

Operation Instruction

[Name] Lyse

[Model] URIT 5L 11

[Specifications] Refer to the packing box or label.

[Microbiological State] Not applicable.

[Intended Use]

This product is used to lyse the RBC promptly, release the hemoglobin and maintain cells' shape.

[Restrictions, Precautions and Notices]

1. Use the reagent under the professional technician's guidance.
2. Avoid contacting with skin and eyes. In case of contact, rinse immediately with plenty of water and seek medical advice.
3. This product should not be consumed, if so, please see a doctor immediately.
4. Deal with the waste according to the local regulations.

[Ingredient]

Boric acid 0.5%, borax 0.1%, dodecyl trimethyl ammonium chloride 3%, myristyl trimethyl ammonium bromide 0.3%.

[Storage and Stability]

This product will be stable for 24 months when stored unopened at 2°C~40°C and away from sunlight. Once opened, this product should be consumed within 60 days and stored at 15°C~30°C.

[Applicability] It's used on URIT 5-Part-Diff Auto Hematology Analyzer.

[Sample Requirement]

1. The blood samples should be venous and capillary specimens collected in EDTA-K₂ anticoagulant. Coagulated, hemolysis and lipoidaemia samples cannot be measured.
2. Blood samples should be stored at 2°C~8°C.

[Operations]

1. Inject the lyse inlet tubing into the lyse container, exhaust air in the container and tighten the lid. Click Change in maintenance interface. Do the blank count in counting interface and make sure that the blank value meets the standards.
2. Place the lyse beneath the analyzer.
3. Avoid direct sunlight, keep away from cooling or heating air outlet, use it at 15°C~30°C.

[Performance]

1. pH value: 4.00 ± 0.50 at $(25 \pm 1) ^\circ\text{C}$.
2. Wavelength of absorption peak: $\lambda_{\text{max}} = (540 \pm 10) \text{ nm}$.
3. Blank value: $\text{WBC} \leq 0.3 \times 10^9 / \text{L}$, $\text{HGB} \leq 2 \text{ g/L}$.
4. Accuracy: WBC relative deviation does not exceed $\pm 7.5\%$, HGB relative deviation does not exceed $\pm 3.5\%$.
5. Batch differences: $\Delta\text{pH value} \leq 1.0$, $\lambda_{\text{max}} \leq 10 \text{ nm}$.

[Test Result]

1. Test results please take reference of the normal range values.
2. If the test result is out of the range of reference value, flagged results will be marked with letter "L" or "H". "L" means the result is below the lower limit; "H" means the result is higher than the upper limit.

[Changes on Processes and Performance]

1. Tight up the container' s cap to prevent from volatilization and contamination. Dispose the remains after 60 days of use after unscrewing the container.

2. If product has been frozen, let product warm to room temperature, and then gently invert product to mix it completely. Verify background results before use.

3. Please note that the reagent shall match with analyzer model. Please do not use the reagent produced by other company, otherwise it may cause measurement errors.

[Quality Control]

Detect three pieces of products in each production lot, two of them should be the first box and the last box in manufacturing process. The production lot shall be determined to be unqualified if there one does not meet inspection standards.

[Quality Control and Traceability of Calibrators] Not applicable.

[Reference Range] Not applicable.

[Reference]

1 .Cong Yulong, Editor. Clinical laboratory equipment, the third volume, Reagents and consumables, wy,Beijing, Science Press, 2016.4.




2. Zhao Guizhi, Clinical Laboratory Science. Chengdu:Sichuan Science and Technology Press,1999.05.



[Production Date] Refer to the packing box or label.

[Expiry date] Refer to the packing box or label.

[Symbols on Packing Box and Label]

 Use by  Batch code  Keep away from sunlight

 Temperature limit  Date of manufacture  Manufacturer

 Consult instructions for use  In Vitro Diagnostic medical device

 Authorized representative in the European Community

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[Release date] In Sep. 2021

[Rev] 09/2021

