

CyFlow™ SHEATH

IVD REF AY104869, BR059434

Identification of the IVD reagent CyFlow™ SHEATH

Intended purpose

CyFlow SHEATH is a sheath fluid for Sysmex flow cytometer, and is used by healthcare professionals and properly trained personnel. For appropriate use of the product, refer to instructions for use of applicable Sysmex flow cytometers.

Principles of the examination method

Immunophenotyping by flow cytometry provides a quick and accurate assessment of cell type and frequency. It is often used for leukocyte subset quantification and provides useful information in the evaluation of autoimmune disorders, immunodeficiencies and hematological malignancies. Leukocyte subsets are differentiated by light scatter properties as well as surface antigen expression in flow cytometry.

Components

Maleic acid < 0.10 %

Warnings and precautions

1. Follow the warnings and precautions, as described on the product container, package box, package insert or device's instructions for use, to handle the product correctly.
2. Do not use the product if it shows signs of contamination or instability, such as turbidity or discoloration.
3. Never use this product on human body. Avoid direct contact with skin, eyes and mucous membranes. Do not ingest. In case of skin contact, rinse immediately with plenty of water. In case of contact with eyes or mucous membranes, rinse immediately with plenty of water, and seek medical attention. In case of ingestion, seek medical attention immediately.
4. Please see the safety data sheet for the country-specific classification.

EUH208 Contains maleic acid. May produce an allergic reaction.
EUH210 Safety data sheet available on request.

Additional required equipment

Consult the instructions for use for the specific devices to be used with.

Examination procedure

1. Remove the cap from the new product container.
2. Register the reagent code (barcode).
3. Gently remove the spout kit from the old product container and insert straight into the new product container.
4. Fasten the spout kit.
5. Refer to the device's instructions for use for further information.

Storage and shelf life of unopened product

Store the product at 2-35 °C. Keep away from direct sunlight. When the product is properly stored in its sealed container, it is stable until the expiration date printed on the label.

Storage and shelf life after first opening

Once opened the product is stable for 60 days.
After opening, store at the operating temperature of the target device with the reagent connected to the device.

Performance characteristics

Performance should be within device specifications. Refer to the device's instructions for use for further information.

Limitations of the examination procedure

1. The reliability of the analysis values cannot be guaranteed if the product is used outside the prescribed intended purpose.
2. The product must not be used after its expiration date.
3. Do not refill and reuse product containers.
4. Handle the product with care to prevent air bubbles. If air bubbles are present, the performed analysis may be incorrect.
5. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting the opened reagent is not recommended.
6. If frozen, thaw, mix thoroughly and allow time for bubbles to dissipate before use.
7. The use of this product is validated on specific devices to optimize product performance and meet product specifications. Please refer to the instructions for use of your device to confirm that the use of this product is authorized by Sysmex. Sysmex cannot take the responsibility for patient results obtained from the use of Sysmex products on unauthorized devices. It is the responsibility of the user to validate modifications to these instructions or use of the product on devices other than those specified by Sysmex.


Primary sample collection, handling and storage

CyFlow SHEATH is intended for use with human specimen such as blood collected by venipuncture.
Refer to the device's instructions for use for further information regarding sample requirements.

Disposal procedures


1. If compressing the container when disposing of fluid, make sure that any remaining liquid has been removed from the container before disposing of the container.
2. Disposal procedures for emptied containers, remaining liquids and waste effluents from the device should meet the requirements of applicable local regulations.

Manufacturer

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Product information


CyFlow SHEATH (CFS-300B) 10 L × 1
CyFlow SHEATH (CFS-310A) 20 L × 1

Notice to the user

For a patient or user or third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative in the European Union and to your national competent authority. Reports to the authorized representative in the European Union, Sysmex Europe SE, must be sent by email to: vigilance@sysmex-europe.com, or by post to Sysmex Europe SE, Bornbarch 1, 22848 Norderstedt, Germany.

Date of issue or revision

10/2022

: Revised parts in this version

Revision history

| Date of issue or revision | Revised section |
|---------------------------|---|
| 10/2022 | • Updated: Limitations of the examination procedure Authorized representatives Notice to the user |