

Luminex[®]

Package Insert | RUO

MAGPIX[®] Performance Verification Kit

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MAGPIX® Performance Verification Kit

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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 MAGPIX® System and xPONENT® fSoftware.

Kit Components

Kit Components	REF
Luminex® MAGPIX® Performance Verification Kit  25	MPX-PVER-K25
25 strip wells	13-52047
MAGPIX® Performance Verification Kit CD	89-20234-00-001
MAGPIX® Verifier Microspheres, 6 mL	MPXVER-05
MAGPIX® Fluidics1 Microspheres, 6 mL	MPXFLUID1-05
MAGPIX® Fluidics2 Microspheres, 6 mL	MPXFLUID2-05

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Description

The Luminex® MAGPIX® Performance Verification Kit verifies the optical calibration of the MAGPIX instrument. This product is not to 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 to be used with the off-plate reagent block provided with the MAGPIX instrument.

Introduction

The MAGPIX® Performance Verification Kit contains all reagents needed for performance verification of the MAGPIX platform with xPONENT® software.

The MAGPIX system operates by using magnetic microspheres that 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 conveyed by Drive Fluid into an imaging chamber. Within the chamber, LEDs excite the internal dyes that identify each microsphere's color signature and the reporter fluorescence from the surface of the microspheres. The reporter fluorescence identifies the analytes captured during the assay. After MAGPIX makes images of the microspheres in the chamber, the microspheres are flushed to the waste container, clearing room for the next sample.

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

Following calibration, use the MAGPIX Performance Verification Kit to run performance verification on the MAGPIX System. The MAGPIX Performance Verification Kit includes reagents to verify the calibration, fluidics channels using observations of pressure, flow rate, and carryover from well-to-well for the MAGPIX system.

Storage

The MAGPIX® Performance Verification Kit must be stored in a dark place at 2°C to 8°C. The kit expires by the expiration 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 the short intervals required for working with the MAGPIX 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.

NOTE:

Kit Contents

- **25 disposable strip wells** - Each strip well holds needed reagents for performance verification and can be inserted into the off-plate reagent block.
- **CD** - The CD includes an importable .xml file that contains the verification target value data for the specific lot of reagent 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 only with the calibration reagents provided within the same kit.

- **Performance Verification Reagents for 25 verifications:**
 - a. **MPXVER** - contains six microsphere regions internally labeled with classification dyes (CL1 and CL2) to six regions on the MAGPIX® 50-plex map. Four of the microspheres are also internally labeled with increasing amounts of reporter dye, to check the reporter channel for reporter response, linearity, and reporter coefficients of variation. Microspheres are suspended in a Phosphate buffer, with a stabilizer and antimicrobial.

- b. **Fluidics1** - Contains a single microsphere set used in conjunction with Fluidics2 to measure well-to-well carryover and detect issues with sample retention in fluidic lines or inefficient presentation of sample to optics. Microspheres are suspended in a Phosphate buffer, with a stabilizer and antimicrobial.
- c. **Fluidics2** - Contains a buffer solution and a second bead region that facilitates measurement of the microspheres contained in Fluidics1. Microspheres are suspended in a Phosphate buffer, with a stabilizer and antimicrobial.



WARNING: Luminex[®] reagents contain ProClin[®] as a preservative. This can cause allergic reactions in some people. The ProClin content is < 0.05%.

Instructions

The following instructions are for performance verification only. This procedure requires the off-plate reagent area and a performance verification kit to complete. If you run calibration at the same time that you run performance verification, refer to the *MAGPIX[®] Calibration Kit Package Insert*. The following instructions describe system start-up procedures.

Run performance verification daily. Prime the system, perform alcohol flushes to remove air from the system, and adjust the probe height 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 to start and run both calibration and performance verification of your system.

Importing Kit Target Values

1. Start the xPONENT[®] software.
2. Insert the MAGPIX[®] 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 MPXVER-XXXXX-yyymmdd, where XXXXX is the kit lot number, and yyymmdd is the kit expiration date, then click **Open**.

NOTE: To import target values for the MAGPIX Calibration Kit, repeat the steps above using the Calibration CD.

System Preparation - Probe Height

Adjust the probe height whenever you use a new plate type, after system maintenance, or as part of troubleshooting.

NOTE: Improper probe height can cause failed verification.



For instructions on adjusting the sample probe height, see the appropriate user manual for your system: *xPONENT[®] for MAGPIX Software User Manual*.

Daily System Start-Up

NOTE: Calibration is required weekly for the instrument. Performance verification should be performed daily to check system integrity and to 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. Fluidics prep, calibration, performance verification
- b. Fluidics prep, performance verification
- d. Fluidics prep

NOTE: Option "Fluidics prep, performance verification" must be selected for the rest of the instructions.

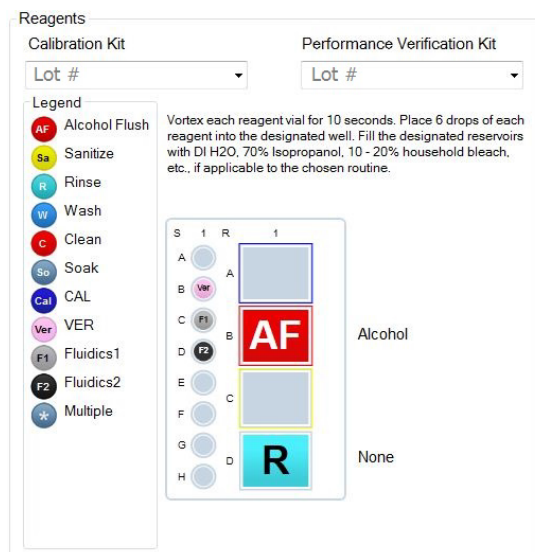
2. Click **Save**.
3. On the **Home** page, click **System Initialization**. The **Auto Maint** tab opens.

NOTE: Make sure the performance verification kit information has been imported into the software using the CD that come 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 performance verification kits.
5. Click the **Eject** button on the **System Status** bar.
6. Add one clean strip well into the off-plate reagent block as shown.

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 70% isopropanol or 70% ethanol to the **Alcohol Flush** reservoir as shown in the *Figure 1 "Plate Layout,"* image. The reservoir used for **Rinse** should be empty because the **Rinse** command only expels fluid.
9. Completely invert bottle and add 6 drops each of the performance verification reagents (MPXVER, Fluidics1, and Fluidics2) to the well strip as shown in the *Figure 1 "Plate Layout,"* image.

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 15 minutes.

Once complete, click **Report**, choose to view either the **Performance Verification** report or the **Calibration & Verification** report, select the appropriate filters, and click **Generate**

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, ensure 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 0.1 N NaOH.
5. Run the **Weekly Maintenance** routine on the **Cmnds & Routines** tab.
6. Calibrate the system and run the **Performance Verification** routine.

Other Resources

Use the following resources to obtain more information about your MAGPIX® System and xPONENT® software.

- *xPONENT® for MAGPIX® Software User Manual*
- *MAGPIX® Hardware Installation and User Manual*
- Luminex® Technical Support