Luminex® 100/200™ Calibration Kit Package Insert

IVD For *In Vitro* Diagnostic Use.
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CE

EC | REP

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Document Revision History

Effective Date	Revision	Section	Description of Change
07/2022	J	Cover Page	Updated revision and date
07/2022	J	Intended Purpose	Added Intended purpose statement
07/2022	J	Symbols Glossary	Updated Manufacturer symbol description Updated footnote
07/2022	J	Luminex Technical Support	Added link to website for translations
07/2022	J	Back Cover	Added European Union Statement
07/2022	J	Legal Page	Updated copyright date to include 2022 Updated trademark statement
06/2023	K	Cover Page	Updated EC Rep information
06/2023	K	Symbols Glossary	Add UK CA and Importer symbols
06/2023	K	Legal Page	Updated trademarks

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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.

NOTE: If you are running an IVD kit, or using the Luminex system in a regulated environment, it is important that you follow any additional instructions provided by the IVD assay kit manufacturer in addition to those in this insert, in accordance with your established laboratory procedure.

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 assay, 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.

Intended Purpose

The Luminex® 100/200™ Calibration Kit is an in vitro diagnostic accessory intended to normalize the settings for the classification channels (CL1 and CL2), the doublet discriminator (DD) and the reporter channel (RP1) for the Luminex 100 and Luminex 200 instruments.

For Laboratory Professional Use Only. This is an automated medical device.

Symbols Glossary

You will encounter these symbols throughout this manual. They represent warnings, conditions, identifications, instructions, and regulatory agencies.

|			
5.1.4*	Use-by date. Indicates the date after which the medical device is not to be used.	5.1.2* EC | REP	Authorized representative in the European Community/European Union. Indicates the Authorized representative in the European Community/European Union
5.5.1* IVD	*In vitro* diagnostic medical device. Indicates a medical device that is intended to be used as an in vitro diagnostic medical device	5.1.5* LOT	Batch Code. Indicates the *manufacturer's batch code* so that the batch or lot can be identified.
‡ CE	Conformite Europeenne (EU CE Marking of Conformity) CE conformity marking	5.1.1*	Manufacturer. Indicates the medical device manufacturer.
5.3.7*	Temperature Limit. Indicates the temperature limits to which the medical device can be safely exposed.	5.5.5*	Contains Sufficient for \<n\> Tests Indicates the total number of tests that can be performed with the medical device.
5.4.3*	Consult instructions for use or consult electronic instructions for use. Indicates the need for the user to consult the instructions for use.	5.1.6* REF	Catalogue Number. Indicates the manufacturer's catalogue number so that the medical device can be identified.
5.3.2*	Keep away from sunlight. Indicates a medical device that needs protection from light sources.	† Rx Only	Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. Only)
2 UK CA	UK Conformity Assessed	5.1.8*	Importer

* ANSI/AAMI/ISO 15223-1:2021, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.

† 21 CFR 809 (FDA Code of Federal Regulations).

‡ Council Directive Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.
2: *Medical Devices Regulations 2002* (UK MDR 2002)

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 Components

Kit Components	**REF**
Luminex® 100/200™ Calibration Kit	LX200-CAL-K25 ⅀ 25
25 strip wells	13-52047
Luminex® 100/200™ Calibration Kit CD	89-20191-00-001
Luminex® 100/200™ Classification Calibrator Microspheres, 5.0 mL	L100-CAL1 ⅀ 25
MagPlex® Classification Calibrator Microspheres, 5.0 mL	MCAL1-05 ⅀ 25
Luminex® 100/200™ Reporter Calibrator Microspheres, 5.0 mL	L100-CAL2 ⅀ 25

Kit Contents

- **25 disposable strip wells** - Each strip well holds the reagents for calibration 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:

- **CAL1** - Contains one microsphere set used to calibrate the system for nonmagnetic 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.
- **MCAL1** - Contains one microsphere set used to calibrate the system for MagPlex® microspheres.

- **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.

Instructions

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

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 and 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, follow the instructions provided with the *Luminex® 100/200™ Performance Verification Kit*.

System Preparation - Probe Height

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

NOTE: For instructions on adjusting the sample probe height, see the appropriate user manual for your system.

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.

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 calibration and verification kits.
5. Click the **Eject** button on the **System Status** bar.
6. Add two clean strip wells into the AMP as shown in Figure: Plate Layout.

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

Figure 1: Plate Layout
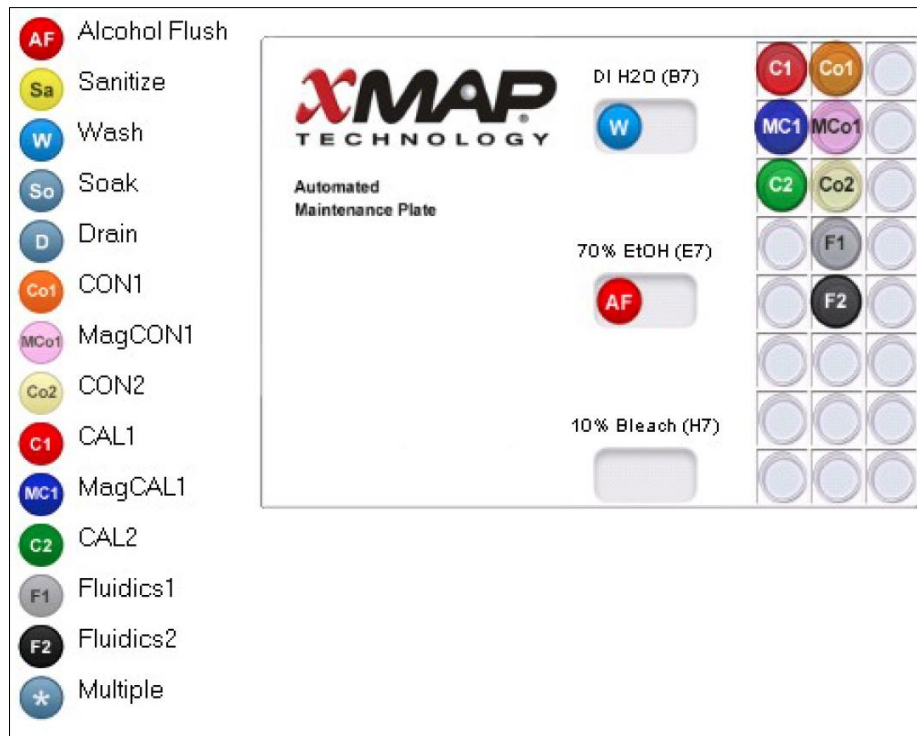
7. Gently vortex all calibration kit reagents for 10 seconds each.
8. Add DI water and 70% isopropanol or 70% ethanol to the reservoirs as shown in Figure: Plate Layout.

   NOTE: Fill reservoirs approximately 3/4 of the way full with appropriate reagent.

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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 Plate Layout.

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

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 Plate Layout.

    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 to 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 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 **Cmds & Routines** tab.
6. Calibrate the system and run the **Performance Verification** routine.

Other Resources

Refer to the appropriate user manual to obtain more information regarding the software or the system. You can also contact Luminex Technical Support.

Luminex Technical Support

Contact Luminex Technical Support by telephone in the U.S. and Canada by calling: 1-877-785-(2323)
Contact outside the U.S. and Canada by calling: +1 512-381-4397
International: + 800-2939-4959
Fax: 512-219-5114
Email: *support@luminexcorp.com*

Additional information is available on the Luminex website. Search on the desired topic, navigate through menus. Also, review the website's FAQ section. Enter *www.luminexcorp.com* in your browser's address field.

This manual can be updated periodically. For the latest version and related translations, contact Technical Support or visit https://www.luminexcorp.com/documents/.

For EU only: Please be aware that any serious incident that has occurred in relation to this IVD medical device should be reported to Luminex Technical Support and the competent authority of the EU Member State in which the user and/or patient is established.