xMAP® Sheath Concentrate PLUS Product Information Sheet (IVD)

Document Revision History

Effective Date	Revision	Section	Description of Change
07/2022	C	Intended Purpose	Added Intended Purpose statement
07/2022	C	Procedure- Note	Added link to website for translations
07/2022	C	Symbols Glossary	Updated Manufacturer symbol description Updated footnote
07/2022	C	Back Cover	Added European Union Statement Updated revision and date
07/2022	C	Legal page	Updated copyright date to include 2022 Updated trademark statement
06/2023	D	Symbols Glossary	Added UK CA and Importer symbol
06/2023	D	Back Cover	Updated EC Rep information
07/2023	E	Back Cover	No content changes.

Summary

Once diluted to the working volume of 20 liters, use xMAP® Sheath Concentrate PLUS (40-50036) 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 Concentrate PLUS act as the delivery medium, which carries the sample to the optics component of 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. Once diluted, take proper precautions when lifting. One full container weighs approximately 23 kg. (50 lbs.). Requires two people for lifting. Sheath Concentrate PLUS is harmful to aquatic life with long lasting effects.

If the Sheath Concentrate PLUS bottle is leaking, DO NOT USE the product. Contact Luminex Technical Support to report the damage.

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

Storage
Store at 15°C to 30°C.

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. xMAP® Sheath Concentrate PLUS is for further dilution only.

Disposal
Undiluted xMAP® Sheath Concentrate PLUS contains sodium azide (less than 0.45%) as a preservative. Once diluted to 20 L, the solution contains less than 0.025% sodium azide 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 undiluted, diluted and used Sheath Concentrate PLUS.

Procedure
1. Gently invert the Sheath Concentrate PLUS bottle 5 to 10 times; additional vigorous inversions may be necessary to dissolve precipitate that may have formed during shipping.
2. Remove cap from the 1 L bottle of Sheath Concentrate PLUS and pour contents into a 20 L secondary container. **NOTE:** Luminex recommends using the 5 gallon carboy with 3"opening, catalog #97028 from US Plastic Corporation (*www.usplastic.com*) as the secondary container for dilution as it will accommodate the sheath delivery assembly.
3. Fill with 19 L of CLRW (Clinical Laboratory Reagent Water) or better. Stir until homogeneous.
4. Complete 1X Dilution Sheath Concentrate PLUS label provided. Apply a three-month expiration date from the preparation date, and apply to the 20 L secondary container.
5. Apply the Sheath Fluid warning label to ensure that correct placement of diluted sheath is maintained.
6. After dilution, place container below level of the Luminex instrument as described in the applicable user manual. **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.

Approximate Targets for 1:20 Dilution:	pH: 7.4
	Conductivity: 15 mS/cm
	Refractive Index: 1.335

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

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Symbols Glossary

5.1.5* 	Batch Code. Indicates the *manufacturer's batch code* 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.	5.4.4* 	Caution. Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
† 	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.
GHS07‡ 	Irritant	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.

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).

‡ ST/SG/AC.10/30/Rev.7 Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh revised edition

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

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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.

89-60000-00-176 Rev E

07/2023

REF Product No: 40-50036

For further dilution only.

Quantity: 1 L

To order more product:

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