STROMATOLYSER™-WH

Identification of the IVD reagent
STROMATOLYSER™-WH

Intended use
For in vitro diagnostic use only
STROMATOLYSER-WH is a reagent that lyses RBC for accurate WBC count determination, WBC trimodal size distribution analysis and hemoglobin level measurement. The reagent is colorless transparent and contains no cyanide or azide compound. It is intended for use in conjunction with selected Sysmex Automated Hematology Analyzer.

Principles of the examination method
Blood sample collected in EDTA anticoagulant is diluted with CELLPACK in a WBC counting container. Then a fixed volume of STROMATOLYSER-WH solution (1 volume of STROMATOLYSER-WH to 2 volumes of CELLPACK) is added automatically to obtain a final dilution of 1:500. The addition of STROMATOLYSER-WH lyses the RBC and so the remaining cell stroma is at a level undetectable by the instrument. At the same time, the WBC membrane is preserved and WBC are stabilized at a level detectable by the instrument. They are then counted by the DC method. Hemoglobin is released during RBC lysis, and is converted to the red methemoglobin. A portion of this diluted sample is transferred automatically to the hemoglobin detector where the absorbance of the red pigment is measured to give blood hemoglobin level.

Components

Organic quaternary ammonium salt	8.5 g/L
Sodium chloride	0.6 g/L

Warnings and precautions
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, induce vomiting and seek medical advice.
STROMATOLYSER-WH is intended for only use with blood samples diluted in the Sysmex diluent CELLPACK. Product performance cannot be guaranteed with use of other diluents.

Examination procedure
1. Use the STROMATOLYSER-WH at a temperature of 15-30 °C. Measuring at a temperature above 30 °C or below 15 °C may give inaccurate WBC count, WBC tri-modal size distribution analysis and hemoglobin level.
2. Loosen and remove the cap of the bottle of STROMATOLYSER-WH and connect to the instrument.
3. Refer to the Operator's Manual of the instrument for detailed information.

Storage and shelf life of unopened product
Storage and shelf life after first opening
Store STROMATOLYSER-WH at 2-35 °C. Unopened STROMATOLYSER-WH stored at 2-35 °C has a product life of 12 months after the date of manufacture. The expiration date is indicated on the container label. Once opened, product stability is 90 days at 2-35 °C. STROMATOLYSER-WH displaying any signs of contamination or instability, as indicated by cloudiness or color change, should be replaced. Please do not use reagent once frozen.

Performance characteristics
Limitations of the examination procedure
When control blood samples (EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L, EIGHTCHECK-3WP-H) are analysed, the WBC count and hemoglobin level should be within the expected ranges. When a normal fresh blood sample is measured by the whole blood mode for 10 consecutive times, the reproducibility (CV %) of the WBC count and hemoglobin level should be below 3.5 % and 1.5 %, respectively. Refer to the Operator's Manual of the instrument for detailed information.
WBC counts may be falsely elevated due to the influences of abnormal samples including the following:
1.Nucleated RBC, 2. Cold Agglutinin Disease, 3. Platelet Aggregation, 4. Cryoglobulins. Consult the Operator's Manual for indications of these conditions. Confirm the WBC count by reference eye count methods if these conditions are indicated.
Hemoglobin measurements may be falsely elevated due to the influences of abnormal samples including leukocytosis, lipemia, and abnormal proteins in blood plasma. Confirm the hemoglobin measurement by plasma replacement or plasma blank procedures if these conditions are encountered.

Primary sample collection, handling and storage
STROMATOLYSER-WH is intended for use with blood specimens collected either by venepuncture or micro-sampling by skin puncture. Venepuncture specimens should be collected in EDTA anticoagulant (EDTA-K_2, EDTA-K_3 or EDTA-Na_2). Micro-sampling specimens can be diluted directly into the diluent without utilization of anticoagulant, or can be collected into micro-collection containers with EDTA anticoagulant for dilution at later time.
Note, that the anticoagulant EDTA-Na_2 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
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Product information
STROMATOLYSER-WH (SWH-200A) 500 mL x 3

Date of issue or revision
03/2019

Printed in Singapore

REF Catalogue number

IVD In vitro diagnostic medical device

Keep away from sunlight

Temperature limitation

Consult instructions for use

Manufacturer

Corrugated recycles

BF909561