xMAP® Sheath Fluid PLUS
Product Information Sheet (IVD)

Document Revision History

Effective Date	Revision	Section	Description of Change
07/2022	B	Intended Purpose	Added Intended Purpose statement
07/2022	B	Procedure Note	Added link to website for translations
07/2022	B	Symbols Glossary	Updated Manufacturer symbol description Updated footnote
07/2022	B	Back Cover	Added European Union Statement Updated revision and date
07/2022	B	Legal page	Updated copyright date to include 2022 Updated trademark statement
06/2023	C	Symbols Glossary	Added UK CA and Importer symbol
06/2023	C	Back Cover	Updated EC Rep information

Summary

Use xMAP® Sheath Fluid PLUS (40-50035) as the delivery medium to carry the sample to the optics component of the xMAP based instruments.

USE OF NON-LUMINEX APPROVED SHEATH FLUID PLUS SHALL CONSTITUTE “IMPROPER USE” AND MAY VOID WARRANTY RIGHTS PROVIDED BY LUMINEX AND/OR ITS AUTHORIZED PARTNER.

Intended Purpose

The xMAP® Sheath Fluid PLUS act as the delivery medium, which carries the sample to the optics component of the Luminex® xMAP® technology-based instruments.

For Laboratory Professional Use Only. This is not an automated medical device.

Safety Precautions

Avoid contact with skin and eyes. A Safety Data Sheet (SDS) is available upon request. Take proper precautions when lifting. One full container weighs approximately 23 kg. (50 lbs.). Requires two people for lifting. Do not stack containers above four (4) high.

Ingredients

xMAP® Sheath Fluid PLUS contains sodium and potassium salts and an antimicrobial cocktail in water.

Storage

Store at 15°C to 30°C.

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Limitations

You must follow these product information sheet instructions. Reliability of results cannot be guaranteed if you deviate from these instructions. When stored at 15°C to 30°C, the product should perform as expected up to the expiration date stated on the container label.

Disposal

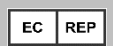
xMAP® Sheath Fluid PLUS contains sodium azide (less than 0.025%) as a preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Refer to local guidelines and regulations for proper disposal of unused and used Sheath Fluid PLUS.

Procedure

1. Remove tape from container.
2. Lift off round white cover.
   NOTE: Product Information Sheets are available in other languages upon request. Contact Luminex Technical Support for information or access on website at *https://www.luminexcorp.com/documents/.* Then, using the Search feature, search for the desired product information sheet.

Refer to the user manual for proper use of the xMAP® Sheath Fluid PLUS as applicable.

Symbols Glossary

5.1.5* 	Batch Code. Indicates the *manufacturer's batch cod*e so that the batch or lot can be identified.	5.1.1* 	Manufacturer. Indicates the medical device manufacturer	5.3.7* 	Temperature Limit. Indicates the temperature limits to which the medical device can be safely exposed.
5.1.4* 	Use-by date. Indicates the date after which the medical device is not to be used.	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.	5.1.6* 	Catalogue Number. Indicates the manufacturer's catalogue number so that the medical device 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.	5.5.1* 	*In vitro* diagnostic medical device. Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.	† 	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.	5.1.2* 	Authorized representative in the European Community/European Union. Indicates the Authorized representative in the European Community/European Union.	2 	UK Conformity Assessed
5.1.8* 	Importer				

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* ANSI/AAMI/ISO 15223-1:2021, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.

Council Directive Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

† 21 CFR 809 (FDA Code of Federal Regulations)

2: *Medical Devices Regulations 2002* (UK MDR 2002)

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.

Rx Only

IVD For *In Vitro* Diagnostic Use.

89-60000-00-174 Rev C

06/2023

REF Product No: 40-50035

Quantity: 1 x 20 L

To order more product:

Email:

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Fax: 512-219-0544

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