

STROMATOLYSER® -4DS

EN

Identification of the IVD reagent STROMATOLYSER® -4DS

Intended use

STROMATOLYSER-4DS is to be used to stain the leukocytes in diluted and lysed blood samples for determination of 4-part differential count, or 5-part differential count* and WBC count* with Sysmex automated hematology analyzers (*on XS series only).

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 the special Sysmex lysing reagent 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 the 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 instrument Operator's Manual 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

STROMATOLYSER-4DS (FFS-800)
 Polymethine dye 0.002%
 Methanol 3.0%
 in ethylene glycol 96.9%

Warnings and precautions (For in vitro diagnostic use only)

1. Wear gloves and a lab coat for protection. Avoid contact with skin and eyes.
2. In case of skin contact, rinse immediately with plenty of soap and water.
3. In case of contact with eyes, rinse immediately with water or normal saline, occasionally lifting upper and lower lids until no evidence of dye remains. Obtain medical attention.
4. If swallowed, seek medical advice immediately.
5. In case of accident or you feel unwell, seek medical advice immediately (show the label where possible).

Warning

H302 Harmful if swallowed.
 P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
 P501 Dispose of contents/container in accordance with local and national regulations.



Examination procedure

1. Loosen and remove the cap on the STROMATOLYSER-4DS bag. Attach the dispenser kit to the dye bag. Tighten the cap. Connect the STROMATOLYSER-4DS line from the instrument to the dispenser kit.
2. Refer to the instrument Operator's Manual for further information.

Storage and shelf life of unopened product

Storage and shelf life after first opening

1. STROMATOLYSER-4DS has an unopened stability of 12 months from date of manufacture when stored at 2-35°C in a dark place. See outer package or label on the bag for expiration date. STROMATOLYSER-4DS displaying any signs of contamination or instability, as indicated by cloudiness or colour change, should be replaced. Please do not use reagent once frozen.
2. Once opened and installed in the instrument. STROMATOLYSER-4DS is stable for 90 days.

Performance characteristics

Limitations of the examination procedure

Performance should be within instrument specifications.

STROMATOLYSER-4DS has to be used within the ambient temperature range of 15-30°C. 4-Part differential count, or 5-part differential count* and WBC count* may be inaccurate due to the influences of abnormal samples. Consult the Operator's Manual for indications of these conditions. Confirm the WBC differential by reference methods if these conditions are indicated (*on XS series only).

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.

Additional required equipment

STROMATOLYSER-4DS is intended for only use in conjunction with Sysmex lysing reagent STROMATOLYSER-4DL. Consult the instrument Operator's Manual for specific reagent requirements.

Primary sample collection, handling and storage

STROMATOLYSER-4DS is intended for use with blood specimens collected either by venepuncture 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. See in the instrument Operator's Manual for further information regarding sample requirements.

Disposal procedures

Disposal procedures should meet requirements of applicable local regulations.

Manufacturer



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

Authorized representative / Distributors



Sysmex Europe GmbH
 Bornbarch 1, 22848 Norderstedt, Germany

Product information

- | | |
|----------------------------------|----------------|
| (1) STROMATOLYSER-4DS (FFS-800A) | 42 mL x 3 bags |
| (2) STROMATOLYSER-4DS (FFS-800C) | 42 mL x 1 bag |

Date of issue or revision

04/2015