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xMAP INTELLIFLEX® Calibration Kit Package Insert

RUO For Research Use Only.
Not for use in diagnostic procedures.
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Symbols Glossary

You will encounter these symbols throughout this manual. They represent warnings, conditions, identifications, instructions, and regulatory agencies.

Symbol	Meaning	Symbol	Meaning
	Use-by-date.		Temperature Limit.
	Caution.		Batch Code.
	Contains sufficient <n> Tests.		Keep away from sunlight.
	Catalog(ue) Number.		Consult instructions for user.
	Manufacturer.		For Research Use Only. Not for use in diagnostic procedures.

Luminex Technical Support

Contact Luminex Technical Support in the U.S. and Canada by calling: 1-877-785-2323
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Additional information is available on the Luminex website. Search on the desired topic, navigate through menus. Also, review the website's FAQ section. Enter *http://www.luminexcorp.com* in your browser's address field.

This manual can be updated periodically. To ensure that you have a current version, contact Technical Support.

Introduction

The xMAP INTELLIFLEX® Calibration Kit calibrates the optics of the xMAP INTELLIFLEX 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. The calibration kit contains all reagents needed for calibration of the xMAP INTELLIFLEX System.

The xMAP INTELLIFLEX 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 xMAP Sheath Fluid PLUS is injected into the cuvette, causing the microspheres to form a narrow column and pass through the laser and detection area one at a time. Within the xMAP INTELLIFLEX System, lasers excite the internal dyes that identify each microsphere's color signature, and any reporter fluorescence captured during the assay.

Calibration is important to ensure the optical system functions effectively and different xMAP INTELLIFLEX Systems report similar results. Calibrating the xMAP INTELLIFLEX System normalizes the settings for classification channels (CL1, CL2, and CL3), the doublet discriminator channel (DD), and the reporter channels (RP1 and RP2). Use the xMAP INTELLIFLEX Calibration Kit to calibrate the system.

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 Dashboard. In addition, the software has multiple alerts if the +/-5°C tolerance has been exceeded.

Following calibration, use the xMAP INTELLIFLEX Performance Verification Kit to run performance verification on the xMAP INTELLIFLEX System. This helps ensure that classification channels, the DD channel, and reporter channels are all performing as intended. The xMAP INTELLIFLEX Performance Verification Kit includes reagents to verify the calibration and optical integrity for the xMAP INTELLIFLEX System. Please refer to the *xMAP INTELLIFLEX Performance Verification Kit Package Insert*, for more information about kit contents and the performance verification results.

A system may pass calibration but fail performance verification. If this occurs, contact *Luminex Technical Support*. The xMAP INTELLIFLEX Dashboard contains shortcuts that are useful to start up and run calibration of your system.

Materials Provided

Kit Components	REF
xMAP® INTELLIFLEX Calibration Kit	IFX-CAL-K20 Σ 20
xMAP INTELLIFLEX Calibrator, 10.0 mL	IFXCAL-10
25 strip wells	13-52047

Calibration Reagent for 20 calibrations:

- **IFXCAL-10** - Contains one microsphere set used to calibrate the system for all microsphere types and reporter settings. During calibration, the system alters voltages within the optics for CL1, CL2, and CL3 until those values match the imported target values. The same occurs for both MicroPlex® and MagPlex® DD settings, RP2, and for the various RP1 modes (Low PMT Luminex® 200™, High PMT Luminex® 200™, and xMAP INTELLIFLEX® operating modes).

Storage

The xMAP INTELLIFLEX® 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 xMAP INTELLIFLEX System.

For more information on ingredients and safety precautions, consult the Safety Data Sheet (SDS) for instructions.

Warnings and Precautions

1. For Research Use Only. Not for use in diagnostic procedures.
2. Using unauthorized third-party software with xMAP INTELLIFLEX® Software can result in corruption or failure of the xMAP INTELLIFLEX Software. Do not use third-party software on the xMAP INTELLIFLEX System.
3. Use of non-Luminex approved sheath fluid shall constitute “Improper Use” and can void the warranty provided by Luminex and/or its authorized partner.
4. Train personnel who use, maintain, or clean the instrument in standard laboratory safety practices and follow those practices when handling the instrument.
5. Samples and waste fluid can contain biohazardous material. Where exposure to biohazardous material, including in an aerosol form, exists, follow appropriate biosafety procedures, use personal protective equipment, and use ventilation devices.
6. Safety Data Sheets (SDS) are available by contacting Luminex Corporation or visiting our website at *www.luminexcorp.com*.
7. Do not eat, drink, or smoke in the work areas.
8. Do not use the kit or any kit components past the expiration date indicated on the kit carton label.

Calibrate the Sample Probe Height

Calibrate the sample probe height to ensure proper acquisition of samples for new plate types, before system maintenance, after replacing the sample probe from the system, or as part of troubleshooting. Calibrating the sample probe height also ensures that the sample probe drops far enough into the well to acquire the sample without compromising the bottom of soft bottom plates or halting before reaching the bottom of steeply sloped wells. To prevent soft-bottom plates from being pierced by the sample probe, use the alignment disk included in the Sample Probe Height Adjustment Kit (CN-0015-01) shipped with the instrument or use the alternative method listed in the subsequent section.

Ensure there is no liquid in the wells or reservoirs before calibrating the sample probe height. Failure to do so will result in the system interpreting the liquid level as the bottom of the plate.

Sample probe height calibrations are saved separately for each of the three sections: **PLATES**, **RESERVOIRS**, and **OFF-PLATE STRIPS**. Ensure all three are calibrated. Refer the *xMAP INTELLIFLEX User Manual* for instructions on adjusting the sample probe height for assay plates.

⚠	Correct sample probe height is critical to successful sample acquisition and calibration. Problems with the sample probe height can lead to fluid leaks and inhibit sample acquisition.
	Ensure that the sample probe height is set correctly before calibrating the system.

Calibrating Reservoir & Strip Well Probe Height

There is one probe height for the reservoirs and one for the strip wells. The probe height is automatically saved after auto calibration.

1. Select in the lower right-hand corner of the screen to eject the plate carrier
2. Place off-plate reagent block on the plate carrier with one replacement strip well in the middle row of the off-plate reagent block. The strip well is provided with the Calibration and Performance Verification kit.

   NOTE: The off-plate reagent block is keyed and can only be installed in one direction.
3. Verify no liquid is present in the strip well or reservoirs.
4. Select to retract the plate carrier.
5. Select in the upper left-hand corner of the screen then navigate to **MAINTENANCE** > **PROBE HEIGHT**.
6. Press **AUTO CALIBRATE** in the **RESERVOIRS** section. The sample probe automatically adjusts to the reservoirs and saves the probe height. A message is displayed indicating the probe height was saved.
7. Once the system finishes calibrating the sample probe height in the **RESERVOIRS** section. Press **AUTO CALIBRATE** in the **OFF-PLATE STRIPS** section. The sample probe automatically adjusts to the wells and saves the probe height. A message is displayed indicating the the probe height was saved.
8. Probe Height Calibration is now complete for Reservoirs and Strip Wells.

Import Calibration or Performance Verification Kits

Before calibrating or verifying the instrument, it's necessary to import a set of target values which are unique to each lot of each reagent. Import lot-specific target values by scanning the barcode included with each reagent kit.

The integrated barcode reader is located below the touchscreen, to the right of the sliding front door. The scanner times out and the dialog closes automatically after a period of time if a readable barcode is not detected.

Find replacement barcodes for the Calibration or Performance Verification Kits at *www.luminexcorp.com/intelliflex*. Print or use a mobile phone screen to scan the replacement barcodes. If the integrated barcode reader is not functioning properly, contact *Luminex Technical Support.*

To import lot-specific target values,

1. Select in the upper left-hand corner of the screen and navigate to **MAINTENANCE** > **CAL/VER**.
2. If not already selected, select the **RUN CAL/VER** tab on the left navigation bar.
3. Select **IMPORT KIT** from the top of the screen.
4. Select **SCAN**.
   a. If the dialog closes because scanner times out, select **IMPORT KIT > SCAN** from the top of the screen again.
5. Use the barcode reader located below the touchscreen to scan the barcode on the Calibration or Performance Verification Kit Target Value Card (provided with the kit). If the scan is successful, a message displays stating the kit lot imported successfully.

   NOTE: An error message is displayed if the lots were previously imported.

   a. The kit lot number and expiration date are displayed in the **SCAN NOW** field.
   b. The imported kit is automatically selected in the appropriate **CALIBRATION**, **PERFORMANCE VERIFICATION**, or **FLUIDICS VERIFICATION** drop-down menu.
6. If necessary, scan another barcode.
7. Select **CLOSE**. If **CLOSE** is not selected, the dialog box closes automatically**.**

Calibrate the System

Calibration is important to ensure the optical system functions effectively. Calibrating the xMAP INTELLIFLEX® System normalizes the settings for the classification channels (CL1, CL2, and CL3), the doublet discriminator (DD), and the reporter channels (RP1 and RP2 (DR-SE model only)). Use the xMAP INTELLIFLEX Calibration Kit to calibrate the system. Following calibration, use the xMAP INTELLIFLEX Performance Verification Kit to check all of the optical 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, the xMAP INTELLIFLEX System may pass calibration but fail performance verification.

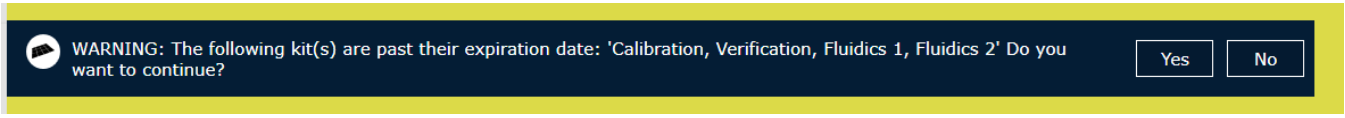
Track the system calibration and verification results through **MAINTENANCE > CAL/VER > HISTORY**. Target value information for calibration and verification microspheres is available on the Calibration or Performance Verification Kit Target Value Card that comes with the kit and on the Luminex website at *www.luminexcorp.com*.

Calibrate the system at least once a week. The xMAP INTELLIFLEX System will notify you when it is time to recalibrate and the Dashboard displays the current calibration status. In addition, recalibrate the system if any of the following occur:

- The delta calibration temperature exceeds +/- 5°C.
- The instrument is moved.
- You experience sample acquisition problems.
- The instrument undergoes hardware maintenance, such as replacement of a part.

Verifier xMAP® microspheres are used to verify the calibration and optical integrity for the system. Do not dilute calibrators or verifiers.

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE** > **CAL/VER**.
2. If not already selected, select **RUN CAL/VER** on the left navigation bar.
3. Select the reagent lot from the **CALIBRATION**, **PERFORMANCE VERIFICATION**, and **FLUIDICS VERIFICATION** drop-down menus. Choose the correct reagent lot numbers for your calibration and performance verification kits by selecting the lot number in the drop-down menu that matches the lot number on the reagent bottle.
4. Select the **RUN** check boxes for **CALIBRATION**, **PERFORMANCE**, and **FLUIDICS**.
   a. If any of the lots are expired, the system will still allow you to run the expired lots but will prompt you to confirm and note the lot expiration in the system log. Expired lots are also indicated in the dashboard.



NOTE: Always perform verification after calibration. Fluidics can be run as part of the calibration and performance verification procedures or as a standalone procedure.

5. Select  to eject the plate carrier.
6. Place one clean strip well in the top row of the off-plate reagent block.
7. Gently vortex all calibration and performance verification kit reagents for approximately 10 seconds each to ensure homogeneity. Do not dilute the reagents.

8. Fill the appropriate reservoirs 3/4 full of deionized water (DI water) and 3/4 full of 70% isopropanol or 70% ethanol, as indicated in the plate layout displayed on the **RUN CAL/VER** tab.
9. Completely invert the reagent bottles, and add six drops per well of each calibration reagent (IFXCAL-10) and performance verification reagent (IFXVER-10, FLUID1-05, and FLUID2-05) to the strip well, as indicated in the plate layout displayed on the **RUN CAL/VER** tab.

   NOTE: Check the label on the bottles to ensure you are dispensing the correct reagent.
10. Select  to retract the plate carrier.
11. Select  to run. The instrument will wait until the lasers are warmed up before calibrating the system.

NOTE: Calibration and verification commonly fail when vials are not mixed thoroughly, reagents are in the wrong well locations, or the wrong kit lot values are selected.

View and Export Calibration or Performance Verification History

The xMAP INTELLIFLEX® System allows you to create a report of your system's calibration, verification, and fluidics history. Each report is a multi-page Excel® file with summary and detail pages, and includes lot numbers, timestamps, and run information. Luminex Technical Support uses this information to aid in troubleshooting failures but the information may also be used for your site's internal QC purposes.

To view a calibration, performance verification, or fluidics verification history report,

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE** > **CAL/VER**.
2. If not already selected, select **HISTORY** on the left navigation bar.
3. Select **CALIBRATION**, **PERFORMANCE VERIFICATION**, or **FLUIDICS VERIFICATION** on the top of the screen to view the history.

To export a calibration, performance verification, or fluidics verification history report:

1. Select **CALIBRATION**, **PERFORMANCE VERIFICATION**, or **FLUIDICS VERIFICATION** on the top of the screen, if it is not already selected.
2. Toggle the **DATE RANGE** radio button to filter the results by a date range, or select **ALL** to view all of the results.
   a. If a date range was selected:
      i. Select the Calendar icon in the **FROM** field, select a date and time, and select **CLOSE**.
      ii. Select the Calendar icon in the **TO** field, select a date and time, and select **CLOSE**.

      Ensure the earlier date is entered in the **FROM** field and the later date is entered in the **TO** field. The system will not prevent you from entering a **FROM** date that is later than the **TO** date. If the range is entered incorrectly, the system will not display results.
3. Select the check box(es) for the data to export.
4. Select **EXPORT**.
5. Choose the USB or network drive location where you want to save the report.
6. Edit the File name, if necessary.
7. Select **EXPORT**. A message displays stating whether the selected result(s) was successfully exported or not.

Maintenance

Any time you experience acquisition problems (or once a week 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 sample probe with water from the narrow end to the larger end by using a syringe or bottle.

   NOTE: You must force water into the probe in order to complete the rinse.

3. Replace and re-calibrate the sample probe height.
4. Run the **Alcohol Flush** command with 70% isopropanol or 70% ethanol on the **ROUTINES** page.
5. Run the **Weekly Maintenance** routine on the **ROUTINES** page.
6. Calibrate the system and perform performance verification.

Other Resources

Refer to the applicable user manual to obtain more information regarding the software or the system. You can also contact *Luminex Technical Support*.