

Product Name Product Code
UF-CELLPACK SF CE604532

UF-CELLPACK SF

General name

UF-CELLPACK SF

Intended use

For in vitro diagnostic use only.

UF-CELLPACK SF is a diluent for Sysmex Fully Automated Urine Particle Analyzers and is intended for use only in conjunction with UF-Fluorocell SF. UF-CELLPACK SF is used to mark formed elements in urine (or in body fluid (cerebrospinal fluid, etc.)) for determination of non-nucleated specimens (red blood cells, casts, etc.).

This reagent is exclusively for use with Sysmex Fully Automated Urine Particle Analyzers. Do not use this reagent for any other purpose.

Components

HEPES 1.2%

1,2-benzisothiazol-3(2H)-one, <0.01%

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 or other particles.
7. Do not use the reagent if it 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. 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.

EUH208 Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

Examination procedure

Put a UF-CELLPACK SF container in the prescribed position and then connect the UF-CELLPACK SF.

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.

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.

This reagent should be used by trained personnel

**Storage and shelf life after first opening**

- Store unopened UF-CELLPACK SF at 2-35 °C and avoid exposure to sunlight.
- Unopened reagent should be stored in its package. Store the container upright.
- The expiration date of the unopened product is printed on the outer package labels.
- Once opened and installed in the instrument, UF-CELLPACK SF is stable for 90 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 International Reagents Co.,Ltd., Ono Factory

17 Takumidai, Ono, Hyogo 675-1322, Japan

Legal manufacturer

SYSTEMEX CORPORATION

1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

Product information

UF-CELLPACK SF 2.1L x 2

Date of issued and revision

03-2021 (INS-UF-4000/5000 ver 2021)