Luminex

Package Insert | IVD

FLEXMAP 3D® Performance Verification 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

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FLEXMAP 3D® Performance Verification Kit
89-30000-00-402 Rev E

July 2022

EC REP

CE

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The Netherlands

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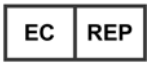
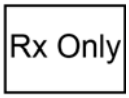
Key to Symbols

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 IVD tests that can be performed with the IVD kit reagents.
5.1.6* 	Catalog(ue) 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, as defined in EU Directives IVDD 98/79/EC and IVDR (2017/746).	5.4.3* 	Consult 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 Indicates the Authorized representative in the European Community
† 	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. Only)	‡ 	Conformite Europeenne (EU CE Marking of Conformity) CE conformity marking

* ISO 15223-1:2012, Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied—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.

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

Kit Components

Kit Components	REF
FLEXMAP 3D® Performance Verification Kit	F3DIVD-PVER-K25
25 strip wells	13-52047
FLEXMAP 3D® Performance Verification Kit CD	89-20371-00-001
FLEXMAP 3D® Classification Verifier Microspheres, 5 mL	F3DVER1-05
FLEXMAP 3D® e Classification Verifier Microspheres, 5 mL	F3DeVER1-05
FLEXMAP 3D® Reporter Verifier Microspheres, 5 mL	F3DVER2-05
xMAP® Fluidics 1 Microspheres, 5 mL	FLUID1-05
xMAP® Fluidics 2 Microspheres, 5 mL	FLUID2-05

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Table of Contents

Description

The FLEXMAP 3D® Performance Verification Kit is used in conjunction with the system calibrators to verify the optical calibration and optical integrity for the FLEXMAP 3D instrument. 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 performance verification kit is intended to be used with the off plate reagent area provided with the FLEXMAP 3D System.

Introduction

The FLEXMAP 3D® Performance Verification Kit contains all reagents needed for verification 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. This causes 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 and verify 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 to run Performance Verification. Performance Verification 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 FLEXMAP 3D Performance Verification Kit includes reagents to verify the calibration and optical integrity for the FLEXMAP 3D 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 verifier microspheres verify the integrity of the classification channels (CL1, CL2, and CL3) 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 FLEXMAP 3D® Performance Verification Kit includes reagents to verify the calibration and optical integrity for the FLEXMAP 3D 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 FLEXMAP 3D 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, FLEXMAP 3D may pass calibration but fail performance verification.

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

Storage

The FLEXMAP 3D® 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 of 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 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 performance verification and can be inserted into the off plate reagent area.
- **CD** - The CD includes an importable .lxl file that contains the verification 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 reagents provided within the same kit.

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

  a. **F3DVER1** - Contains eleven microsphere regions internally labeled with classification dyes (CL1, CL2 and CL3) to eleven regions on the 500-plex map that are most sensitive to optical misalignment and also verifies that the doublet discriminator settings are correct for use with MicroPlex® microspheres.

  b. **F3DeVER1** - Contains eleven microsphere regions internally labeled with the classification dyes (CL1, CL2, and CL3) to eleven regions on the 500-plex map and also verifies that the doublet discriminator settings are correct for use with MagPlex® microspheres.

  c. **F3DVER2** - Contains seven microspheres internally labeled with increasing amounts of reporter dye. F3DVER2 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 *FLEXMAP 3D® Calibration Kit Package Insert*. This procedure requires the off plate reagent area 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 ±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 and performance verification of your system

Importing Kit Target Values

1. Start the xPONENT® software.
2. Insert the FLEXMAP 3D® 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 and select the .lxl file F3DIVDVER-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 calibration kit, follow the instructions provided in the calibration kit CD.

System Preparation - Probe Height

Adjust the probe height whenever 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 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.

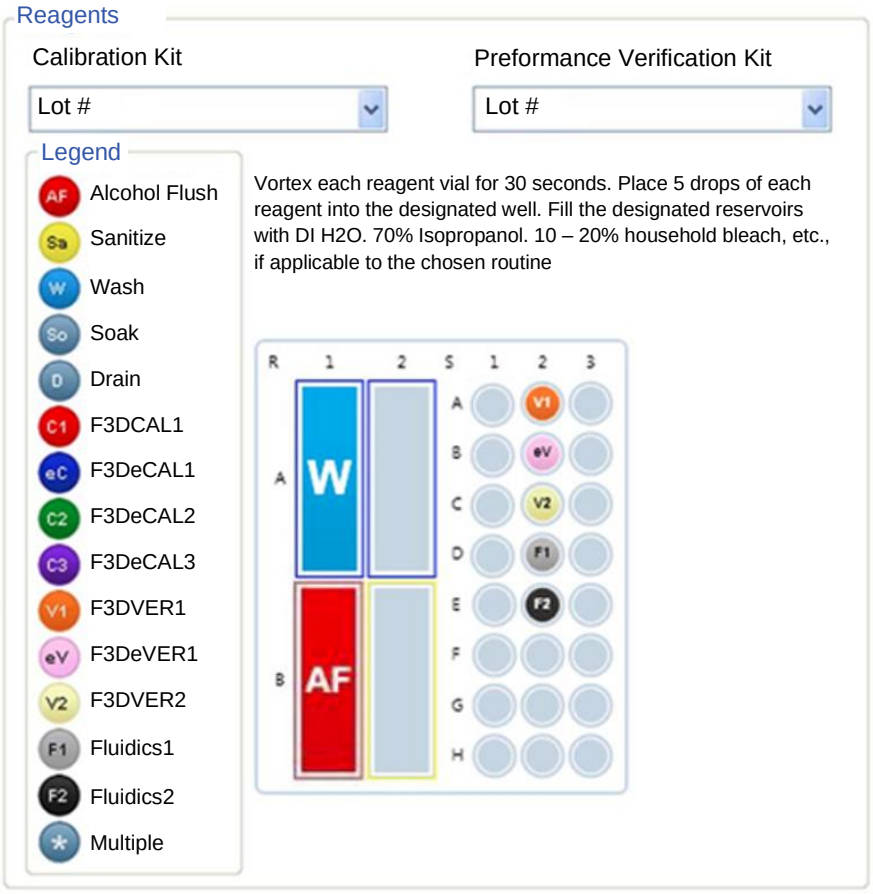
1. Navigate to the **Admin** page > **System Setup** tab; there are three options available for system initialization:
   a. Laser warm-up, fluidics, calibration, and performance verification
   b. Laser warm-up, fluidics, performance verification
   c. Warm-up, fluidics

   NOTE: Option “Laser warm-up, fluidics, 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 performance verification kit information has been imported into the software using the CD that comes with the kit. If not, follow the instructions in *“Importing Kit Target Values”* .
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. Choose the correct kit lot number for your calibration and verification kit.
5. Click the **Eject** button on the **System Status** bar.
6. Add one clean strip well into the off plate reagent area as shown in *Figure 1, “Plate Layout”*.

   NOTE: The plate layout in the software which directs 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, "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 (F3DVER1, F3DeVER1, F3DVER2, Fluidics1, and Fluidics2) to the second well strip, as shown in *Figure 1, "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 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, 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 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 Manual*
- 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.