Luminex

Package Insert | RUO

Luminex® 100/200™ Calibration Kit

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

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Luminex® 100/200™ Calibration Kit

89-60000-00-144 Rev B
June 2017

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™ Calibration Kit	LX2R-CAL-K25 Σ 25
25 strip wells	13-52047
Luminex® 100/200™ Calibration Kit CD	89-20777-00-001
Luminex® 100 Classification Calibrator Microspheres, 5.0 mL	L100-CAL1 Σ 25
MagPlex® Classification Calibrator Microspheres, 5.0 mL	MCAL1-05 Σ 25
Luminex® 100/200™ Reporter Calibrator Microspheres, 5.0 mL	L100-CAL2 Σ 25

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89-30000-00-185 Rev E

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Description

The Luminex® 100/200™ Calibration Kit calibrates the optics and verifies the controls of 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.

This calibration kit uses the Automated Maintenance Plate (AMP) provided with the xPONENT® software.

Introduction

The Luminex® 100/200™ Calibration Kit contains all reagents needed for 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 Verification Kit to run performance verification on the Luminex 100/200 System. The Luminex 100/200 Performance Verification Kit includes reagents to verify the calibration and optical integrity for the Luminex 100/200 System.

Storage

The Luminex® 100/200™ Calibration 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 the reagents and can be inserted into the AMP.
- **CD** - The CD includes an importable .lxl file that contains the calibration target value data for the specific lots of calibrator 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 calibration reagents provided within the same kit.

- **Calibration Reagents for 25 calibrations**:
  a. **CAL1** - Contains one microsphere set used to calibrate the system for non-magnetic MicroPlex® microspheres . During calibration, the system alters voltages within the optics for CL1 and CL2 until those values match the imported target values, thus calibrating the classification map. The same occurs for the DD signal.
  b. **MCAL1** - Contains one microsphere set used to calibrate the system for MagPlex® microspheres.

c. **CAL2** - Contains one microsphere set used to calibrate the system for reporter intensity. During calibration, the system alters the voltage on the RP1 parameter within the optics until the MFI values match the input target value.

WARNING: Luminex® reagents contain ProClin® as a preservative. This can cause allergic reactions. The ProClin content is < 0.05%.

Instructions

The following instructions require the AMP, a calibration kit, and a performance verification kit to complete. Please refer to the *Luminex® 100/200™ Performance Verification Kit Package Insert*, for more information about kit contents and the performance verification results. The following instructions describe system start-up procedures. To calibrate the system at other times, please refer to the notes following the instructions.

Calibrate the system weekly using the calibration kit. Adjust the probe height and perform fluidics prep before calibrating the system. Run performance verification after calibration.

Run calibration and performance verification as part of regular system maintenance, when troubleshooting data acquisition problems, or when the current system temperature changes by ±3°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 ±3°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 needed.

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

Importing Kit Target Values

1. Start the xPONENT® software.
2. Insert the Luminex® 100/200™ Calibration 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 LXCAL-AXXXX-yymmdd, where AXXXX is the kit lot number, and yymmdd is the kit expiration date, then click **Open**.

NOTE: To import target values for the Performance Verification kit, perform this procedure according to the instructions provided with the *Luminex® 100/200™ Performance Verification 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 calibration.

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. After calibration, perform verification.

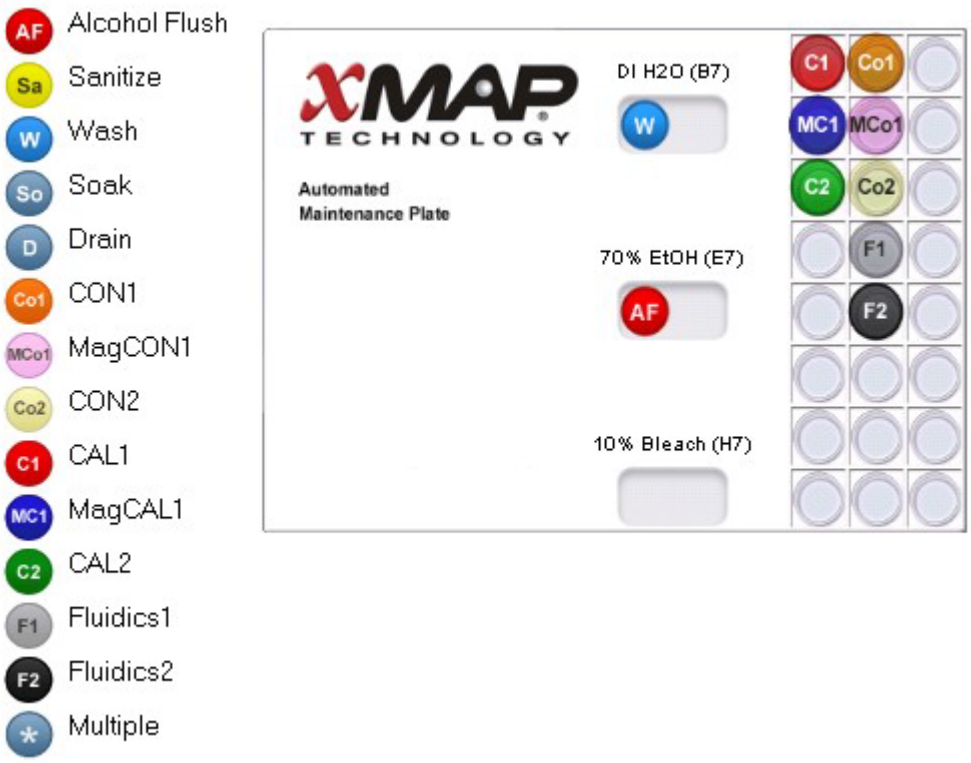
1. Navigate to the **Admin** page > **System Setup** tab; there are three options available for system initialization:
   - Laser warm-up, fluidics, calibration and performance verification
   - Laser warm-up, fluidics, performance verification
   - Warm-up, fluidics

   NOTE: Option “Laser warm-up, fludiics, calibration and 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 calibration kit and performance verification kit information has been imported into the software using the CDs provided with the kits. 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 tab. Choose the correct kit lot numbers for your calibration and verification kits.
5. Click **Eject** on the **System Status** bar.
6. Add two clean strip wells 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 calibration 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.

9. Completely invert bottle and add five complete drops each of the calibration reagents (CAL1, MCAL1, and CAL2) to the first strip well as shown in *Figure 1* on page 3.
10. Add five complete drops each of the performance verification reagents (CON1, MCON1, CON2, Fluidics1, and Fluidics2) to the second strip well as shown in *Figure 1* on page 3.

    NOTE: Luminex® recommends checking the label to ensure you are dispensing the correct reagent.

11. Retract plate.
12. 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.

13. Once complete, click **Report**, choose the view either the **Performance Verification** report or the **Calibration and 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, Luminex strongly recommends against this as it will compromise data quality.

    NOTE: Custom routines will not generate enhanced **Performance Verification** reports when creating custom routines on the **Cmds & 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 **Cmds & Routines** tab,. ensure the correct lot numbers are chosen 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 **Cmds & Routines** tab.
6. 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® Technical Support