



Sample

Validation Protocol

Document information

<i>Revision history</i>	Document version	Software version	Revision date	Changes
	1.0	Software version 11.2	April 2013	

Edition notice This is the *Validation Guide* for the **Sample system**
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Overview

Purpose of this Validation Guide

The purpose of this *Validation Guide* is to assist users of the **Sample system** in creating a site-specific Validation Plan to qualify their system according to current FDA guidelines. This *Validation Guide* should be used only as a guideline; users may elect to use, modify, or not use each section as they deem appropriate.

Refer to the **Sample system Operator's Manual** for a complete description of the **Sample system**. Refer to the test-specific package inserts for instructions on collection, storage, and handling of samples.

Test Case Design

The test cases are designed to mimic actual runs. Both reactive and non-reactive donor samples are included in the runs, and all donor samples are tracked from pipetting through reporting of results. The test cases also include various error simulation test cases.

Acceptance Criteria

A test case is complete and passes when the *Expected Result* has been obtained and entered in the *Observed Result* column, *Pass* is circled in the *Pass/Fail* column, and (if required by your facility) each completed step is initialed and dated. Sections that are not applicable should be marked **N/A**.

Running Test Cases

Choose test cases that are appropriate for your facility. The following workflow is recommended:

1. Operator training
(TC01: Safety and Training)
2. System installation
(TC02: Instrument Installation)
3. Pooling
(TC03: First Pooling Test through TC06: Manual Pipetting)
4. Results review
(TC09: Results Review through TC13: LIS Transmission)
5. Reactive Resolution
(TC07: Reactive Resolution)
6. Error handling
(TC08: Error Handling and TC14: Error Handling)

Login Requirements

Obtain login IDs, last names associated to **Sample system** login IDs, and passwords as indicated below and record the information in the space provided.

System component	User group	Login ID/Last name	Password
Software component 1	Technician		
Software component 2	Administrator		
Software component 3	Technologist		
Software component 3	Administrator		

Documentation Requirements

Obtain the required documentation and record the publication date in the space provided.

Document name	Publication date
<i>Sample system Operator's Manual</i>	
<i>Sample system Instrument Manual</i>	
Package Insert(s)	

Preparation

Materials

Materials required are listed below:

- Donor samples in barcode labeled sample tubes (reactive and non-reactive)
- Controls
- High-volume CO-RE tips

TC01: Safety and Training

Place a check mark to indicate operators have been trained to observe the indicated safety procedures.

- Correctly load the instrument.
- Follow electrical safety procedures.
- Follow universal safety procedures.
- Use good laboratory practices.
- Keep the cover closed during operation.
- Do not stare into the beam of the barcode scanner.
- Follow recommended cleaning and maintenance schedules.

TC02: Instrument Installation

Action	Expected Result	Observed Result	Pass/ Fail	Initials /Date
1 Examine the front and sides of the instrument.	Personnel have access at the front and sides of the instrument, for operation, maintenance, and opening of the protective covers.		Pass Fail	_____ _____
2 Examine the rear of the instrument.	There is sufficient space for ventilation.		Pass Fail	_____ _____
3 Examine the instrument location.	The instrument is positioned away from: <ul style="list-style-type: none"> • heating ducts • air conditioning vents • direct sunlight • intense artificial light • laboratory equipment that emits electromagnetic RF fields (e.g., X-ray machine, elevator) 		Pass Fail	_____ _____
4 Check the temperature and humidity in the laboratory where the Instrument is installed.	Temperature is between 15 °C and 30 °C (59 °F to 86 °F). Humidity is between 15% and 85% without condensation.		Pass Fail	_____ _____
5 Examine the left-hand side of the Instrument.	A USB cable connects the Instrument to the workstation.		Pass Fail	_____ _____
6 Examine the power connection on the left-hand side of the Instrument.	The Instrument is plugged in directly (no extension cords) to an approved power source.		Pass Fail	_____ _____
7 Examine the workstation network card.	A network cable connects the workstation to the system 24-ports switch.		Pass Fail	_____ _____
8 Power on the workstation if it is powered off.	A window displays to press the CTRL+ALT+DEL keys simultaneously to logon.		Pass Fail	_____ _____
9 Press CTRL+ALT+DEL .	The logon dialog box displays.		Pass Fail	_____ _____
10 Enter the Technician login ID and password (recorded on page 5), then click OK . Record the software version.	The software starts automatically. The software version displays in the title bar.	Software version: _____	Pass Fail	_____ _____
11 Examine the communication icon on the right side of the workstation taskbar.	The icon displays as shown (without a red "X"), indicating that the workstation is communicating with the server.		Pass Fail	_____ _____

Pooling

TC03: First Pooling Test

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
1 Record the selected test, pool size, and number of donor samples.	N/A	Test / Pool size _____ Number of donor samples: _____	N/A	N/A
2 Record the instrument serial number.	N/A	Instrument S/N: _____	N/A	N/A
3 Record the donor tube barcodes (see <i>Forms</i> on page 35). Circle the reactive donor samples.	N/A	N/A	N/A	N/A
4 If not already logged on as the Technician (ID recorded on page 5), logon to the workstation now.	N/A	N/A	N/A	N/A
5 Access the Run tab and ensure the correct pool size (recorded above) is selected.	N/A	N/A	N/A	N/A
6 Click Start .	The Control Selection dialog box displays.		Pass Fail	_____ _____
Load the control samples and record the lot number and expiration date.	N/A	Lot number: _____ Expiration date: _____	N/A	N/A
7 Load the donor tubes.	The Consumables dialog box prompts for consumable loading		Pass Fail	_____ _____
8 Load consumables.	Once all consumables are loaded the run ID is displayed and the run begins.	Run ID: _____	Pass Fail	_____ _____
9 Allow the run to complete.	The run completes successfully and all tubes are automatically unloaded.		Pass Fail	_____ _____
10 Access the Pooling tab.	The run ID (recorded in step 8) is listed.	N/A	Pass Fail	_____ _____
11 Select the Details panel.	All donor samples and controls are listed.		Pass Fail	_____ _____

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
12 Click Print , and save the report as an attachment.	Report for pooling run prints on the default printer.		Pass Fail	_____ _____
13 Examine the printed report.	The correct instrument S/N (page 8), login user's last name (page 5), and software version (recorded in <i>TC02: Instrument Installation</i>) display at the top of the report. The control lot number and expiration date are listed. All donor samples were pooled and are listed in the report.		Pass Fail	_____ _____
14 Circle the pools containing reactive donor samples.	N/A	N/A	N/A	N/A

Forms

Validation Report		
Comments:		
Results:		
Pass	___	All tests were successfully completed.
Pass with Retest	___	All tests were successfully completed, some retesting required.
Pass with Deviations	___	Tests were successfully completed, with acceptable deviations.
Fail	___	Some tests were not successfully completed (deviation reports attached).
Verified By:		Date:

Donor Barcode List					
Test _____		Pooling Method: _____		Carrier Code: _____	
Position	Barcode ID	Position	Barcode ID	Position	Barcode ID
1		17			
2		18			
3		19			
4		20			
5		21			
6		22			
7		23			
8		24			
9		25			
10		26			
11		27			
12		28			
13		29			
14		30			
15		31			
16		32			