CE

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sysmex

SULFOLYSER®

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Identification of the IVD reagent
SULFOLYSER®

Intended use
SULFOLYSER is a reagent for the automated determination of hemoglobin concentration of blood with Sysmex automated hematology analyzers.

Principles of the examination method
SULFOLYSER is a clear, cyanide free, low toxicity reagent. Hemoglobin measurement using SULFOLYSER is based on a Sodium Lauryl Sulfate method developed by Iwao Oshiro, et al (SLS-Hb method). In the SLS-Hb method, an anionic surfactant, Sodium Lauryl Sulfate (SLS) lyses the red blood cell membrane, releasing hemoglobin. The same SLS reagent subsequently combines with the released hemoglobin to form a stable hemichrome. The concentration of hemoglobin is then quantified by colorimetry using a filter photometer. SULFOLYSER has advantage over other cyanide free methods in that it is able to measure the hemoglobin derivatives deoxyhemoglobin, oxyhemoglobin, carboxyhemoglobin and methemoglobin.

Components
Sodium Lauryl Sulfate 1.7 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, seek medical advice immediately.

Examination procedure
1. Gently invert the unopened bottle of SULFOLYSER approximately 10 times to mix the contents thoroughly.
2. Loosen and remove the cap on the SULFOLYSER bottle.
3. Attach the Dispenser Kit to the SULFOLYSER bottle. Tighten the cap. Connect the SULFOLYSER line from the instrument to the Dispenser Kit.
4. Prime the SULFOLYSER through the hydraulic system of the instrument by cycling the instrument several times in the whole blood mode to fill all SULFOLYSER tubing with reagent and to remove air bubbles in the lines.
5. Refer to the Instrument Operator's Manual for further information.

Storage and shelf life of unopened product
Storage and shelf life after first opening
Store SULFOLYSER at 1-30°C. If the product has been frozen, the Sodium Lauryl Sulfate may form a white, cloudy precipitate. Redissolve the precipitate completely by warming the SULFOLYSER bottle in a water bath at 30°C, and occasionally mixing the contents. Unopened SULFOLYSER has a product life of 12 months after date of manufacture. The expiration date is printed on container label. Once opened, product stability is 60 days. SULFOLYSER displaying any signs of contamination or instability, as indicated by cloudiness or color change, should be replaced.

Performance characteristics
Limitations of the examination procedure
When control blood samples are analyzed, the Hgb result should be within the expected ranges. When fresh normal whole blood samples are analyzed 10 times consecutively in the whole blood mode, the reproducibility of the Hgb should be within the specifications of 1.5% C.V. or less.
Refer to the Operator's Manual of the instrument for detailed information.
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.
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.

Reagent preparation
SULFOLYSER is intended for only use with blood specimens diluted in the Sysmex diluents. Product performance cannot be guaranteed with use of other diluents.

Primary sample collection, handling and storage
SULFOLYSER 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.

Literature references
Oshiro, I. et al: New method for hemoglobin determination by using Sodium Lauryl Sulfate (SLS), Clinical Bio. 15:83-88, 1982.

Manufacturer
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Product information
SULFOLYSER (SLS-210A) 500 mL x 3 bottles
SULFOLYSER (SLS-210B) 500 mL x 1 bottle

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