

STROMATOLYSER™ -4DL

Identification of the IVD reagent

STROMATOLYSER™ -4DL

Intended use

For in vitro diagnostic use only
STROMATOLYSER-4DL is a reagent that lyses RBC for determination of 4-part differential count, or 5-part differential count* and WBC count* with Sysmex automated hematology analyzers (*on XS series only). This reagent is to be used by connecting to an automatic hematology analyzer specified by Sysmex.

Principles of the examination method

A sample volume of a whole blood specimen is introduced into the analyzer where a portion of it is automatically diluted into a 1:50 dilution and lysed by addition of STROMATOLYSER-4DL. STROMATOLYSER-4DS is then added and the entire dilution is maintained at a constant temperature for a defined time period in order to stain the nucleated cells in the sample. The stained sample is then introduced into the sheath flow detector where side light scatter and side fluorescent emission are measured allowing WBC count (WBC#)*, the neutrophil count (NEUT#), the lymphocyte count (LYMPH#), the monocyte count (MONO#), the eosinophil count (EO#), the basophil count (BASO#)*, the neutrophil percent (NEUT%), the lymphocyte percent (LYMPH%), the monocyte percent (MONO%), the eosinophil percent (EO%) and the basophil percent (BASO%)* to be computed. Consult your specific Sysmex analyzer's Instruction for Use for additional information with respect to procedures and principles of 4-part differential analysis, or 5-part differential analysis* and WBC count analysis* (*on XS series only).

Components

Nonionic surfactant	0.18 %
Organic quaternary ammonium salts	0.08 %

Warnings and precautions

- 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.
- Do not use the product if it shows signs of contamination or instability, such as turbidity or discoloration.
- 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.

Examination procedure

- Remove the cap from the new product container.
- Register the reagent code (barcode). (If necessary)
- Gently remove the spout kit from the old product container and insert straight into the new product container.
- Fasten the spout kit.
- 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. 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.

Performance characteristics

Performance should be within device specifications. Refer to the device's Instructions for Use for further information.

Limitations of the examination procedure

- The reliability of the analysis values cannot be guaranteed if the product is used outside the prescribed intended use.
- The product must not be used after its expiration date.
- Do not refill and reuse product containers.
- Handle the product with care to prevent air bubbles. If air bubbles are present, the performed analysis may be incorrect.
- 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 an open reagent is not recommended.
- Do not use a product that is suspected to have been frozen.
- 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

STROMATOLYSER-4DL is intended for use with blood specimens collected either by venipuncture or micro-sampling by skin puncture. Specimens should be collected in EDTA anticoagulant (EDTA-K₂, EDTA-K₃ or EDTA-Na₂).

Note, that the anticoagulant EDTA-Na₂ may not dissolve easily in blood, and thus causing fibrin formation or platelet aggregation in some samples. Thorough mixing is required until all dry anticoagulant is dissolved. Refer to the device's Instructions for Use for further information regarding sample requirements.

Disposal procedures

- 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.
- Disposal procedures for emptied containers, remaining liquids and waste effluents from the device should meet the requirements of applicable local regulations.

Manufacturer

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

Authorized representatives

Europe, Middle East and Africa:

 **Sysmex Europe GmbH**
Bornbarch 1, 22848 Norderstedt, Germany

Americas: **Sysmex America, Inc.**
577 Aptakisic Road, Lincolnshire, IL 60069, U.S.A.

Asia-Pacific: **Sysmex Asia Pacific Pte Ltd.**
9 Tampines Grande #06-18, Singapore 528735

Product information

STROMATOLYSER-4DL (FFD-200A) 5 L x 1

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