

Lyse used for Hematology analysis

Instruction for use

PRODUCT NAME

Lyse used for Hematology analysis

MODEL

SXHA610/650/660/680 LH Lyse

PACKING SPECIFICATION

100ml 、 250ml

INTENDED USE

It is used to destroy red blood cells, lyse hemoglobin, and maintain the morphology of the analyzed cells, so as to facilitate cell classification and counting or quantitative measurement of hemoglobin.

INSPECTION PRINCIPLE

SXHA610 LH Lyse (SXHA610 LH Vet) further functions in the process of blood cells for blood cells treated with SXHA610 DIFF Lyse (SXHA610 DIFF Vet) to convert hemoglobin into methemoglobin and detect hemoglobin related parameters by colorimetric method; treat white blood cells to increase the difference between basophils and white blood cell group, and detect basophils in combination with laser scattering method and flow cell technology.

MAIN COMPONENTS

Sodium chloride, quaternary ammonium salt, buffer agent, water.

STORAGE CONDITIONS AND SHELF-LIFE

This product shall be stored in a non-corrosive gas with a temperature of 2°C -38°C and a relative humidity of not exceeding 90% and a well-ventilated room. The storage period is valid for 24 months. The use temperature of this product is 15°C -30°C, and the expiration period is 60 days after opening the cover.

APPLICABLE INSTRUMENT

Hematology Analyzer

SAMPLE REQUIREMENTS

EDTA, either fresh or stored at 2°C to 8°C. K₂Anticoagulation fluid.

METHOD OF CALIBRATION

Open the plastic bottle cap, connect with the corresponding pipe of the instrument, and then operate according to the instrument operating instructions.

REFERENCE INTERVAL

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INTERPRETATION OF TEST RESULTS

When abnormal characters appear in the result, a review is recommended.

LIMITATIONS OF THE TEST METHOD

The test result is affected by temperature and shall be in the temperature range specified in the instructions for the instrument Use inside.

PRODUCT PERFORMANCE INDEX

1. Blank value: White blood cell count (WBC) 0.510⁹/L, Hemoglobin content (HGB): 2g / L.

MATTERS NEED ATTENTION

1. Check whether there is any pollution or color change before use, and replace it once found. If frozen, thaw and mix.
2. This product is only used for in vitro diagnosis, do not take internal service, ask a doctor in time; avoid contact with skin or eyes; if contact with skin, rinse with water immediately and receive doctor treatment.
3. For disposable use, please use according to the requirements of the hospital or environmental protection department.

4. Please use it within the validity period.

INTERPRETATION OF THE IDENTIFICATION OF THE

REFERENCE DOCUMENTATION

ESSENTIAL INFORMATION

Name of the applicant / manufacturer: Dezhou Guoke Medical Technology Co., Ltd

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DATE OF SPECIFICATION APPROVAL AND MODIFICATION DATE

Date of approval: 09 November 2022



【Symbols explanation】

Label	Meaning
	Date of manufacture
	In vitro diagnostic medical device
	Manufacturer
	Biological risks
	Batch code
	Temperature limit
	Use-by date
	Authorized representative in the European Community
	Volume
	Consult instructions for use
	Do not re-use
	Keep away from sunlight
	Contains sufficient for <n>tests
	Catalogue number
	CE Marking