Operation Instruction for Lytic Reagent

【Name】Lytic Reagent

【Model】URIT L 21

【Specifications】Refer to the packing box or label.

【Microbiological State】

Not applicable.

【Intended Use】

Lyse is appropriate to series of URIT automated hematology analyzers. With the function of measuring the blood cell content, it has an important effect to clinical diagnosis.

【Restrictions, Precautions and Notices】

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

【Ingredient】

Boric acid, borax, sodium dodecyl trimethyl ammonium chloride, cetyl trimethyl ammonium bromide accompanied by water.

【Storage and Stability】

1. Store in a dark place, keep away from direct sunlight, temperature should be 2℃-40℃.
2. Valid for 24 months, the reagent is considered invalid after unsealing for 60 days.

【Applicability】It's used on URIT Automated Hematology Analyzer.

【Blood Samples】

1. The blood samples should be venous and capillary specimens collected in EDTA-K_2 anticoagulant. Coagulated, hemolysis and lipoidaemia samples cannot be measured.
2. Blood samples should be stored at 2℃~8℃.

【Operations】

1. When testing by quasi-automated hematology analyzer, the diluter samples the anticoagulated blood automatically and discharges a mixture of blood and diluents for WBC and HGB testing. Mix the mixture and diluents which is used for RBC and PLT testing. Add the lyse to the cup of WBC probe filled with mixture, it is used to classify the WBC, HGB and WBC.
2. When testing by automated hematology analyzer, the analyzer adds blood and relative reagents automatically.

【Performance】

1. pH value: 7.60 ± 0.20 at (25±1) ℃.
2. Blank value: WBC≤0.2×10^9 / L, HGB≤1g / L.

【Test Results】

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.
2. Dispose the remains after 60 days of use after unscrewing the container.

【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】

Items	Adult male	Adult female	Children	Newborn
WBC（×10^9/L）	3.5～9.5	3.5～9.5	5.0～12.0	15.0～20.0
LY/LYM（%）	20.0～50.0	20.0～50.0	20.0～40.0	20.0～40.0
MO/MID（%）	3.0～10.0	3.0～10.0	1.0～15.0	1.0～15.0
GR/GRAN（%）	40.0～75.0	40.0～75.0	50.0～70.0	50.0～70.0
LY/LYM（×10^9/L）	1.1～3.2	1.1～3.2	1.0～4.1	1.0～4.1
MO/MID（×10^9/L）	0.1～0.6	0.1～0.6	0.1～1.8	0.1～1.8
GR/GRAN（×10^9/L）	1.8～6.3	1.8～6.3	2.0～7.8	2.0～7.8
RBC（×10^{12}/L）	4.30～5.80	3.80～5.10	4.00～6.00	6.00～7.00
HGB（g/L）	130～175	115～150	110～150	170～200
HCT（L/L）	0.40～0.50	0.35～0.45	0.36～0.48	0.36～0.48
MCV（fL）	82.0～100.0	82.0～100.0	73.0～87.0	70.0～87.0
MCH（pg）	27.0～34.0	27.0～34.0	26.0～32.0	26.0～32.0
MCHC（g/L）	316～354	316～354	320～360	320～360
RDW-CV（%）	11.5～14.5	11.5～14.5	11.5～14.5	11.5～14.5
RDW-SD（fL）	37.0～54.0	37.0～54.0	37.0～54.0	37.0～54.0
PLT（×10^9/L）	125～350	125～350	100～300	100～300
PDW（%）	10.0～14.0	10.0～14.0	10.0～14.0	10.0～14.0
MPV（fL）	7.4～10.4	7.4～10.4	7.4～10.4	7.4～10.4
PCT（fL）	0.10～0.28	0.10～0.28	0.10～0.28	0.10～0.28

【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.

3. WS/T 405-2012. Blood cell analysis reference interval.

【Production Date】 Refer to the packing box or label.

【Service Life】 Refer to the packing box or label.

【Symbols on Packing Box and Label】

Use by　LOT Batch code　Keep away from sunlight　Temperature limitation

Date of manufacture　Manufacturer　Consult instructions for use

IVD In Vitro Diagnostic medical device

EC REP Authorized representative in the European Community

URIT Medical Electronic Co., Ltd.

No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China.

Tel: +86（773）2288586　Fax: +86（773）2288560

Web: www.urit.com　Email: service@uritest.com

Supplied by: **URIT Medical Electronic Co., Ltd.**

EC REP Wellkang Ltd

Enterprise Hub, NW Business Complex,

1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland,UK

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