Operation Instruction for Diluent

【Name】Diluent

【Model】URIT D 31

【Microbiological State】Not applicable.

【Intended Use】

Diluent 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 diluent 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.

【Ingredients】Sodium chloride, anhydrous sodium sulfate, preservative solution and the buffer solution.

【Storage and Shelf Life】

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

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

【Blood Samples】

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℃~8℃.

【Operations】

1. Inject the diluent 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 diluent beneath the analyzer.
3. Avoid direct sunlight, keep away from cooling or heating air outlet, use it at 15℃~30℃.

【Performance】

1. pH value: 7.45±0.20 at (25±1) ℃.
2. ρ= (18.50 ± 0.50) mS / cm at (25±1) ℃.
3. Osmotic concentration= (320 ± 10) mOsm / kg.
4. Particle counting: if the particle size is ≥2.5 fL, particle counting should be ≤ 2.5×105/L.
5. Accuracy: WBC count is within ±7.5%, RBC count is within ± 3.0%, HGB count is within ± 3.5%, PLT count is within ±10%, MCV count is within ±3.0%.
6. Batch differences: ΔPH value≤0.20, Conductivity≤0.50mS / cm, osmotic concentration≤10 mOsm / kg.

【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. 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】

Items	Adult male	Adult female	Children	Newborn
WBC ($\times10^9$/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 ($\times10^9$/L)	1.1 ~ 3.2	1.1 ~ 3.2	1.0 ~ 4.1	1.0 ~ 4.1
MO/MID ($\times10^9$/L)	0.1 ~ 0.6	0.1 ~ 0.6	0.1 ~ 1.8	0.1 ~ 1.8
GR/GRAN ($\times10^9$/L)	1.8 ~ 6.3	1.8 ~ 6.3	2.0 ~ 7.8	2.0 ~ 7.8
RBC ($\times10^{12}$/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 ($\times10^9$/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.

【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

CE

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