

**PRODUCT CODE: SIC3LH-HR0500**

## HEMIA 3D Lyse Instruction

**【Product Name】**

Sicuro 3D Lyse Solution

**【Package Specification】**

Specification :500ML      REF: 22001500

**【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 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 Auto Hematology Analyzer manufactured by Sicuro Bioengineering Ltd

**【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 <sup>9</sup> /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 the 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        |

|                                                                                    |                                                     |
|------------------------------------------------------------------------------------|-----------------------------------------------------|
|   | 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                                    |

**【Manufacturer】**

Sicuro Bioengineering Ltd.



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**【Instruction approved and revised date】**

Approved date: Nov. 15th, 2023

 Revised date: 24<sup>th</sup> April 2026

**【Guarantee and Technical Support】**

If invalid message repeats or need technical support, please contact Sicuro Customer Service and Support Center @+2348037219600