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Luminex® 100/200™ Performance Verification Kit Package Insert

IVD For *In Vitro* Diagnostic Use.
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CE

EC REP

DiaSorin Italia S.p.A
Via Crescentino snc
13040 Saluggia (VC)
Italy

UK CA

DiaSorin Italia S.p.A.
UK Branch
Central Road
Dartford Kent DA1 5LR
UK

Technical Support
Telephone: 512-381-4397
North America Toll Free: 1-877-785-2323
International Toll Free: + 800-2939-4959
Email: *support@luminexcorp.com*
www.luminexcorp.com

Luminex Corporation
12212 Technology Blvd.
Austin, Texas 78727

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

Table of Contents

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 Verification Kit 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 verifier microspheres verify the integrity of the reporter channel (RP1). The fluidics microspheres verify the integrity of the system fluidics including well to well carryover.

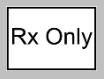
Intended Purpose

The Luminex® 100/200™ Performance Verification Kit includes reagents to verify the calibration and optical integrity for the Luminex 100/200 Instrument as well as reagents to verify the fluidics channels using observations of pressure, flow rate, and well-to-well carryover. Following calibration, use the Luminex 100/200 Performance Verification Kit to check all of the optic channels in the system for correct calibration. Be sure to verify every time you calibrate. If there is a problem with optical alignment or fluidics, Luminex 100/200 may pass calibration but fail performance verification.

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* 	Authorized representative in the European Community/European Union. Indicates the Authorized representative in the European Community/European Union.
5.5.1* 	*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* 	Batch Code. Indicates the *manufacturer's batch code* so that the batch or lot can be identified.
‡ 	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* 	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.	† 	Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. Only)
2 	UK Conformity Assessed	5.1.8* 	Importer

* 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™ 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 in this kit 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™ Performance Verification Kit	LX200-CON-K25 Σ 25
25 strip wells	13-52047
Luminex® 100/200™ Performance Verification Kit CD	89-20192-00-001
xMAP® Classification Control Microspheres, 5.0 mL	L100-CON1 Σ 25
MagPlex® Classification Control Microspheres, 5.0 mL	MCON1-05 Σ 25
xMAP® Reporter Control Microspheres, 5.0 mL	L100-CON2 Σ 25
xMAP® Fluidics 1 Microspheres, 5.0 mL	FLUID1-05 Σ 25
xMAP® Fluidics 2 Microspheres, 5.0 mL	FLUID2-05 Σ 25

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:

- **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.
- **MCON1** - Contains five microspheres internally labeled to the 100-plex map, but verifies that the size settings are correct for use of MagPlex® microspheres.
- **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.
- **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.
- **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. Adjust the probe height and perform fluidics prep 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 +/-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 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 CD.

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 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.

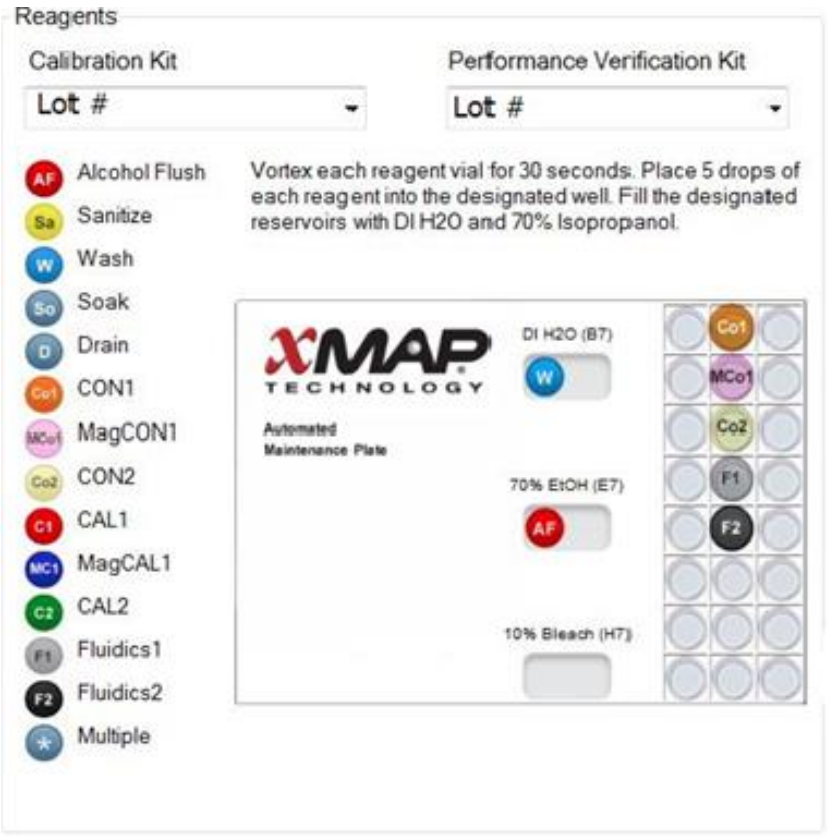
2. Click **Save**.
3. On the **Home** page, click **System Initialization**. The **Auto Maint** tab opens.

   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 section.

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 as shown in Figure 1 : Plate Layout.

   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: Plate Layout.

   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 strip well as shown in Figure Plate Layout.

   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 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

Any time you experience 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 by using a syringe or bottle.

   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 *http://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.

Luminex Corporation (Luminex) reserves the right to modify its products and services at any time. Notifications will be sent to end users regarding changes that impact the use, performance and /or safety and effectiveness of the device. Any modifications to the device will be made in accordance with applicable regulatory requirements. Luminex assumes no liability for any damages resulting from the off-label application or misuse of this information.