

Product Name Product Code
UF-CELLSHEATH ZPPBY074501

UF-CELLSHEATH

General name

UF-CELLSHEATH.

Intended use

For in vitro diagnostic use only.

UF-CELLSHEATH is a sheath fluid for Sysmex Fully Automated Urine Particle Analyzers. This reagent is used in combination with other reagents to obtain a count of the target substance by means of the flow cytometry method.

Composition

Tris Buffer: 0.14 %

Warnings and precautions

1. Use the reagent according to the written intended use in the Instructions for Use. The reliability of the analysis values cannot be guaranteed if the reagent is used outside of the written intended use, or not according to the written directions for use.
2. Do not use expired reagents, as the reliability of the analysis values cannot be guaranteed.
3. Do not use a reagent which you suspect has been frozen.
4. When replacing the reagent, do not refill and use the same container.
5. Handle the reagent with care to prevent air bubbles. If air bubbles are present, the performed analysis may be incorrect.
6. After setting, reset of the package is not recommended. Removing the reagent container from the analyzer may cause deterioration of the reagent by contamination with bacteria and other particle.
7. Do not use the reagent which shows signs of contamination or instability, such as turbidity or discoloration.
8. Always wear protective gloves and coat for safety when handling the reagent.
9. NEVER make contact of this reagent with the human body. Avoid contact with skin and eyes, and avoid ingestion. In case of skin contact, rinse immediately with plenty of water. In case of contact with eyes, rinse immediately with water or normal saline, occasionally lifting upper and lower eyelids until no evidence remains. Obtain medical attention. If swallowed, seek medical advice immediately.

Examination procedure

Put a UF-CELLSHEATH container in the position as described in the Instructions For Use. Place the reagent at a level no more than 1 meter above or below the bottom of the analyzer. Do not put reagents on top of the instrument. Connect the UF-CELLSHEATH container to the designated place on the instrument.

The new reagent must be left undisturbed for over 24 hours at 10 to 30°C before using. Please refer to Instructions For Use – “Reagent Replacement” for more detail information.

Reagent should be used by trained personnel.

Storage and shelf life of unopened product

- Store unopened UF-CELLSHEATH at 2-35°C and avoid exposure to sunlight.
- The expiration date of the unopened product is printed on the outer package labels.

Storage and shelf life after first opening

- Once opened and installed in the instrument, UF-CELLSHEATH is stable for 60 days.

Shelf life: 12 months after manufacturing.

**Disposal procedures**

- When disposing of the container, make sure that any remaining fluid has been removed from it before disposing.
- Disposal procedures for the used container, remaining fluid, and waste fluid including samples should meet requirements of applicable local regulations.

Manufacturing site:**SYSMEX ASIA PACIFIC PTE. LTD.**

19 Jalan Tukang, Sambo Innovation Building, Singapore 619265

Legal manufacturer:**SYSMEX CORPORATION**

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Product Information

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03-2021 (INS – UF-4000/5000 ver 2021)