

Luminex

Package Insert | RUO

FLEXMAP 3D[®] Performance Verification

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FLEXMAP 3D® Performance Verification Kit

89-60000-00-051 Rev E










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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 FLEXMAP 3D[®] System and xPONENT[®] Software.

Kit Components


Kit Components	REF
FLEXMAP 3D [®] Performance Verification Kit RUO  25	F3D-PVER-K25
25 strip wells	13-52047
FLEXMAP 3D [®] Performance Verification Kit CD	89-20190-00-001
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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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 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 performance verification kit is 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.

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 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 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 that 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 $\pm 5^{\circ}\text{C}$ 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 $\pm 5^{\circ}\text{C}$ 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 F3DVER-XXXXX-yymmdd, where XXXXX is the kit lot number, and yymmdd is the kit expiration date, then click **Open**.

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.

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.

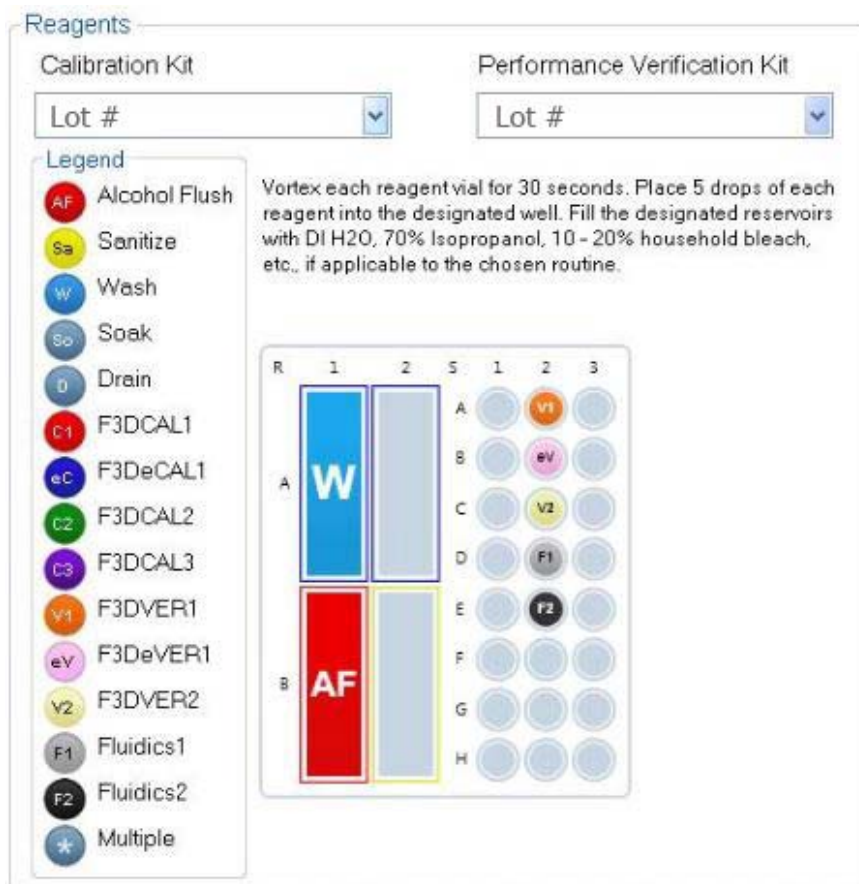
2. Click **Save**.
3. On the **Home** page, click **System Initialization**. The **Auto Maint** tab opens.

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 the "Importing Kit Target Values" section.

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 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 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 the 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 the system is already warmed up, the run cycle will take less time.

12. Once complete, click **Report**, choose to view either the enhanced **Performance Verification** report or the **Calibration & Verification** 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 **Cmnds & 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 **Cmnds & 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: 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 **Cmnds & Routines** tab.
6. Calibrate the system and run the **Performance Verification** routine.

Other Resources

See your appropriate FLEXMAP 3D[®] user manual for more information regarding FLEXMAP 3D[®] and xPONENT[®] software or contact Luminex Technical Support.