

SULFOLYSER™

Identification of the IVD reagent

Intended use (For in vitro diagnostic use only)
SULFOLYSER is a reagent for the automated determination of hemoglobin concentration of blood. SULFOLYSER is manufactured for use on all Sysmex automated hematology analyzers, excluding the CC-700, CC-720, CC-780, CC-800 and M-2000. SULFOLYSER cannot be used on

Principles of the examination method

SULFOLYSER is a clear, azide and cyanide free, low toxicity reagent. Hemoglobin measurement using SULFOLYSER is based on a new 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.
- 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

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.

SULFOLYSER is intended for only use with blood specimens diluted in the Sysmex diluent

Primary sample collection, handling and storage

SULFOLYSER is intended for use with blood specimens collected either by venepuncture or sour-Octates is intellected in sew with blood specimients collected either by Venepuncture or micro-sampling by skin puncture. Venepuncture specimens should be collected in EDTA anticoagulant (EDTA-K2, EDTA-K3 or EDTA-Na2). 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-Naz 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

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

Manufacturer

SYSMEX CORPORATION

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

Authorized representative / Distributors

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Product information
SULFOLYSER (SLS-210A) 500 mL x 3 bottles

Date of issue or revision

Printed in Japan

血细胞分析用溶血剂说明书

ΕN

通用名称:血细胞分析用溶血剂 英文名称:SULFOLYSER

[包装规格]

500mL×3;

1.5L×2。

用于血细胞分析前破坏红细胞、溶出血红蛋白、从而便于血红蛋白定量测定。 血红蛋白(Hb)是一种结合蛋白,分子量约64458,占红细胞干重的95%,占红细胞 。正常血红蛋白由珠蛋白和亚铁血红素构成, 其合成受铁的供应、原卟啉 和珠蛋白合成的影响。

CN

[基本信息]

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[说明书核准及修改日期]

国械备20160303号

2016年3月1日 批准 2017年1月20日 修改

2018年7月3日 修改

住所:兵库县神户市中央区胁浜海岸通1丁目5番1号

代理人名称:希森美康医用电子(上海)有限公司

[医疗器械备案凭证编号/产品技术要求编号]

售后服务单位名称:希森美康医用电子(上海)有限公司

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血红蛋白的功能是运输氧气和二氧化碳。

贫血是最常见的临床症状之一,是指患者的血红蛋白浓度、红细胞计数及红细胞比容低于相应的年龄组、性别组和地域组人群的参考范围下限的一种症状。 贫血并非一种疾病,而是临床常见症状,其正确诊断需要综合分析临床症状、体征 和各种实验室检查结果。因此,在临床上,对血红蛋白的检测,目的就是参与鉴别 和诊断贫血种类和贫血的程度。

血细胞分析用溶血剂(SULFOLYSER)是一个环保的,不含叠氮化物和氰化物,低毒 性的试剂。SULFOLYSER含有表面活性剂硫酸月桂酯钠等活性成分,基于SLS-Hb方法 测定血红蛋白浓度。SLS为阴离子表面活性剂,主要功能是溶解红细胞膜,释放出血红蛋白。随后可以和Hb形成稳定的SLS-Hb用作比色分析。SULFOLYSER优于其它不含 氰化物的试剂,因为它还可用于检测血红蛋白DNA, 氧基血红蛋白, 羧基血红蛋白

[主要组成成分]

硫酸月桂脂钠等活性成分 1.7g/L

未开封试剂,1~30°C保存,有效期12个月。 如果试剂冻结,请于30°C的温水中溶解,并摇匀后使用。

生产日期及失效期:见外标签

XF-2100, XE-2100D, XE-2100L, XE-5000

XT-2000i, XT-1800i, XT-4000i

XN-20[A1], XN-20[A2], XN-10[B1], XN-10[B2], XN-10[B3], XN-10[B4] XN-20[A1] XN-20[A1], XN-20[A1] XN-20[A2], XN-20[A1] XN-10[B1], XN-20[A1] XN-10[B2], XN-20[A1] XN-10[B3], XN-20[A1] XN-10[B4], XN-20[A2] XN-20[A2], XN-20 [A2]XN-10[B1], XN-20[A2]XN-10[B2], XN-20[A2]XN-10[B3], XN-20[A2]XN-10 [B4], XN-10[B1]XN-10[B1], XN-10[B1]XN-10[B2], XN-10[B1]XN-10[B3], XN-10 [B1]XN-10[B4], XN-10[B2]XN-10[B2], XN-10[B2]XN-10[B3], XN-10[B2]XN-10 [B4], XN-10[B3]XN-10[B3], XN-10[B3]XN-10[B4], XN-10[B4]XN-10[B4]

抗凝剂请使用EDTA-K2盐。用其他抗凝剂(如肝素,草酸盐)的正常使用量对血红蛋 白的检测值无影响,但可能会使其他检测项目(WBC, PLT数等)产生误差。

- 1. 将未开启的SULFOLYSER瓶轻微地来回颠倒约10次左右,使内容物充分混合。 2. 拧开SULFOLYSER的瓶盖。将分配器与SULFOLYSER瓶相连,然后拧紧盖子,确认 分析仪到分配器SULFOLYSER管连接完好。
- 3. 在全血模式下数次循环运行仪器,通过仪器的液压系统注入SULFOLYSER试剂,使 所有的SULFOLYSER管充满试剂并将气泡从管中排除
- 4. 更详细的信息请参见仪器操作手册。

[检验方法的局限性]

胆红素及白细胞几乎不会影响血红蛋白的浓度。

吸收峰波长: 试剂溶血后血红蛋白衍生物的吸收峰中心波长λmax应在仪器测量波长 λ_o(535nm)+10 nm范围内。

使用血液分析仪测定时,测量结果血红蛋白(HGB)含量应≤1g/L

在适配的血液分析仪上使用该试剂检测定值质控血, 血红蛋白 准确性:

(HGB) 结果应在质控标示的靶值范围内。

吸收峰波长的批间差应符合: $Δλ_{max} \le 10 \text{ nm}$ 。 试剂应规定有效期,取到期后三个月内的留样检测2.1、2.3-2.5,结果 效期稳定性

应符合各项目规定的要求。 试剂作用于新鲜人血后在750 nm处的吸光度值应≤0.012。

吸光度值: 批内不精密度:相同批号的试剂的HGB检测结果的变异系数(CV)应≤1.5

测定HGB的线性范围 (0.0~250.0) g/L,线性偏差应在±2g/L或

[注意事项]

批问差:

线性:

仅为体外诊断用产品,

- 2. 应避免与眼睛、皮肤接触。若不慎与皮肤接触,请立即用水冲洗接触部位。若不 慎入眼, 立刻用大量水淋洗并就医, 如不慎误服, 诱导呕吐并尽力呕出, 请及时
- 。SULFOLYSER仅用于处理经Sysmex稀释液(CELLPACK)稀释过的血液样本,当使用其他稀释液时不能保证产品操作的可靠性。

[参考文献]

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

REF

Catalogue number



In vitro diagnostic medical device 体外诊断试剂



Manufacture



Consult instructions for use 参考使用说明



储存温度





Sysmex Corporation 54539118T