



Sample

Validation Protocol

Document information

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	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

TC04: Second 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 pipettor serial number.	N/A	STAR S/N:	N/A	N/A
3 Load donor tubes into donor tube carrier(s) and record the donor tube barcodes (see <i>Forms</i> on page 35). Circle the reactive (or \geq cutoff for B19) donor samples and identify the targets.	N/A	N/A	N/A	N/A
4 If not already logged on as the LABUSER (ID recorded on page 5), logon to the Pooling Management workstation now.	N/A	LABUSER login ID:	N/A	N/A
5 Access the Pooling Wizard Plate Run tab.	N/A	N/A	N/A	N/A
6 Click Start .	N/A	N/A	N/A	N/A
7 If a dialog box displays to select the type of Plate Run, click Intermediate Plate Run , then Next .	N/A	N/A		
8 Ensure the correct donor tube carrier size is selected.	N/A	N/A	N/A	N/A
9 Load the donor tube carrier(s) onto the autoloader tray in the track numbers indicated by the Pooling Wizard workflow guide.	N/A	N/A	N/A	N/A
10 Click Done when donor tube carrier loading is complete.	The workflow guide prompts for consumable loading.		Pass Fail	_____ _____
11 Load the Intermediate Plate and pipette tips in the track numbers indicated by the workflow guide.	The Plate Run starts automatically once the tip carrier is loaded.		Pass Fail	_____ _____
12 Record the Pooling Run ID.	N/A	Pooling Run ID:	N/A	N/A
13 Allow the run to complete.	The run completes successfully and all carriers unload to the autoloader tray.		Pass Fail	_____ _____
14 Access the Pooling Manager.	N/A	N/A	N/A	N/A

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
15 Query for the pooling run ID recorded in step 12.	The pooling run record is listed in the Query Results panel.		Pass Fail	_____ _____
16 Double-click the pooling run entry to display the corresponding Details tab.	The Alarms View tab displays.		Pass Fail	_____ _____
17 Display the Plate View tab.	The number of samples successfully pipetted into each well displays (OK).		Pass Fail	_____ _____
18 Display the Plate Map tab, click Print Plate Map , then click Print . Save the report as an attachment.	The Intermediate Plate Report prints on the default printer.		Pass Fail	_____ _____
19 Exit the Pooling Manager and access the Pooling Wizard Batch Run tab.	N/A	N/A	N/A	N/A
20 Click Assay/Start . If multiple assays are configured, select the test, and click OK .	N/A	N/A	N/A	N/A
21 Select the pool type and Deep Well Plate carrier.	N/A	N/A	N/A	N/A
22 If UDECs are configured, the UDEC Selection dialog box displays. Choose a Batch Option , then click Next . If 1st Batch or Each Batch is selected, record the UDEC lot and expiration date.	N/A	UDEC lot ID: _____ Expiration date: _____	N/A	N/A
23 Place the Intermediate Plate in position one on a plate carrier and load the carrier onto the autoloader tray in the track numbers indicated by the Pooling Wizard workflow guide.	N/A	N/A	N/A	N/A
24 Click Done .	The workflow guide prompts for consumable loading.		Pass Fail	_____ _____
25 Load SK24 racks, RMECs, (optional) UDECs, and pipette tips in the track numbers indicated by the workflow guide. Record the RMEC lot ID and expiration date.	Once all carriers have been loaded, the pooling deck layout appears and the run begins.	RMEC lot ID: _____ Expiration date: _____	Pass Fail	_____ _____
26 Record the Pooling Run ID.	N/A	Pooling Run ID: _____	N/A	N/A

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
27 Allow the run to complete.	The run completes successfully and all carriers unload to the autoloader tray.		Pass Fail	_____ _____
28 Ensure the S-tubes and barcode clips are correctly seated in the SK24 racks. Carefully place the caps on each of the S-tubes.	N/A	N/A	N/A	N/A
29 Access the Pooling Manager.	N/A	N/A	N/A	N/A
30 Query for the pooling run ID recorded in step 26.	The pooling run record is listed in the Query Results panel.		Pass Fail	_____ _____
31 Double-click the pooling run entry to display the corresponding Details tab. Record the Batch ID.	The Alarms View tab displays.	Batch ID: _____	Pass Fail	_____ _____
32 Display the Pools View tab.	All pools (RMEC, donor sample, and UDEC if any) in the batch are listed.		Pass Fail	_____ _____
33 Click Print , leave all reports selected, and click Print again. Save the reports as an attachment.	Pooling Manager reports print on the default printer.		Pass Fail	_____ _____
34 Examine the Pooling Batch Report(s) .	The correct test and STAR S/N (page 10), login user's last name (page 5), and software version (recorded in <i>TC02: Instrument Installation</i>) appear at the top of the report. All donor samples were pooled in an S-tube and are listed in the report.		Pass Fail	_____ _____
35 Circle the pools containing reactive (or \geq cutoff for B19) donor samples and identify the targets in the Pooling Batch Report(s) . Copy the RMEC/UDEC lot and expiration date (page 11) to the report.	N/A	N/A	N/A	N/A

TC05: Third Pooling Test

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
1 Record the pipettor serial number.	N/A	STAR S/N: _____	N/A	N/A
2 Load donor tubes into donor tube carrier(s) and record the donor tube barcodes (see <i>Forms</i> on page 35). Circle the reactive (or \geq cutoff for B19) donor samples and identify the targets.	N/A	N/A	N/A	N/A
3 If not already logged on as the LABUSER (ID recorded on page 5), logon to the Pooling Management workstation now.	N/A	LABUSER login ID: _____	N/A	N/A
4 Access the Pooling Wizard Plate Run tab.	N/A	N/A	N/A	N/A
5 Click Start .	A dialog box displays to select the type of plate run.		Pass Fail	_____ _____
6 Select Library Plate Run , then click Next .	N/A	N/A	N/A	N/A
7 Load the donor tube carrier(s) onto the autoload tray in the track numbers indicated by the Pooling Wizard workflow guide.	N/A	N/A	N/A	N/A
8 Click Done when donor tube carrier loading is complete.	The workflow guide prompts for consumable loading.		Pass Fail	_____ _____
9 Load the Library Plate(s) and pipette tips in the track numbers indicated by the workflow guide.	The Library Plate Run starts automatically once the tip carrier is loaded.		Pass Fail	_____ _____
10 Record the Pooling Run ID.	N/A	Pooling Run ID: _____	N/A	N/A
11 Allow the run to complete.	The run completes successfully and all carriers unload to the autoload tray.		Pass Fail	_____ _____
12 Access the Pooling Manager.	N/A	N/A	N/A	N/A
13 Query for the pooling run ID recorded in step 10.	The pooling run record is listed in the Query Results panel.		Pass Fail	_____ _____
14 Double-click the pooling run entry to display the corresponding Details tab.	The Alarms View tab displays.		Pass Fail	_____ _____

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
15 Display the Plate View tab.	The number of samples successfully pipetted into each well displays (OK).		Pass Fail	_____ _____
16 Display the Plate Map tab, click Print Plate Map , then click Print . Save the report as an attachment.	The Pooling Plate Report prints on the default printer.		Pass Fail	_____ _____
17 Store the Library Plate until the quarantine time ends. The laboratory administrator can view the quarantine end time in the Report Manager > Workflow Reports > Library Plate Status report.	N/A	N/A	N/A	N/A
18 Remove the Library Plate(s) from storage. Allow them to thaw completely and place on a plate carrier(s).	N/A	N/A	N/A	N/A
19 Access the Pooling Wizard Plate Run tab.	N/A	N/A	N/A	N/A
20 Click Start .	A dialog box displays to select the type of plate run.		Pass Fail	_____ _____
21 Select Intermediate Plate Run from the displayed dialog box, then click Next .	N/A	N/A	N/A	N/A
22 Ensure Deep Well Plate is selected as the carrier.	N/A	N/A	N/A	N/A
23 Load the plate carrier onto the autoloader tray in the track numbers indicated by the Pooling Wizard workflow guide.	N/A	N/A	N/A	N/A
24 Click Done .	The workflow guide prompts for consumable loading.		Pass Fail	_____ _____
25 Load the Intermediate Plate and pipette tips in the track numbers indicated by the workflow guide.	The Plate Run starts automatically once the tip carrier is loaded.		Pass Fail	_____ _____
26 Record the Pooling Run ID.	N/A	Pooling Run ID: _____	N/A	N/A
27 Allow the run to complete.	The run completes successfully and all carriers unload to the autoloader tray.		Pass Fail	_____ _____
28 Access the Pooling Manager.	N/A	N/A	N/A	N/A
29 Query for the pooling run ID recorded in step 26.	The pooling run record is listed in the Query Results panel.		Pass Fail	_____ _____

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
30 Double-click the pooling run entry to display the corresponding Details tab.	The Alarms View tab displays.		Pass Fail	_____ _____
31 Display the Plate View tab and select the Intermediate Plate.	The number of samples successfully pipetted into each well displays (OK).		Pass Fail	_____ _____
32 Display the Plate Map tab, click Print Plate Map , then click Print . Save the report as an attachment.	The Intermediate Plate Report prints on the default printer.		Pass Fail	_____ _____
33 Exit the Pooling Manager and access the Pooling Wizard Batch Run tab.	N/A	N/A	N/A	N/A
34 Click Assay/Start . If multiple assays are configured, select the test, and click OK .	N/A	N/A	N/A	N/A
35 If UDECs are configured, the UDEC Selection dialog box displays. Choose a Batch Option , then click Next . If 1st Batch or Each Batch is selected, record the UDEC lot and expiration date.	N/A	UDEC lot ID: _____ Expiration date: _____	N/A	N/A
36 Select Load Secondary and Deep Well Plate carrier.	N/A	N/A	N/A	N/A
37 Place the Intermediate Plate in position one on a plate carrier and load the carrier onto the autoloader tray in the track numbers indicated by the Pooling Wizard workflow guide.	N/A	N/A	N/A	N/A
38 Click Done .	The workflow guide prompts for consumable loading.		Pass Fail	_____ _____
39 Load SK24 rack, RMECs, (optional) UDECs, and pipette tips in the track numbers indicated by the workflow guide. Record the RMEC lot ID and expiration date.	Once all carriers have been loaded, the pooling deck layout appears and the run begins.	RMEC lot ID: _____ Expiration date: _____	Pass Fail	_____ _____
40 Record the Pooling Run ID.	N/A	Pooling Run ID: _____	N/A	N/A
41 Allow the run to complete.	The run completes successfully and all carriers unload to the autoloader tray.		Pass Fail	_____ _____
42 Ensure the S-tubes and barcode clips are correctly seated in the SK24 racks. Carefully place the caps on each of the S-tubes.	N/A	N/A	N/A	N/A

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
43 Access the Pooling Manager.	N/A	N/A	N/A	N/A
44 Query for the pooling run ID recorded in step 40.	The pooling run record is listed in the Query Results panel.		Pass Fail	_____ _____
45 Double-click the pooling run entry to display the corresponding Details tab. Record the Batch ID.	The Alarms View tab displays.	Batch ID: _____	Pass Fail	_____ _____
46 Display the Pools View tab.	All pools (RMEC, donor sample, and UDEC if any) in the batch are listed.		Pass Fail	_____ _____
47 Click Print , leave all reports selected, and click Print again. Save the reports as an attachment.	Pooling Manager reports print on the default printer.		Pass Fail	_____ _____
48 Examine the Pooling Batch Report(s) .	The STAR S/N (page 13), login user's last name (page 5), software version (recorded in <i>TC02: Instrument Installation</i>) appear at the top of the report. All donor samples were pooled in an S-tube and are listed in the report.		Pass Fail	_____ _____
49 Circle the pools containing reactive (or \geq cutoff for B19) donor samples and identify the targets in the Pooling Batch Report(s) . Copy the RMEC/UDEC lot and expiration date (page 15) to the report.	N/A	N/A	N/A	N/A

TC06: Manual Pipetting

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
1 Record the selected test and number of donor samples.	N/A	Test: _____ Number of donor samples: _____	N/A	N/A
2 Record the donor tube barcodes (see <i>Forms</i> on page 35). Circle the reactive (or \geq cutoff for B19) donor samples and identify the targets.	N/A	N/A	N/A	N/A
3 If not already logged on as the LABUSER (ID recorded on page 5), logon to the Pooling Management workstation now.	N/A	N/A	N/A	N/A
4 Access the Pooling Wizard Manual Pipetting tab.	N/A	N/A	N/A	N/A
5 Click Assay/Start . If multiple assays are configured, select the test, and click OK . Record the Run ID.	N/A	Run ID: _____	N/A	N/A
6 Scan the SK24 rack ID.	The Input Barcode panel prompts for the first RMEC.		Pass Fail	_____ _____
7 For each required RMEC and donor sample to be tested, place an empty, uncapped S-tube with attached barcode clip on an SK24 rack. Record the RMEC lot ID and expiration date.	N/A	RMEC lot ID: _____ Expiration date: _____	N/A	N/A
8 Pipette 1 mL of the required RMEC into the first S-tube, then cap the S-tube.	N/A	N/A	N/A	N/A
9 Scan the S-tube barcode clip ID where the RMEC was pipetted.	The information updates in the Rack Information panel.		Pass Fail	_____ _____
10 Scan the control tube from which the RMEC was pipetted.	The system performs a check to verify the proper RMEC was loaded and prompts for the next RMEC.		Pass Fail	_____ _____
11 Repeat steps 8 through 10 for the remaining RMECs, using the next available S-tube position.	The information updates in the Rack Information panel.		Pass Fail	_____ _____
12 Pipette 1 mL of the first donor sample into the next available S-tube, then cap the S-tube.	N/A	N/A	N/A	N/A

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
13 Scan the S-tube barcode clip ID where the donor sample was pipetted.	The information updates in the Rack Information panel.		Pass Fail	_____ _____
14 Scan the donor tube from which the donor sample was pipetted.	The information updates in the Rack Information panel.		Pass Fail	_____ _____
15 Repeat steps 12 through 14 for the remaining donor samples.	The information updates in the Rack Information panel.		Pass Fail	_____ _____
16 Click Done when finished.	N/A	N/A	N/A	N/A
17 Access the Pooling Manager.	N/A	N/A	N/A	N/A
18 Query for the run ID recorded in step 5.	The requested record is listed in the Query Results panel.		Pass Fail	_____ _____
19 Double-click the entry to display the corresponding Details tab. Record the Batch ID.	The Alarms View tab displays.	Batch ID: _____	Pass Fail	_____ _____
20 Display the Pools View tab.	All pools (RMEC and donor sample) in the batch are listed.		Pass Fail	_____ _____
21 Click Print , leave all reports selected, and click Print again. Save the reports as an attachment.	Pooling Manager reports print on the default printer.		Pass Fail	_____ _____
22 Examine the Pooling Batch Report(s) .	Manual displays for the STAR S/N. The login user's last name (page 5), and software version (recorded in <i>TC02: Instrument Installation</i>) appear at the top of the report. All donor samples are listed in the report.		Pass Fail	_____ _____
23 Circle the pools containing reactive (or \geq cutoff for B19) donor samples and identify the targets in the Pooling Batch Report(s) . Copy the RMEC lot and expiration date (page 17) to the report.	N/A	N/A	N/A	N/A

TC07: Reactive Resolution

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
1 Obtain the Required Pooling Report printed in <i>TC09: Results Review</i> .	N/A	N/A	N/A	N/A
2 Obtain the samples that require follow-up testing. If the plate ID is listed in the Required Pooling Report , Secondary Pooling for that sample must be performed from the plate; otherwise the donor tube is used for Secondary Pooling.	N/A	N/A	N/A	N/A
3 If Deep Well Plates will be loaded, place them on a plate carrier(s).	N/A	N/A	N/A	N/A
4 If donor tubes will be loaded, place them on donor tube carrier(s).	N/A	N/A	N/A	N/A
5 Record the selected test and pipettor serial number.	N/A	Test _____ STAR S/N: _____	N/A	N/A
6 If not already logged on as the LABUSER (ID recorded on page 5), logon to the Pooling Management workstation now.	N/A	N/A	N/A	N/A
7 Access the Pooling Wizard Batch Run tab.	N/A	N/A	N/A	N/A
8 Click Assay/Start . If multiple assays are configured, select the test, and click OK .	N/A	N/A	N/A	N/A
9 If UDECs are configured, the UDEC Selection dialog box displays. Choose a Batch Option , then click Next . If 1st Batch or Each Batch is selected, record the UDEC lot and expiration date.	N/A	UDEC lot ID: _____ Expiration date: _____	N/A	N/A
10 Select Load Secondary .	N/A	N/A	N/A	N/A
11 If Deep Well Plate(s) will be loaded, select Deep Well Plate , then load the plate carrier onto the autoloader tray in the track numbers indicated by the Pooling Wizard workflow guide.	N/A	N/A	N/A	N/A

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
12 If donor tubes will be loaded, ensure the correct donor tube carrier size is selected, then load the donor tube carrier(s) onto the autoloader tray in the track numbers indicated by the Pooling Wizard workflow guide.	N/A	N/A	N/A	N/A
13 Click Done when donor sample loading is complete.	The workflow guide prompts for consumable loading.		Pass Fail	_____ _____
14 Load SK24 racks, RMECs, (optional) UDECs, and pipette tips in the track numbers indicated by the workflow guide. Record the RMEC lot ID and expiration date.	Once all carriers have been loaded, the pooling deck layout appears and the run begins.	RMEC lot ID: _____ Expiration date: _____	Pass Fail	_____ _____
15 Record the Pooling Run ID.	N/A	Pooling Run ID: _____	N/A	N/A
16 Allow the run to complete.	The run completes successfully and all carriers unload to the autoloader tray.		Pass Fail	_____ _____
17 Ensure the S-tubes and barcode clips are correctly seated in the SK24 racks. Carefully place the caps on each of the S-tubes.	N/A	N/A	N/A	N/A
18 Access the Pooling Manager.	N/A	N/A	N/A	N/A
19 Query for the pooling run ID recorded in step 15.	The pooling run record is listed in the Query Results panel.		Pass Fail	_____ _____
20 Double-click the pooling run entry to display the corresponding Details tab. Record the Batch ID(s).	The Alarms View tab displays.	Batch ID(s): _____ _____ _____ _____	Pass Fail	_____ _____
21 Display the Donor View tab for the selected batch.	All donors in the batch are listed. The Pooling Type for each donor matches the Request listed in the Required Pooling Report .		Pass Fail	_____ _____

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
22 Click Print , leave all reports selected, and click Print again. Save the reports as an attachment.	Pooling Manager reports for the first batch print on the default printer.		Pass Fail	_____ _____
23 Repeat steps 21 and 22 for each additional batch (if any) in the pooling run. Save the reports as an attachment.	Pooling Manager reports for the remaining batches print on the default printer.		Pass Fail	_____ _____
24 If Deep Well Plates were used, display the Plate Map tab, click Print Plate Map , then click Print . Save the report as an attachment.	The Pooling Plate Report prints on the default printer.		Pass Fail	_____ _____
25 Examine the Pooling Batch Report(s) .	The correct test and STAR S/N (page 8), login user's last name (page 5), and software version (recorded in <i>TC02: Instrument Installation</i>) appear at the top of the report. All donor samples were pooled in an S-tube and are listed in the report. The Pooling Type for each donor matches the Request listed in the Required Pooling Report		Pass Fail	_____ _____
26 Identify the reactive (or \geq cutoff for B19) targets on the Pooling Batch Report(s) . Copy the RMEC/UDEC lot and expiration date (page 20) to the report.	N/A	N/A	N/A	N/A

TC08: Error Handling

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
1 Record the selected test.	N/A	Test _____	N/A	N/A
2 Record the pipettor serial number.	N/A	STAR S/N: _____	N/A	N/A
3 Load a donor tube that already has a result for the selected test (the donor tube saved in <i>Pooling</i> 4 <i>TC03: First Pooling Test</i> 5 can be used) in position 1 in a donor tube carrier. Load previously untested, barcode labeled donor tubes to fill the rest of the donor tube carrier.	N/A	N/A	N/A	N/A
6 If not already logged on as the LABUSER (ID recorded on page 5), logon to the Pooling Management workstation now.	N/A	N/A	N/A	N/A
7 Access the Pooling Wizard Batch Run tab.	N/A	N/A	N/A	N/A
8 Click Assay/Start . If multiple assays are configured, select the test, and click OK .	N/A	N/A	N/A	N/A
9 Select Pools of 1 and the correct donor tube carrier size.	N/A	N/A	N/A	N/A
10 If UDECs are configured, the UDEC Selection dialog box displays. Choose Off , then click Next .	N/A	N/A	N/A	N/A
11 Record the donor tube carrier track number listed in the Pooling Wizard workflow guide.	N/A	Track number: _____	N/A	N/A
12 Load the donor tube carrier onto the autoloader tray in the indicated track.	The instrument auto loads the carrier and reads the barcode IDs of the donor tubes. The donor tube carrier is transferred back to the loading deck. An error message displays, indicating that a donor cannot be pooled in the pooling run.		Pass Fail	_____ _____

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
13 Replace the previously used donor tube in position one with a new, barcode labeled donor tube. Using opaque adhesive tape, cover the barcode label on the donor tube in position 1. Close the error message. Slide the carrier to the stop pin.	The instrument auto loads the carrier and attempts to read the barcodes. The carrier is transferred back to the loading deck, and the Manual ID Entry dialog box displays. <i>nn</i> appears in the Track field (where <i>nn</i> is the track recorded above) and 1 appears in the Position field, indicating a barcode read error was encountered for the donor tube in carrier position 1 .		Pass Fail	_____ _____
14 Remove the opaque tape, slide the carrier to the pin, and select Retry . Then, click Done .	The instrument auto loads the carrier and successfully reads the barcodes.		Pass Fail	_____ _____
15 If your system is configured to create Library Plates, place a Library Plate in a plate carrier and load the carrier onto the autoloader tray in the indicated track.	The consumable Calculation panel displays the required consumables. The workflow guide prompts to load the S-tube carrier.		Pass Fail	_____ _____
16 Place the required S-tubes, seated in barcode clips, in an SK24 rack. One of the barcode clips should be from a previous run (saved from Error! Reference source not found.).	N/A	N/A	N/A	N/A
17 Load the S-tube carrier onto the autoloader tray in the indicated track.	The instrument auto loads the carrier and reads the barcode IDs of the S-tubes. The S-tube carrier is transferred back to the loading deck. An error message displays, indicating a unique S-tube ID is required.		Pass Fail	_____ _____
18 Remove the used S-tube barcode clip and replace it with a new S-tube barcode clip. Close the error message. Slide the carrier to the stop pin.	The instrument auto loads the carrier. The deck layout updates to show the loaded carrier. The workflow guide prompts to load the negative control carrier.		Pass Fail	_____ _____
19 Load the POSITIVE control carrier onto the autoloader tray in the indicated track. Note: the pipettor is expecting the negative control carrier.	The instrument auto loads the carrier. The carrier is transferred back to the loading deck. An error message displays, indicating the control ID loaded is invalid.		Pass Fail	_____ _____
20 Remove the carrier containing the positive RMECs from the load deck. Close the error message and load the negative control carrier onto the autoloader tray in the indicated track.	The instrument auto loads the carrier. The deck layout updates to show the loaded carrier. The workflow guide prompts to load the positive control carrier.		Pass Fail	_____ _____

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
21 Load a control carrier with all except one of the required positive RMECs. Place the carrier onto the autoloader tray in the indicated track.	The instrument auto loads the carrier. The carrier is transferred back to the loading deck. An error message displays indicating that not all the expected RMECs are loaded.		Pass Fail	_____ _____
22 Place the missing RMEC on the control carrier. Close the error message. Slide the carrier to the stop pin.	The instrument auto loads the carrier. The deck layout updates to show the loaded carrier. The workflow guide prompts to load the tip carrier.		Pass Fail	_____ _____
23 Load the pipette tips in the track numbers indicated by the workflow guide. Record the RMEC lot ID and expiration date.	Once all carriers have been loaded, the pooling deck layout appears and the run begins.	RMEC lot ID: _____ Expiration date: _____	Pass Fail	_____ _____
24 Record the Pooling Run ID.	N/A	Pooling Run ID: _____	N/A	N/A
25 Allow the run to complete.	The run completes successfully and all carriers unload to the autoloader tray.		Pass Fail	_____ _____
26 Ensure the S-tubes and barcode clips are correctly seated in the SK24 racks. Carefully place the caps on each of the S-tubes.	N/A	N/A	N/A	N/A
27 Access the Pooling Manager.	N/A	N/A	N/A	N/A
28 Query for the pooling run ID recorded in step 24.	The pooling run record is listed in the Query Results panel.		Pass Fail	_____ _____
29 Double-click the pooling run entry to display the corresponding Details tab. Record the Batch IDs.	The Alarms View tab displays.	Batch IDs: 1 st _____ 2 nd _____	Pass Fail	_____ _____
30 Display the Pools View tab for the selected batch.	All pools (RMEC, donor sample, and UDEC if any) in the batch are listed.		Pass Fail	_____ _____
31 Click Print , leave all reports selected, and click Print again. Save the reports as an attachment.	Pooling Manager reports for the batch print on the default printer.		Pass Fail	_____ _____
32 Repeat steps 30 and 31 for the second batch. Save the reports as an attachment.	Pooling Manager reports for the remaining batch print on the default printer.		Pass Fail	_____ _____

Action	Expected Result	Observed Result	Pass/ Fail	Initials/ Date
33 If Library Plates were used, display the Plate Map tab, click Print Plate Map , then click Print . Save the report as an attachment.	The Pooling Plate Report prints on the default printer. An aliquot of each donor sample was preserved in a Library Plate well.		Pass Fail	_____ _____

Result Analysis

TC09: Results Review

Allow time for the results to be accepted and archived by PDM software (within 10 minutes) before performing this test case.

Action	Expected Result	Observed Result	Pass/ Fail	Initial s/Date
1 Obtain the Pooling Batch Report and Donor Barcode List for the batch to be reviewed. Record the batch ID.	N/A	Batch ID: _____	N/A	N/A
2 If not already logged on to the Data Management workstation as the LABADMIN (ID recorded on page 5), logon now.	The Data Manager starts.		Pass Fail	_____ _____
3 Using the Pooling Batch Report for reference, locate the batch in the Review Batches or Query tab. Select the batch. Note: Only batches not yet reviewed appear in the Review Batches tab.	Batch information displays in the lower portion of the tab.		Pass Fail	_____ _____
4 Click Next .	Batch results appear in the Details tab. The Alarms Review tab displays by default. Any alarms that occurred processing the AMPLILINK software export file are listed.		Pass Fail	_____ _____
5 If any alarms are listed, acknowledge the alarms by clicking Mark All , then click Confirm Alarms .	The ACK By column updates with the login ID.		Pass Fail	_____ _____
6 Select the Controls Review tab.	Results for the positive and negative controls (RMECs, and if included, UDECs) in the batch display. The lot number and expiration date matches the information copied to the Pooling Batch Report .		Pass Fail	_____ _____
7 Examine the results for the controls.	Valid appears under RMEC (or UDEC) Status for all controls.		Pass Fail	_____ _____
8 Select the Pools Review tab.	Results for the pools in the batch display.		Pass Fail	_____ _____

Action	Expected Result	Observed Result	Pass/ Fail	Initial s/Date
<p>9 Compare the results displayed in the Pools Review tab with information recorded in the Pooling Batch Report.</p> <p>Note: The known reactive (or \geq cutoff for B19) targets were identified in the Pooling Batch Report when the pools were created.</p>	<p>Reactive (or \geq Cutoff for B19) displays under Sample Result for the S-tube(s) circled in the Pooling Batch Report.</p> <p>Non-Reactive (or $<$ Cutoff for B19) displays under Sample Result for the remaining S-tubes in the Pooling Batch Report.</p>		Pass Fail	_____ _____
<p>10 Select the Donor Review tab.</p> <p>Note: If necessary, click the + symbol in the first column to expand the tree and display the donor tubes in each S-tube.</p> <p>Note: Ensure ALL is selected for Filters so all results display.</p>	<p>All of the donor tubes contained in the batch display.</p> <p>Each donor tube is identified by its barcode ID in the Donor Tube ID column.</p> <p>The S-tube for each donor appears in the S-Tube ID column.</p>		Pass Fail	_____ _____
<p>11 Examine the Donor Status and target displayed for each donor in the Donor Review tab.</p>	<p>Multi-sample pools containing a know reactive (or \geq cutoff for B19) donor sample:</p> <ul style="list-style-type: none"> • Donor Status = Created • Target = blank <p>Single-sample pools containing a know reactive (or \geq cutoff for B19) donor sample:</p> <ul style="list-style-type: none"> • Donor Status = Completed Reactive (or Completed for DPX/B19) • Target = Reactive (or \geq Cutoff for B19) <p>All other pools:</p> <ul style="list-style-type: none"> • Donor Status = Completed Non-Reactive (or Completed for DPX/B19) • Target = Non-Reactive (or $<$ Cutoff for B19) 		Pass Fail	_____ _____
<p>12 Select the Mark check box for each donor tube with a Donor Status of Completed, Completed Reactive, or Completed Non-Reactive and click the Accept button</p>	<p>A confirmation message box displays, prompting confirmation of accepting the donor tubes.</p>		Pass Fail	_____ _____
<p>13 Click OK.</p>	<p>An acknowledgement message box displays, prompting acknowledgement of donor tube acceptance.</p>		Pass Fail	_____ _____
<p>14 Click OK.</p>	<p>Donor Status of Completed changes to Accepted.</p>		Pass Fail	_____ _____

Action	Expected Result	Observed Result	Pass/ Fail	Initial s/Date
15 Click Print , leave all reports selected, then click Print again. Save the reports as an attachment.	The Data Manager reports print on the default Windows operating system printer.		Pass Fail	_____ _____
16 Examine the Donor Result Report .	<p>The S-Tube ID, donor tube ID, Final Result, and Donor Status are listed for each donor in the batch. They match the information in the Donor Review tab.</p> <p>The STAR S/N, control lot ID, and expiration date matches the information copied on the Pooling Batch Report. The CAP S/N, reagent lot, and reagent expiration date match the information recorded in Error! Reference source not found.</p> <p>The CTM S/N matches the serial number recorded in Error! Reference source not found.</p> <p>The last name of the operator who accepted the results (recorded on page 5) is listed.</p>		Pass Fail	_____ _____
17 Examine the Required Pooling Report .	Either the Plate ID (if Secondary Pooling should be performed from a deep well plate) or Donor ID (if Secondary Pooling should be performed from the donor tube) is listed for all donor samples with a Donor Status of Created .		Pass Fail	_____ _____

TC10: Result Analysis

TC11: Result Acceptance

TC12: Printing Results

TC13: LIS Transmission

TC14: Error Handling

Allow time for the results to be accepted and archived by PDM software (within 10 minutes) before performing this test case. Examines results from samples processed in **Error! Reference source not found.**

Action	Expected Result	Observed Result	Pass/ Fail	Initials /Date
1 If not already logged on to the Data Management workstation as the LABUSER (ID recorded on page 5), logon now.	The Data Manager starts.		Pass Fail	_____ _____
2 Locate the first batch prepared for error handling (batch ID recorded in step 29 in <i>TC08: Error Handling</i>) in the Review Batches or Query tab. Select the batch. Note: Only batches not yet reviewed appear in the Review Batches tab.	Batch information appears in the lower portion of the tab.		Pass Fail	_____ _____
3 Click Next .	Batch results appear in the Details tab. The Alarms Review tab displays by default. Any alarms that occurred processing the AMPLILINK software export file are listed.		Pass Fail	_____ _____
4 If any alarms are listed, acknowledge the alarms by clicking Mark All , then click Confirm Alarms .	The ACK By column updates with the login ID.		Pass Fail	_____ _____
5 Select the Controls Review tab.	Results for the positive and negative controls (RMECs, and if included, UDECs) in the batch display. The RMEC Status for the RMEC in position 1 is Invalid . The Batch Status (at the top of the tab) is Complete, Invalid .		Pass Fail	_____ _____
6 Select the Pools Review tab.	Results for the pools in the batch display. The Final Result for all pools in the batch is Invalid .		Pass Fail	_____ _____
7 Highlight the sample in position 7.	Yes appears in the Flags column. The Flag/Description at the bottom of the tab contains AP12 Sample Input missing .		Pass Fail	_____ _____
8 Highlight the sample in position 10.	Yes appears in the Flags column. The Flag/Description at the bottom of the tab contains flags TM75 and TM50 .		Pass Fail	_____ _____

Action	Expected Result	Observed Result	Pass/ Fail	Initials /Date
9 Click Print , leave all reports selected, then click Print again. Save the reports as an attachment.	The Data Manager reports print on the default Windows operating system printer.		Pass Fail	_____ _____
10 Locate the second batch prepared for error handling (batch ID recorded in step 29 in TC08: Error Handling) in the Review Batches or Query tab. Select the batch. Note: Only batches not yet reviewed appear in the Review Batches tab.	Batch information appears in the lower portion of the tab.		Pass Fail	_____ _____
11 Click Next .	Batch results appear in the Details tab. The Alarms Review tab displays by default. Any alarms that occurred processing the AMPLILINK software export file are listed.		Pass Fail	_____ _____
12 If any alarms are listed, acknowledge the alarms by clicking Mark All , then click Confirm Alarms .	The ACK By column updates with the login ID.		Pass Fail	_____ _____
13 Select the Controls Review tab.	Results for the positive and negative controls (RMECs, and if included, UDECs) in the batch display. The RMEC Status for all RMECs is Invalid . The Batch Status (at the top of the tab) is Complete, Invalid .		Pass Fail	_____ _____
14 Select the Pools Review tab.	Results for the pools in the batch display. The Final Result for all pools in the batch is Invalid . No appears in the Flags column for all pools.		Pass Fail	_____ _____
15 Highlight any pool.	The Flag/Description at the bottom of the tab contains TM19 Test-specific check for run expiry failed .		Pass Fail	_____ _____

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			