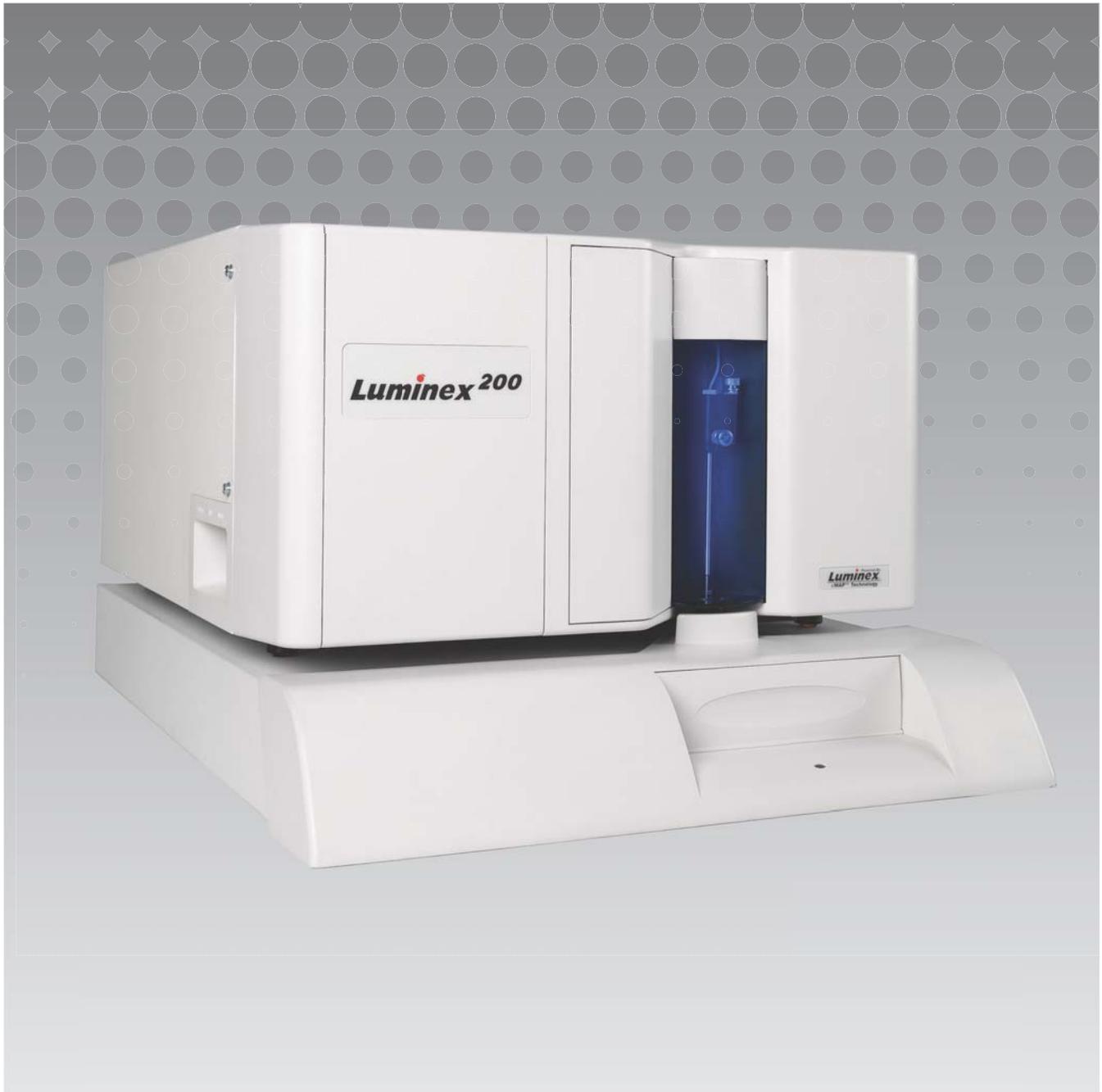


Luminex[®]

Package Insert | RUO

Luminex[®] 100/200[™] Performance Verification Kit

For Research Use Only. Not for use in diagnostic procedures.



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Luminex® 100/200™ Performance Verification Kit

89-60000-00-145 Rev B

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Key to Symbols

	Use-by date		Temperature Limit
	Batch Code		Contains Sufficient for <n> Tests
	Catalog(ue) Number		Keep away from sunlight.
	Manufacturer		Consult instructions for use
	Research Use Only. Not for Use in Diagnostic Procedures.		

For use with the Luminex® 100/200™ System and xPONENT® Software.

Kit Components

Kit Components	REF
Luminex® 100/200™ Performance Verification Kit	LX2R-PVER-K25 $\nabla \Sigma$ 25
25 strip wells	13-52047
Luminex® 100/200™ Performance Verification Kit CD	89-20778-00-001
xMAP® Classification Control Microspheres, 5.0 mL	L100-CON1 $\nabla \Sigma$ 25
MagPlex® Classification Control Microspheres, 5.0 mL	MCON1-05 $\nabla \Sigma$ 25
xMAP® Reporter Control Microspheres, 5.0 mL	L100-CON2 $\nabla \Sigma$ 25
xMAP® Fluidics 1 Microspheres, 5.0 mL	FLUID1-05 $\nabla \Sigma$ 25
xMAP® Fluidics 2 Microspheres, 5.0 mL	FLUID2-05 $\nabla \Sigma$ 25

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89-30000-00-185 Rev E

Table of Contents

- Description 1
- Introduction 1
- Storage 1
- Kit Contents 2
- Instructions 2
 - Importing Kit Target Values 2
 - System Preparation - Probe Height 3
 - Daily System Start-Up 3
- Other Suggested Maintenance 4
- Other Resources 4

Description

The Luminex® 100/200™ Performance Verification Kit is used in conjunction with the system calibrators to verify the optical calibration and optical integrity for the Luminex 100/200 System. This product should not be used in place of the assay calibrators or assay controls that are required to verify the proper function of a given assay.

The performance verification kit uses the Automated Maintenance Plate (AMP) provided with the xPONENT® software.

Introduction

The Luminex® 100/200™ Performance Verification Kit contains all reagents needed for verifying calibration of the Luminex platform with xPONENT® software.

The Luminex 100/200 System operating principle is similar to a flow cytometer. Microspheres are coated with a reagent, specific to a particular bioassay, allowing the capture and detection of specific analytes from a sample. The sample mixture is aspirated by the sample probe and injected into the sample cuvette at a slower rate than the sheath fluid is injected into the cuvette causing the microspheres to form a narrow column and pass through the laser and detection area one at a time. Within the Luminex 100/200, lasers excite the internal dyes that identify each microsphere's color signature, and also any reporter fluorescence captured during the assay.

For the optics to function effectively and for different Luminex 100/200 Systems to report similar results, it is important to calibrate the system. Calibrating the Luminex 100/200 System normalizes the settings for both classification channels (CL1 and CL2), the doublet discriminator channel (DD), and the reporter channel (RP1). This is accomplished by using the Luminex 100/200 Calibration Kit.

Following calibration, use the Luminex 100/200 Performance VerificationKit to run Performance Verification. Performance Verification Kit checks all of the optical channels in the system for correct calibration. It is essential to run performance verification every time you calibrate. If there is a problem with optical alignment or fluidics, the analyzer may pass calibration but will fail performance verification. If this occurs, contact Luminex Technical Support. The Luminex 100/200 Performance Verification Kit includes reagents to verify the calibration and optical integrity for the Luminex 100/200 System, as well as reagents to verify the fluidics channels using observations of pressure, flow rate, and carryover from well to well.

The verification reagents consist of mixtures of different microspheres internally labeled with either classification or reporter dyes. The classification control microspheres verify the integrity of the classification channels (CL1 and CL2) and the doublet discriminator channel (DD) as well as classification efficiency and misclassification. The reporter control microspheres verify the integrity of the reporter channel (RP1). The fluidics microspheres verify the integrity of the system fluidics including well to well carryover.

Storage

The Luminex 100/200 Performance Verification Kit must be stored in a dark place at 2°C to 8°C. The kit expires according to the date on the label. Do not use the kit or any kit components past the expiration date indicated on the kit carton label. Reagents are stable at room temperature for short intervals, as needed to work with the Luminex 100/200 System.

In the event of damage to the protective packaging, consult the Safety Data Sheet (SDS) for instructions.

For more information on ingredients and safety precautions, consult the Safety Data Sheet (SDS) for instructions.

Kit Contents

- **25 disposable strip wells** - Each strip well holds needed reagents and can be inserted into the AMP.
- **CD** - The CD includes an importable .lxl file that contains the verification target value data for the individual lot of reagents in the kit, Certificates of Quality for the kit reagent components, and this package insert.

NOTE: Target values differ from lot to lot. Only use the CD with the verification reagents provided within the same kit.

• **Performance Verification Reagents for 25 verifications:**

- a. **CON1** - Contains five microsphere regions internally labeled with classification dyes (CL1 and CL2) to five regions on the 100-plex map that are most sensitive to optical misalignment.
- b. **MCON1** - Contains five microspheres internally labeled to the 100-plex map, but verifies that the size settings are correct for use of Luminex® MagPlex® microspheres.
- c. **CON2** - Contains four microspheres internally labeled with increasing amounts of reporter dye. CON2 is used to check the reporter channel for reporter response, linearity, and reporter coefficients of variation.
- d. **Fluidics1** - A single microsphere set used in conjunction with Fluidics2 to measure inter-well carryover and detect issues with sample retention in fluidic lines or inefficient presentation of sample to optics.
- e. **Fluidics2** - A buffer solution and second bead region that allows measurement of microspheres originating from Fluidics1.

Instructions

The following instructions are for performance verification only. If you are running calibration at the same time you are running performance verification, please refer to the *Luminex 100/200 Calibration Kit Package Insert*. This procedure requires the AMP and a performance verification kit to complete. The following instructions describe system start-up procedures.

Run performance verification daily. Warm and prime the system, perform alcohol flushes to remove air from the system, and adjust the probe height before running performance verification. Run calibration and performance verification as part of regular system maintenance, when troubleshooting data acquisition problems, or when the current system temperature changes by $\pm 3^{\circ}\text{C}$ compared to the system temperature when last successfully calibrated. System temperature changes are monitored by the "delta cal temp" value in the system status area. In addition, the software has multiple alerts if the $\pm 3^{\circ}\text{C}$ tolerance has been exceeded. A system may pass calibration but fail performance verification. If this occurs, contact Luminex Technical Support. Running a performance verification following calibration helps ensure that classification channels, reporter channels, and fluidics channels are all performing as intended.

The xPONENT **Home** page contains shortcuts that are useful to start up and run calibration and performance verification of your system.

Importing Kit Target Values

1. Start the xPONENT® software.
2. Insert the Luminex® 100/200™ Performance Verification Kit CD into the CD drive on the PC.
3. On the **Home** page of the software, click **System Initialization**. The **Auto Maint** tab opens.
4. Click **Import Kit**.
5. Browse to the kit CD, open the parent folder, and select the .lxl file LXVER-AXXXX-yymmdd, where AXXXX is the kit lot number, and yymmdd is the kit expiration date, then click **Open**.

NOTE: If you need to import target values for the calibration kit, perform this procedure according to the instructions provided with the calibration kit.

System Preparation - Probe Height

Adjust the probe height when using new plate types, before system maintenance, or as part of troubleshooting.



For instructions on adjusting the sample probe height, see the appropriate user manual for your system: xPONENT® for Luminex® 100/200™ Software User Manual.

NOTE: Improper probe height can cause failed verification.

Daily System Start-Up

NOTE: Calibration is required weekly for the instrument. Performance verification should be performed daily to check system integrity and ensure calibration remains valid.

1. Navigate to the **Admin** page > **System Setup** tab; there are three options available for system initialization:
 - Laser warm-up, fluidics, calibration and performance verification
 - Laser warm-up, fluidics, performance verification
 - Warm-up, fluidics

NOTE: Option "Laser warm-up, fluidics, performance verification" must be selected to complete the remainder of the instructions.

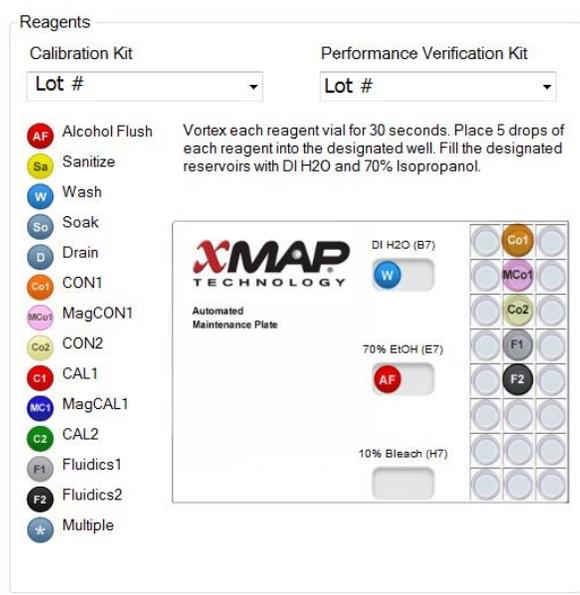
2. Click **Save**.
3. On the **Home** page, click **System Initialization**. The **Auto Maint** tab opens.

NOTE: Make sure the performance verification kit information has been imported into the software using the CD that comes with the kit. If not, follow the instructions in the "Importing Kit Target Values" on page 2.

4. On the **Auto Maint** tab, activate the newly entered lot by choosing it from the drop-down menu at the top right of the screen. Choose the correct kit lot numbers for your verification kit.
5. Click the **Eject** button on the **System Status** bar.
6. Add one clean strip well into the AMP in *Figure 1* on page 3.

NOTE: The plate layout in the software indicates reagent locations.

FIGURE 1. Plate Layout



7. Gently vortex all performance verification kit reagents for 10 seconds each.
8. Add DI water and 70% isopropanol or 70% ethanol to the reservoirs as shown in *Figure 1* on page 3.

NOTE: Fill reservoirs approximately 3/4 of the way full with appropriate reagent.
9. Completely invert bottle and add five complete drops each of the performance verification reagents (CON1, MCON1, CON2, Fluidics1, and Fluidics2) to the second well strip as shown in *Figure 1* on page 3.

NOTE: Luminex recommends checking the label to ensure you are dispensing the correct reagent.
10. Retract plate.
11. Click **Run**. The run cycle should take up to 45 minutes.

NOTE: If the system is already warmed up, the run cycle will take less time.

12. Once complete, click **Report**, choose to view either the **Performance Verification** report or the **Calibration & Performance** report, select the appropriate filters, and click **Generate**.

NOTE: Although the xPONENT software allows for calibrating the system when it is not warmed up, we strongly recommend against this as it will compromise data quality.

NOTE: Custom routines will not generate enhanced **Performance Verification** reports when creating custom routines on the **Cmnds & Routines** tab.

NOTE: Calibration and verification commonly fail when vials are not mixed thoroughly, reagents are in the wrong well locations, or the wrong kit lot values are selected.

NOTE: When running calibration or verification individually from the **Cmnds & Routines** tab, be sure that the correct lot numbers are selected as the current active lots on the **Lot Management** tab.

Other Suggested Maintenance

When experiencing acquisition problems (or once weekly as part of routine maintenance), you should perform the following procedure:

1. Remove the sample probe and place it in a sonicator bath for 5 minutes, narrow end down.

NOTE: Watch for water emerging from the opposite end.

2. Rinse the probe with water from the narrow end to the larger end.

NOTE: You must force water into the probe in order to complete the rinse.

3. Replace and readjust the probe height.
4. Run an alcohol flush command with 0.1N NaOH.
5. Run the **Weekly Maintenance** routine on the **Cmnds & Routines** tab.

Calibrate the system and run the **Performance Verification** routine.

Other Resources

Use the following resources to obtain more information about your Luminex® 100/200™ System and xPONENT® software:

- *xPONENT for Luminex 100/200 Quick Guide*
- xPONENT® Software User Manual
- *Luminex® 200™ System User Manual*
- *Luminex® 100™ IS User Manual Version 2.3*
- Luminex® Technical Support