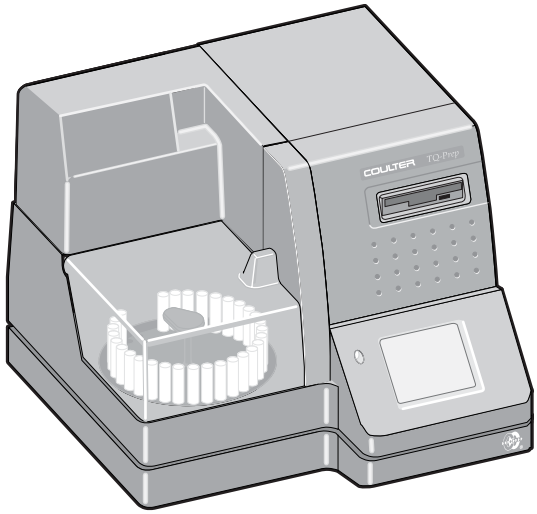
COULTER® TQ-Prep™ Workstation

Reference



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PN 4237395AA (June 2010)

Beckman Coulter, Inc.
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Brea, CA 92821

BECKMAN COULTER

WARNINGS AND PRECAUTIONS

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT. DO NOT ATTEMPT TO PERFORM ANY PROCEDURE BEFORE CAREFULLY READING ALL INSTRUCTIONS. ALWAYS FOLLOW PRODUCT LABELING AND MANUFACTURER'S RECOMMENDATIONS. IF IN DOUBT AS TO HOW TO PROCEED IN ANY SITUATION, CONTACT YOUR BECKMAN COULTER REPRESENTATIVE.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING - Can cause injury.
CAUTION - Can cause damage to the instrument.
IMPORTANT - Can cause misleading results.

BECKMAN COULTER, INC. URGES ITS CUSTOMERS TO COMPLY WITH ALL NATIONAL HEALTH AND SAFETY STANDARDS SUCH AS THE USE OF BARRIER PROTECTION. THIS MAY INCLUDE, BUT IT IS NOT LIMITED TO, PROTECTIVE EYEWEAR, GLOVES, AND SUITABLE LABORATORY ATTIRE WHEN OPERATING OR MAINTAINING THIS OR ANY OTHER AUTOMATED LABORATORY ANALYZER.

WARNING Risk of operator injury if:

- All doors, covers and panels are not closed and secured in place prior to and during instrument operation.
- The integrity of safety interlocks and sensors is compromised.
- Instrument alarms and error messages are not acknowledged and acted upon.
- You contact moving parts.
- You mishandle broken parts.
- Doors, covers and panels are not opened, closed, removed and/or replaced with care.
- Improper tools are used for troubleshooting.

To avoid injury:

- Keep doors, covers and panels closed and secured in place while the instrument is in use.
- Take full advantage of the safety features of the instrument. Do not defeat safety interlocks and sensors.
- Acknowledge and act upon instrument alarms and error messages.
- Keep away from moving parts.
- Report any broken parts to your Beckman Coulter Representative.
- Open/remove and close/replace doors, covers and panels with care.
- Use the proper tools when troubleshooting.

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

REVISION STATUS

Issue A, 8/97

Software Version 1.1.

Issue AA, 06/10
Software Version 1.1.

Updates were made to the company corporate address.

Note: Changes that are part of the most recent revision are indicated in text by a bar in the margin of the amended page.

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 to the Beckman Coulter website. For labeling updates, go to www.beckmancoulter.com and download the most recent manual or system help for your instrument.

REVISION STATUS

CONTENTS

This introductory section contains the following topics:

- How to use your COULTER® TQ-Prep™ Workstation manuals
- About the Reference manual
- Conventions

HOW TO USE YOUR COULTER TQ-PREP WORKSTATION MANUALS

Use the Reference manual for in-depth information about:

- What the instrument does
- The methods it uses
- Its specifications
- Information about installation.

A Master Index is included at the back of the Reference manual, which lists entries from the entire documentation set.

Use the Operator's Guide for the day-to-day running of your instrument:

- To run a gravimetric validation test
- To clean, to replace or adjust a component
- To troubleshoot the instrument.

Read the Controls and Indicators chapter to become familiar with the different parts of your system. Then go through the detailed step-by-step procedures of daily startup, processing samples and shutdown. The calibration chapter contains the gravimetric validation and precision tests. The remaining chapters contain the cleaning, replacement and adjustment procedures and troubleshooting tables. A Master Index is included at the back, which lists entries from the entire documentation set.

Use the Operating Summary after you are trained and familiar with using the system. It contains:

- A brief summary of the daily startup, sample processing and shutdown procedures
- Descriptions of the touch screen symbols.

See the Documentation page on the back cover of this manual for the contents of each manual. It can help you to determine which manual contains the information that you need.

ABOUT THE REFERENCE MANUAL

Your TQ-Prep Workstation Reference manual is a source of information on what the system does.

This information is organized as follows:

- Chapter 1, Use and Function

  Contains the intended use of the instrument, a brief history of the methods used, the reagents used and a short description of the major components and options.
- Chapter 2, Installation

  Contains the instrument requirements and instructions on how to install the instrument.
- Chapter 3, Operation Principles

  Contains the description of the normal sample flow on the instrument.
- Chapter 4, Specifications/Characteristics

  Details the instrument and performance specifications and the performance characteristics.
- Appendices

  The appendices provide reference material on the following topics:
  - Log Sheets
  - Operator Certification.
- References

  References used throughout the manuals.
- Glossary

  Definitions of words, abbreviations and acronyms used throughout the manuals.
- Index

  This is a Master Index that contains entries from all manuals in the documentation set.

CONVENTIONS

- All figures showing reagent containers on the software screens or in the instrument include the OPTION reagent.
- Within text and instructions, buttons and icons appear as they do on the touch screen:
  - Button - example: 
  - Troubleshooting icon - example: 

1.1 INTENDED USE

The COULTER TQ-Prep Workstation, Figure 1.1, is a general purpose laboratory instrument used with the COULTER ImmunoPrep Reagent System to prepare leukocytes from whole blood for quantitative immunofluorescence measurements on optical flow cytometers. The system is intended For In Vitro Diagnostic Use.

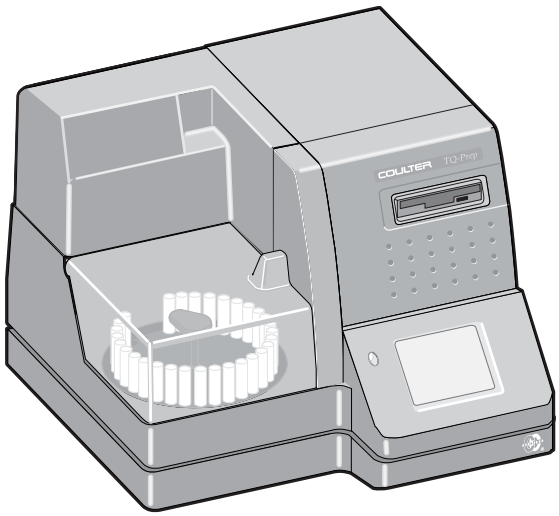


Figure 1.1 COULTER TQ-Prep Workstation

1.2 METHOD HISTORY

The ability to classify human white cells based on their expression of cell surface antigens has provided investigators with valuable diagnostic and prognostic information.[1, 2]

Historical methods of isolating leukocytes for immunofluorescence include whole-blood lysing techniques and density gradient separation techniques.[3]

Such commercially available procedures require washing the sample to remove unbound antibody and debris. The repeated trauma of mixing, vortexing and centrifugation can selectively damage malignant or "activated" cells. In addition, nonrandom cell loss can occur by adherence to containers or failure to form a complete pellet during centrifugation.[4] Most procedures are labor intensive, require exacting technique and become unmanageable when processing large numbers of samples.

In 1987, the COULTER ImmunoPrep™ Reagent System and Q-Prep™ Workstation were introduced for rapid, automated, whole-blood preparation for immunophenotyping and are widely used in a variety of flow cytometry laboratories today.[5, 6] Then in 1992, the COULTER ImmunoPrep Reagent System and Multi-Q-Prep™ Workstation were introduced, extending the Q-Prep system automated preparation of whole blood from one sample at a time to up to 32 samples per batch.

The TQ-Prep Workstation automatically prepares 32 sample batches, like the Multi-Q-Prep Workstation, but is designed for laboratories with high-workload requirements.

1.3 SYSTEM COMPONENTS

The system has three main work areas:

- Sample processing area
- Reagent storage and dispense area
- Touch screen.

Sample Processing Area

See Figure 1.2. The sample processing area consists of a 32-tube capacity removable carousel, an indexing base, dispensing head with tube detector, sensing and sequencing devices, a tube lifter/vortex mixer, a reagent delivery system and electronics. The lid to the sample processing area has a safety interlock switch so sample processing can only occur with the lid closed.

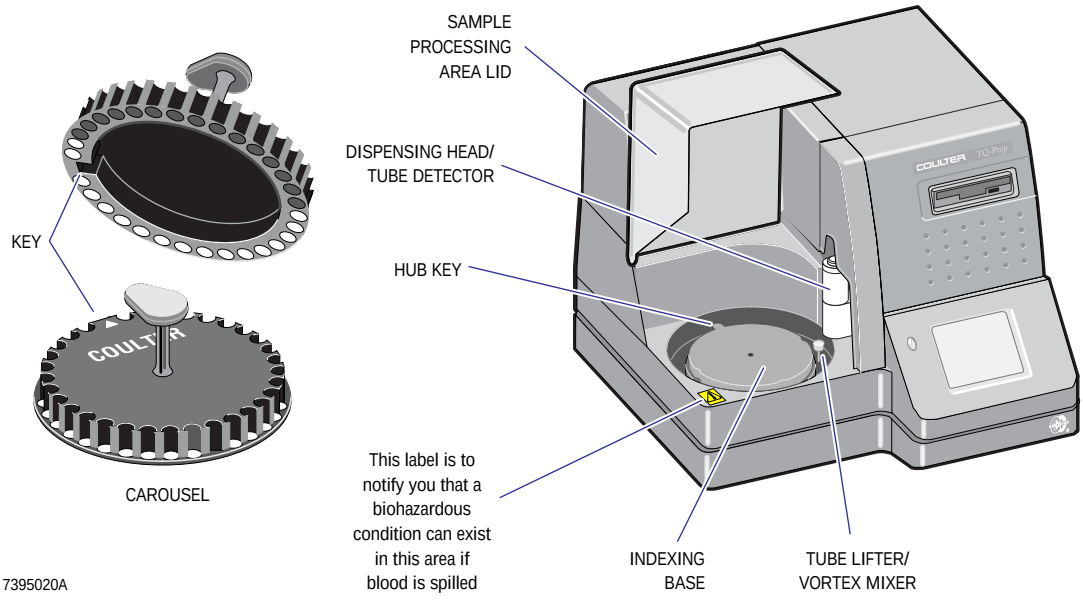


Figure 1.2 Sample Processing Area

Carousel

Two sample carousels, each with a handle and 32-test tube slots, are provided with each unit. The key located on the carousel aligns with the hub key on the indexing base to correctly position the carousel for sample processing.

Indexing Base

The indexing base moves the carousel to its home position and moves the carousel during sequential sample processing.

Dispensing Head

The retractable dispensing head adds a precise amount of multiple reagents to the sample.

Tube Detector

The tube detector is an optical flag switch located within the dispensing head that senses the presence of a test tube in a carousel at the reagent dispense position.

Tube Lifter/Vortex Mixer

The tube lifter/vortex mixer uniformly first lifts the tube up into the dispensing head, then mixes reagents in the sample.

Reagent Delivery System

Three (or four if you have the LALS OPTION) syringes dispense reagents to the dispensing head via Teflon® tubing.

Electronics

The system microprocessor (386) assembly controls the touch screen, disk drive, power indicator, beeping device, and an internal communication link to the Control Interface card.

A microcontroller, located on the Control Interface card, controls the motors, sensors, syringes, the cover/lid interlock switches, reagent level sense probes and an internal communication link to the system microprocessor assembly.

A universal input power module supplies all the necessary dc voltages to the system components.

Reagent Storage and Dispense Area

The reagent storage and dispense area is covered and located behind the sample processing area. See Figure 1.3. It contains:

- Storage tray for Reagent A, Reagent B, Reagent C, OPTION reagent (optional) and WASTE containers.
- Cap assemblies.
  - The three (or four) reagent cap assemblies are attached by tubing to their corresponding syringes.
  - The WASTE cap assembly is attached by tubing directly to the dispensing head.
  - The Reagent A, B, and C, and the WASTE cap assemblies have liquid level sensors.
- Three dispensing syringes (or four if you have the LALS OPTION).

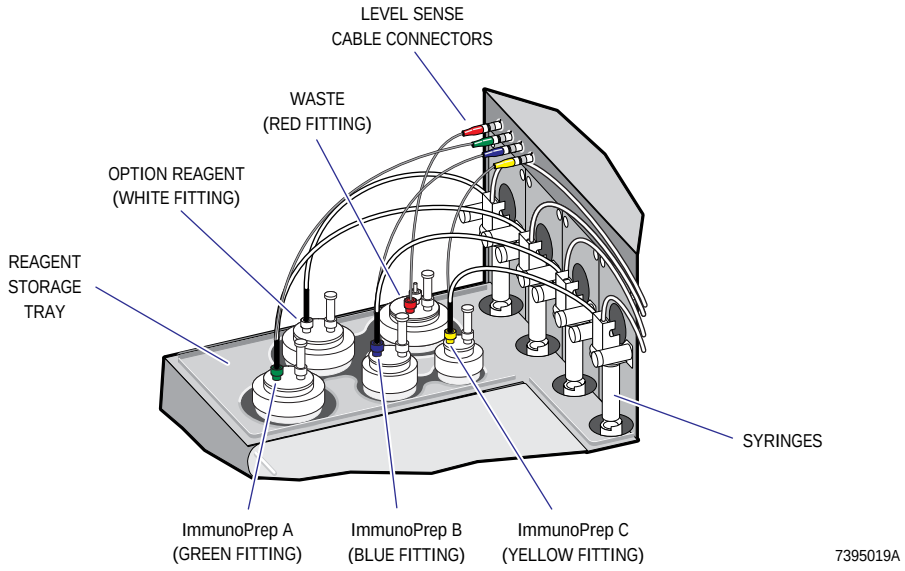


Figure 1.3 Reagent Storage Area with OPTION Reagent

Touch Screen

The touch screen is the user interface on the instrument. You press a displayed button on the touch screen to request a function.

1.4 OPTIONS

LALS OPTION

This option is for use on flow cytometers that measure a low angle of forward scatter (FALS) light. The LALS OPTION includes a dispensing syringe, tubing and an OPTION reagent container.

1.5 REAGENTS

Coulter recommends the use of the following reagents or their equivalents. The TQ-Prep Workstation is designed for use with the ImmunoPrep Reagent System. All stated performance characteristics in this manual are based on the use of the TQ-Prep Workstation with these reagents. Refer to the reagents' package insert for detailed information before using the reagents.

Reagent A

ImmunoPrep A, a lysing reagent, causes simultaneous rapid destruction of the erythrocytes while leaving the leukocytes intact.

Reagent B

ImmunoPrep B, a stabilizing reagent, stops the action of the lysing reagent (ImmunoPrep A).

Reagent C

ImmunoPrep C, a fixing reagent, fixes the cell membranes. This preserves the form and structure of the leukocytes.

OPTION Reagent

Use distilled or deionized water as the OPTION reagent if your system has the LALS OPTION. This reagent is for use on flow cytometers to allow the measurement of a low angle of forward scatter light.

1.6 MATERIAL SAFETY DATA SHEETS (MSDS)

To obtain an MSDS for Coulter reagents used on the TQ-Prep Workstation:

1. In the USA, either call Coulter Customer Operations (800-526-7694) or write to:

   Coulter Corporation
   Attn: MSDS Requests
   P.O. Box 169015
   Miami, FL 33116-9015

2. Outside the USA, contact your local Coulter Representative.

Your Coulter Representative will install the system; however, in some cases, you will be instructed to install your system.

2.1 SPECIAL REQUIREMENTS

The system is intended for installation and operation in a conventional clinical laboratory setting. Determine the system location before installation of the system. Consider the following special requirements.

Space and Accessibility

In addition to the space required for the instrument, consider:

- Comfortable working height
- Access to the rear and left side of the instrument for maintenance and service. Allow
  - At least 15 cm (6 in.) of space behind instrument for air flow. Only 7.5 cm (3 in.) if the instrument is in a safety cabinet/laminar flow hood.
  - At least 15 cm (6 in.) above instrument to lift sample processing area lid.
  - Adequate space on the right side for access to power and screen contrast controls.
  - Adequate space on the left side to remove reagent cover and replace reagent containers. If your instrument is located in a safety cabinet/laminar flow hood, you can remove the reagent cover permanently.

Electrical Input

CAUTION Do not use an extension cord. Overheating, melting and burning of the extension cord can occur if you use an extension cord. Plug the power cord directly into an electrical outlet. Position the instrument close enough to an electrical outlet so you do not need to use an extension cord.

This system requires:

- An independent, protected circuit.
- A ground path capable of carrying the full current of the circuit (confirmed third-wire, earth ground).
- A transient-protected outlet.

Ambient Temperature and Humidity

Operate the system in a room with a temperature of 10 to 35°C (50 to 95°F) and relative humidity of 30 to 85%, without condensation.

Ventilation

Position instrument ventilation fans at least 15 cm (6 in.) away from walls or obstructions that could interfere with air flow. If in a safety cabinet/laminar flow hood, position instrument ventilation fans 7.5 cm (3 in.) away from the back wall.

2.2 COULTER REPRESENTATIVE

Delivery Inspection

CAUTION Possible instrument damage could occur if you improperly uncrate the instrument, install it or set it up. If you have not been directed to install the instrument, keep the instrument in its packaging until your Coulter Representative uncrates it for installation and set up.

Your instrument is tested before it is shipped from the factory. International symbols and special handling instructions printed on the cartons tell the carrier how to handle this electronic instrument.

Carefully inspect all cartons when they arrive. If you see any sign of mishandling or damage, file a claim with the carrier immediately. If the instrument is insured separately, file a claim with the insurance company.

Operator Certification

After the system is installed, each operator should perform the Operator Certification procedure in Appendix B before running samples.

2.3 CUSTOMER INSTALLATION

Inspecting After Delivery

CAUTION Possible instrument damage could occur if you improperly uncrate the instrument, install it or set it up incorrectly. If you have been directed to install the instrument, follow the customer installation instructions exactly, to set up your instrument.

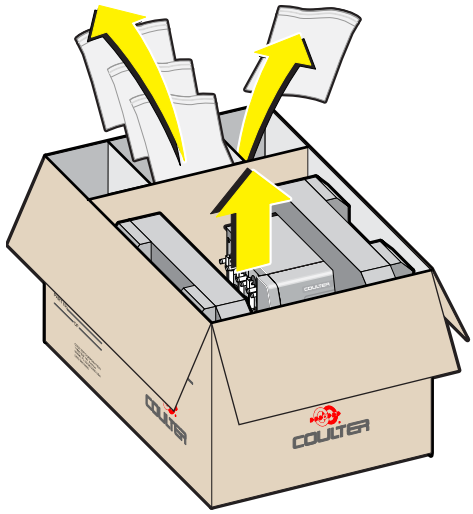
Your instrument is tested before it is shipped from the factory. International symbols and special handling instructions printed on the cartons tell the carrier how to handle this electronic instrument.

Carefully inspect all cartons when they arrive. If you see any sign of mishandling or damage, file a claim with the carrier immediately. If the instrument is insured separately, file a claim with the insurance company.

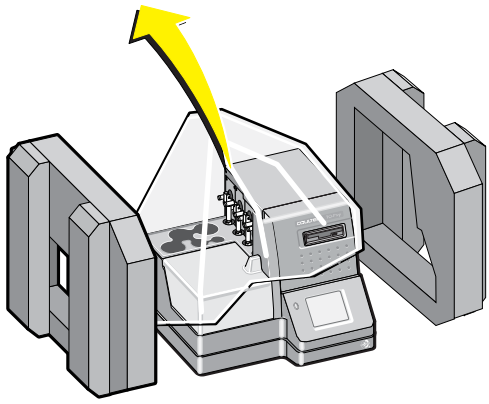
Unpacking and Checking Instrument

1 Open the carton and remove the instrument.

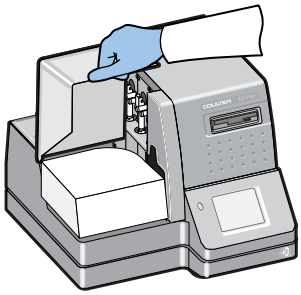
Note: It is easier if two people lift the instrument out of the carton.



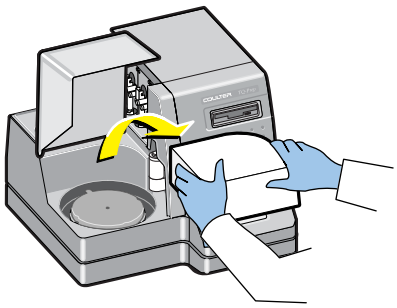
2 Remove the foam packing material, unwrap the plastic packing and set the instrument on a flat surface.



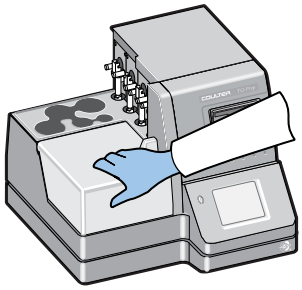
3 Lift the sample processing area lid.



4 Remove the foam packing material.

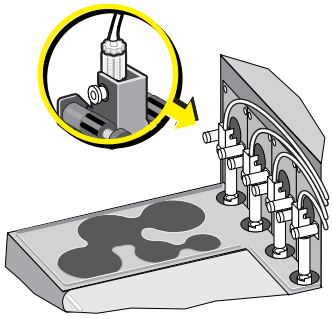


5 Close the sample processing area lid.



6 Check the fittings at the top of the syringes for visible damage.

The connections should be finger tight. See the Replacing the Syringe procedure in Chapter 7 in the Operator's Guide for more details.



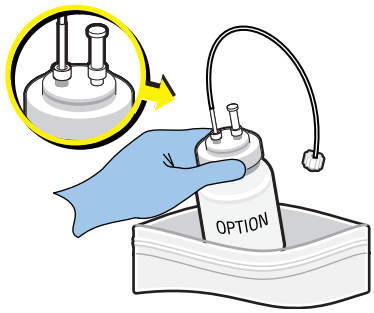
Connecting the OPTION Reagent Container

1

- If your instrument has the LALS OPTION, perform steps 1 through 6 to connect the OPTION reagent container.
- If your instrument does not have the LALS OPTION, proceed to Connecting Reagent A, B, and C Containers.

2

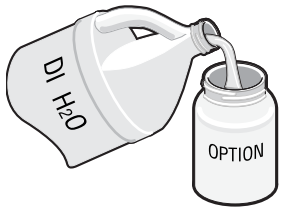
- Remove the empty OPTION reagent container and cap assembly from its packaging.
- Check the cap assembly fittings for visible damage.



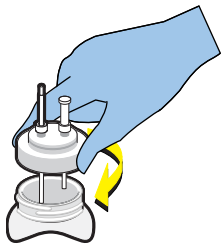
3

Unscrew the cap assembly from the empty OPTION reagent container.

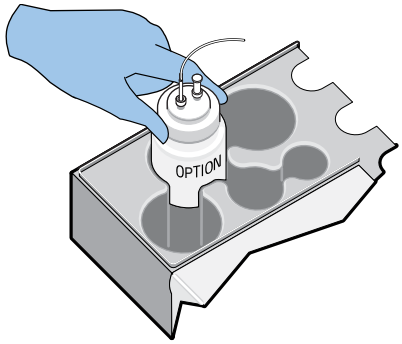
4 Fill the OPTION reagent container with distilled or deionized water.



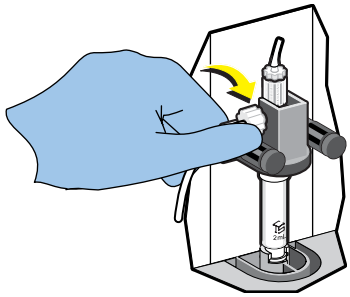
5 Screw the cap assembly with the white fitting onto the OPTION reagent container.



6 Place the OPTION reagent container in the instrument.



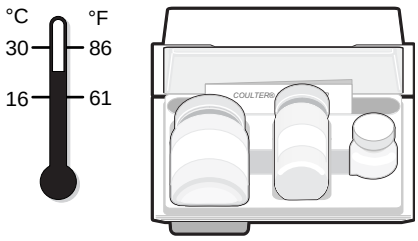
7 Screw the tubing connector from the OPTION reagent onto the side fitting of the OPTION syringe.



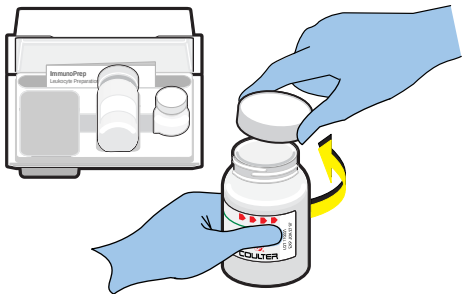
Connecting the Reagent A, B, and C Containers

1 Open a new ImmunoPrep Reagent System.

Note: Store and use the reagents at room temperature. Make sure the reagents are at room temperature before they are placed in the instrument.

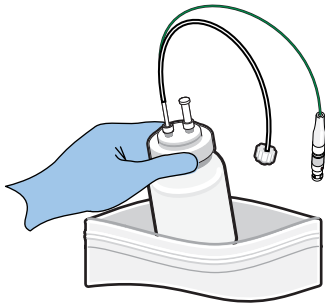


2 Remove the reagent cap from a reagent. Save the cap for later.



3 Remove the protective seal so that the cap assembly's level sensor probe and tubing fit easily through the container opening.

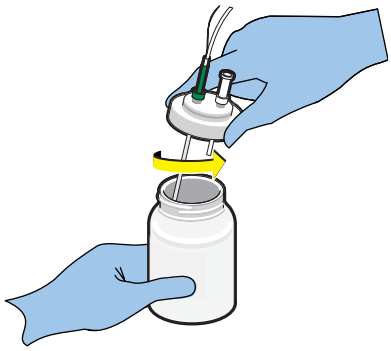
4 Remove the empty corresponding reagent container and cap assembly from its packaging.



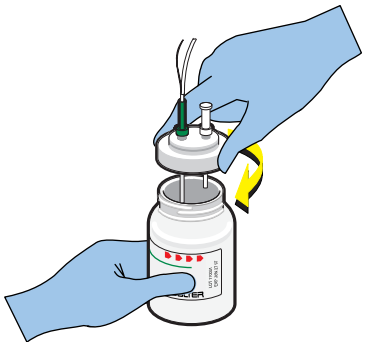
5 Unscrew the cap assembly from the empty reagent container. Save the empty container for step 11.

Note: The cap assembly fittings are color coded:

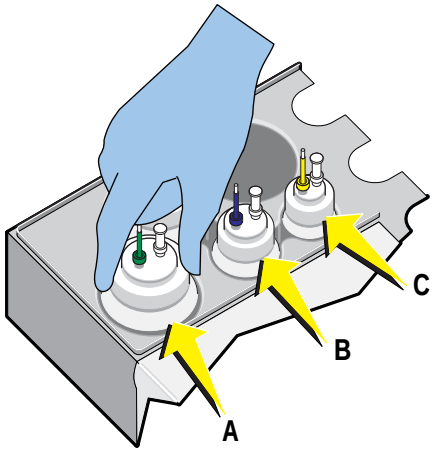
- Green - Reagent A
- Blue - Reagent B
- Yellow - Reagent C
- Red - WASTE
- White - OPTION Reagent.



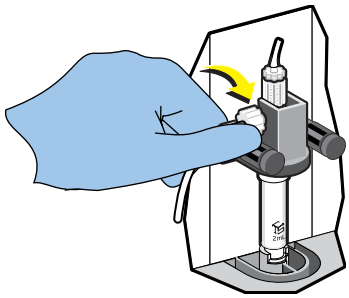
6 Screw the cap assembly onto the full reagent container.



7 Place the full reagent container in the instrument.



8 Screw the tubing connector from the reagent container onto the side fitting of the corresponding syringe.

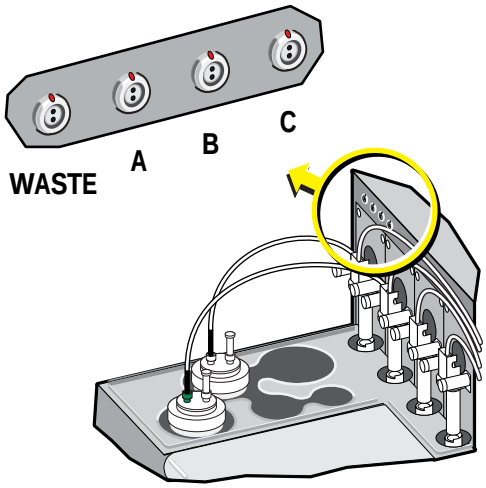


9

Locate the opening for the level sense connector.

Note: The level sense fittings are color coded to match the cap assemblies:

- Red - WASTE
- Green - Reagent A
- Blue - Reagent B
- Yellow - Reagent C

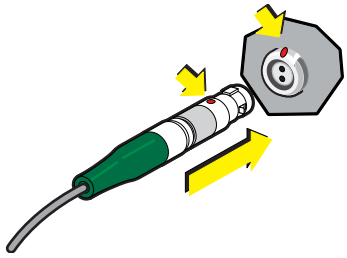


10

Connect the level sense connector from the cap assembly to the instrument by:

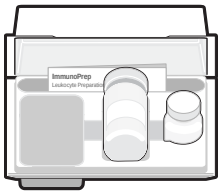
a. Lining up the two red dots:
   - Red dot on the level sense connector
   - Red dot on the corresponding color-coded opening.

b. Pushing the level sense connector into the opening.



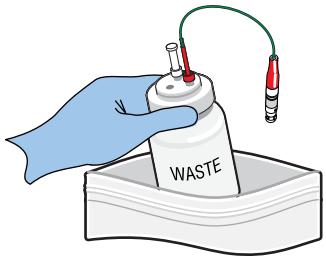
11 Screw the saved cap onto the empty reagent container. Save this container for future use, such as in the long-term shutdown procedure.

12 Repeat steps 2 through 11 for the other two ImmunoPrep reagents.

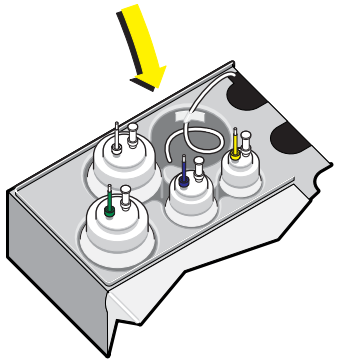


Connecting the WASTE Container

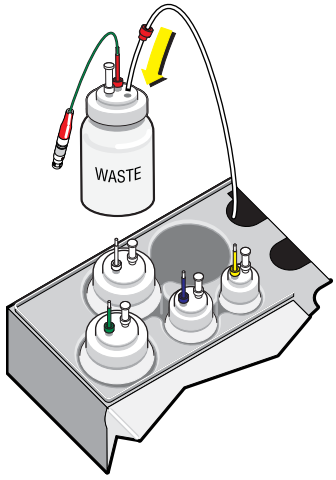
1 Remove the WASTE container and its cap assembly from its packaging. Check that the cap assembly is on tight.



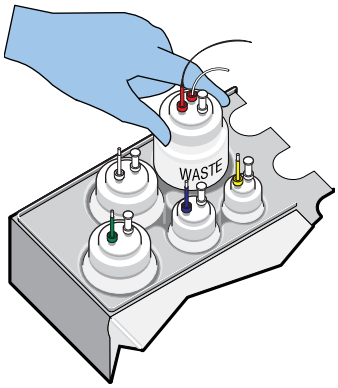
2 Locate the tubing taped to the instrument.



3 Insert the tubing into the opening on the WASTE container. Screw in the red connector.



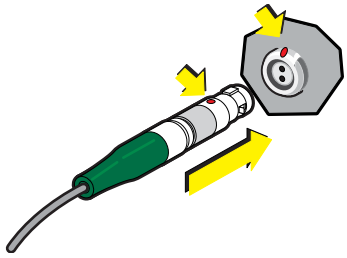
4 Place the WASTE container in the instrument.



5 Connect the level sense connector from the WASTE container's cap assembly to the instrument by:

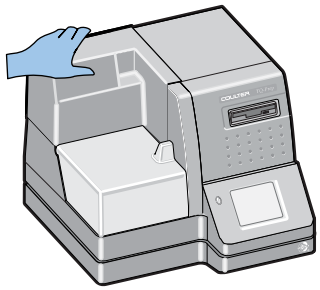
a. Lining up the two red dots:
   - Red dot on the level sense connector
   - Red dot on the corresponding color-coded opening.

b. Pushing the level sense connector into the opening.



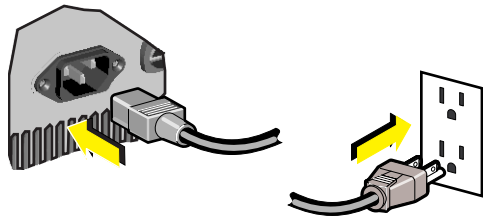
6 Remove the reagent cover from its packaging and place it on the instrument.

Note: If your instrument is located in a safety cabinet/laminar flow hood, you do not need to use the reagent cover.

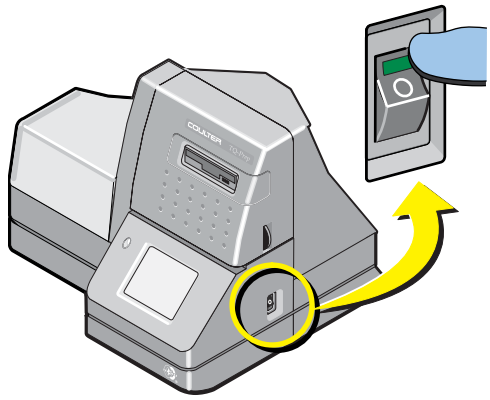


Powering On the Instrument

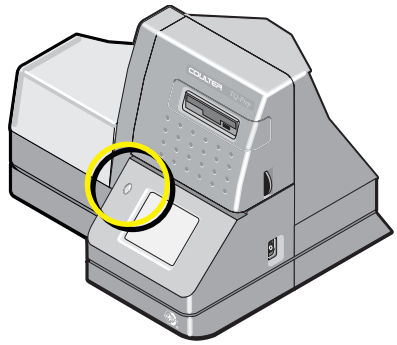
1 Plug the power cord into the electrical receptacle at the back of the instrument and then into the wall receptacle.



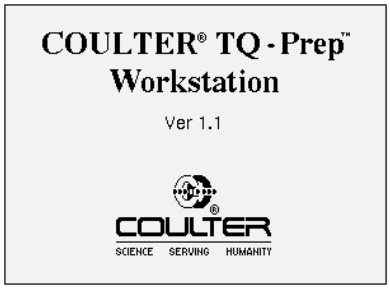
2 Turn on the power switch.



3 Check that the front power indicator light is on.

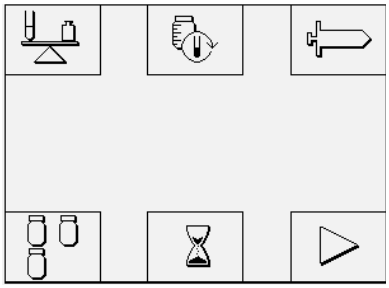


4 After system initialization, the **Power Up** screen appears briefly on the touch screen.

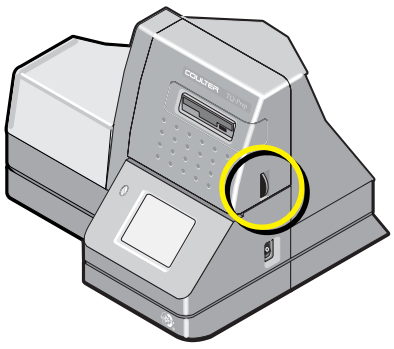


5 Check that:

- The **Main** screen appears.
- No troubleshooting icon appears on the **Main** screen. If a troubleshooting icon does appear, go to Chapter 8 in the Operator's Guide to correct the problem.



6 Adjust the contrast of the touch screen for best viewing angle, as needed.

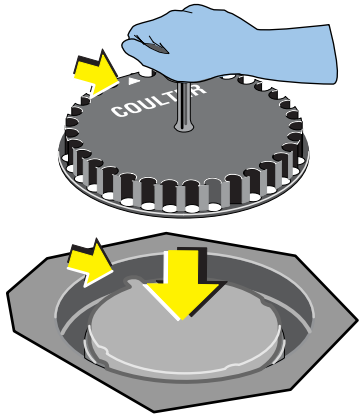


Checking Carousel Alignment

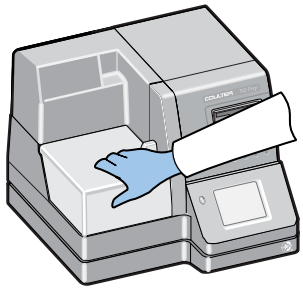
1 Open the sample processing area lid.

2 Place an empty carousel onto the indexing base:

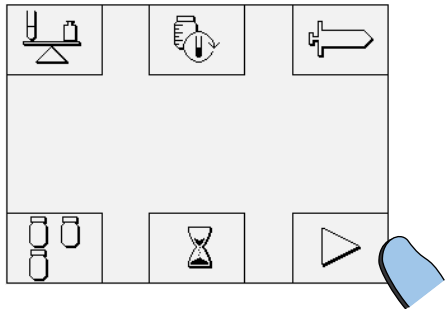
Note: To correctly secure the carousel, line up the arrow on the carousel above the hub key on the indexing base before placement.



3 Close the sample processing area lid.



4 Press ▷.



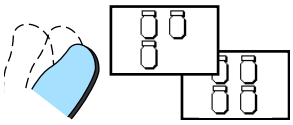
5

- When the carousel completes processing, if any of these conditions occur, then you need to align the carousel as described in Chapter 7 of the Operator's Guide:
  - ▸  or  appears on the touch screen.
  - ▸ The instrument pauses and beeps.
- If none of the above conditions occur, continue with installation.

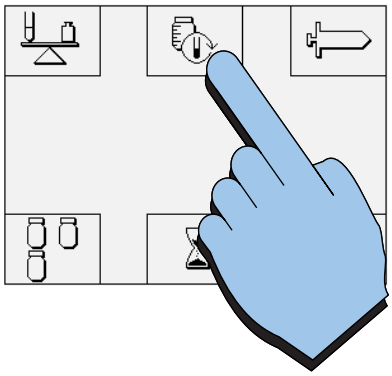
Priming and Preparing the Instrument for Use

1 If your system has the LALS OPTION, select the correct reagent mode (3 or 4 reagents).

Note: The displayed mode is the active mode.

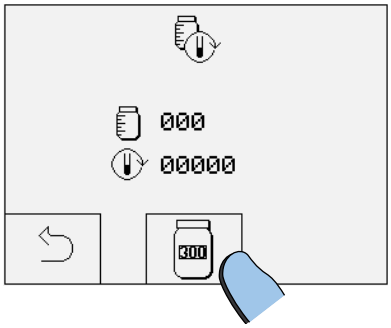


2 Press  .



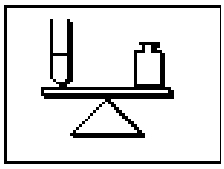
3 Press  to prime the instrument with reagents and to set the reagent counter to 300.

- The **Prime** screen appears during priming.
- When priming is done, the **Main** screen appears.



4

Perform the Gravimetric Validation test listed in Chapter 5, Calibration, of the Operator's Guide.



Note: If your test tubes meet the specification criteria in Chapter 4 and none of these three troubleshooting icons  ,  or  appears on the touch screen during this test, then your tubes are compatible with the instrument.

5

Each system operator should perform the Operator Certification procedure in Appendix B before running samples.

3.1 GENERAL PRINCIPLES

- The TQ-Prep Workstation automatically adds, in this order, lysing reagent, stabilizer and fixative to a premixed sample of whole blood and anticoagulant with monoclonal antibody. For systems that have the LALS OPTION, the OPTION reagent is added last.
- Up to 32 samples containing a premixed sample of blood and antibody are presented to the reagent system from a carousel capable of holding up to 32 samples.
- On completion of red cell lysis, the samples are removed from the device and presented separately to a flow cytometer.
- The ImmunoPrep Reagent System is a rapid, gentle, no-wash erythrocyte lysing system that maintains leukocyte morphology and cell surface integrity.[4]
- Cell loss due to washing and centrifugation is eliminated. Because these steps are not required, processing time is substantially reduced.
- Automation further provides reproducible standardized sample preparation.

3.2 NORMAL SAMPLE FLOW

1. At power up, startup diagnostics are run on the TQ-Prep Workstation. This includes:
   - Moving all of the syringe plungers up and then down, to fill the syringes
   - Moving the carousel to its home position (only if it is not at the home position already)
   - Moving the vortex mixer assembly up and down once
   - Moving the dispensing head in and out once.
2. With the lid to the sample processing area open, a carousel loaded with samples prepared according to the reagent package insert, is placed onto the carousel indexing base. The carousel is then in the home position, Figure 3.1.

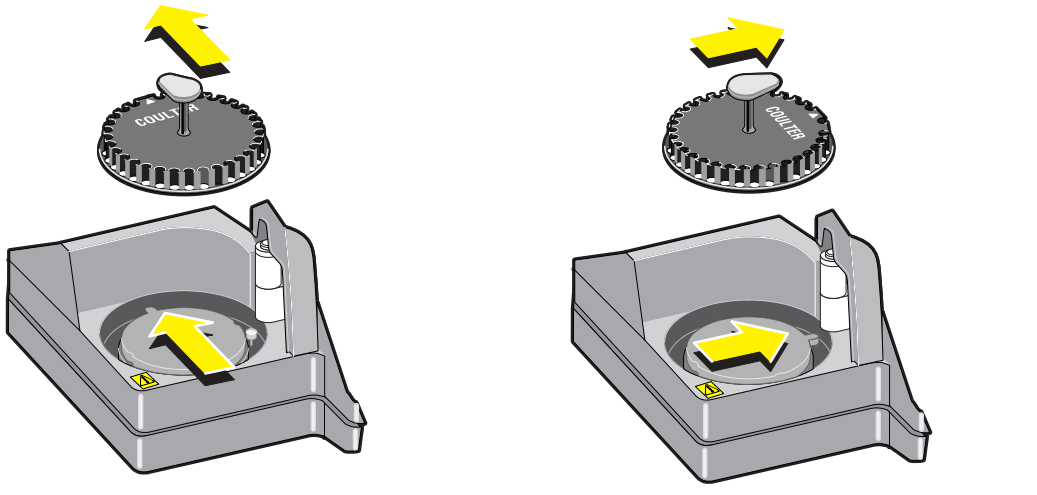


Figure 3.1 Carousel Home and Tube Loading Positions

3. After you press  , the carousel is indexed sequentially until tube position 1 is located at the sample processing position under the dispensing head. The carousel is then in the tube loading position, Figure 3.1.

   Note: If you pressed  , the carousel indexes when the run cycle starts after the preincubation.
4. The tube lifter pushes the test tube up from its slot in the carousel and into the dispensing head.
5. The tube detector senses the presence of a test tube and continues the processing.

   Note: If no tube is detected, the carousel moves to the next position and step 4 occurs. If the tube detector detects a second consecutive empty slot in the carousel, sample processing ends for this carousel.
6. The vortex mixer premixes the sample for 2 seconds before the first reagent is added.
7. The vortex mixer stops mixing and an electronically controlled syringe adds 600 µL of ImmunoPrep Reagent A to the sample. At the completion of the reagent dispensing, the vortex mixer mixes the sample for 8 seconds.
8. The vortex mixer stops mixing and an electronically controlled syringe adds 265 µL of ImmunoPrep Reagent B to the sample. At the completion of the reagent dispensing, the vortex mixer mixes the sample for 10 seconds.
9. The vortex mixer stops mixing and an electronically controlled syringe adds 100 µL of ImmunoPrep Reagent C to the sample. At the completion of the reagent dispensing, the vortex mixer mixes the sample for 10 seconds.
10. In systems with the LALS OPTION, if you selected the OPTION reagent (4 reagent) mode, the vortex mixer stops mixing and an electronically controlled syringe adds 500 µL of the OPTION reagent to the sample. At the completion of the reagent dispensing, the vortex mixer mixes the sample for 8 seconds.
11. The tube lifter lowers, returning the test tube to its original position in the carousel.
12. The carousel indexes to the next position and repeats the process for up to 32 sample tubes. Any empty tube slot is ignored unless two consecutive empty slots are detected.
13. The cycle is complete when the carousel has completed one full revolution or two consecutive empty slots are detected.

3.3 TYPES OF PRIMING

User-Requested

- This prime dispenses 100 µL of each reagent through the dispensing tubing.
- Use it during troubleshooting to clear air bubbles from the dispensing tubing.
- Press  to request this prime.

New Reagent

- This prime dispenses enough reagent to replace the reagent currently in all the syringes, in the tubing from the syringes to the dispensing head and in the tubing from the syringes to the reagent containers.
- See Chapter 4, Specifications/Characteristics, for amounts of dispensed reagent.
- Press 

to request this prime.

Automatic

This prime dispenses 20 µL of each reagent automatically when you request a function (sample processing, sample processing with preincubation, Gravimetric Validation, user requested prime or new reagent prime) after the instrument has been inactive for at least 12 hours.

4.1 PHYSICAL SPECIFICATIONS

Dimensions

Height	Width	Depth	Weight
39.1 cm (15.4 in.)	44.7 cm (17.6 in.)	44.2 cm (17.4 in.)	18.7 kg (41.5 lb)

Power

Installation Category
II (per IEC 1010-1 standard)

Input
100 to 240 Vac, 50-60 Hz

Consumption
Approximately 430 W

Noise
<70 decibels

Ambient Operating Temperature
10-35°C (50-95°F)

Humidity
30-85%, without condensation

Recommended Reagents
- The COULTER ImmunoPrep Reagent System, which contains:
  - ImmunoPrep A (erythrocyte lysing reagent)
  - ImmunoPrep B (leukocyte stabilizing reagent)
  - ImmunoPrep C (cell membrane fixing reagent)
- Distilled or deionized water for the OPTION reagent used with the LALS OPTION

Reagent Usage

Cycle Type	Reagent A (µL)	Reagent B (µL)	Reagent C (µL)	OPTION Reagent (µL)
Automatic prime: Occurs before any active function that is requested after 12 hours of instrument inactivity.	20	20	20	20
User requested prime: Occurs after pressing  .	100	100	100	100
New reagent prime: Occurs after pressing  .	871	694	635	920
Sample processing	600	265	100	500

Anticoagulant

Use a salt of EDTA (ethylenediaminetetraacetic acid) as the anticoagulant.

The performance characteristics of the TQ-Prep Workstation were established using K_3EDTA at a concentration of 1.5 mg of anticoagulant per mL of whole blood.

Specimen Type

Whole blood

Sample Size

100 µL anticoagulated whole blood for use with monoclonal antibodies CYTO-STAT®/COULTER CLONE® monoclonal antibody reagents

Tube Size

12 x 75 (+1/-2) mm test tube, round bottom, glass or plastic, that fits in the TQ-Prep Workstation's carousel. Plastic tubes are recommended.

Mixing Speed

1,200-1,800 rpm

Throughput

- Three-reagent mode - 80 tubes per hour
- Four reagent mode - 64 tubes per hour

Sample Processing Time

- ImmunoPrep A, B, and C: 38 seconds ±2 seconds
- ImmunoPrep A, B, and C, and OPTION reagent: 47 seconds ±2 seconds

4.2 PERFORMANCE SPECIFICATIONS

Accuracy of Delivery Volume of Distilled Water

- Volume delivery of syringe for Reagent A: 600 µL ±5%
  Lysing time: 8 seconds ±1 second
- Volume delivery of syringe for Reagent B: 265 µL ±5%
  Stabilizing time: 10 seconds ±1 second
- Volume delivery of syringe for Reagent C: 100 µL ±5%
  Fixative time: 10 seconds ±1 second
- Volume delivery of syringe for OPTION reagent: 500 µL ±10%
  Mixing time: 8 seconds ±1 second

Precision (Reproducibility)

The precision (reproducibility) of the reagent delivery volumes is the coefficient of variation (CV%) as listed below:

- Reagent A = 5%
- Reagent B = 5%
- Reagent C = 5%
- OPTION Reagent =15%

Calibration

Gravimetric measurement of delivery volumes (*density of distilled or deionized water = 1.0 g/mL).

* The density of ImmunoPrep A and C is insignificantly different from distilled water. The density of ImmunoPrep B is 1.04 g/mL

4.3 PERFORMANCE CHARACTERISTICS

The TQ-Prep system was tested with normal and abnormal specimens in comparison to the COULTER Multi-Q-Prep system and substantially equivalent results were observed.

The precision (reproducibility) of the unit based on 32 replicate samples tested for CD4 have a coefficient of variation (CV) of 1.2%.

LOG SHEETS A

This Appendix contains these log sheets:

Make photocopies as needed.

COULTER® TQ-PREP™ WORKSTATION REAGENT LOG

TQ-Prep/ImmunoPrep Reagent System			
Date Opened	**Lot Number**	**Expiration Date**	**Technician**

SERIAL NO. _____

LAB. _____

COULTER®
SCIENCE SERVING HUMANITY

COULTER® TQ-PREP™ WORKSTATION MAINTENANCE AND OPERATIONAL CHECKS LOG

Daily				Every 6 Months or As Needed		As Needed		
Startup/QC Check		Shutdown/Clean		Gravimetric Validation		Indicate Procedure		
Date	Tech	Date	Tech	Date	Tech	Procedure	Date	Tech

SERIAL NO. _____

LAB. _____

COULTER®
SCIENCE SERVING HUMANITY

COULTER® TQ-PREP™ WORKSTATION ACTION LOG

Date	Condition Noted	Tech (Initials)	Date	Action Taken	Tech (Initials)

SERIAL NO. _____

LAB. _____

COULTER®
SCIENCE SERVING HUMANITY

B.1 PURPOSE AND SCOPE

The TQ-Prep Workstation is a precision dispensing instrument designed to increase the productivity of the flow cytometry laboratory. To achieve the expected test precision and accuracy, correct pipeting technique is needed.

Coulter recommends that all operators complete this certification procedure before using the system.

B.2 OPERATOR CERTIFICATION PROCEDURE

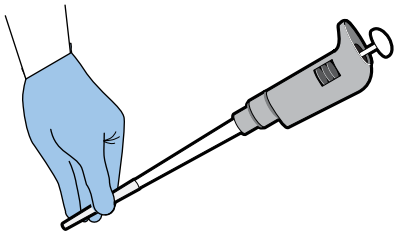
1. Use the Operator Certification form at the end of this appendix to record your results.
2. Calibrate a pipet using the appropriate Pipet Calibration Procedure (air-displacement or positive-displacement) listed below.
3. Use the pipet calibrated in step 2 above to perform the TQ-Prep Workstation Precision Procedure.

B.3 PIPET CALIBRATION PROCEDURE

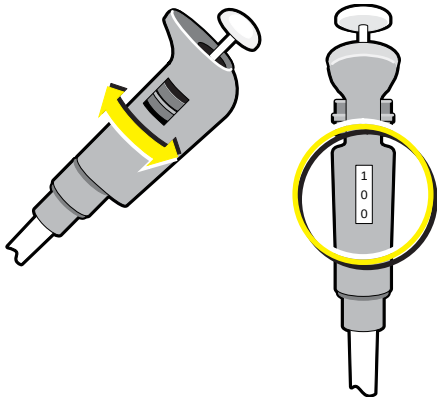
Use the pipet calibration procedure corresponding to the type of pipet used in your laboratory to prepare samples.

With Air-Displacement Pipet (Reverse Mode)

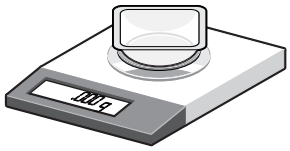
1 Securely fasten a new tip to the pipet.



2 Adjust the volume to 100 µL if it is not a fixed volume pipet.



3 Tare a weigh boat on a microbalance.

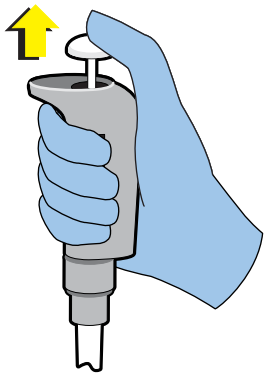


4 Press the plunger down to the first stop.

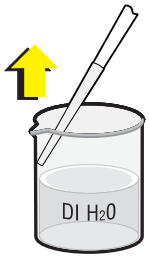
5 Place the tip 2 to 3 mm below the surface of a container of deionized or distilled water.

6 Continue to press the plunger down 2 to 3 mm more.

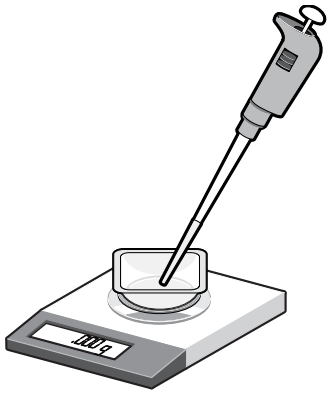
7 Slowly release the plunger to overdraw the required volume.



8 Remove the tip from the deionized or distilled water while touching the tip to an inside wall to remove any adhering liquid.

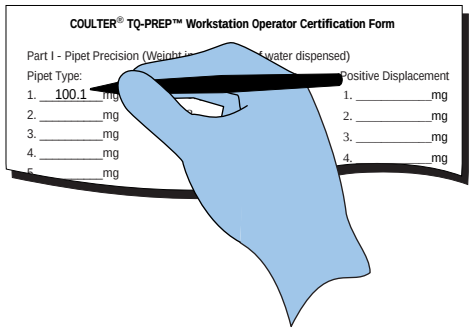


9 While touching the tip to the tared weigh boat, slowly dispense the water by depressing the plunger to the first stop only. There must be liquid remaining inside the tip.



10

Record the weight in milligrams (mg) on the Operator Certification form at the end of this appendix.


COULTER® TQ-PREP™ Workstation Operator Certification Form

Part I - Pipet Precision (Weight [illegible] water dispensed)

Pipet Type: Positive Displacement

1. 100.1 mg 1. _____mg
2. _____mg 2. _____mg
3. _____mg 3. _____mg
4. _____mg 4. _____mg
5. _____mg

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Repeat steps 3 through 10 until you have recorded 10 results on the form.

COULTER® TQ-PREP™ Workstation Operator Certification Form

Part I - Pipet Precision (Weight of water dispensed)

Pipet Type:	✓ Air Displacement	____ Positive Displacement
1. 100.1 mg	1. _____mg	1. _____mg
2. 100.0 mg	2. _____mg	2. _____mg
3. 100.0 mg	3. _____mg	3. _____mg
4. 99.8 mg	4. _____mg	4. _____mg
5. 99.9 mg	5. _____mg	5. _____mg
6. 100.1 mg	6. _____mg	6. _____mg
7. 100.0 mg	7. _____mg	7. _____mg
8. 100.1 mg	8. _____mg	8. _____mg
9. 100.0 mg	9. _____mg	9. _____mg
10. 99.8 mg	10. _____mg	10. _____mg
Mean _____mg	Mean _____mg	Mean _____mg
SD _____mg	SD _____mg	SD _____mg

12

Calculate the mean and the standard deviation (SD).

- The mean must be 100 ±0.5. Adjust the pipet's volume to dispense if the mean is not correct.
- The SD must be less than 1.0. This represents your skill level. Repeat this procedure until the SD is less than 1.0.

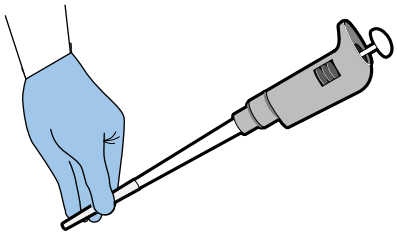
COULTER® TQ-PREP™ Workstation Operator Certification Form

Part I - Pipet Precision (Weight of water dispensed)

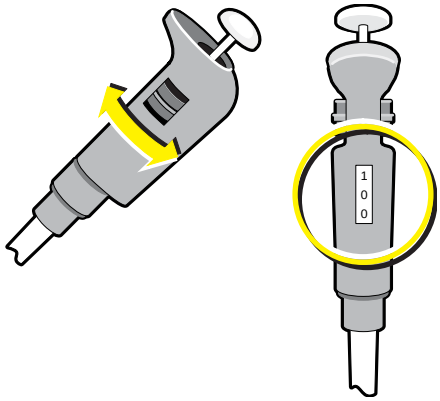
Pipet Type:	✓ Air Displacement	____ Positive Displacement
1. 100.1 mg	1. _____mg	1. _____mg
2. 100.0 mg	2. _____mg	2. _____mg
3. 100.0 mg	3. _____mg	3. _____mg
4. 99.8 mg	4. _____mg	4. _____mg
5. 99.9 mg	5. _____mg	5. _____mg
6. 100.1 mg	6. _____mg	6. _____mg
7. 100.0 mg	7. _____mg	7. _____mg
8. 100.1 mg	8. _____mg	8. _____mg
9. 100.0	9. _____mg	9. _____mg
10. 99.8 mg	10. _____mg	10. _____mg
Mean 99.98 mg	Mean _____mg	Mean _____mg
SD .11352924 mg	SD _____mg	SD _____mg

With Positive-Displacement Pipet

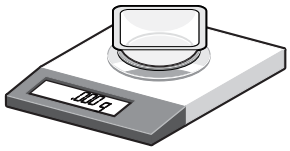
1 Securely fasten a new tip to the pipet.



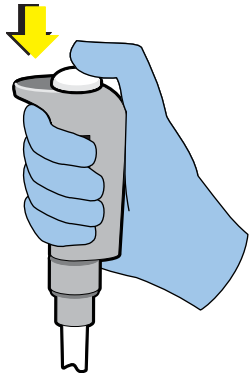
2 Adjust the volume to 100 µL if it is not a fixed volume pipet.



3 Tare a weigh boat on a microbalance.

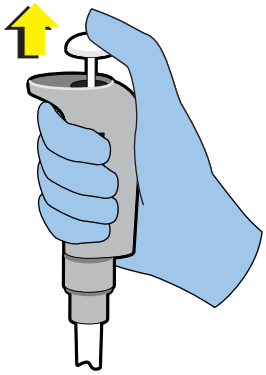


4 Press the plunger all the way down.

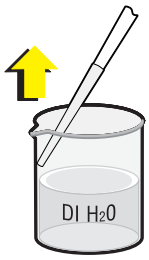


5 Place the tip 2 to 3 mm below the surface of a container of deionized or distilled water.

6 Slowly release the plunger to draw the required volume.

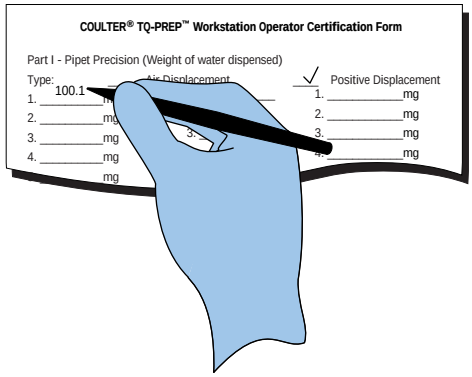


7 Remove the tip from the deionized or distilled water while touching the tip to an inside wall to remove any adhering liquid.



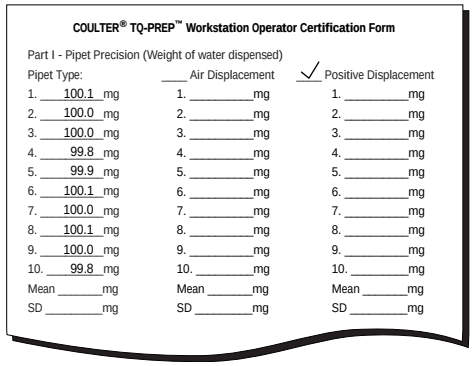
8 While touching the tip to the tared weigh boat, slowly dispense the water by depressing the plunger all the way down.

9 Record the weight in milligrams on the Operator Certification form at the end of this appendix.



10

Repeat steps 3 through 9 until 10 results are listed.



COULTER® TQ-PREP™ Workstation Operator Certification Form

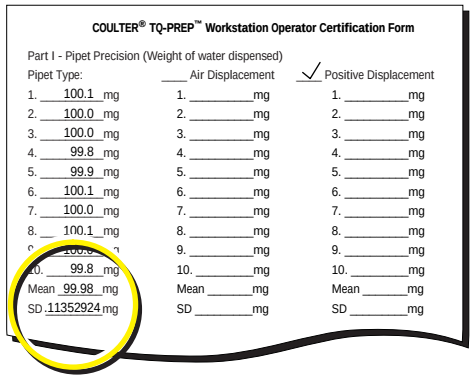
Part I - Pipet Precision (Weight of water dispensed)

Pipet Type:	____ Air Displacement	✓ Positive Displacement
1. 100.1 mg	1. _____mg	1. _____mg
2. 100.0 mg	2. _____mg	2. _____mg
3. 100.0 mg	3. _____mg	3. _____mg
4. 99.8 mg	4. _____mg	4. _____mg
5. 99.9 mg	5. _____mg	5. _____mg
6. 100.1 mg	6. _____mg	6. _____mg
7. 100.0 mg	7. _____mg	7. _____mg
8. 100.1 mg	8. _____mg	8. _____mg
9. 100.0 mg	9. _____mg	9. _____mg
10. 99.8 mg	10. _____mg	10. _____mg
Mean _____mg	Mean _____mg	Mean _____mg
SD _____mg	SD _____mg	SD _____mg

11

Calculate the mean and the standard deviation (SD).

- The mean must be 100 ±0.5. Adjust the pipet's volume to dispense if the mean is not correct.
- The SD must be less than 1.0. This represents your skill level. Repeat this procedure until the SD is less than 1.0.



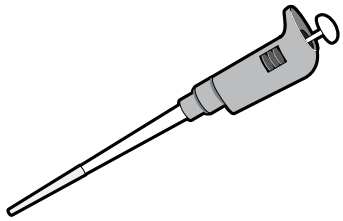
COULTER® TQ-PREP™ Workstation Operator Certification Form

Part I - Pipet Precision (Weight of water dispensed)

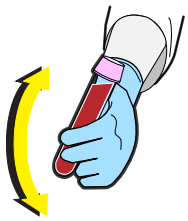
Pipet Type:	____ Air Displacement	✓ Positive Displacement
1. 100.1 mg	1. _____mg	1. _____mg
2. 100.0 mg	2. _____mg	2. _____mg
3. 100.0 mg	3. _____mg	3. _____mg
4. 99.8 mg	4. _____mg	4. _____mg
5. 99.9 mg	5. _____mg	5. _____mg
6. 100.1 mg	6. _____mg	6. _____mg
7. 100.0 mg	7. _____mg	7. _____mg
8. 100.1 mg	8. _____mg	8. _____mg
9. 100.0 mg	9. _____mg	9. _____mg
10. 99.8 mg	10. _____mg	10. _____mg
Mean 99.98 mg	Mean _____mg	Mean _____mg
SD .11352924 mg	SD _____mg	SD _____mg

B.4 TQ-PREP WORKSTATION PRECISION PROCEDURE

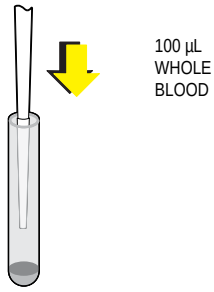
1 Use the pipet calibrated above to perform this procedure.



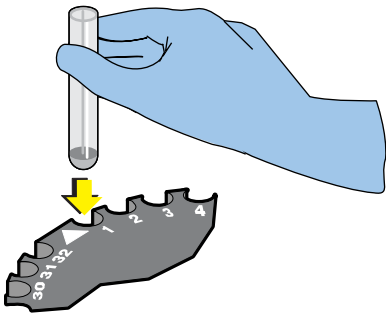
2 Completely mix a tube of normal donor blood by inversion.



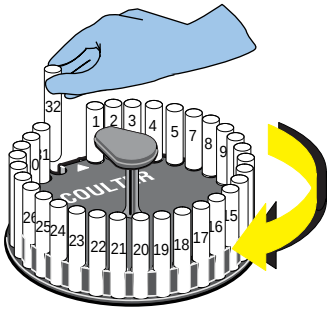
3 Pipet 100 µL of blood into a 12 x 75 mm test tube.



4 Place the test tube into the TQ-Prep Workstation carousel.



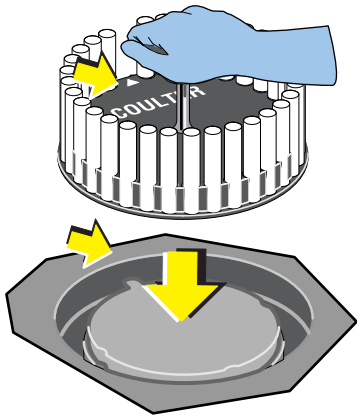
5 Repeat steps 2 through 4 until all 32 positions of the carousel are filled.



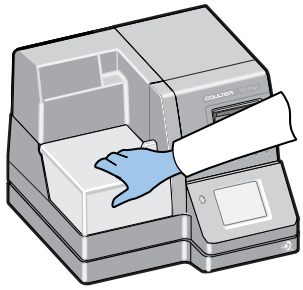
6 Open the sample processing area lid.

7 Load the carousel.

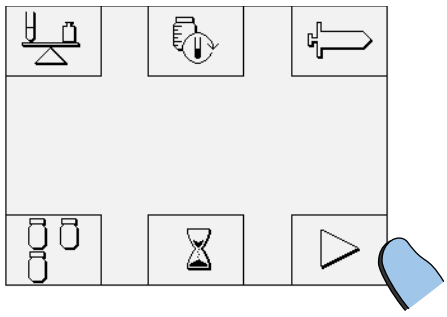
Note: To correctly secure the carousel, line up and place the arrow on the carousel over the hub key on the indexing base.



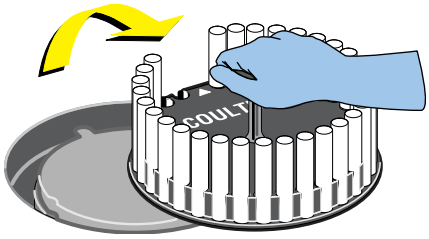
8 Close the sample processing area lid.



9 Press ▷.



10 When processing is done, remove the carousel and assay the samples for lymphocytes on a flow cytometer per the instrument's manual.



11 Acceptable results:

a. The histograms must not show unlysed erythrocytes.

b. All 32 tubes must recover the same percent lymphocytes ±2% of the mean using the same analysis region.

COULTER® TQ-PREP™ Workstation Operator Certification Form

Part I - Pipeting Precision (Weight of water dispensed)

Pipet Type:	_____ Air Displacement	_____ Positive Displacement
1. _____ mg	1. _____ mg	1. _____ mg
2. _____ mg	2. _____ mg	2. _____ mg
3. _____ mg	3. _____ mg	3. _____ mg
4. _____ mg	4. _____ mg	4. _____ mg
5. _____ mg	5. _____ mg	5. _____ mg
6. _____ mg	6. _____ mg	6. _____ mg
7. _____ mg	7. _____ mg	7. _____ mg
8. _____ mg	8. _____ mg	8. _____ mg
9. _____ mg	9. _____ mg	9. _____ mg
10. _____ mg	10. _____ mg	10. _____ mg
Mean _____ mg	Mean _____ mg	Mean _____ mg
SD _____ mg	SD _____ mg	SD _____ mg

Part II - COULTER TQ-Prep Workstation Precision (Percent Lymphocytes from FS vs. SS Histogram)

1. _____	13. _____	25. _____
2. _____	14. _____	26. _____
3. _____	15. _____	27. _____
4. _____	16. _____	28. _____
5. _____	17. _____	29. _____
6. _____	18. _____	30. _____
7. _____	19. _____	31. _____
8. _____	20. _____	32. _____
9. _____	21. _____	
10. _____	22. _____	
11. _____	23. _____	Mean _____
12. _____	24. _____	SD _____

Tech:_____ Date: _____

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REFERENCES

GLOSSARY

A	Ampere, a unit of electric current.
Accuracy	Ability of an instrument to agree with a predetermined reference value.
AG	Automotive glass.
Air-displacement pipet	A pipet that entraps a measured quantity of liquid then delivers the liquid by a piston stroke mechanism.
Ambient temperature	Temperature in the surrounding environment.
Button	Touch screen icon enclosed in a box that starts a function when pressed.
Carousel home position	The position used for carousel loading where the key (arrow) on the carousel is at the 12 o'clock position and the tube position 10 is at the dispensing head position.
CD4	Cluster designation for a T4 cell.
Centrifugation	Separation of particulate matter from a suspending liquid with a centrifuge.
cm	Centimeter, a unit of linear measurement.
CV (Coefficient of Variation)	An expression, in percent, of the data spread as related to the mean. CV% = (SD/Mean) x 100
dc	Direct current.
Deionized water (DI H_20)	Water freed of salts and some organisms by an ion-exchange process. Can be used interchangeably with distilled water in these procedures.
Density	The mass of a substance per unit volume.
Distilled water	Water freed of solids and organisms by distillation. Can be used interchangeably with deionized water in these procedures.
Erythrocyte	Red blood cell.
Flow cytometry	A process for measuring the characteristics of cells or other biological particles as they pass through a measuring apparatus in a fluid stream.
g	Gram, a unit of weight.
Gravimetric	Of or relating to measurement by weight.
Histogram, light-scatter	A two-dimensional graphic presentation of multidimensional accumulated data. Usually the X-axis is set to Side Scatter and the Y-axis is set to Forward Scatter.
Hz	Hertz, a unit of frequency.
Icon	Touch screen graphic that displays processing or troubleshooting information to the user or as a button requests a function.
IEC	International Electrical Commission.
Immunofluorescence	Fluorescence as the result of, or identifying, an immune response.
Immunophenotyping	Process of identifying/categorizing cells through the use of cell surface antigen marking.
in.	Inch, a unit of measure.
Instrument cycle	Number of sample processing cycles (prime and gravimetric validation cycles are not included).
In vitro	Latin phrase meaning outside of a living system, as in a laboratory or in an artificial container such as a test tube.
K_3EDTA	(tripotassium ethlyenediaminetetraacetic acid) A salt solution that prevents clotting of blood specimens placed in purple-stoppered blood collection tubes.
kg	Kilogram, a unit of weight equal to 1,000 g.

LALS OPTION	This option is for use on flow cytometers that measure a low angle of forward scatter (FALS) light.
Laminar flow hood	Also called: safety cabinet.
lb	Pound, a unit of weight.
Leukocyte	White blood cell.
Lot number	A manufacturer's code that identifies when a reagent was manufactured.
Lysing/Lysis	Disruption of the cellular membrane.
Mean	Arithmetic average of a group of data.
mg	Milligram, a unit of weight, equal to 10^{-3} gram.
Microcontroller	An integrated circuit that can organize the functions of multiple components.
Microprocessor	The integrated circuitry for electronically controlled devices.
mL	Milliliter, a unit of volumetric measurement, equal to 10^{-3} liter.
mm	Millimeter, a unit of linear measurement, equal to one-thousandth of a meter.
Monoclonal antibodies	Antibodies produced by a single cell or its identical progeny, specific for a given antigen.
MSDS	Material Safety Data Sheets.
µL	Microliter, a unit of volumetric measurement, equal to 10^{-6} liter.
Optical flag switch	A switch that moves to the ON position when its optical sensor detects the presence of an object, such as the test tube.
Positive-displacement pipet	A pipet that entraps a measured quantity of liquid, increases its pressure and then delivers the liquid.
Precision	A measure of the ability of the instrument to reproduce similar results when a sample is run repeatedly. Also called: reproducibility.
Preincubation	Maintaining a chemical mixture at a specified temperature for a specific time period.
Quality Control (QC)	A comprehensive set of procedures your laboratory sets up to ensure that an instrument is working accurately and precisely.
Reproducibility	A procedure to check that the system gives similar results (within established limits) every time it measures the same sample. Also called: precision.
rpm	Revolutions per minute.
Safety cabinet	Also called: laminar flow hood.
SD (Standard Deviation)	A measure of deviation from the mean. $$SD = \sqrt{\frac{\sum(\bar{x} - x)^2}{N - 1}}$$
Tare weight	A deduction from the gross weight made to allow for the weight of a container.
Tube loading position	The position where the carousel starts processing; tube position 1 is at the dispensing head position (3 o'clock position).
Transient	A temporary phenomenon such as a pulse, that occurs before a system's power reaches the steady state condition.

V	Volt, a unit of electrical potential difference measurement.
Vac	Volts of alternating current.
Vortex	A whirling motion of liquid.
W	Watt, a unit of power.

Symbols

A

B

C

D

E

F

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T

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V

W

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Documentation

■ Reference PN 4237395	Use and Function • Installation • Operation Principles • Specifications/Characteristics • Log Sheets • Operator Certification • References • Glossary • Index
■ Operator's Guide PN 4237396	Controls and Indicators • Startup • Sample Processing • Shutdown • Calibration • Cleaning Procedures • Replace/Adjust Procedures • Troubleshooting • Master Index
■ Operating Summary (In English) PN 4237389	Overview of daily procedures and description of screen buttons and icons.

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