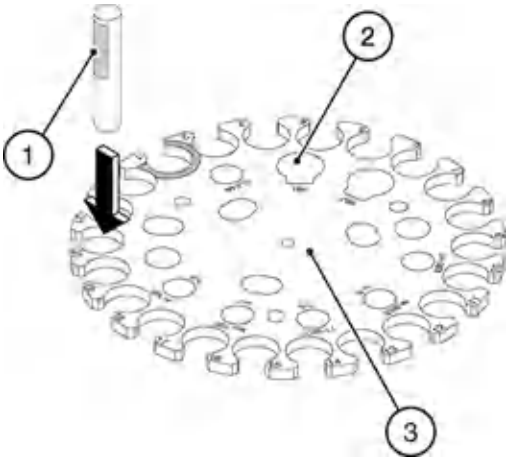


1. NE rack
2. Bar code label
3. Sample tube
4. Slit in NE rack

Bar Code Labels for STAT Table Analysis

The outer positions (1 to 22) are used for STAT analysis. Place the tube on the table with the bar code label facing out from the center of the table.

Figure 3.5 Placing Tubes with Bar Code Labels on the STAT Table



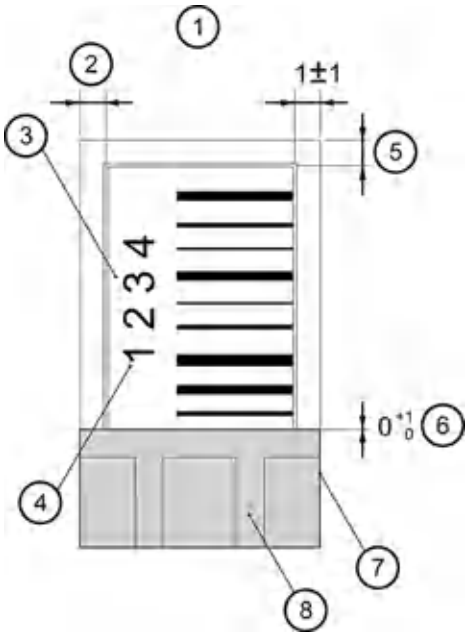
1. Place the tube in outer position 1-22 with the label facing out from the center of the table.
2. Inner positions are not available for bar code mode.
3. STAT table

Apply a Rack ID Bar Code Label on the Rack

Apply a bar code label to all racks except the blue rack (yellow, green, white, and red) before processing them.

Apply the rack ID label to the front of the rack, perpendicular to the protruding part of the rack. Refer to Figure 3.6 Rack ID Bar Code Label Application. The units are in mm.

Figure 3.6 Rack ID Bar Code Label Application



1. Rack front
2. Confirm that the label does not protrude from the rack
3. Rack ID label (Attach the label on the rack parallel with the side face.)
4. Orient the label so that the numbers are located to the left if viewed from the front
5. Confirm that the label does not protrude from the rack
6. Do not place the label on the protruding part of the rack
7. Rack side
8. Protruding part of the rack

Warning

The system might read bar code labels in bad condition incorrectly. If you observe any of the following conditions, replace bar code labels:

- **The bar code label is smudged, scratched, or damaged.**
- **The bar code label is stained or dirty.**
- **The bar code label is torn or peeling.**

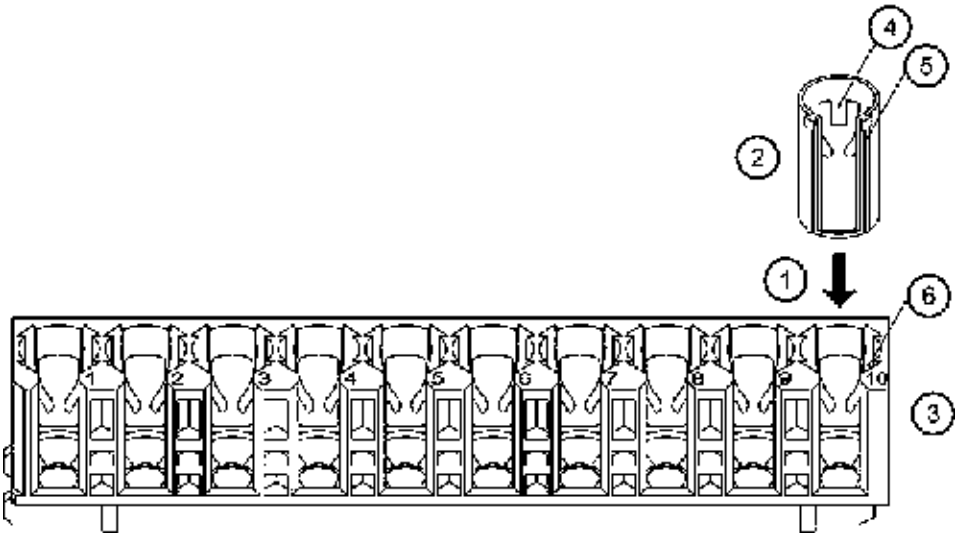
Use Adapters on Sample Racks

To hold smaller diameter tubes (approximately 11.5 mm to 13.5 mm) firmly in position in the racks, use adapters. Larger diameter tubes (approximately 13.6 mm to 16 mm) do not require adapters.

To decide whether to use an adapter, place the tube into a rack with and without an adapter, and observe which option holds the tube to the center of the rack position.

Insert an Adapter into a Rack

Figure 3.7 Insert an Adapter into a Rack



1. Push in
2. Adapter
3. Rack
4. Adapter lock
5. Guide
6. Guide groove

1 Align the adapter opening and the rack opening.

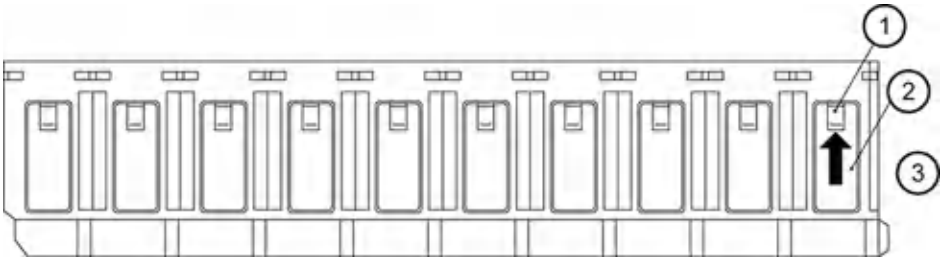
2 Insert the adapter guide into the guide groove of the rack.

3 Push the adapter into the rack until you hear a click.

4 Be sure the adapter has engaged the rack.

Remove an Adapter from a Rack

Figure 3.8 Remove an Adapter from a Rack



1. Adapter lock
2. Rack window
3. Push up lightly with a finger

1 To disengage the lock, push the adapter lock lightly with a finger from the outside of the rack window.

2 When the upper edge of the adapter comes out from the rack, pull the remainder of the adapter out.

CHAPTER 4

System Monitoring and Results

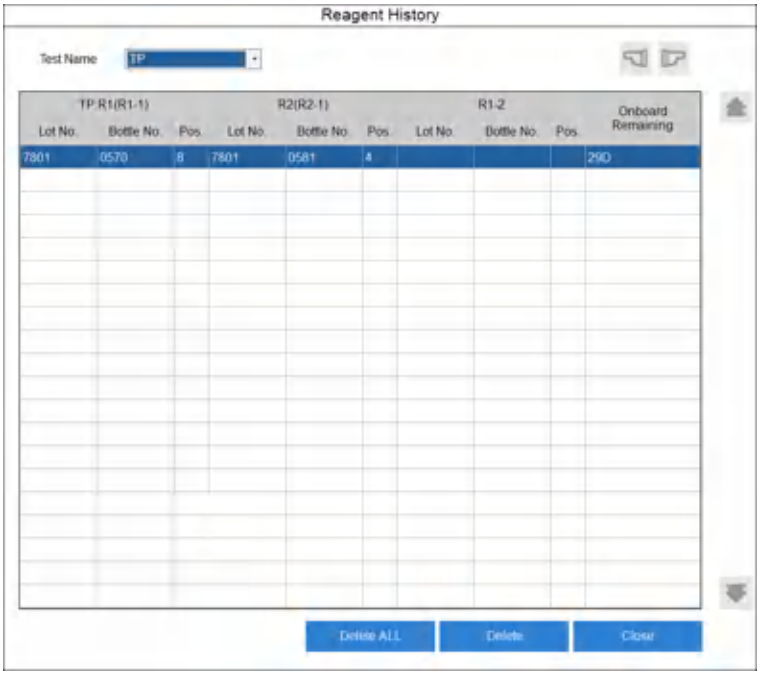
Reagent Management

Review and Delete Reagent History

Display the lot number, bottle number, position, and onboard time remaining for the history of R1 and R2 reagents. Conflicting information programmed for Advanced Calibration in the Calibration Setup: General tab (**CONFIG.** > **Calibration Setup** > **General**) and for automatic calibration in the AUTO ACAL/QC Setup: ACAL tab (**CONFIG.** > **Auto ACAL/QC Setup** > **ACAL**) for the same test, might cause you to have to delete the reagent history for that bottle of reagent.

1 Select **REAGENT** > **Reagent Management** > **Details**, and then select **Reagent History** [F6].

Figure 4.1 Reagent History Dialog



2 In **Test Name**, select the test to display.

Note

For sample blank tests (total and direct bilirubin), use the arrow buttons to change the display between the color and blank reagent. For HbA1c, use the arrow buttons to change the display between A1c and T-Hb.

The system displays a list of the previous lot numbers and bottle numbers. The most current bottle data displays on the first line and includes the R1/R2 reagent position and onboard remaining.

3 Select **Delete All** to delete all information for the test, and **Delete** to delete the line of information at the cursor.
The Reagent History dialog opens.

4 Select **OK**.
The selected information is deleted.

5 To close the dialog, select **Close**.

Recovering from a Bottle Position Error

Note

After a bottle position error occurs, confirm the reagent bottle status from the previous reagent check. You can access the Previous Setting dialog only in *PAUSE* mode.

The system displays `Bottle Position Error` in the Comment column in **Reagent Management** > **Details** and continues analysis. To move the system to *PAUSE* mode, select **Pause**.

1 Select **REAGENT** > **Reagent Management** > **Details**, and then select **Previous Setting**.

Figure 4.2 Previous Setting Dialog

2 Select **R1** or **R2**.
The system displays reagent information.

3 Confirm the information, and select **Close**.

Initialize Onboard Stability

This function initializes the reagent onboard stability. You can initialize onboard stability only for reagents in fixed positions. You must enter a lot number and bottle number before the function becomes operational.

When replacing reagents in fixed positions to update the onboard stability, select **Initialize Onboard Stability** in the Details tab (**REAGENT** > **Reagent Management** > **Details**).

Reagent Inventory

The system can calculate the reagent volume required for each test for each day of the week from data obtained from the analyzer (in the Auto tab), or you can enter a value for each test for each day of the week (in the Manual tab).

The Reagent Inventory screen (**REAGENT**> **Reagent Inventory**) displays the number of tests used each day of the week for each sample type within the period set by the index range. Use the Reagent Inventory screen to determine the reagent volume required to be onboard for each day of the week.

The Reagent Management > Main tab (**REAGENT** > **Reagent Management** > **Main**) displays tests below the required volume for the day of the week in green. The indicator bar displays the volume using the percentage specified in **Margin**.

Auto Calculation of Reagent Inventory

1 Select **REAGENT** > **Reagent Inventory** > **Auto**.

Figure 4.3 Reagent Inventory: Auto Tab

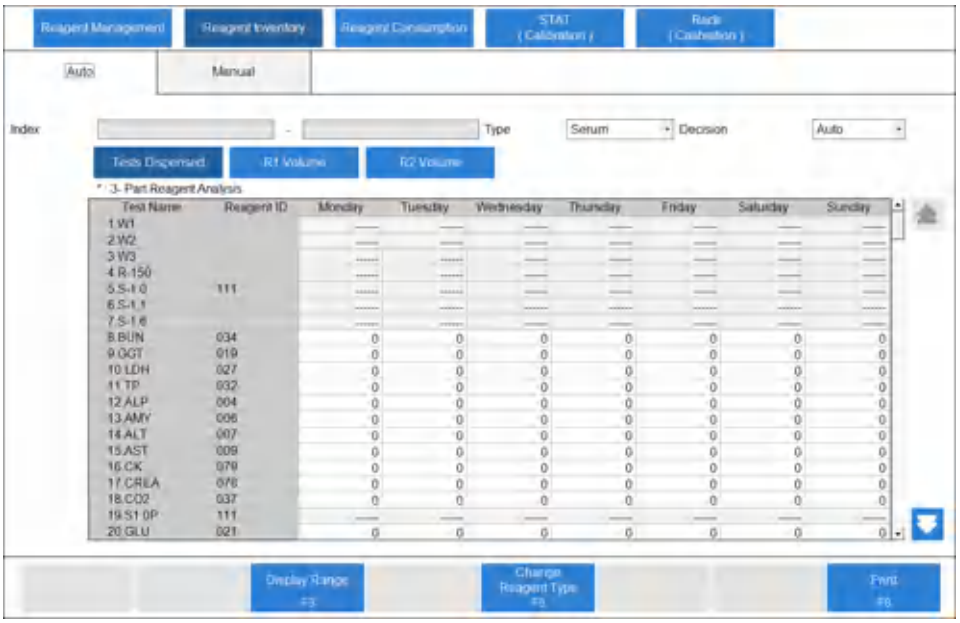


Table 4.1 Auto Tab Description

Option	Description
Display Range [F3]	Select the start index and end index to calculate the reagent usage.
Change Reagent Type [F5]	Changes the display from information for the R1-1 to information for the R1-2 reagent. Only available when **R1 Volume** is selected.

2 Select the sample type in **Type**.

3 Select **Display Range** [F3].
The Display Range dialog opens.

Figure 4.4 Display Range Dialog

4 Select the start index and the end index.
You can select the indexes from the indexes one day before.

5 Select **OK**.
The system displays the number of tests selected within the index range in the list.

6 Select **R1 Volume** or **R2 Volume**. The reagent consumption is automatically calculated from a result and then displayed in the list in mL.
The system calculates the reagent consumption with the following formula:

Actual result x (the amount of reagent dispensing + the amount of surplus dispensing)

7 Select **Auto** in **Decision**. The system uses the calculated reagent consumption as the required reagent volume in the Reagent Management screen (**REAGENT** > **Reagent Management**).

Manual Calculation of Reagent Inventory

1 Select **REAGENT** > **Reagent Inventory** > **Manual**.

2 Select **Edit** [F1].

3 Select the sample type in **Type**.

4 Enter the number of tests run for each test for each day of the week.

5 Confirm that the information is correct, and then select **Save** [F1].

6 Select **R1 Volume** or **R2 Volume**.

The system automatically calculates the reagent consumption input from entered test numbers and then displays it in the list in mL.

7 Select **Manual** in **Decision**.
The system uses the test count entered for reagent consumption as the required reagent volume in the Reagent Management screen (**REAGENT** > **Reagent Management**).

Reagent Consumption

The Reagent Consumption screen displays the amount of reagent used for each test programmed on the analyzer. Set a range of indexes to display the reagent consumption used for analysis for each test by sample type.

1 Select **REAGENT** > **Reagent Consumption**.

Figure 4.5 Reagent Consumption Screen

1. Tests dispensed
2. R1 volume
3. R2 volume
4. Reportable tests
5. Cumulative tests dispensed

The Reagent Consumption screen defaults to display the Shot Total tab. The shot total is the cumulative number of tests run on the analyzer since the installation of the analyzer.

2 Select the sample type in **Type**.

3 Select **Display Range** [F3].

4 Select the start date and end date in **Date**.

5 Select **OK**.

The system displays the number of cumulative tests.

Confirm Reagent Consumption by Samples Measured And Reagent Dispenses

1 After setting a range of dates to display the reagent consumption used for analysis for each test by sample type in the Reagent Consumption screen, select **Test Dispensed**. The system displays the Test Dispensed tab with the number of reagent dispenses, including for rerun tests, for each test and sample type.

   The number of reagent dispenses displays for routine, emergency, STAT, and rerun samples, and for reagent blank, calibration, and QC.

   The number of dispenses for ISE measurement displays as the number of ISE samples.

2 Select **R1 Volume** or **R2 Volume**.

   The volume (in mL) of reagent dispensed for each test and sample type displays.

   The system calculates the reagent consumption with the following formula:

   Actual analysis result × (the amount of reagent dispensing + the amount of surplus dispensing)

3 After setting a range of dates to display the reagent consumption used for analysis for each test by sample type in the Reagent Consumption screen, select **Reportable Tests**. The system displays the Reportable Tests tab with the number of analyzed tests, not including for rerun tests, for each test and sample type.

   The number of tests displays for routine, emergency, STAT, and rerun samples, and for reagent blank, calibration, and QC.

   The number of dispenses for ISE measurement displays as the number of ISE tests (Na, K, and Cl).

Print Reagent Consumption Data

1 After setting a range of indexes to display the reagent consumption used for analysis for each test by sample type in the Reagent Consumption screen, select **Print** [F8].

2 Select all sample types.

3 Select **Test Shots**.

4 Select **OK**.

   The system prints the reagent consumption data.

Save Reagent Consumption Data

1 After setting a range of indexes to display the reagent consumption used for analysis for each test by sample type in the Reagent Consumption screen, select **Copy to Disk** [F2].

2 Connect the external memory device or insert CD-R.

3 Select **External Memory Device** or **CD-R**.

4 Select **OK**. The system displays Copy to Disk dialog to ask to connect an external memory device or to insert a CD-R.

5 Select **OK**. The system displays Copy to Disk dialog to ask to remove the external memory device or CD-R.

6 Select **OK**.

7 Remove the external memory device or CD-R.

Display Reaction Monitor

The Reaction Monitor screen displays sample information, reagent information, reaction data, and analyzer components used for analysis of reagent blank, calibration, QC, and samples. Inspect data or troubleshoot in the Reaction Monitor screen.

- Store a maximum of 100,000 samples, or 10,000 samples per index on the hard drive.
- Display a maximum of 200,000 tests on the Reaction Monitor screen.

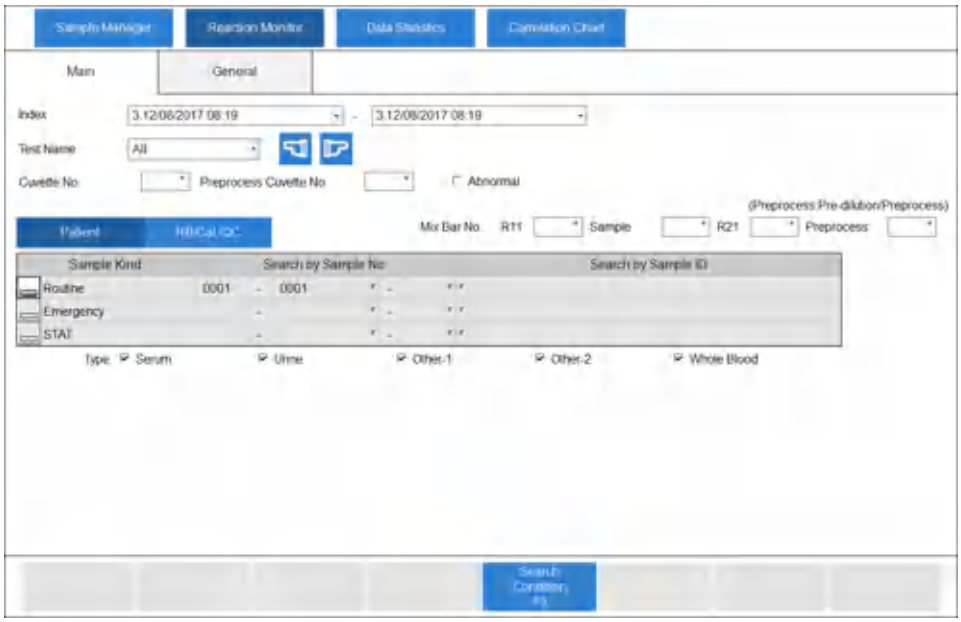
1 Select **Result** > **Reaction Monitor** [F6].

The system displays the Reaction Monitor: General tab with the results for the current index.

2 To search the results for a specific sample or in another index, select **Main**.

The system displays the Reaction Monitor: Main Tab (Patient).

Figure 4.6 Reaction Monitor: Main Tab (Patient)



3 Specify the search parameters for the data to display, according to the following table.

Table 4.2 Main Tab (Patient) Description

Item	Contents	Input Notes
Index	Indexes	You can select from all available indexes, from the newest index to the oldest.
Test Name	All, or the abbreviated name of the test	You cannot select calculated tests.
Cuvette No.	1 to 165, or *	Specify the cuvette number used for analysis. Enter an asterisk to view every cuvette.
Preprocess Cuvette No.	1 to 165, or *	Specify the cuvette number used for pre-processing. Enter an asterisk to view every cuvette.
Mix Bar No.	1 to 3, or *	Specify the mix bar used for analysis in **R1 (R11)**, **Sample**, **R2 (R21)**, and **Preprocess**. Enter an asterisk to view every mix bar.
Sample Kind	Routine, Emergency, or STAT If programmed to one sample type in the same rack, the system displays the sample kind and sample type in the field for rack analysis.	Select the sample kind to search. You cannot select sample kinds that have not undergone processing.

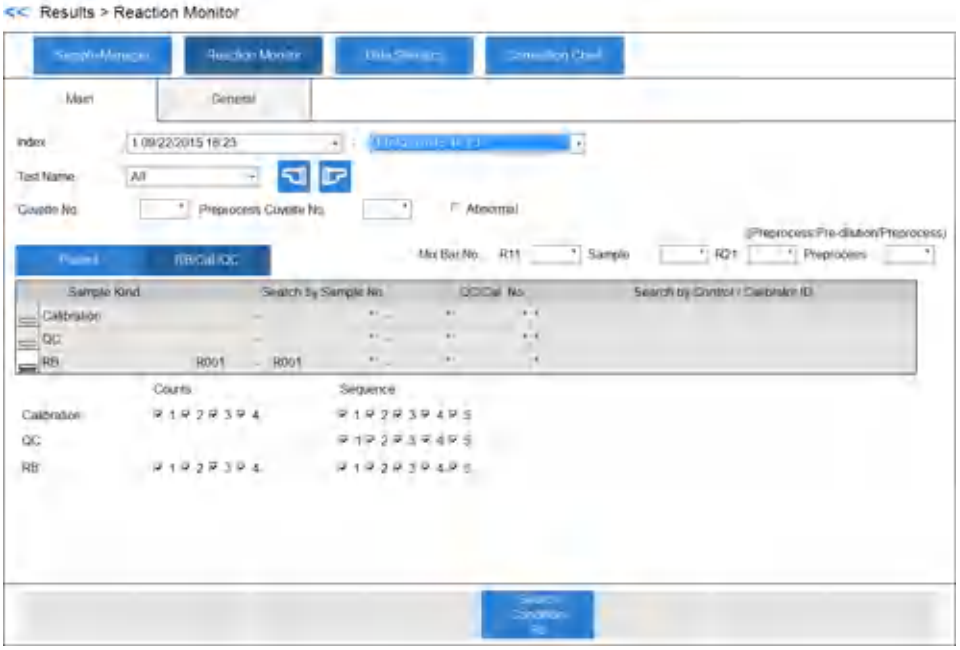
Table 4.2 Main Tab (Patient) Description (Continued)

Item	Contents	Input Notes
Sample Type	Serum, Urine, Other-1, Other-2, or Whole Blood	Select the sample type to search. **Note** You can select a sample type for any sample kind, except if the system is programmed to run one sample type in the same rack. With that programming, you can select a sample type for only the STAT sample kind.
Search by Sample No.	The starting and ending sample numbers, or * If no results for the sample kind exist, the system displays empty.	Leave the asterisk to search all of the numbers of samples that have undergone processing, or enter a specific sample number or range of sample numbers.
Search by Sample ID	A sample ID, or *	Leave the asterisk to search all sample IDs processed, or enter a specific sample ID.

4 Select **RB/Cal./QC**.

The system displays the Reaction Monitor: Main tab (RB/Cal./QC).

Figure 4.7 Reaction Monitor: Main Tab (RB/Cal./QC)



5 Specify the search parameters for the data to display, according to the following table.

Table 4.3 Main Tab (RB/Cal./QC) Description

Item	Contents	Input Notes
Sample Kind	Calibration, QC, or RB	Select the sample kind to search. You cannot select sample kinds that have not undergone processing.
Search by Sample No.	The starting and ending sample numbers, or * If no results for the sample kind exist, the system displays empty.	Leave the asterisk to search all of the numbers of samples that have undergone processing, or enter a specific sample number or range of sample numbers.
QC/Cal No.	A control material or calibrator number, or *	Leave the asterisk to search all calibrator numbers or control material numbers processed, or enter a specific calibrator number or control material number.
Search by Control/ Calibrator ID	A control material or calibrator ID, or *	Leave the asterisk to search all calibrator IDs or control material IDs processed, or enter a specific calibrator ID or control material ID.
Counts	Select the boxes for counts for calibration and reagent blank, replicates 1 to 4.	Available only for Calibration and RB (reagent blank) data. Program the replicate number 1 to 4 in the Calibration Setup screen.
Sequence	Select the boxes for reagent bottle sequence 1 to 5 for calibration, QC, and reagent blank.	Available only for Calibration, QC, and RB (reagent blank) data. The serial reagent bottle number 1 to 5 for each test. When all boxes are cleared, the system displays data matching the specified sample number and bottle sequence number.

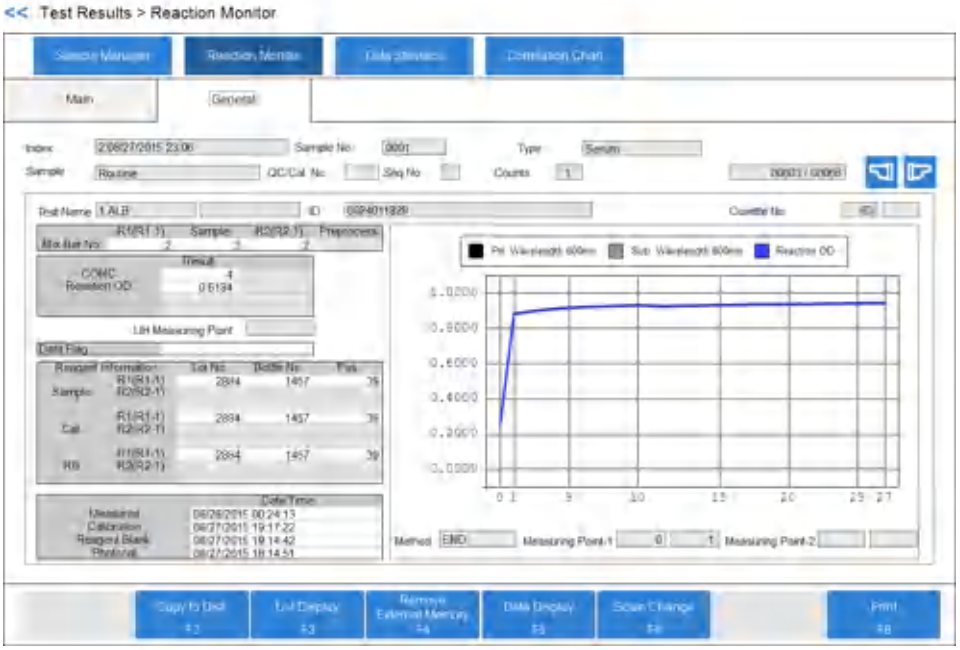
6 Select **General**.
The General tab displays. The search starts. If there is data that meets the search criteria, the General tab displays the first sample found. If the system finds no data meeting the search criteria, it displays a `No Data Found` message. Select **OK** to return to the Main tab.

7 Review the data in the General tab.

Figure 4.8 Reaction Monitor: General Tab

8 Select **Chart View** [F5].
The display changes to chart view. The chart includes colored lines for primary wavelength, secondary wavelength, and a calculation of the reaction absorbance.

Figure 4.9 Reaction Monitor: General Tab: Chart View [F5]



Note

When the total dispensing volume is below the minimum test volume[1], the chart displays dotted lines instead:

— If (R1[R1-1] dispensing volume + R1[R1-1] diluent quantity) < minimum test volume [1], the chart displays the straight line between P0 and P1 as a dotted line.

— If (R1[R1-1] dispensing volume + R1[R1-1] diluent quantity) + (sample dispensing volume + sample diluent quantity) < minimum test volume [1], the chart displays the straight lines between P0 and P10 as dotted lines.

9 To change the absorbance scale of the chart, select **Scale Change** [F6].
The Scale Change dialog displays.

10 Enter the lower limit value and the upper limit value and select **Manual**.

The setting range for the lower limit value and the upper limit value is from -2.000 to 3.000 (in units of 0.001). If you select **Auto**, the system sets the scale automatically.

Monitor the Reagent Blank and Calibration

Use the following procedure to monitor and confirm reagent blank and calibration results.

Reagent Blank and Calibration Status

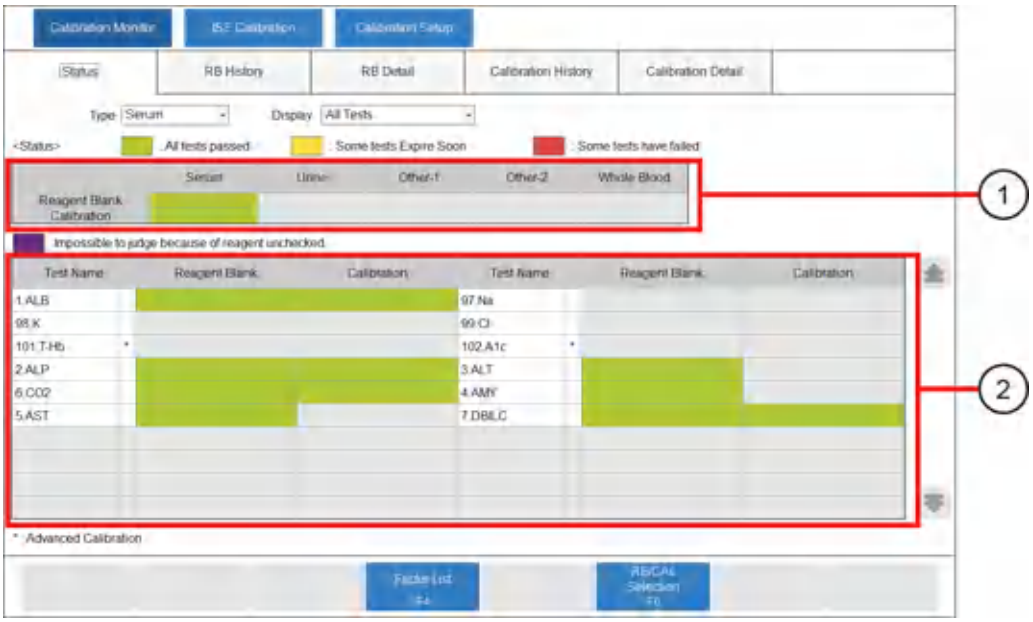
1 Select **MENU** > **Calibration** > **Calibration Monitor** > **Status**.

[1] Minimum test volume:

120 µL (for all countries and regions except Japan)

90 µL (for Japan only)

Figure 4.10 Calibration Monitor: Status Tab



1. Sample Type list
2. Test list

Table 4.4 Sample Type List

Color	Status
Red	No data, Failed, or Expired.
Gray	The sample type is not available according to the selection in **Type**.
Green	No errors.
Yellow	The calibration expires soon.

Table 4.5 Test List

Display	Color	Status
No data	Red	Bottles without calibration data exist.
Failed		Bottles with failed calibrations exist.
Expired		Bottles with expired calibrations exist.
Expires soon	Yellow	Bottles with calibration data that expires soon exist.
Passed RB or Passed Calibration	Green	No errors.
-	Purple	Reagent unchecked and judgment is impossible.

The test list is a list of analysis tests registered for each group. The asterisk in **Test Name** indicates that advanced calibration is programmed for the test.

2 Select the sample type in **Type**. The system displays the current reagent blanks and calibration status as a list. A test that displays an asterisk indicates that advanced calibration is programmed for the test.

3 Select **All Tests** or **Tests with Error** in **Display**.

- **All Tests**: Displays all the test data for the Group.
- **Tests With Error**: Displays data for tests with an error in calibration or reagent blanks.

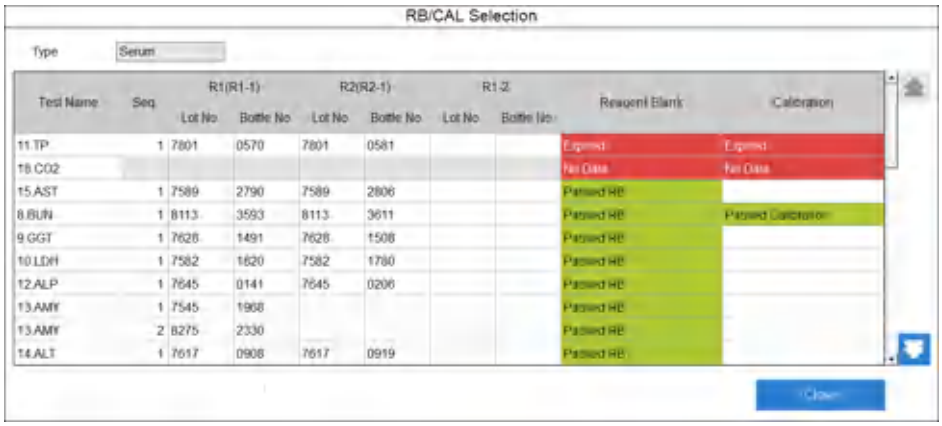
4 Select the cell under the Reagent Blank column or Calibration column of a test to view the RB History tab or Calibration History tab.

The most recent reagent blank or calibration data displays. Select the date on the x-axis of the graph to view the corresponding calibration data.

5 Select **RB Detail** to display and print the detailed reagent blank data for each test. Select **Calibration Detail** to display and print the detailed calibration data and charts for each test.

6 To view the individual status on multiple bottles, select **RB/CAL Selection** [F6].
The RB/CAL Selection dialog opens.

Figure 4.11 RB/CAL Selection Dialog



7 Select the cell under the Reagent Blank column or Calibration column to view the RB Detail tab or Calibration Detail tab, where detailed information displays.

8 Select the **Status** tab to return to reagent blank and calibration status.

9 Select **Factor List** [F4].
The Factor List dialog opens. Factor A for tests where the interpolation formula for the calibration curve is the type Y = AX + B is displayed.

10 After confirmation of the factor, select **Close**.
The Factor List dialog closes.

Review Reagent Blank and Calibration History

Review Reagent Blank History

1 Select **MENU** > **Calibration** > **Calibration Monitor** > **Status**. Select the Reagent Blank column of the test name to go to the RB History tab.

Figure 4.12 Calibration Monitor: RB History Tab

— P0: Measuring point 0.
— Px: The read point programmed in the Measuring Point-1 First field in the Test Volume and Methods: General tab (**Test Volume and Methods** > **General**).
— Py: The read point programmed in the Measuring Point-1 Last field in the Test Volume and Methods: General tab. When the Measuring Point-1 First field is programmed to 0, this field is blank (not accessible).

2 View the chart of the OD of the reagent blank.

The system saves a maximum of 100 points of data per sample type per test. The vertical line indicates a new lot number of reagent. The vertical line indicates a new lot number or new bottle number of reagent when you program **Advanced Calibration Interval (RB)** and **Interval (ACAL)** to **Bottle** in the Calibration setup: General tab (**CONFIG.** > **Calibration Setup** > **General**).

3 Select the test to display in **Test Name**.

Review Calibration History

1 Select **MENU** > **Calibration** > **Calibration Monitor** > **Status**. To go to the Calibration History tab, select the Calibration column of the test name.

Figure 4.13 Calibration Monitor: Calibration History Tab

2 View the chart of the OD of the calibration.

The system saves a maximum of 100 points of data per sample type per test. The vertical line indicates a new lot number of reagent. The vertical line indicates a new lot number or new bottle number of reagent when you program **Yes** for **Operation**, **Bottle** for **Interval (RB)**, and **Bottle** for **Interval (ACAL)** in Advanced Calibration in the Calibration setup: General tab (**CONFIG.** > **Calibration setup** > **General**).

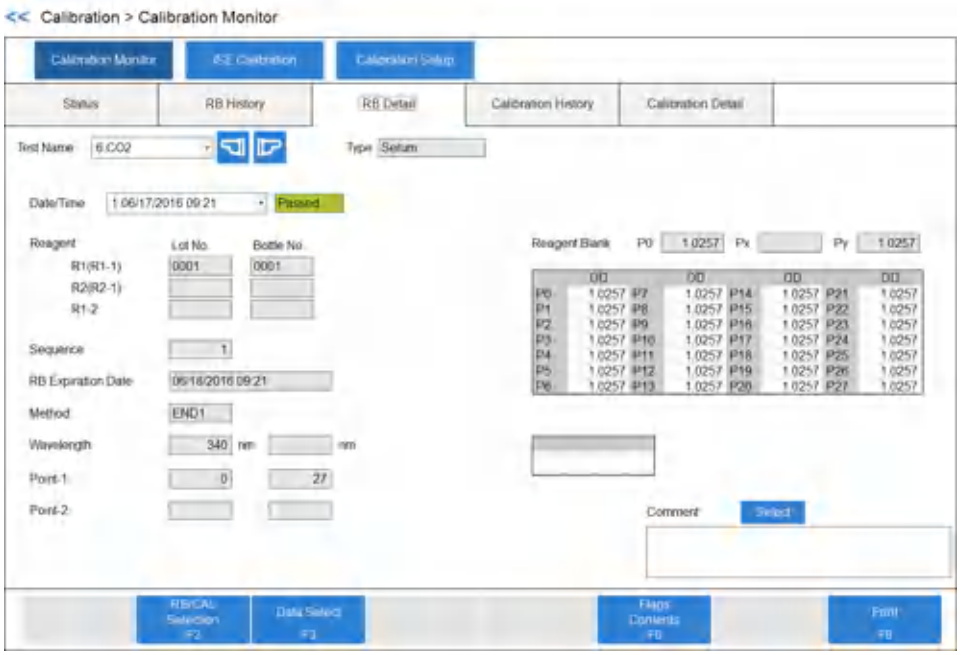
3 Select the test to display in **Test Name**.

Review Reagent Blank and Calibration Detailed Data

Review RB Detail

1 Select **MENU** > **Calibration** > **Calibration Monitor** > **Status**. To go to the RB Detail tab, select **RB/CAL Selection** [F6], and then select the Reagent Blank column of the test name.

Figure 4.14 Calibration Monitor: RB Detail Tab



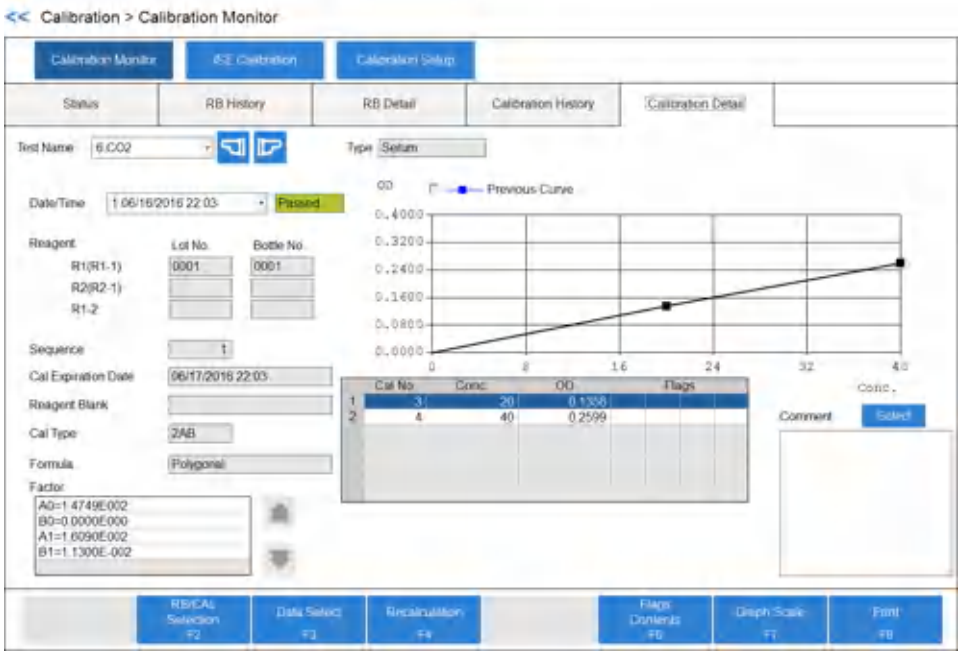
2 View detailed reagent blank data information.

3 Select the test to display in **Test Name**.

Review Calibration Detail

1 Select **MENU** > **Calibration** > **Calibration Monitor** > **Status**. To go to the Calibration Detail tab, select **RB/CAL Selection** [F6], and then select the Calibration column of the test name.

Figure 4.15 Calibration Monitor: Calibration Detail Tab



2 View detailed calibration data.

3 Select the test to display in **Test Name**.

Print Reagent Blank and Calibration Data

1 In the RB Detail tab or Calibration Detail tab, select **Print** [F8].
The system opens the Print dialog with options.

- **Recent/History**: Recent data or History (maximum of 100 points)
- **Sample Kind**: Reagent Blank and Calibration
- **RB Data Options**: P0-P27 or P0, Px, Py
- **Factor**: Without Factor or With Factor
- **Output Item**: Display Item or All Items (Serum, Urine, Other-1, Other-2, and Whole Blood)

2 Select **OK** to print.

Display Data History

Displaying data history and adding a comment are common features of the RB History, RB Detail, Calibration History, and Calibration Detail tabs. Changing the graph scale is a common feature of the RB History, Calibration History, and Calibration Detail tabs.

1 To display a history of the R1 and R2 lot numbers and bottle numbers, select **Data Select** [F3].

Figure 4.16 Data Select Dialog

2 In the Date column, select the reagent blank data to display, then select **OK**.

Note

You can also display reagent blank and calibration history data by selecting a date and time in **Date/Time** in the RB History tab or Calibration History tab, or by selecting the date on the x-axis of the graph.

Add a Comment

You can avoid having to retype common comments by selecting master comments, which are pre-programmed comments. Program master comments in the Comment Master screen (**CONFIG.** > **Comment Master**). For more information, refer to Comment Master Screen.

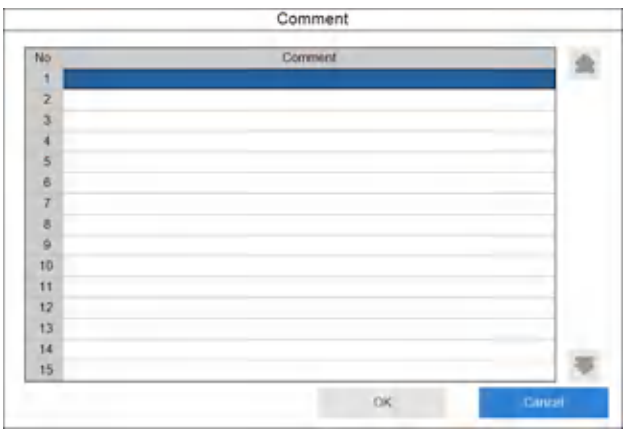
You can add master comments to RB and calibration data.

Comments created in the RB History or RB Details tabs display in both tabs. Comments created in the Calibration History and Calibration Details tabs display in both tabs.

1 Select **Select**.

The system displays the Comment dialog.

Figure 4.17 Comment Dialog



2 Select the comment to set.

3 Select **OK**.

The system closes the dialog, and displays the selected comment in **Comment** field.

Edit the comment if necessary.

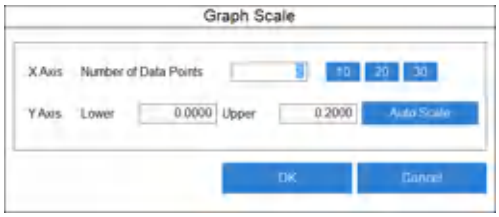
4 If master comments are not programmed, enter a comment.

Change the Graph Scale

You can change the graph display size.

1 Select **Graph Scale** [F7].
The Graph Scale dialog displays.

Figure 4.18 Graph Scale Dialog



2 In **X Axis**, to specify the number of data points, select **10**, **20**, or **30**, or enter a number in **Number of Data Points**.

3 In **Y Axis**, set the lower limit value and upper limit value in **Lower** and **Upper**.

When you select **Auto Scale**, the system automatically sets the upper limit and lower limit values and displays the scale calculation.

4 Select **OK**.
The system redraws the graph with the set scale.

Monitor QC

The following are options for monitoring QC results:

- Monitor the QC Using the Daily Variation Chart
- Monitor the QC Using the Day-to-Day Variation Chart
- Monitor the QC Using the Twin Plot Chart

Monitor the QC Using the Daily Variation Chart

You can review QC results by plotting the individual QC points from one index or a range of indexes on a single chart. Always review the daily chart after performing daily QC analysis.

1 Select **QC** > **Chart** > **Main**.

The system displays the Main tab with the tests selected that performed quality controls in the current index for all sample kinds.

Figure 4.19 Chart: Main Tab

Table 4.6 Data Review Column Colors

Color	Description
Green	Normal data
Yellow	Data outside the range of the Single Check Level programmed in the QC Setup screen (**CONFIG.** > **QC Setup**)
Red	Error data (data not included in the QC statistical values)

2 To change the tests to display in the chart:

— To select by sample type, select the sample type from **Type**.
— To select the QC results in another index range, select **Filter** [F3].
— To select a specific test, select or clear individual test names.
— To clear all tests, select **Clear All Tests** [F6].
— To select all tests, select **Select All Tests** [F5].

3 Select **Chart View**.

The system displays either **Daily** [F7] or **Day to Day** [F7], defaulting to the previous selection made after selecting **Chart View**.

— To see individual QC points for the displayed test, select **Daily** [F7].
— To see an average of the QC points for the displayed test, select **Day to Day** [F7].

After selecting **Daily** [F7], the system displays the Daily - Chart View with the daily chart for all individual QC points for the displayed test. Change the display to other control material assigned to the test by selecting **Control Name**. The system does not plot results on the chart that exceed ± 3SD from the mean value.

Figure 4.20 Chart View Tab: Daily Chart

1. Daily - Chart View
2. Individual Control Sample No.

— **Test Name**: Select the test name to display the chart.
— **Type**: Select the sample type to display the chart.
— **Control Name**: Select a control to highlight the graph on the chart and to display the statistical results and the detailed data for the control.
— **Statistics**: The screen displays the statistical values for the control selected in **Control Name**.
— **Detail Data**: The screen displays the detailed data for the individual control sample number selected below the chart. The detailed data includes the index, measured time, sample number, result, flag, and reagent lot number and bottle number.
— **Scale Change** [F5]: When selected, you can specify the number of data points to display on the x-axis (10, 20, or 30). You cannot change the display of the y-axis.
— **Individual Control Sample No.**: Select an individual control sample No. below the chart to display the detailed data. A number from one to five displays after the '/' indicating the reagent bottle sequence number if QC analysis is performed on a test with multiple reagent bottles on-board.

Note

— Select **Reaction Monitor**.

The system displays the Reaction Monitor: General Tab with the displayed data in Daily Chart.

— To return to the Chart tab, select **<< icon**.

— Select **Calibration Monitor**.

The system displays the Calibration Monitor: Calibration History Tab for the displayed test in Daily Chart.

— To return to the Chart tab, select **<< icon**.

4 Optional: Select **Print** [F8].
The Print dialog displays.

— In **List Type**, select the list type options (**Statistics**, **Detail Data**, **Graph**, and **with Comments**) to print.
— In **Output Data**, select the output data to print (**Display Data or All Data**).
— Select **OK**.

Printing starts.

Monitor the QC Using the Day-to-Day Variation Chart

The day-to-day variation chart compares QC results by plotting multiple days of QC analysis on a chart that displays the variation. The system averages all QC points for a specific control within an index, then plots them on the day-to-day chart.

1 Select **QC** > **Chart** > **Main**.

The system displays the Main tab with the tests that performed quality controls in the current index for all sample kinds selected.

Figure 4.21 Chart: Main Tab

Table 4.7 Data Review Column Colors

Color	Description
Green	Normal data
Yellow	Data outside the range of the Single Check Level programmed in the QC Setup screen (**CONFIG.** > **QC Setup**)
Red	Error data (data not included in the QC statistical values)

2 To change the tests to display in the chart:

— To select by sample type, select the sample type from **Type**.
— To select the QC results in another index range, select **Filter** [F3].
— To select a specific test, select or clear individual test names.
— To clear all tests, select **Clear All Tests** [F6].
— To select all tests, select **Select All Tests** [F5].

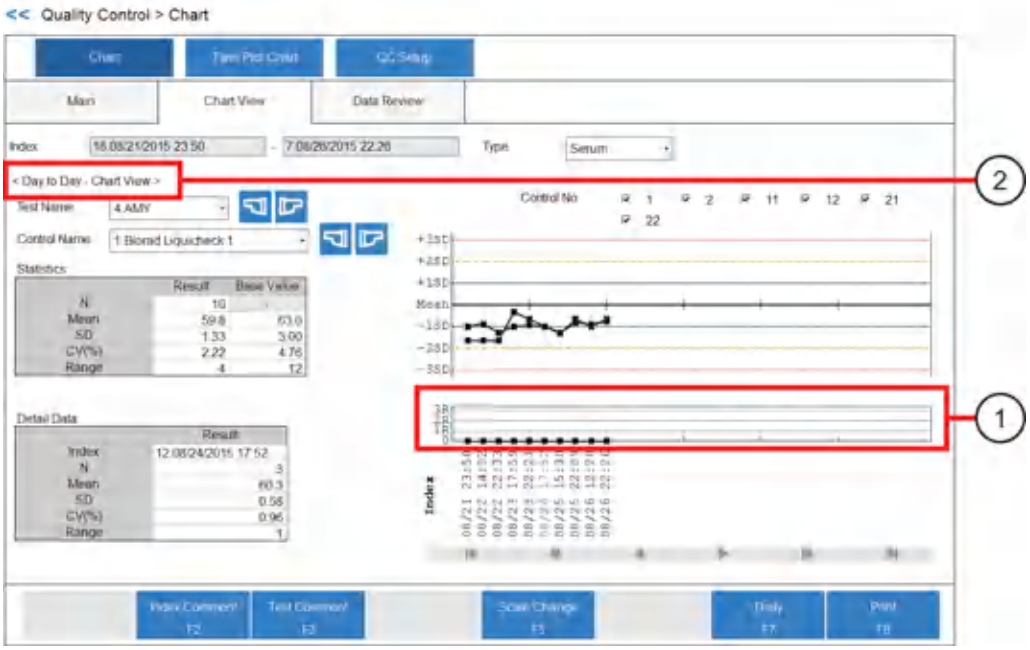
3 Select **Chart View**.

The system displays either **Daily** [F7] or **Day to Day** [F7], defaulting to the previous selection made after selecting **Chart View**.

— To see individual QC points for the displayed test, select **Daily** [F7].
— To see an average of the QC points for the displayed test, select **Day to Day** [F7].

After selecting **Day to Day** [F7], the system displays the Day to Day - Chart View with an average of the QC points for the displayed test within the index. Change the display to other control material assigned to the test by selecting **Control Name**.

Figure 4.22 Chart Tab: Day to Day Chart



1. Range (R) Graph
2. Day to Day - Chart View

— **Test Name**: Select the test name to display the chart.
— **Type**: Select the sample type to display the chart.
— **Control Name**: Select a control to highlight the graph on the chart and to display the statistical results and the detailed data for the control.
— **Statistics**: The screen displays the statistical values for the control selected in **Control Name**.
— **Detail Data**: The screen displays the detailed data for the control selected in **Control Name** for the selected date and time on the x-axis of the chart.
— **Scale Change** [F5]: When selected, you can specify the number of data points to display on the x-axis (10, 20, or 30). You cannot change the display of the y-axis.
— **Range (R) Graph**: The difference in the range of the QC data for each index. The system determines the R value by the range programmed in the QC Setup screen. For example, for an R value of 12, then 1R on the graph has a value of 12 and 2R has a value of 24. The Range Graph is more effective for evaluating precision than accuracy.

4 Optional: Select **Print** [F8].
The Print dialog displays.

— In **List Type**, select the list type options (**Statistics**, **Detail Data**, **Graph**, and **with Comments**) to print.
— In **Output Data**, select the output data to print (**Display Data** or **All Data**).
— Select **OK**.

Printing starts.

Monitor the QC Using the Twin Plot Chart

Use twin plot analysis to determine whether the system caused a QC variation or a random error caused the variation. The system normally performs QC analysis using two control samples:

- A sample in the reference interval
- A sample in the pathological range

The twin plot function displays the first control sample on the x-axis of a 2-dimensional plot and the second control sample on the y-axis. Confirm that all points fall within the 2SD range in the center of the twin plot.

1 Select **QC** > **Twin Plot Chart** > **Test Select**.

2 In **Index**, select the start index and end index range to display.

3 Select the sample type in **Type**.

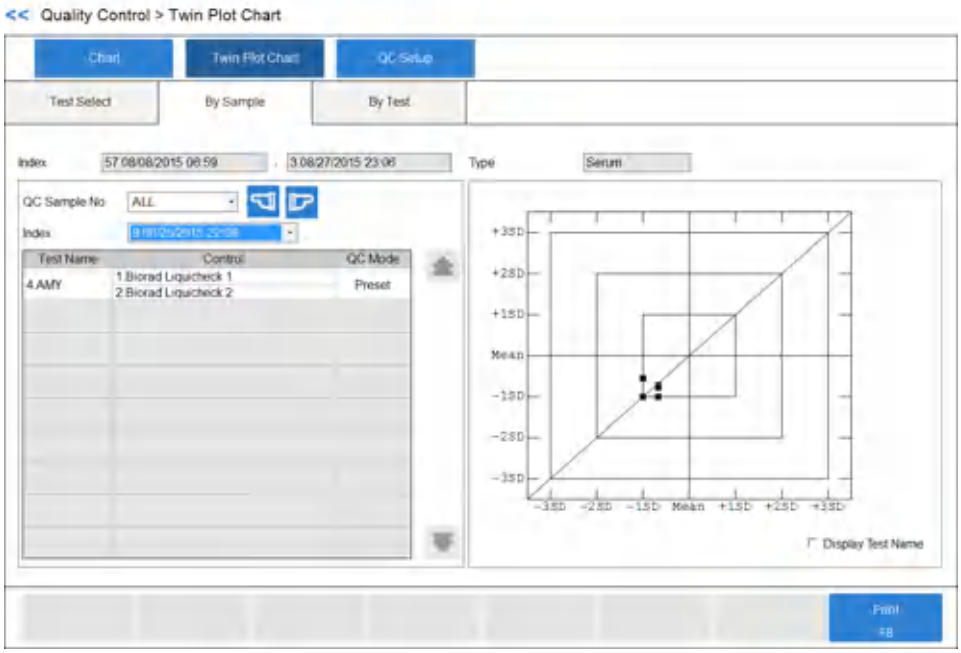
4 Select the tests to display.

Note

Select **Select All Tests** [F5] to select all tests. Select **Clear All Tests** [F6] to clear all tests.

5 Select **By Sample**.
The system displays QC data by sample number for the range of indexes selected.

Figure 4.23 Twin Plot Chart: By Sample Tab



Note

When the tests selected in the Test Select tab are displayed together, you can estimate the causes for fluctuations regarding temperature and calibrator more effortlessly.

6 Select **Display Test Name** to display test names on the chart.

When a test name is selected, the system displays the test name on the chart highlighted in red.

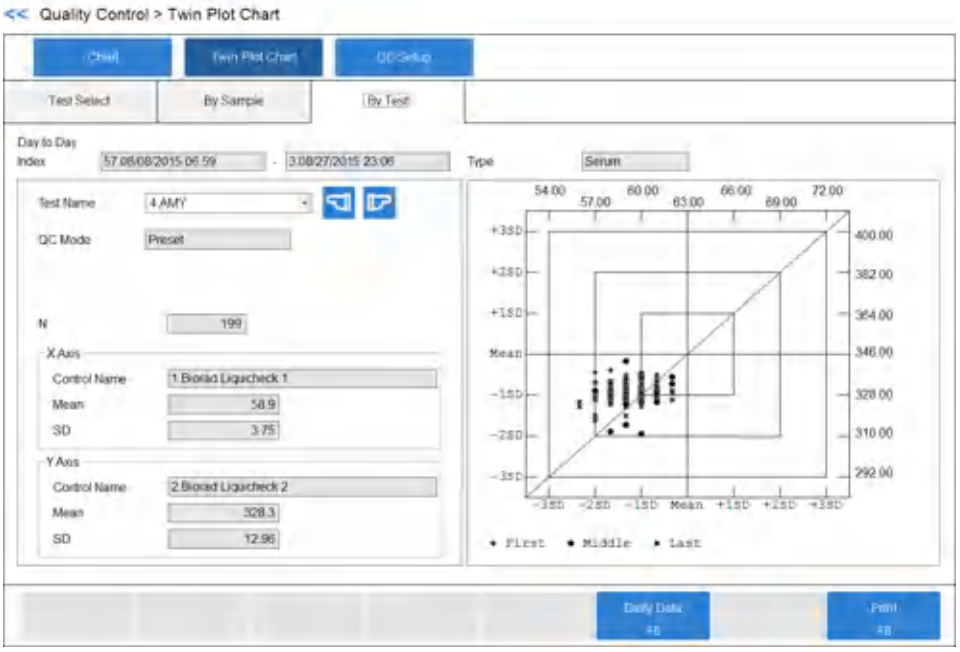
7 In **QC Sample No.**, select the control sample number to view.

Note

When an abnormal condition occurs, refer to *DxC 700 AU Instructions for Use*.

8 Select **By Test**.

Figure 4.24 Twin Plot Chart: By Test Tab



The system displays the tests selected in the Test Select tab for each test.

The system displays QC data chronologically, divided into three blocks to review high shifts or other errors.

9 To display the daily statistical results, select **Daily Data** [F6].

Add a QC Comment

You can avoid having to retype common comments by selecting master comments, which are pre-programmed comments. Program master comments in the Comment Master screen (**CONFIG.** > **Comment Master**). For more information, refer to Comment Master Screen.

You can add comments to QC data.

You can add comments in the Chart View tab (**QC** > **Chart** > **Chart View**) or the Data Review tab (**QC** > **Chart** > **Data Review**).

An Index Comment adds a comment by the index title for all QC in the index. A Test Comment adds a comment for a specific test within the index.

Add an Index Comment

1. Select **QC** > **Chart** > **Chart View** or **QC** > **Chart** > **Data Review**.
2. Select **Index Comment** [F2].
   The system displays the Index Comment dialog.

   Figure 4.25 Index Comment Dialog

3. Enter a comment or select **Comment Master** to select the comment programmed in Comment Master screen (**CONFIG.** > **Comment Master**).
4. Select **OK**.
   The dialog closes.
5. To view comments, select **Index Comment** [F2].

Add a Test Comment

1. Select **QC** > **Chart** > **Chart View** or **QC** > **Chart** > **Data Review**.
2. Select **Test Comment** [F3].
   The system displays the Test Comment dialog.

Figure 4.26 Test Comment Dialog

3 Enter a comment or select **Comment Master** to select the comment programmed in the Comment Master screen (**CONFIG.** > **Comment Master**).

4 Select **OK**.
The dialog closes.

5 To view comments, select **Test Comment** [F3].

Edit Quality Control Data

You can search for and edit analyzed QC data.

You can edit, omit, or add a comment by control sample number or test.

Caution

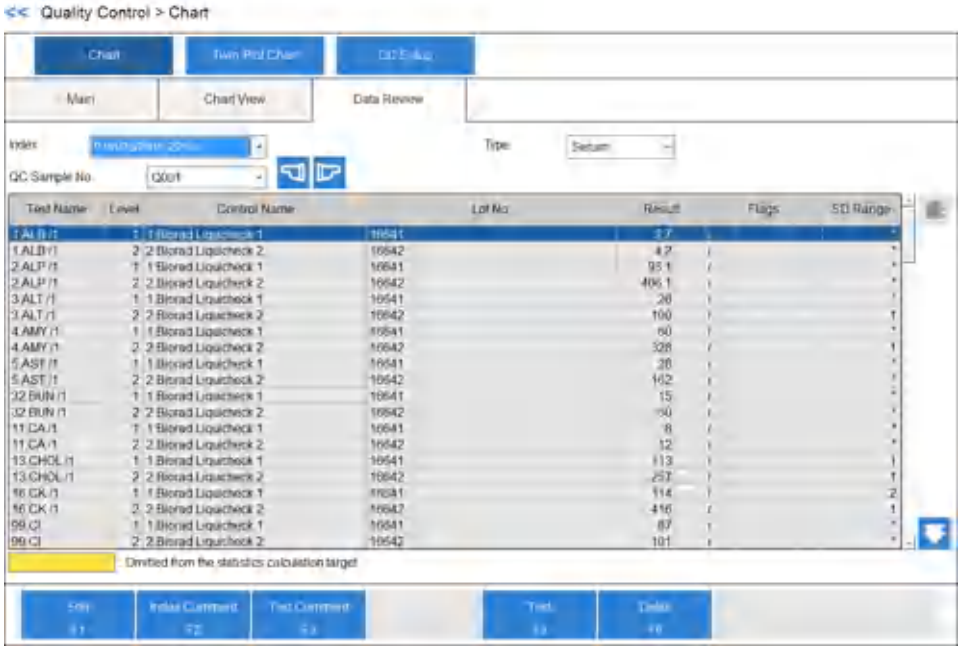
You can edit analyzed QC data. To prevent an erroneous diagnosis caused by numerous changes to the quality control data, edit according to your laboratory procedure.

Note

After editing QC analysis data results, confirm that the edited data falls within the cumulative period. If it falls within the cumulative period, the cumulative values must reflect the editing of the contents. Update the cumulative values. For more information, refer to QC Setup Menu.

1 Select **QC** > **Chart** > **Data Review**.

Figure 4.27 Data Review Tab: by Sample Display



2 Select the index in **Index**.

3 In **Type**, select the sample type.

4 Select **Test** [F5] or **Sample** [F5] to alternate the display between by test or by sample.

5 Select **Edit** [F1].

6 To omit all of the data displayed on the screen from the statistical calculation, select **Omit** [F4].

7 To apply all of the data to the statistical calculation, select **Apply** [F5].

8 To edit an individual result, edit the result or flag on **Result** or **Flags**.

9 To omit the individual result from the statistical calculation, enter d in **Flags**.

10 To edit a comment, select **Index Comment** [F2] or **Test Comment** [F3].

11 Select **Save** [F1].

Sample Management

The system displays manually edited analysis data with an e flag. The system displays analysis data that has been edited with a correction formula with a c flag, indicating manual data correction.

The following are methods for editing analysis data:

- Edit Patient Sample Data
- Correct Patient Sample Data
- Recalculate Analysis Data Using a Previous Calibration Curve
- Send Data to Laboratory Information System

Caution

Edit only according to your laboratory procedures.

Edit Patient Sample Data

You can review and edit results and flags. If you edit a result or flag, the system attaches an e flag to the result.

1 Select **RESULT** > **Sample Manager** > **Main**.

The system displays a list of samples in the current index, selected (highlighted in blue).

Figure 4.28 Sample Manager: Main Tab

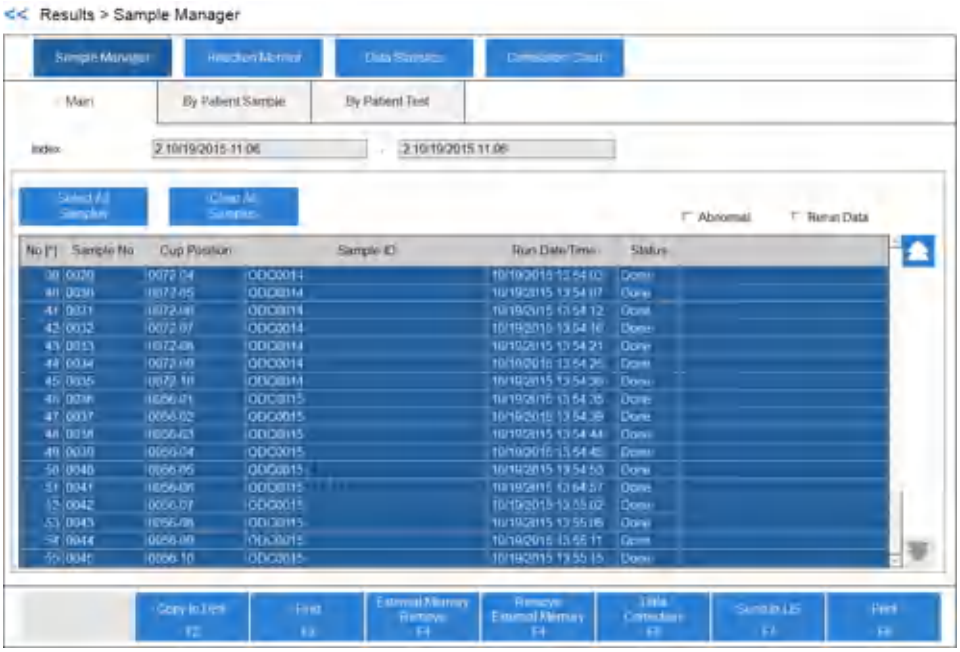


Table 4.8 Main Tab Description

Option	Description
Select All Samples	Select all samples displayed in the list.
Clear All Samples	Clear the selection of all samples displayed in the list.
Copy to Disk [F2]	Copy the results to external memory device or CD-R.
Find [F3]	Search for data according to the following parameters: Index Range, Sample Number, Sample ID, Data Not Yet Transferred to LIS, Data Not Yet Printed, or Patient Information.

Table 4.8 Main Tab Description (Continued)

Option	Description
Remove External Memory [F4]	Remove the external memory media safely.
Recalculate Data [F5]	Recalculate results using a previous calibration factor.
Data Correction [F6]	Correction by A and B of the correction coefficient AX + B is possible by test and by sample type.
Send to LIS [F7]	Send the patient sample results and RB, calibration, and QC results to an LIS.
Print [F8]	Print the selected samples in a list format.

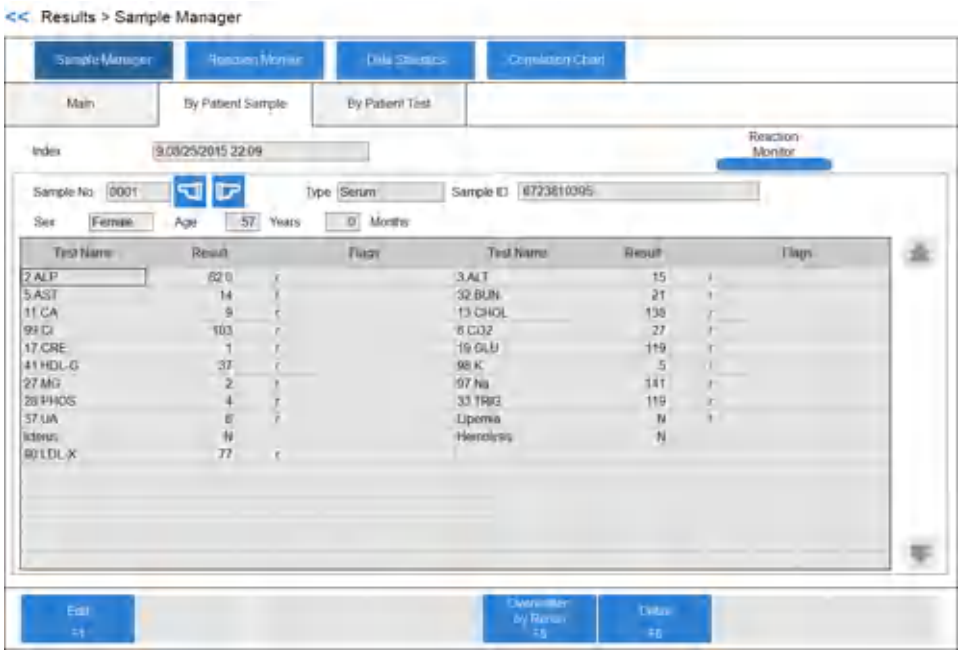
2 If necessary, select **Find** [F3] to search for data according to the following parameters: Index Range, Sample Number, Sample ID, Data Not Yet Transferred to LIS, Data Not Yet Printed, or Patient Information.

3 Select **OK** to update the contents of the Main tab.

The system displays a list with the samples found using the search criteria.

4 Select **By Patient Sample** or **By Patient Test**.
The system displays the search results.

Figure 4.29 Sample Manager: By Patient Sample Tab



You can review and edit results and flags. If you edit a result or flag, the system attaches an e flag to the result.

5 If the data indicates problems, select **Reaction Monitor** to display the Reaction Monitor screen and review specific information regarding the sample. Select **Back** in the Reaction Monitor screen to return to the Sample Manager screen.

6 Select **Edit** [F1].
You can edit results or flags.

7 In the By Patient Sample tab, select the test name for which to perform edits. In the By Patient Test tab, select the sample number for which to perform edits.

8 Select **Detail** [F6] to view the sample dilution rate, reagent lot number, and reagent bottle number.

9 Edit the desired result or flags.

10 Select **Save** [F1] to save the edited data.

Correct Patient Sample Data

The system uses the correction formula Y = AX + B to correct the data for the selected samples for a test or for all tests.

Y Data after correction

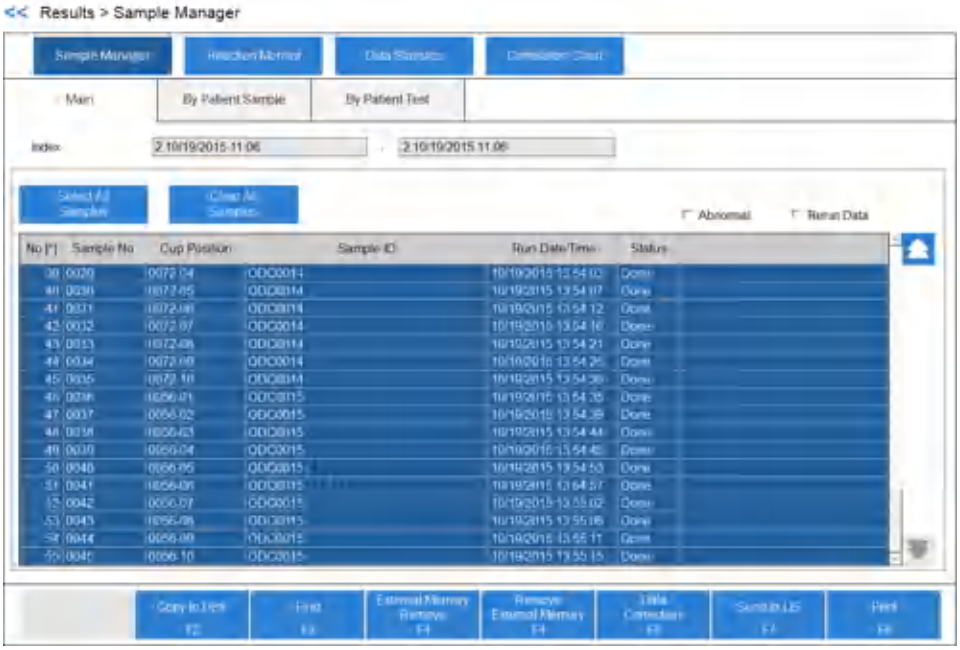
X Data before correction

A, B An optional correction factor (9 digits, including sign and decimal point)

1 Select **RESULT** > **Sample Manager** > **Main**.

The system displays a list of samples in the current index, selected (highlighted in blue).

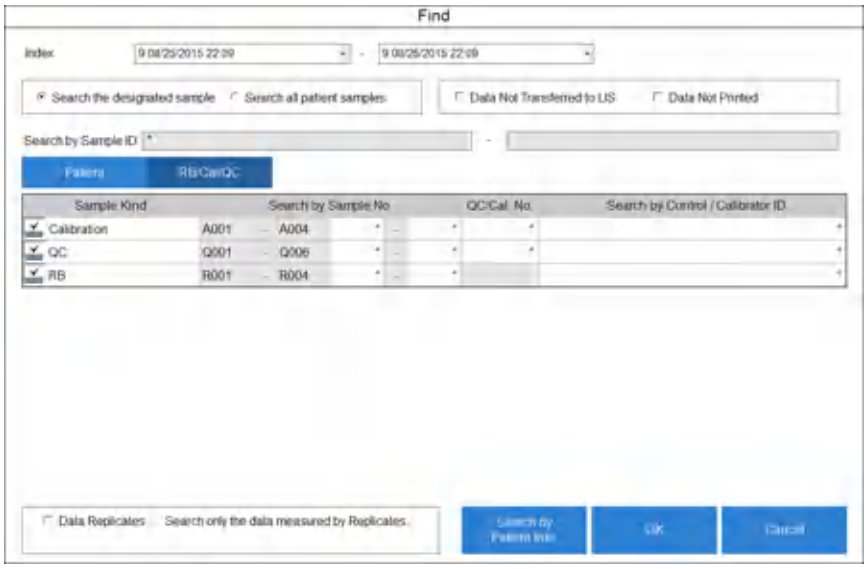
Figure 4.30 Sample Manager: Main Tab



The screen displays the current index data.

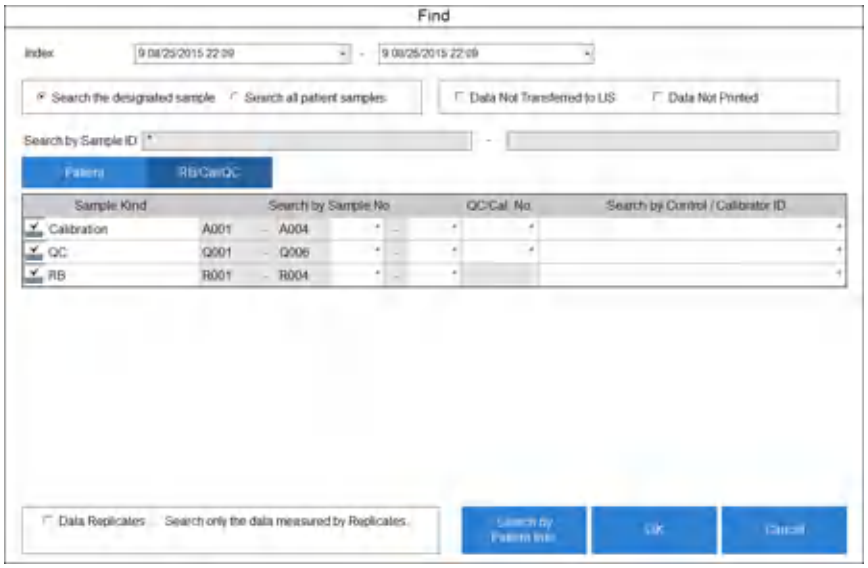
2 Select **Find** [F3] to search for data according to the following parameters: Index Range, Sample Number(s), Sample ID, Data Not Yet Transferred to LIS, Data Not Yet Printed, or Patient Information.

Figure 4.31 Find Dialog: Patient Tab



3 Select **RB/Cal/QC**. Clear **RB, Cal, and QC** .

Figure 4.32 Find Dialog



4 Select **OK**.
The system displays a list with the samples found using the search criteria.

5 Select **Data Correction** [F6].
The system displays the Data Correction dialog.

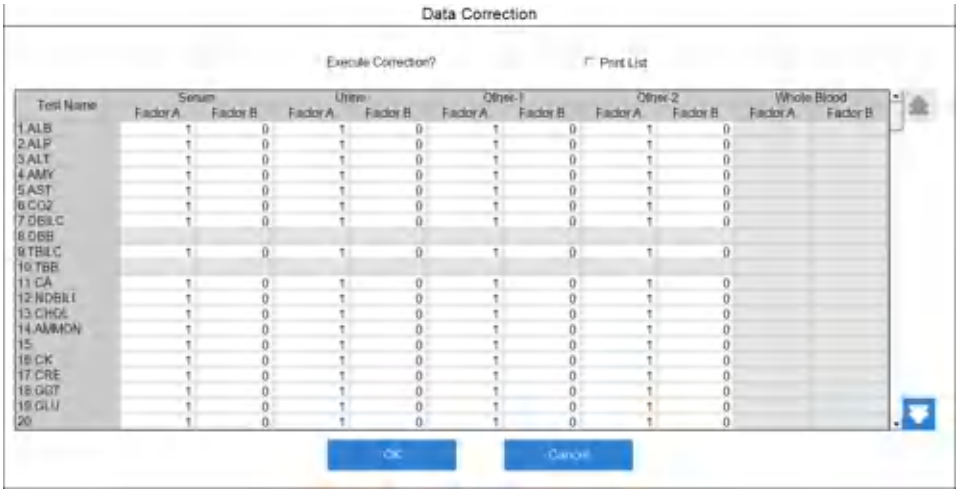
Figure 4.33 Data Correction Dialog

6 Select the test to correct or **All** in **Test Name**, and then select **Correction**.
When you select a specific test, the dialog to enter factors A and B displays.

Figure 4.34 Data Correction Dialog (One Test Selected)

When you select **All**, the dialog for programming the factors A and B for all tests displays.

Figure 4.35 Data Correction Dialog (All Tests Selected)



Select **Print List** to print the factor list.

7 Enter values for factors A and B and select **OK**.
The Data Correction dialog displays with the message `Operating: Please wait`.

When the correction completes, a message displays with the last sample number corrected.

8 Select **OK**.

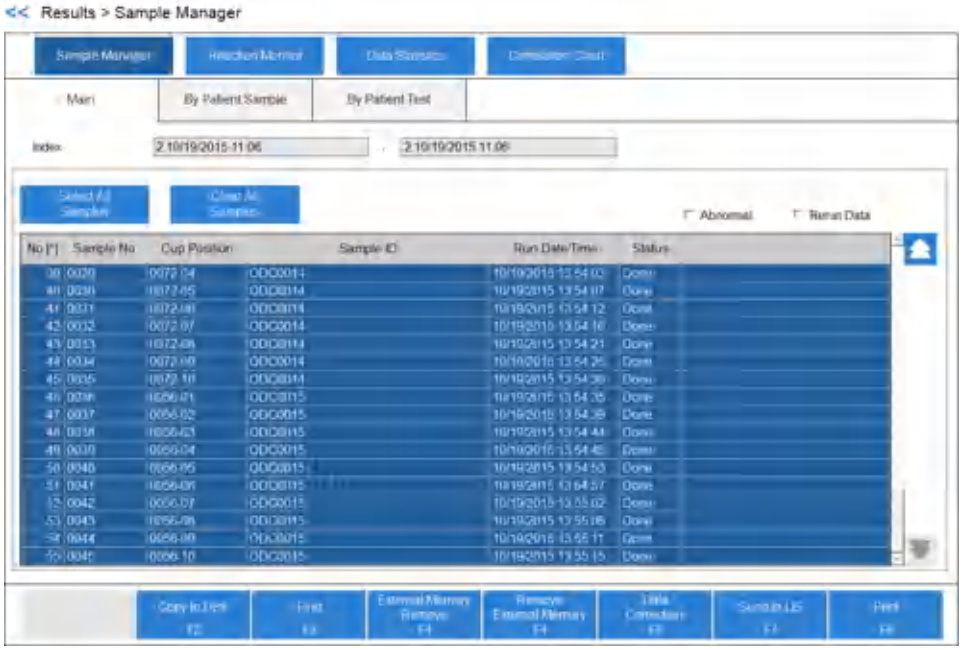
The dialog closes and the Main tab displays. The system attaches a c flag to any corrected result.

Recalculate Analysis Data Using a Previous Calibration Curve

1 Select **Result** > **Sample Manager** > **Main**.

The system displays a list of samples in the current index, selected (highlighted in blue).

Figure 4.36 Sample Manager: Main Tab



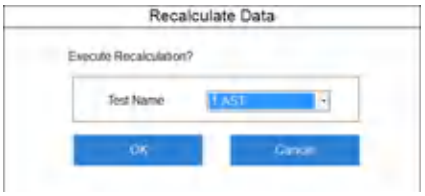
2 Select **Find** [F3] to search for data according to the following parameters: Index Range, Sample Number, Sample ID, Data Not Yet Transferred to LIS, Data Not Yet Printed, or Patient Information.

3 Select **RB/Cal/QC**. Clear **RB, Cal, and QC**.

4 Select **OK**.
The system displays a list of the samples found using the search criteria.

5 Select **Recalculate Data** [F5].
The Recalculate Data dialog displays.

Figure 4.37 Recalculate Data Dialog



6 Select the test to recalculate in **Test Name**.

7 Select **OK**.

When the recalculation completes, a message displays with the last sample number involved in the recalculation. If the test is not performed on any samples selected using the search criteria, a dialog displays `Data Not Found`. The system does not attach a flag to the recalculated data.

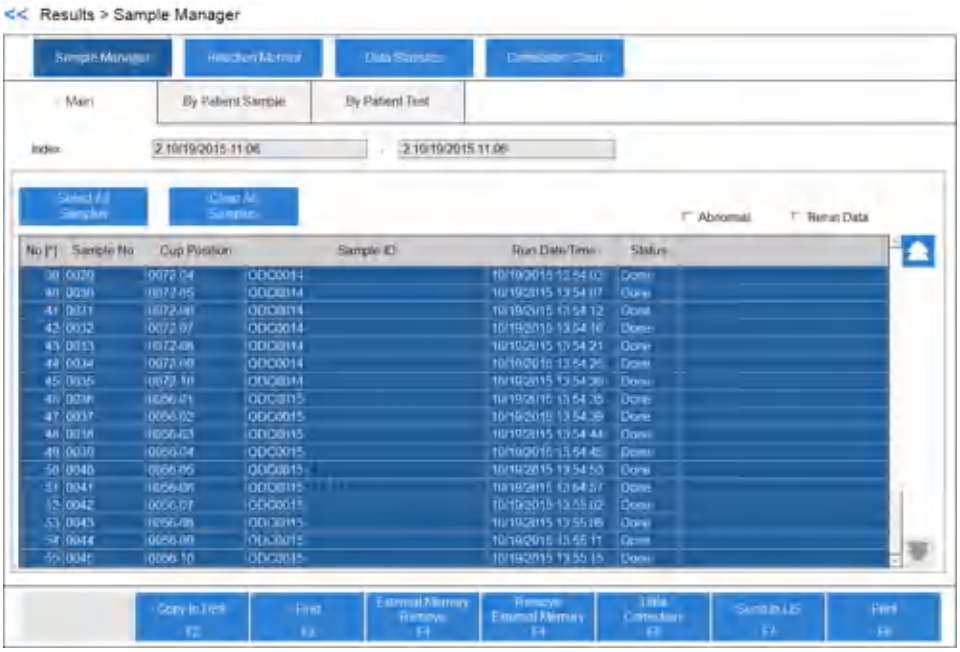
Send Data to Laboratory Information System

Online transfer is possible if you select **Batch** or **Realtime** in **Analysis Results Transfer Mode** in the Online: Setup tab (**CONFIG.** > **Online** > **Setup**). For more information, refer to Online Menu.

1 Select **Result** > **Sample Manager** > **Main**.

The system displays a list of samples in the current index, selected (highlighted in blue).

Figure 4.38 Sample Manager: Main Tab



2 To search for data according to the following parameters: Index Range, Sample Number, Sample ID, Data Not Yet Transferred to LIS, Data Not Yet Printed, or Patient Information:

   a. Select **Find** [F3].

   b. Select **RB/Cal/QC** to search the reagent blank, calibration, and quality control results to send to LIS.

   c. Select **OK**.

3 Select **Send to LIS** [F7].
The Online Transfer dialog displays.

4 Select **OK**.

The system transfers the data. Select **Stop Sending to LIS** [F7] to stop the transfer.

Calculate Data Statistics

The system displays statistical values of analyzed patient sample results with graphs and numerical data, providing easy-to-understand views, such as variations in results and changes in the same sample.

View Data Statistics

Review key statistics of sample results for a specified range of indexes.

To select samples to use to generate sample statistics:

1 Select **RESULT** > **Sample Manager** > **Data Statistics** > **Main**.

Figure 4.39 Data Statistics: Main Tab

2 Select the index range in **Index**.

3 Select **Search all samples** or **Search the designated sample**.

— If you select **Search all samples**, and you search the result with a specific sample ID, enter the sample ID in **Search by Sample ID**.
— If you select **Search the designated sample**, set the search conditions in the tab.

1. Select the sample kind to search in **Sample Kind**.
2. Enter a specific sample number or sample ID to search as required.

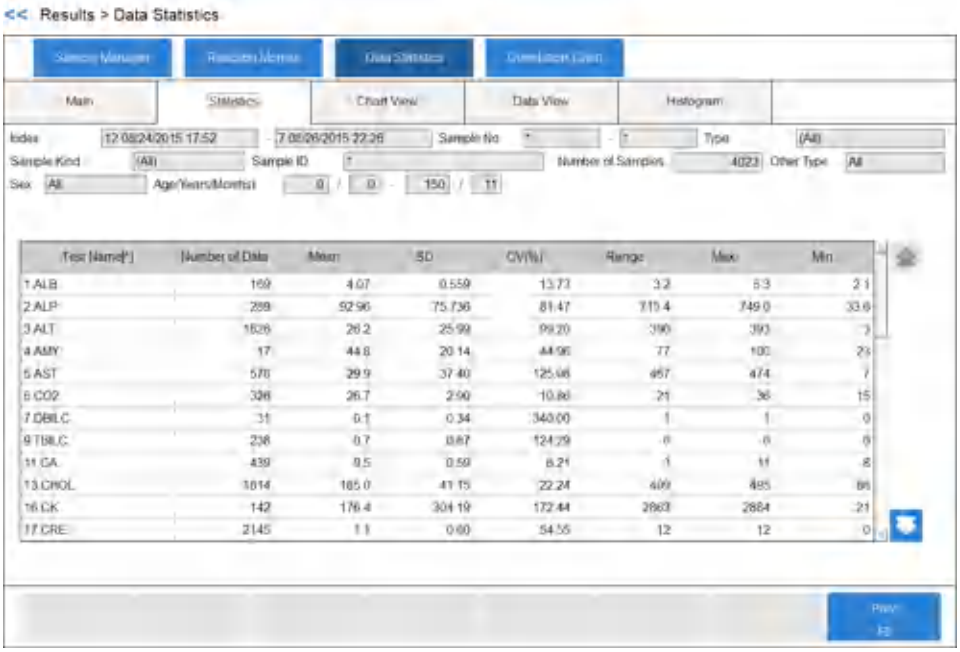
   The Search by Sample No. and Search by Sample ID fields default to search all (indicated by the *) sample numbers and ID numbers.
3. Select the sample type to search in **Type**.

4 To use patient demographic information to search the data, select **Search by Patient Info.** [F5].

5 Select the search condition in the dialog, then select **OK**.

6 Select **Statistics** to display the data statistics in the Statistics tab.

Figure 4.40 Data Statistics: Statistics Tab



The data statistics include the number of data points, mean, SD, CV (%), range, and maximum and minimum results.

7 Select **Test Name** to display tests in test number order from 1 to 120, **Number of Data** to display tests from the highest to lowest number of data points, and **CV(%)** to display tests from the highest to lowest CV.

8 Select up to 12 tests to display data statistics for in the Chart View, Data View, or Histogram tabs.

9 Select **Chart View** to display data statistics and a graph.

Figure 4.41 Data Statistics: Chart View Tab

10 Select a test in **Test Name** to display the statistical information for that test in the **Statistics** section. Select a specific date, time, result, or sample number displayed on the X axis of the graph to display the information in the **Detail Data** section.
The selected test displays with a thick line on the graph.

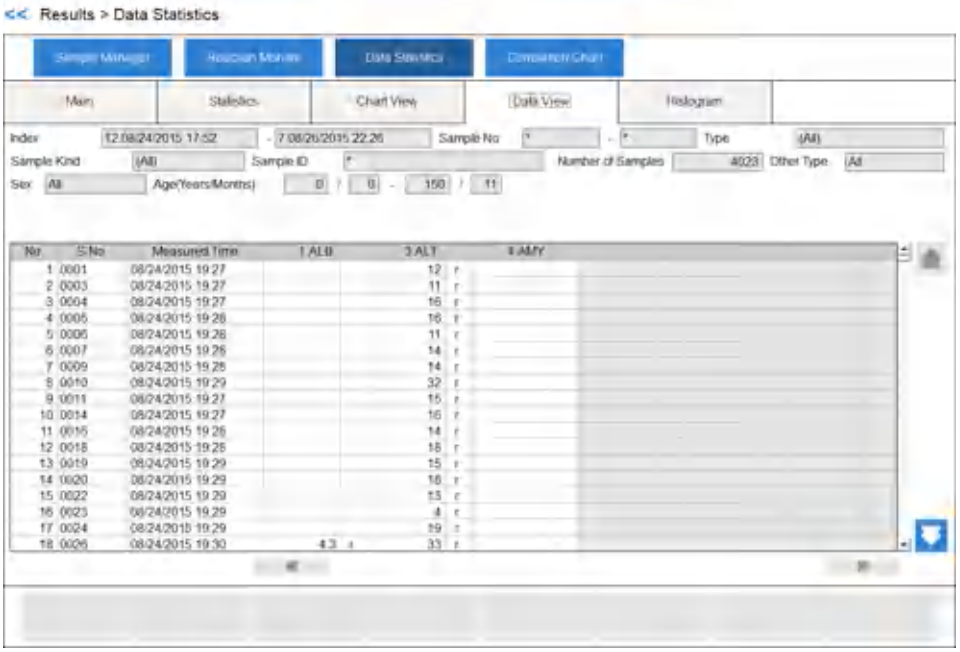
11 To change the graph display parameters, select **Graph Scale** [F5].
The Graph Scale dialog displays.

Figure 4.42 Graph Scale Dialog

12 Select a number in **Number of Display** and an option in **X Scale** option, then **OK**.
The graph display changes.

13 Select **Data View** to display the sample numbers, measure times, and results for the tests selected in the Statistics tab.

Figure 4.43 Data Statistics: Data View Tab

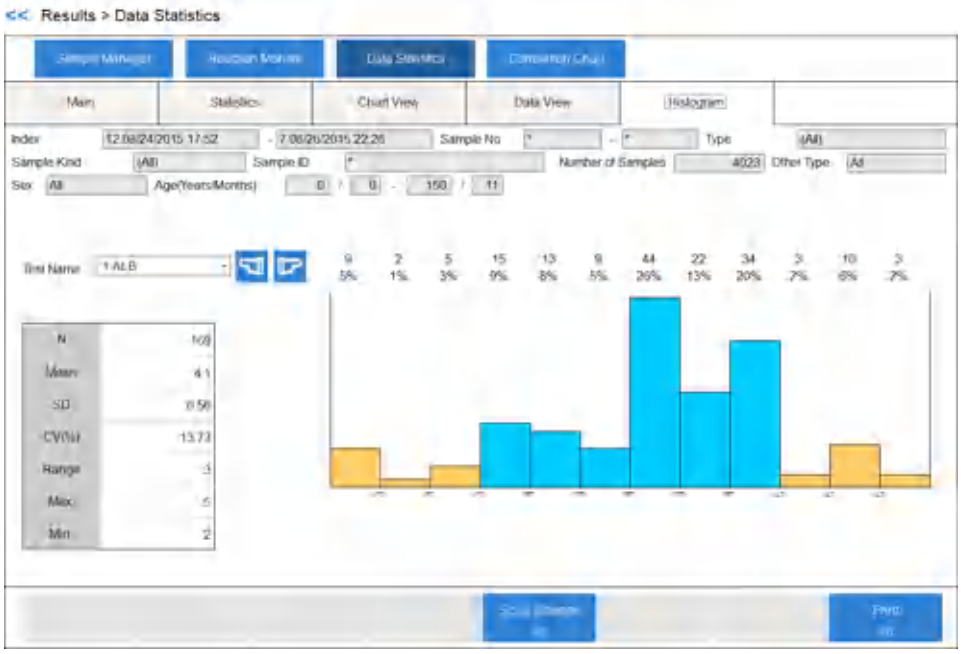


View data corresponding to 10,000 samples using the up or down scroll button.

Change the test display using the left or right scroll button.

14 Select **Histogram** to display test data statistics and a bar graph of the data.

Figure 4.44 Data Statistics: Histogram Tab

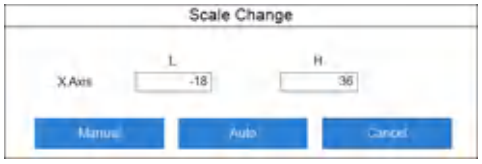


The system displays data within the range of the mean +/- 1 SD with a blue bar. The system displays data outside of the mean +/- 1 SD with an orange bar.

15 Select the test name in **Test Name**.

16 Select **Scale Change** [F5] to change the display range of the histogram.

Figure 4.45 Scale Change Dialog



a. Select **Auto** to display the entire range of results.

b. Enter the lowest result and highest result to display in **X-Axis**, then select **Manual**.

Create a Correlation Chart

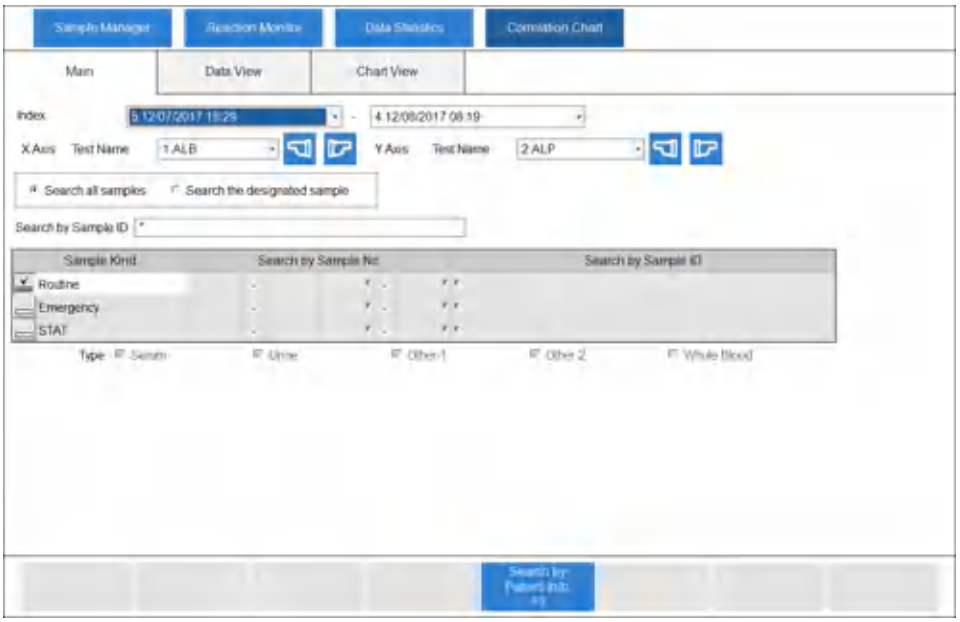
The Correlation Chart allows a comparison of two tests of the same samples within a specified index range.

This function calculates how well two tests correlate using different parameters.

To create a correlation chart, take the following steps:

1 Select **RESULT** > **Sample Manager** > **Correlation Chart** > **Main**.

Figure 4.46 Correlation Chart: Main Tab



2 Select the index range in **Index**.

3 Select the respective test name in **X Axis Test Name** and **Y Axis Test Name**.

4 Select **Search all samples** or **Search the designated sample**.

— If you select **Search all samples**, and you search the result with a specific sample ID, enter the sample ID in **Search by Sample ID**.
— If you select **Search the designated sample**, set the search conditions in the tab.

1. Select the sample kind to search in **Sample Kind**.
2. Enter a specific sample number or sample ID to search as required.

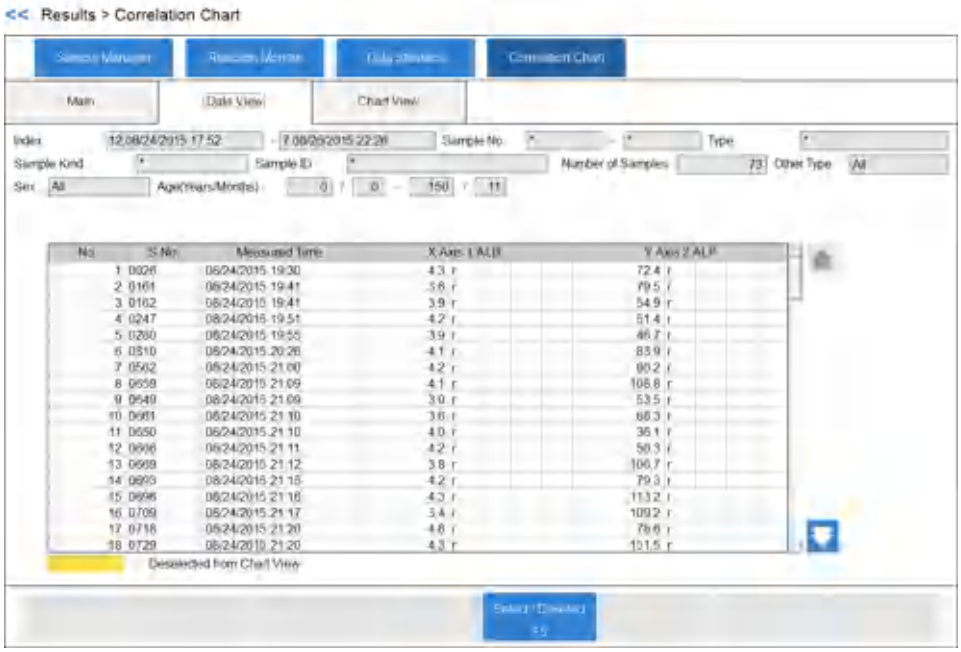
   The Search by Sample No. and Search by Sample ID fields default to search all (indicated by the *) sample numbers and ID numbers.
3. Select the sample type to search in **Type**.

5 To use patient demographic information to search the data, select **Search by Patient Info.** [F5].

Enter information and then select **OK**.

6 To exclude data from the correlation chart, select **Data View**.

Figure 4.47 Correlation Chart: Data View Tab



View data corresponding to 10,000 samples using the up or down scroll button.

---

7 Select the item to exclude.

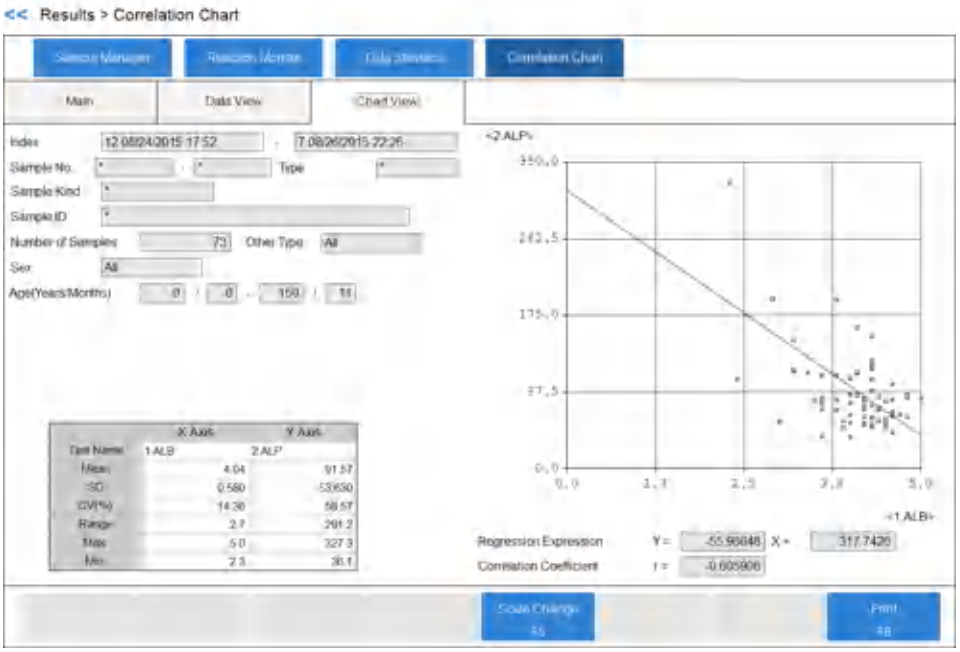
---

8 Select **Select/Clear** [F5].
The color of the item row changes, and the system deletes the item from the Chart View tab. If you select **Select/Clear** [F5] again, the system restores the item. The background color of the excluded sample changes to pink.

---

9 Select **Chart View** to display the correlation chart.

Figure 4.48 Correlation Chart: Chart View Tab



10 To change the display size of the correlation chart, select **Scale Change** [F5].

Figure 4.49 Scale Change Dialog

a. Select **Auto** for the correlation chart to display the maximum range of all the data.

b. Enter the lower limits and upper limits in **X Axis** and **Y Axis**.

c. Select **Manual** to display the correlation chart with the defined limits.

11 To print the statistics and correlation chart, select **Print** [F8].
The Print Start dialog displays. Select **OK**.

Save or Load Parameters

The system can save or load parameters to a backup folder on the hard drive or external media. If you make programming changes, Beckman Coulter recommends saving parameters or following your laboratory procedure.

If you have multiple DxC 700 AUs in the laboratory, Beckman Coulter recommends saving the parameter files for each DxC 700 AU on separate external media.

1 Select **MAINT.** > **File Management**.

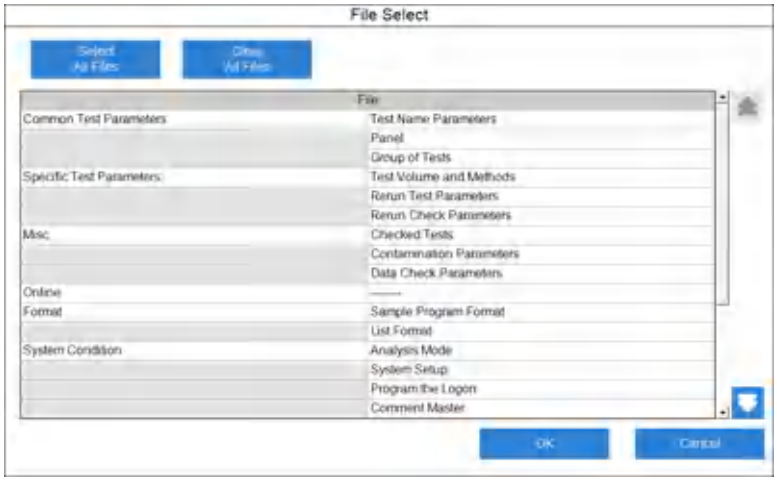
Figure 4.50 File Management Screen

2 In **Operation**, select **Save Files to HD**, **Load Files from HD**, **Save Files to External Media**, or **Load Files from External Media**.

When you save files to HD, you save them to a backup folder on the hard drive.

3 Select **File Select** [F6].
The system displays the File Select dialog.

Figure 4.51 File Select Dialog



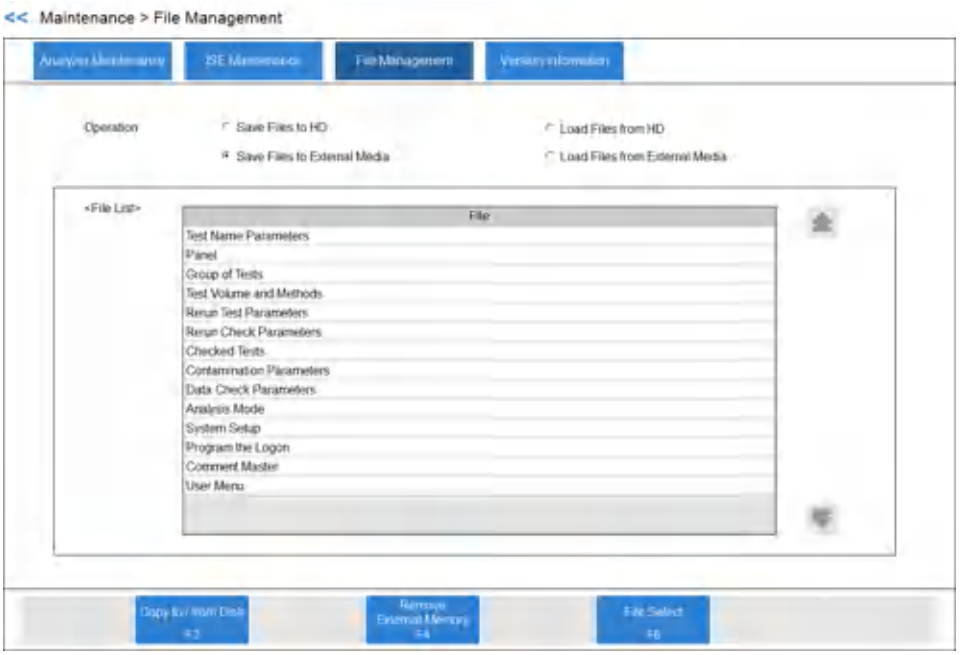
4 Select the files to save or load. Select a menu in the left column to include all the submenus, or select individual submenus in the right column.

5 Select **Select All Files** to select all files. Select **Clear All Files** to clear the selection of all files.

6 Select **OK**.

The system displays the selected files.

Figure 4.52 File Management Screen



7 Select **Copy to/from Disk** [F2].

a. If saving or loading using external media, select **CD-R** or **External Memory Device**, and then select **OK**.

Figure 4.53 Copy to/from Disk Dialog

b. If saving or loading using HD, select **OK**.

Figure 4.54 Copy to/from Disk Dialog

Caution

If you save parameters to a hard drive or external memory device, the system overwrites the existing parameters without warning.

The Copy to Disk dialog or Copy to/from Disk dialog displays when the operation completes.

Figure 4.55 Copy to Disk Dialog

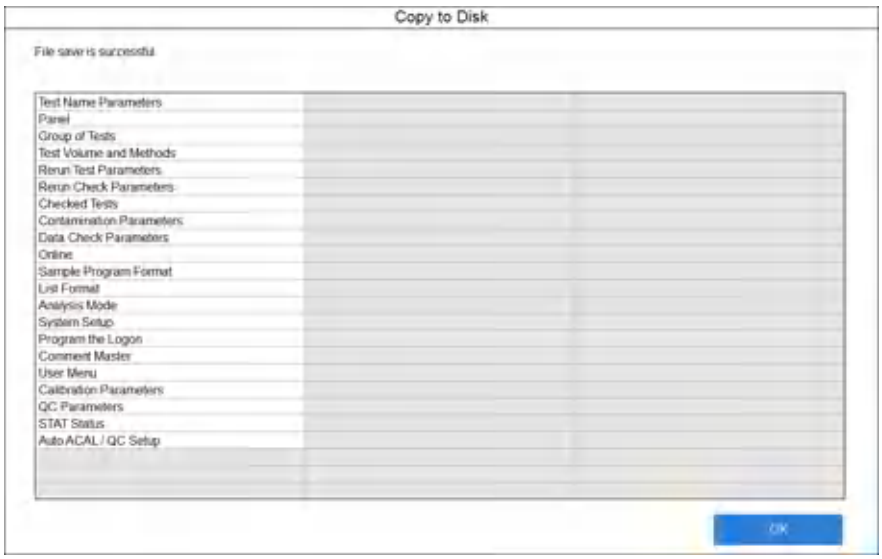
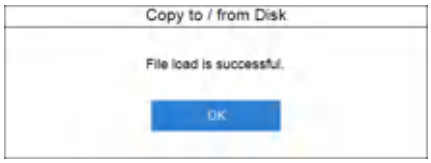


Figure 4.56 Copy to/from Disk Dialog



8 Select **OK**.
You can remove the external media.

APPENDIX A

Specifications

Sample Bar Code Label Specifications

Use a bar code label for the sample ID for analysis. The following sections define the bar code label specifications used for identifying samples on the DxC 700 AU.

Bar Code Types

Sample bar codes include the following types:

- NW-7
- CODE 39
- CODE 128, ISBT-CODE 128
- INT (Interleaved 2 of 5)
- Standard 2 of 5

The system can read multiple bar code types when using a mixture of NW-7, CODE 39, CODE 128, INT (interleaved 2 of 5), or Standard 2 of 5. The specifications of individual bar codes comply with the following standards.

Table A.1 Compatible Standard

Bar Code	Compatible Standard
NW-7	JIS-X-0506, USS-NW7
CODE 39	JIS-X-0503, USS-CODE 39
CODE 128	JIS-X-0504, USS-CODE 128
ISBT-CODE 128	ISBT 128
INT (Interleaved 2 of 5)	JIS-X-0502, USS-I2/5

Table A.2 Character Font

Bar Code	Character Font
NW-7	0 to 9
CODE 39	Alphanumerics, special characters
CODE 128	Alphanumerics, special characters
ISBT-CODE 128	Alphanumerics, special characters
INT (Interleaved 2 of 5)	0 to 9
Standard 2 of 5	0 to 9

Bar Code Digit Numbers

Bar codes can contain a maximum of 26 digits.

Note

Refer to the Laboratory Automation System manual for bar code types available when the DxC 700 AU is connected to a Laboratory Automation System.

The bar code digit specification is 0 to 17 digits when the DxC 700 AU is connected to a Laboratory Automation System.

Bar Code Label Size

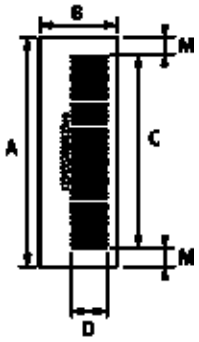
The size of sample bar code labels must follow the following specifications. (The units are in millimeters.)

- Label length (A) < Sample tube length -12
- Label width (B) = a minimum of D+10, and not so wide that the label interferes with the bar code area.

  In other words, B is equal to or less than the tube circumference. If the label is wider than the tube circumference, it wraps around the tube and might overlap the bar code.
- Bar code height (D) ≥10
- Top and bottom margin (M)
  - — CODE 128: 10 times X or 2.54, whichever is larger

    (X: minimum width of a module)
  - — Other than CODE 128: 3 or more
- Bar code area (C) = A - 2 x M

Figure A.1 Sample Bar Code Label Specifications



- A: Label length
- B: Label width
- C: Bar code area
- D: Bar code height
- M: Top and bottom margin (quiet zone)

Bar and Space Widths

Bars and spaces must have the following widths:

Table A.3 Bar and Space Widths

	NB (narrow bar)	NS (narrow space)	WB (wide bar)	WS (wide space)	G (gap)	X[1]
Minimum	0.165 to 0.2 mm	NB to 1.25 NB	2.2 NB to 3.0 NB	2.2 NB to 3.0 NB	NB to 3.0 NB	0.191 or more
Maximum	0.2 to 0.5 mm		2.0 NB to 3.0 NB	2.0 NB to 3.0 NB	NB to 3.0 NB	

1. Minimum width of a module for CODE 128

Bar Code Check Methods

To configure the mode for bar code checking, select the mode in **Check Mode** in the Analysis Mode screen (**CONFIG.** > **Analysis Mode**). Refer to Analysis Mode Screen.

Available bar code check methods:

1. **Yes**: Reads the bar code with a check character, and performs the check with a method listed in Table A.4 Check Method.

   The system does not output the check character.
2. **No (With Chk. Chr.)**: Reads the bar code with a check character, but does not perform the check.

   The system does not output the check character.
3. **No (No Chk. Chr.)**: Reads the bar code without a check character, and does not perform the check.

CODE 128 and ISBT-CODE 128 require a check character. You cannot select these codes with the above methods 2 and 3.

Table A.4 Check Method

Bar Code	Check Character Position and Method
NW-7	Least significant digit, MODULUS-16
CODE 39	Least significant digit, MODULUS-43
CODE 128, ISBT-CODE 128	Least significant digit, MODULUS-103
INT (Interleaved 2 of 5) and Standard 2 of 5	Least significant digit, MODULUS-10

The check method is fixed for each bar code type. You cannot select the check method.

Requirements for Printing Bar Code Labels

To maintain readout accuracy, print bar code labels according to the following requirements.

- PCS value

If the NB (narrow bar) width is between 0.165 and 0.50 mm the PCS value must be 0.60 or more.

If the NB (narrow bar) width is between 0.130 and 0.156 mm the PCS value must be 0.85 or more.

Figure A.2

$$\text{PCS Value} = \frac{R_L - R_D}{R_L}$$

R_L : white bar and margin reflection rate
R_D : black bar reflection rate

- CODE 128: The MRD must be 37.5% or more.
- A void on a white bar (damage or print loss on a bar), ink spot (ink stain), or thin spot must satisfy the following restrictions:

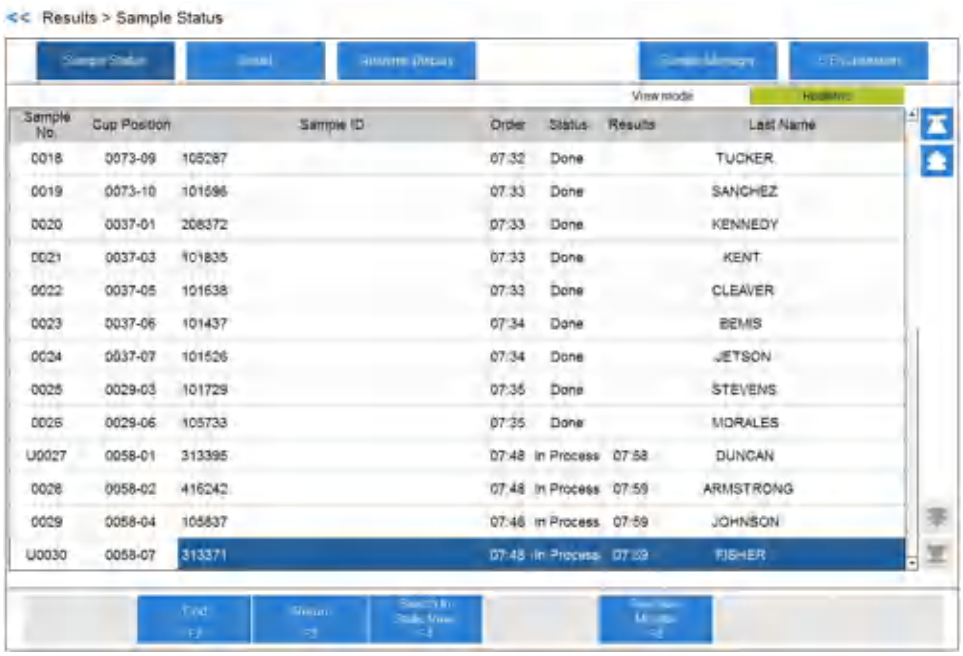
  — The spot diameter is 0.05 mm or less.
  — The void is 25% or less in a circular area with a diameter of 0.1 mm.
  — No marked blurring.

APPENDIX B

Additional Software Screens

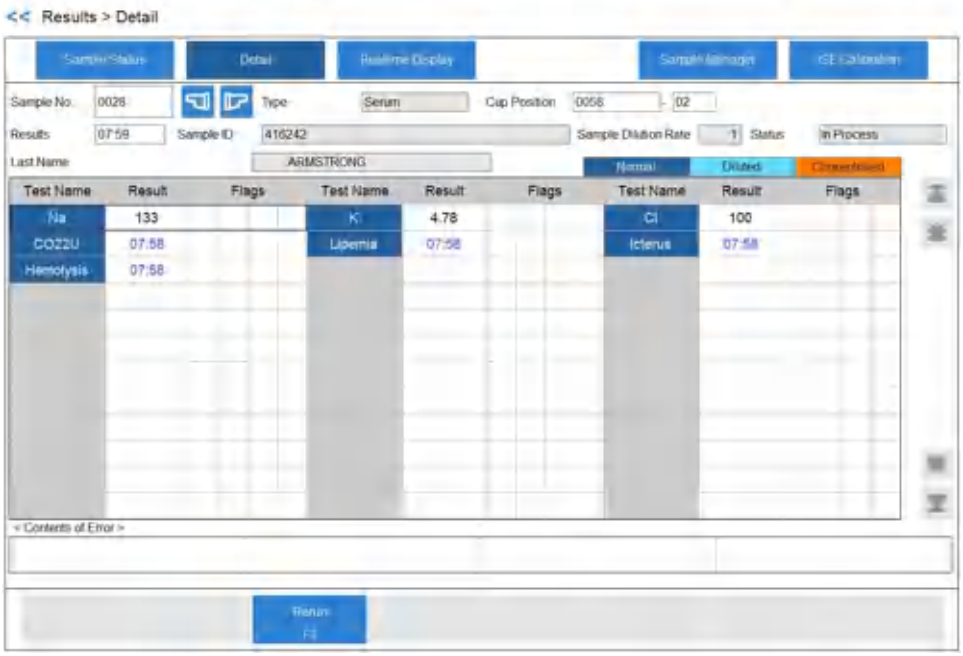
Sample Status Screen

Figure B.1 Test Results: Sample Status Screen



Detail Screen

Figure B.2 Test Results: Detail Screen

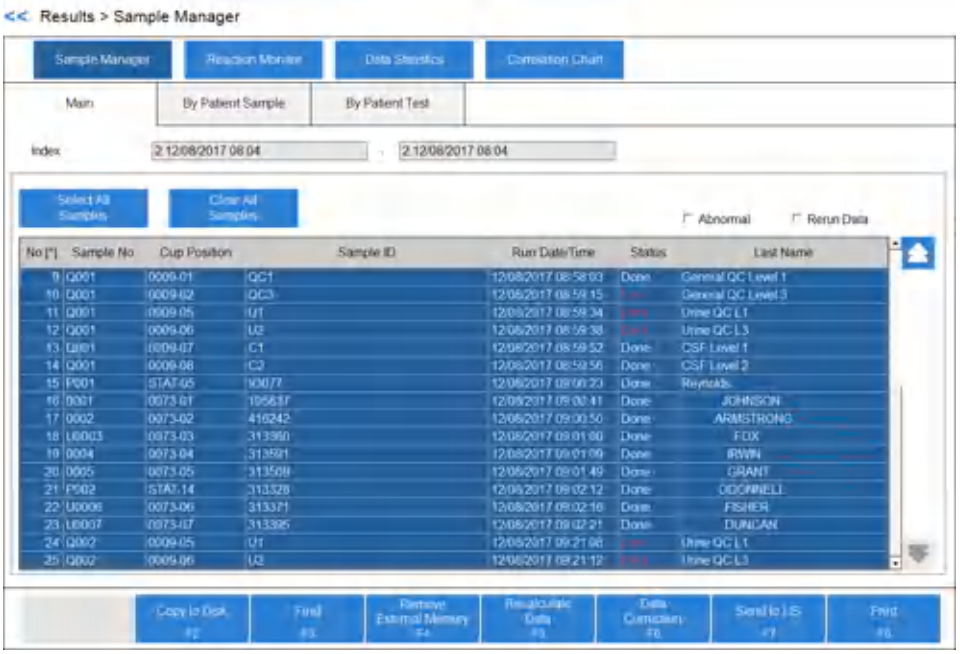


Realtime Display Screen

Figure B.3 Realtime Display: All Tab

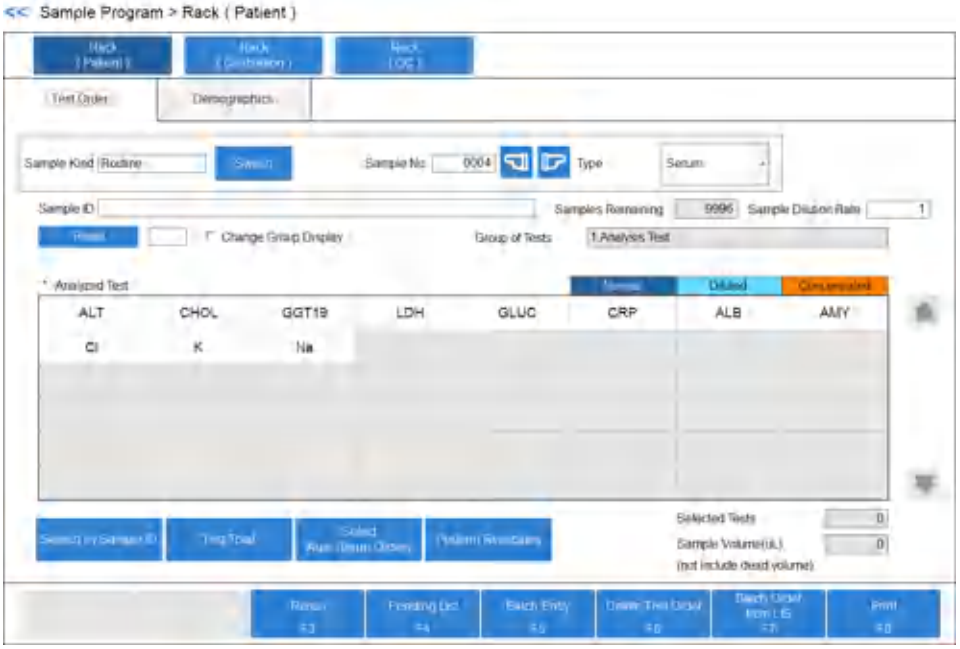
Sample Manager Screen

Figure B.4 Sample Manager: Main Tab



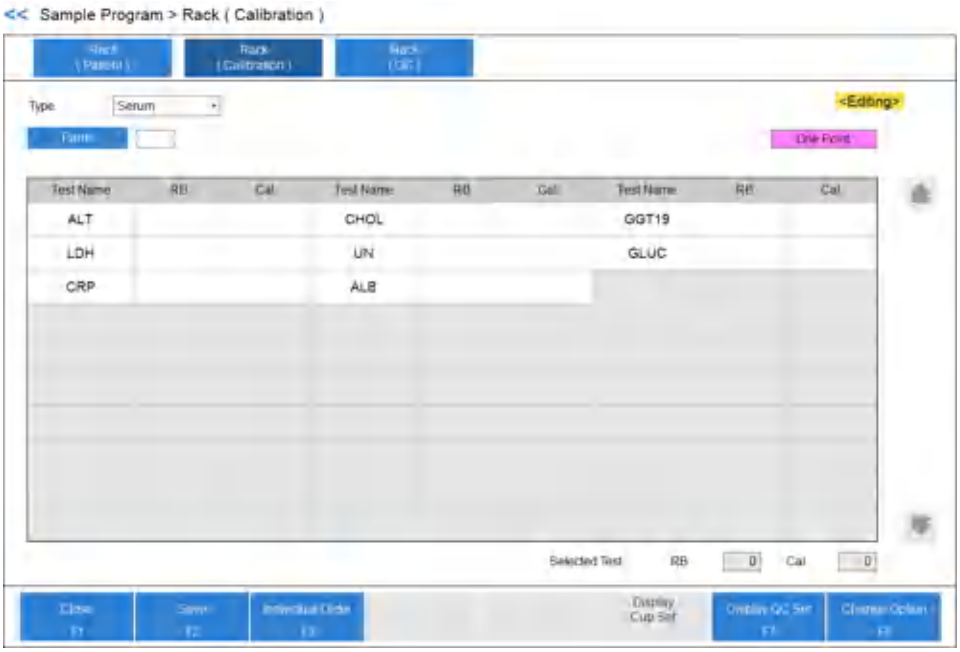
Rack (Patient) Screen

Figure B.5 Rack (Patient): Test Order Tab



Rack (Calibration) Screen

Figure B.6 Sample Program: Rack (Calibration) Screen

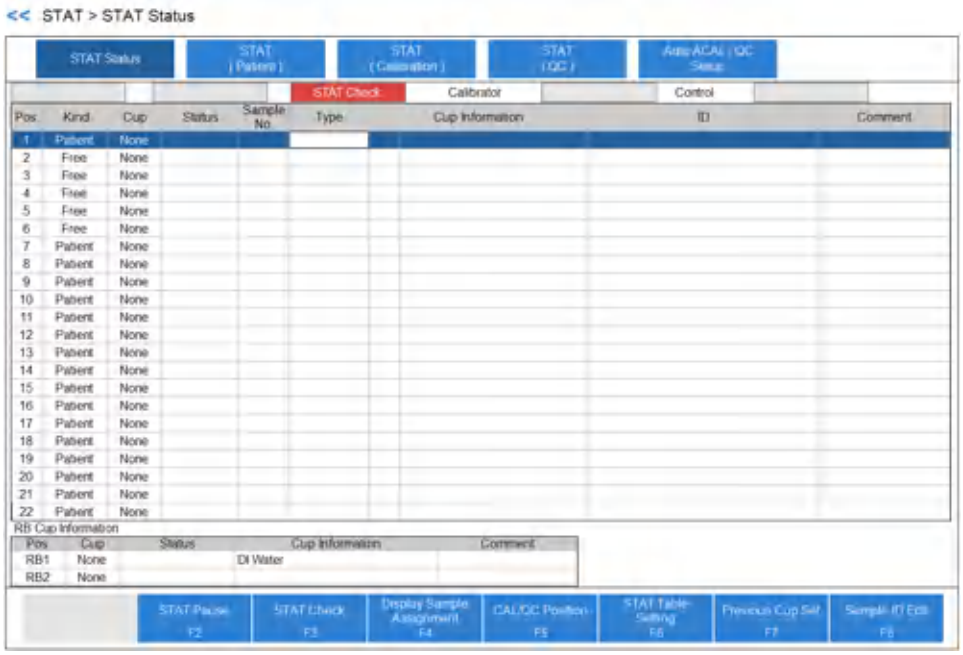


Rack (QC) Screen

Figure B.7 Sample Program: Rack (QC) Screen

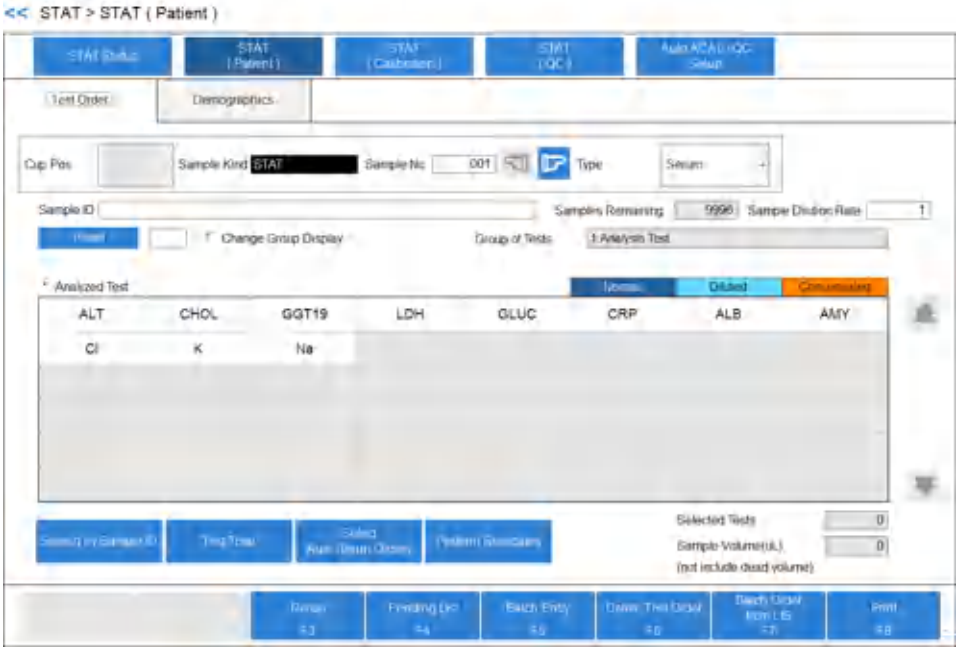
STAT Status Screen

Figure B.8 STAT Status Screen



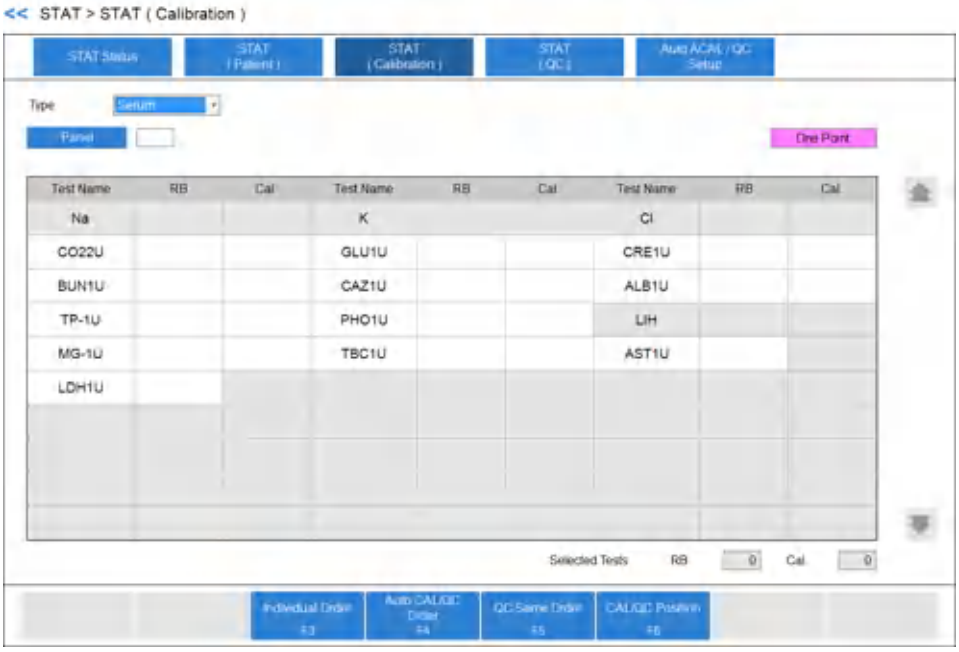
STAT (Patient) Screen

Figure B.9 STAT (Patient): Test Order Tab



STAT (Calibration) Screen

Figure B.10 STAT (Calibration) Screen

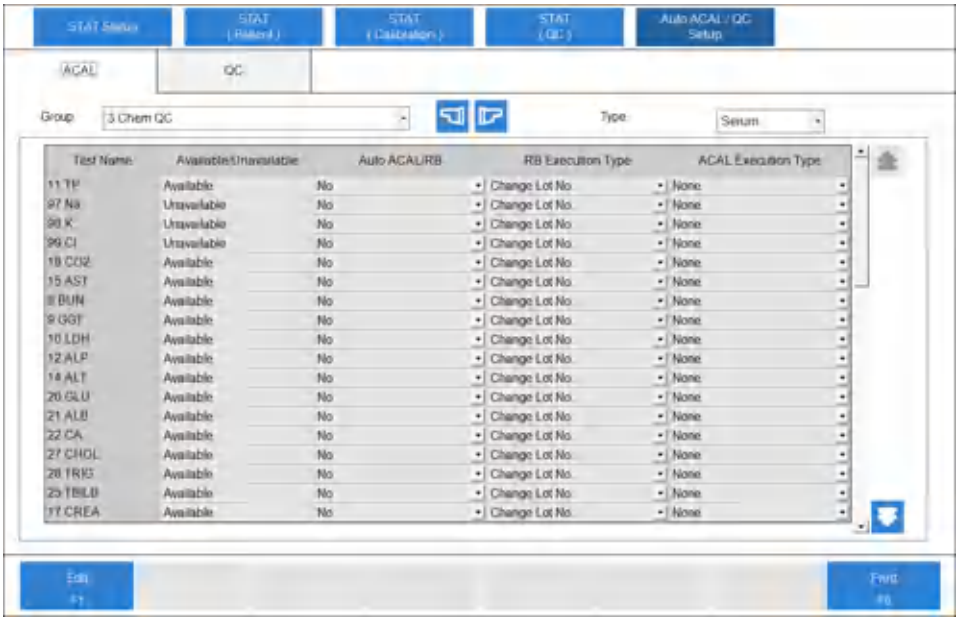


STAT (QC) Screen

Figure B.11 STAT (QC) Screen

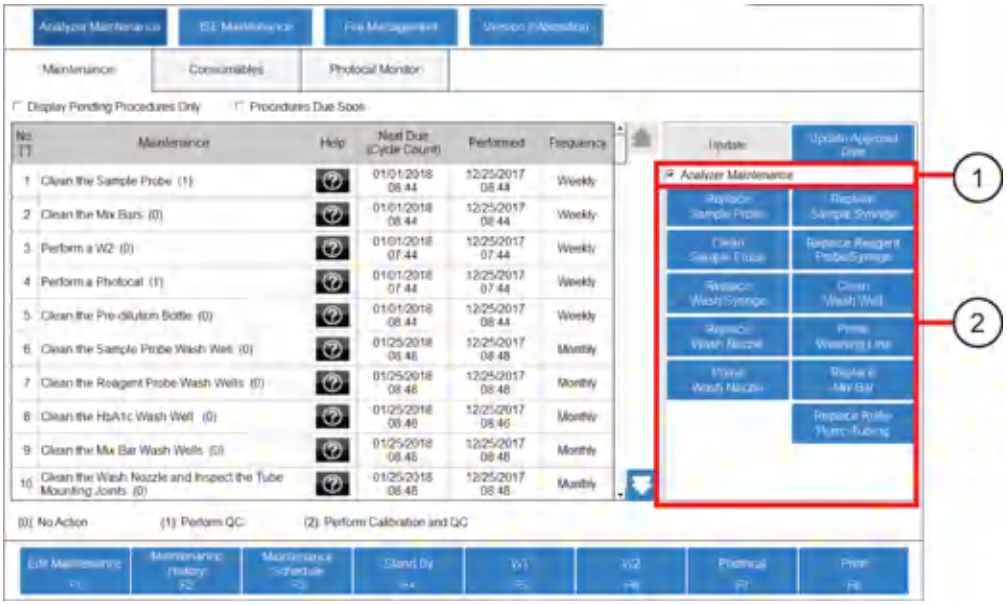
AUTO ACAL/QC Setup Screen

Figure B.12 AUTO ACAL/QC Setup Screen



Analyzer Maintenance Screen

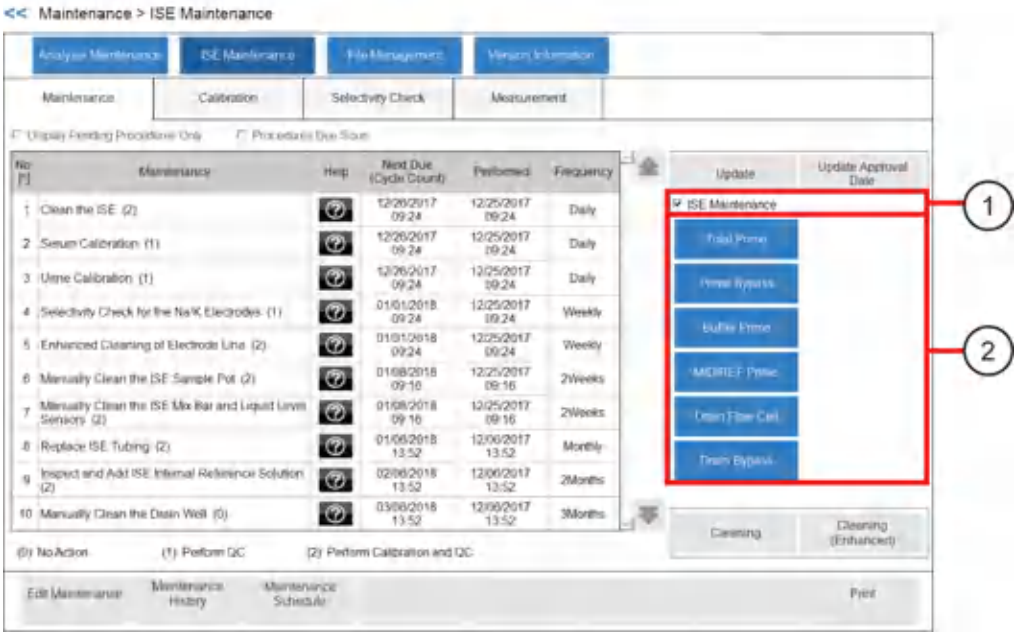
Figure B.13 Analyzer Maintenance Operation Buttons



1. Analyzer Maintenance box
2. Maintenance operation buttons

ISE Maintenance Screen

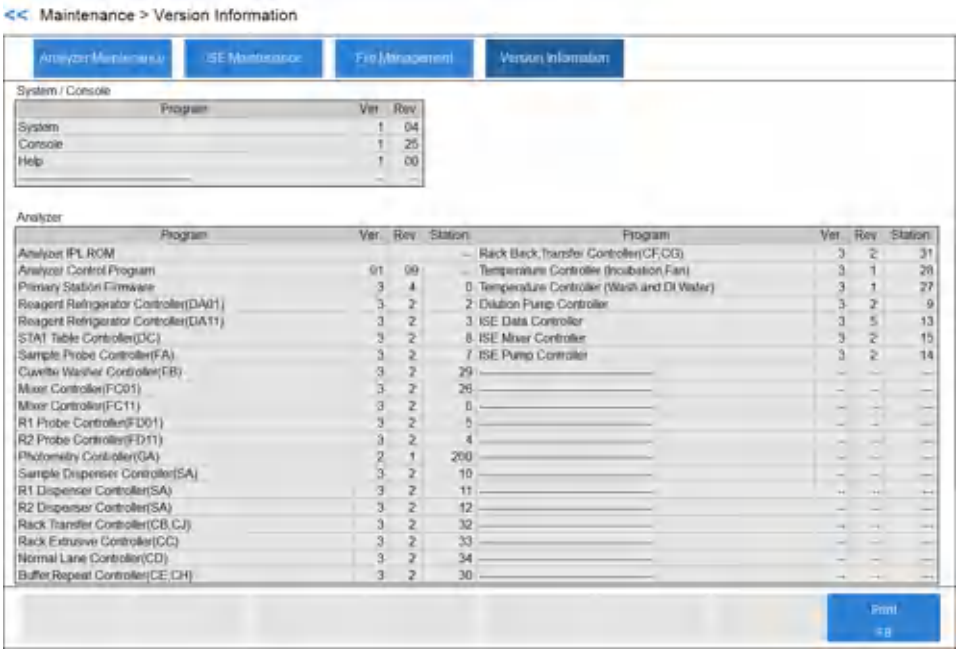
Figure B.14 ISE Maintenance Operation Buttons



1. ISE Maintenance box
2. Maintenance operation buttons

Version Information Screen

Figure B.15 Version Information Screen



Calibrate the ISE Screen

Figure B.16 ISE Maintenance: Calibration Tab

User Menu Screen

Figure B.17 User Menu Screen

Additional Software Screens

User Menu Screen

APPENDIX C

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