Luminex

Package Insert | IVD

MAGPIX® Performance Verification Kit

IVD For *In Vitro* Diagnostic Use.

Document Revision History

Effective Date	Revision	Section	Description of Change
07/2022	F	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	F	Key to Symbols	Updated Manufacturer symbol description Updated footnote
07/2022	F	Intended Purpose	Added Intended Purpose statement
07/2022	F	Back Cover	Added European Union Statement
05/2023	G	Front Cover	Updated EC Rep information Updated legal disclaimer
05/2023	G	Key to Symbols	Added UK CA and Importer symbols

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MAGPIX® Performance Verification Kit

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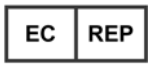
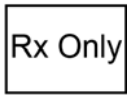
Key to Symbols

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 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)	‡ 	Conformite Europeenne (EU CE Marking of Conformity) CE conformity marking
2 	UK Conformity Assessed	5.1.8* 	Importer

* ANSI/AAMI/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 MAGPIX® System and xPONENT® Software.

Kit Components

Kit Components	REF
MAGPIX® Performance Verification Kit  25	MPXIVD-PVER-K25
25 strip wells	13-52047
MAGPIX® Performance Verification Kit CD	89-20287-00-001
MAGPIX® Verifier Microspheres, 6 mL	MPXVER-05
MAGPIX® Fluidics1 Microspheres, 6 mL	MPXFLUID1-05
MAGPIX® Fluidics2 Microspheres, 6 mL	MPXFLUID2-05

Table of Contents

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.

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 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 and fluidics channels using observations of pressure, flow rate, and carryover from well-to-well for the MAGPIX system.

Intended Purpose

Following calibration, the MAGPIX® Performance Verification Kit is used to check all of the optical channels in the system for correct calibration. It is essential to verify every time calibration is performed. If there is a problem with optical integrity or fluidics, MAGPIX may pass calibration but fail performance verification. The MAGPIX Performance Verification Kit includes reagents to verify the calibration and optical integrity for the MAGPIX system as well as reagents to verify the fluidics channels using observations of bead count and well-to-well carryover.

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

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.

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 .lxl 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.

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 ±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 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 folderand select the .lxl file MPXVER-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 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, before 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.

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.

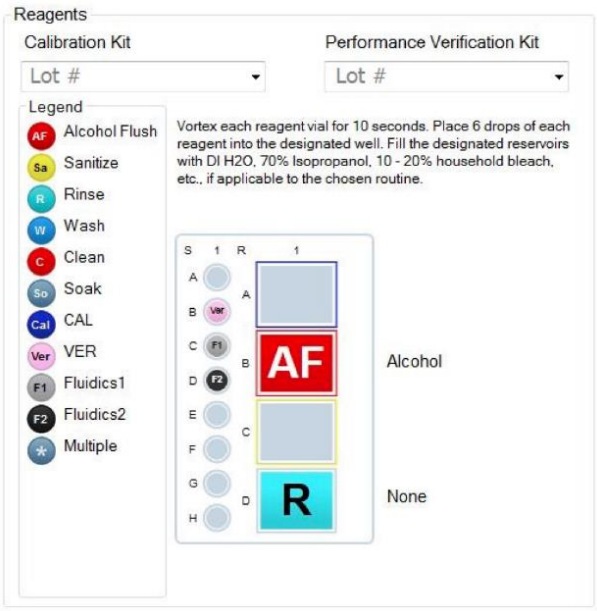
1. Navigate to the **Admin** page > **System Setup** tab; there are three options available for system initialization:
   a. Fluidics prep, calibration, performance verification
   b. Fluidics prep, performance verification
   c. Fluidics prep

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

Other Resources

See your appropriate MAGPIX® user manual for more information regarding MAGPIX® and xPONENT® software or contact 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.