

CELLCLEAN®

Identification of the IVD reagent CELLCLEAN®

Intended use

CELLCLEAN is to be used as a strong alkaline detergent to remove Sysmex lysing reagents, cellular residuals and blood proteins remaining in the hydraulics of Sysmex Fully Automated Hematology Analyzers.

Principles of the examination method

CELLCLEAN is a detergent to clean the instrument to prevent protein buildup in the Transducer Chambers and Sample Rotor Valves, Whole Blood Aspiration tubes and Hgb Flow Cell.

Components

Sodium Hypochlorite (available chlorine concentration 5.0%)

Warnings and precautions (For in vitro diagnostic use only)

Avoid contact with skin and eyes. In case of skin contact, flush the area with water. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If swallowed, seek medical advice immediately.

Danger

H314 Causes severe skin burns and eye damage.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/protective clothing/
eye protection/face protection.



P303+P361+P353

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P501 Dispose of contents/container in accordance with local and national regulations.

EUH031 Contact with acids liberates toxic gas.

Examination procedure

Refer to Sysmex Operator's Manual to obtain instrument-specific instructions for the appropriate use of CELLCLEAN.

Keep CELLCLEAN between 15 to 30°C during use.

Storage and shelf life of unopened product

Storage and shelf life after first opening

1. CELLCLEAN has an unopened stability of 12 months from date of manufacture when stored at 1-30°C in a dark place.
2. CELLCLEAN should be stored in a dark place. Avoid exposing to direct sunlight, or chlorine component is deformed and the effectiveness of this detergent will be lost depending upon the time period of exposure.
3. Once opened, CELLCLEAN is stable for 60 days.

Limitations of the examination procedure

The use of this reagent, respectively control or calibrator, is validated on specific analyzers to optimize product performance and meet product specifications. Please refer to Instructions For Use of your analyzer whether the use of this reagent, respectively control or calibrator, is authorised by Sysmex. Sysmex cannot take the responsibility for patient results received from the use of Sysmex reagents, controls or calibrators on unauthorised analyzers. It is the responsibility of the user to validate modifications to these instructions or use of the reagent, control or calibrator on analyzers other than those specified by Sysmex.

Disposal procedures

Disposal procedures should meet requirements of applicable local regulations.

Manufacturer



Sysmex Corporation
1-5-1 Wakinhama-Kaigandori, Chuo-ku, Kobe 651-0073,
Japan

Authorized representative / Distributors



Sysmex Europe GmbH
Bornbarch 1, 22848 Norderstedt, Germany

Product information

CELLCLEAN (CL-50) 50 mL x 1 bottle

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