Luminex

Package Insert | IVD

FLEXMAP 3D® Calibration Kit

IVD For *In Vitro* Diagnostic Use.

Document Revision History

Effective Date	Revision	Section	Description of Change
07/2022	E	Cover Legal Disclaimer Page	Added reference to website for downloading the latest revisions of content Updated copyright, copyright date, revision, revision date Corrected authorize representative name
07/2022	E	Key to Symbols	Updated Manufacturer symbol description Updated footnote
07/2022	E	Intended Purpose	Added Intended Purpose statement
07/2022	E	Back Cover	Added European Union Statement
06/2023	F	Cover Legal Disclaimer Page	Updated EC Rep information Updated legal disclaimer Removed terms and conditions
06/2023	F	Key to Symbols	Added UK CA and Importer symbol

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FLEXMAP 3D® Calibration Kit
89-30000-00-401 Rev F
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EC REP

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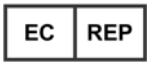
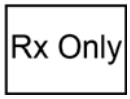
Luminex Corporation (Luminex) reserves the right to modify its products and services at any time. Notifications will be sent to end users regarding changes that impact the use, performance and /or safety and effectiveness of the device. Any modifications to the device will be made in accordance with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

Key to Symbols

5.1.4* 	Use-by date Indicates the date after which the medical device is not to be used.	5.3.7* 	Temperature Limit Indicates the temperature limits to which the medical device can be safely exposed.
5.1.5* 	Batch Code Indicates the *manufacturer's batch code* so that the batch or lot can be identified.	5.5.5* 	Contains Sufficient for <n> Tests Indicates the total number of tests that can be performed with the medical device.
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.
5.1.1* 	Manufacturer Indicates the medical device manufacturer.	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.
5.5.1* 	*In vitro* diagnostic medical device Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.	5.1.2* 	Authorized representative in the European Community/European Union Indicates the Authorized representative in the European Community/European Union.
† 	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. Only)	‡ 	Conformité Européenne (EU CE Marking of Conformity) CE conformity marking
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)

For use with the FLEXMAP 3D® System and xPONENT® Software.

Kit Components

Kit Components	REF
FLEXMAP 3D® Calibration Kit	F3DIVD-CAL-K25
25 strip wells	13-52047
FLEXMAP 3D® Calibration Kit CD	89-20370-00-001
FLEXMAP 3D® Classification Calibrator Microspheres, 5 mL	F3DCAL1-05
FLEXMAP 3D® e Classification Calibrator Microspheres, 5 mL	F3DeCAL1-05
FLEXMAP 3D® Reporter Calibrator Microspheres, 5 mL	F3DCAL2-05
FLEXMAP 3D® EDR Calibrator Microspheres, 5 mL	F3DCAL3-05

Table of Contents

Description

The FLEXMAP 3D® Calibration Kit calibrates the optics of the FLEXMAP 3D 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 is intended to be used with the off plate reagent area provided with the FLEXMAP 3D System.

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 FLEXMAP 3D® Calibration Kit contains all reagents needed for calibration of the FLEXMAP 3D platform with xPONENT® software.

The FLEXMAP 3D 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 which passes through the laser and detection area one microsphere at a time. Within the Luminex analyzer, lasers excite the internal dyes that identify each microsphere particle's color signature, and also any reporter fluorescence captured during the assay.

For the optics to function effectively and for different FLEXMAP 3D Systems to report similar results, it is important to calibrate the system. Calibrating the FLEXMAP 3D System normalizes the settings for the classification channels (CL1, CL2, and CL3), the doublet discriminator channel (DD), and the reporter channel (RP1). This is accomplished by using the FLEXMAP 3D Calibration Kit.

Following calibration, use the FLEXMAP 3D Performance Verification Kit (part number F3DIVD-PVER-K25) to run performance verification on the FLEXMAP 3D System. The FLEXMAP 3D Performance Verification Kit includes reagents to verify the calibration and optical integrity for the FLEXMAP 3D System.

Intended Purpose

Calibration is important to ensure the optical system functions effectively and different FLEXMAP 3D® systems report similar results. Calibrating the FLEXMAP 3D Instrument normalizes the settings for the classification channels (CL1, CL2 and CL3), the doublet discriminator (DD), and the reporter channel (RP1). Use the FLEXMAP 3D Calibration Kit to calibrate the system. After calibration, perform verification.

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

Storage

The FLEXMAP 3D® 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 FLEXMAP 3D 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 for calibration and can be inserted into the off plate reagent area.
- **CD** - The CD includes an importable .lxl file that contains the calibration target value data for the specific lots 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 calibration reagents provided within the same kit.

- **Calibration Reagents for 25 calibrations:**
  a. **F3DCAL1** - Contains one microsphere set used to calibrate the system for nonmagnetic MicroPlex® microspheres. During calibration, the system alters voltages within the optics for CL1, CL2 and CL3 until those values match the imported target values, thus calibrating the classification map. The same occurs for the DD signal.
  b. **F3DeCAL1** - Contains one microsphere set used to calibrate the system for MagPlex® microspheres.

c. **F3DCAL2** - 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.
d. **F3DCAL3** - Contains one microsphere set used to calibrate extended RP1 range for all xMAP® beads.

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 off plate reagent area, a calibration kit, and a performance verification kit to complete. Please refer to the *FLEXMAP 3D® 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 ±5°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 ±5°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 of your system.

Importing Kit Target Values

1. Start the xPONENT® software.
2. Insert the FLEXMAP 3D® 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 F3DIVDCAL-XXXXX-yymmdd, where XXXXX 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 *FLEXMAP 3D® Performance Verification Kit*.

System Preparation - Probe Height

Adjust the probe height whenever using new plate types, before system maintenance, or whenever there is a data acquisition problem.

For instructions on adjusting the sample probe height, see the appropriate user manual for your system: *xPONENT® for FLEXMAP 3D® 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.

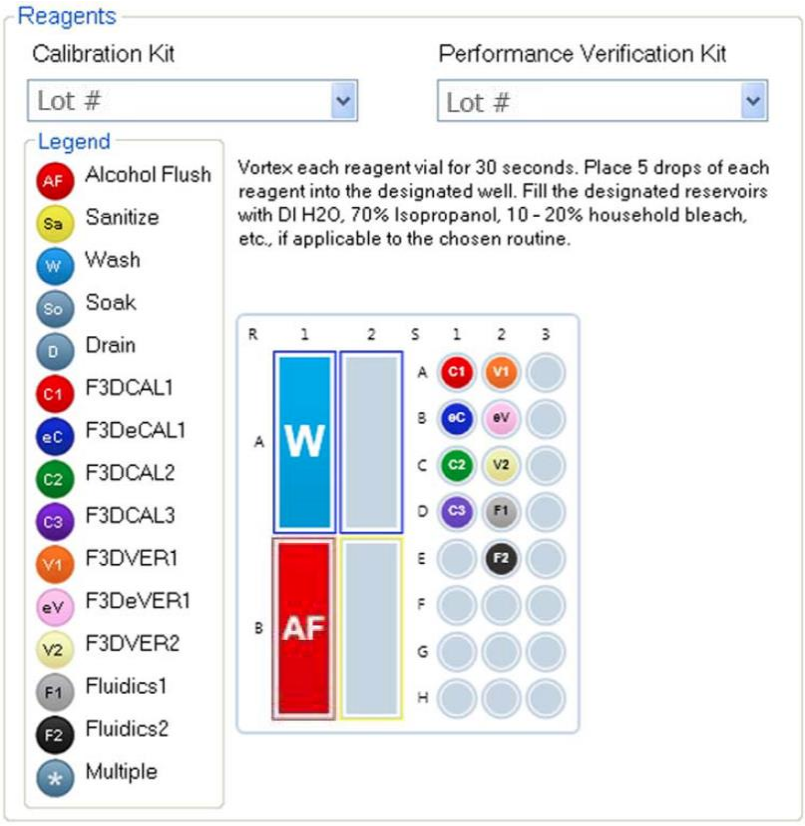
1. Navigate to the **Admin** page > **System Setup** tab; there are three options available for system initialization:
   a. Laser warm-up, fluidics, calibration and performance verification
   b. Laser warm-up, fluidics, performance verification
   c. Warm-up, fluidics

   NOTE: Option ”Laserwarm-up, fluidics, calibration and performance verification” must be selected for 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 that come 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 selecting it from the drop-down menu at the top right of the screen. Select the correct kit lot number for your calibration and verification kits.
5. Click **Eject** on the **System Status** bar.
6. Add two clean strip wells into the off plate reagent area 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 calibration kit reagents for 10 seconds each.

8. Add DI water and 70% isopropanol or 70% ethanol to the reservoirs as shown in the *Figure 1, "Plate Layout"*.
9. Completely invert the bottle and add five complete drops each of the calibration reagents (F3DCAL1, F3DeCAL1, F3DCAL2 and F3DCAL3) to the first well strip as shown in the *Figure 1, "Plate Layout"*.
10. Add five complete drops each of the performance verification reagents (F3DVER1, F3DeVER1, F3DVER2, Fluidics1, and Fluidics2) to the second well strip as shown in the *Figure 1, "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 & 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 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 **Cmds & Routines** tab.

    NOTE: Calibration and verification commonly fail when vials are not vortexed 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, 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), 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: 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.

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

Other Resources

Use the following resources to obtain more information about your FLEXMAP 3D® System and xPONENT® software:

- *xPONENT® for FLEXMAP 3D® Software User Manual*
- *FLEXMAP 3D® Hardware User Manua*l
- Luminex Technical Support

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.