

KT03/KT03A Lyse Solution Instruction

【Product Name】

Generic name:KT03/KT03A Lyse Solution

【Package Specification】

KT03 Specification

Specification 1: 0.25L	REF: 22014001
Specification 2: 0.5L	REF: 22019001
Specification 3: 1L	REF: 22020001
Specification 4: 0.25L (For card)	REF: 22014014
Specification 5: 0.5L (For card)	REF: 22019014
Specification 6: 1L (For card)	REF: 22020014

KT03A Specification

Specification : 0.5L	REF: 22019017
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【Intended Use】

Dissolving red blood cells to release hemoglobin, maintaining the cell structure to be analyzed, for the purpose of cell count and quantitative determination of hemoglobin.

【Test Principle】

Determination of hemoglobin: this reagent dissolves red blood cells so as to release hemoglobin, which then reacts with specific substance in the reagent and forms a stable brown compound. The number of hemoglobin is determined via the absorbance of this compound at 540nm.

White blood cell (WBC) count: In addition to dissolving red blood cells, this reagent modifies WBCs without changing their structure. When WBCs pass through the hole in ruby in sequence, they are classified as large, medium, and small via the impedance which varies depending on cell size.

【Main Compositions】

Sodium sulfate, surfactant, and glycerol.

【Storage and Transportation】

If store at 2°C-30°C, relative humidity ≤90%, noncorrosive gas, well-ventilated room, the close vial stability is 2 years. If used at 15°C-30°C, the open vial stability is 60 days.

【Applicable Instruments】

Applicable to 3-part KT series of Automatic Hematology Analyzer manufactured by Genrui Biotech Inc.

【Sample Requirements】

Samples have no coagulation or contamination and are used within 4 hours after sampling.

【Test Methods】

Electrical impedance measurements are used. WBC membrane is compressed by the reagent and the cell size reduces. The number of WBC is then determined via the pulse rate. In addition, red blood cells are dissolved by the reagent to release hemoglobin, which then reacts with the reagent and determined by colorimetry.

【Reference Range】

Not applicable.

【Quality Indicators】

Characteristics	Clear and colorless liquid, free from precipitates, particulates, or cotton-like substances.
Blank count	WBC ≤ 0.3×10 ⁹ /L, HGB ≤ 2g/L.

【Interpretation of Test Results】

If test results do not agree with facts, check if there is any hemolysis, coagulation, or contamination of the sample.



【Limitations of Test Method】














White blood cells are classified as large, medium, and small sizes due to the limitation of analyzers.

【Precautions】


1. Avoid cross-contamination of blood samples.
2. For trained professionals use only.
3. Do not use after expiration date.
4. If the reagent is frozen, thaw at room temperature. Gently invert and mix.
5. Stop use if any precipitates, particulates, or cotton-like substances are observed.
6. Dispose of waste, residual reagents, and contaminated packages in accordance with local regulations.
7. Avoid direct contact with the reagent. In the event of exposure to skin or eyes, rinse immediately with clean water. Seek medical advice if needed.

【Icon Illustration】

Label	Meaning
	Date of manufacture
	Manufacturer

	Biological risks
	In vitro diagnostic medical device
	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

【Manufacturer】

 Genrui Biotech Inc.
Address: 4-10F, Building 3, Geya technology Park, Guangming District, 518106, Shenzhen, China

【Instruction approved and revised date】

Approved date: Apr 3, 2019

Revised date: NA

【Guarantee and Technical Support】

If invalid message repeats or need technical support, please contact Genrui Customer Service and Support Center.

