

Operation Instruction for Detergent

【Name】 Detergent

【Model】 URIT D 41

【Microbiological State】 Not applicable

【Intended Use】

With the function of cleaning, it has an important effect to clinical diagnosis.

【Restrictions, Precautions and Notices】

1. Use the detergent 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, the buffer solution and surfactant

【Storage and Shelf Life】

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 Automated Hematology Analyzer.

【Blood Samples】

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

【Operations】

1. Inject the detergent inlet tubing into the detergent 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 reagent 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: 7.40 ± 0.30 at $(25 \pm 1) ^\circ\text{C}$.
2. Blank value: $\text{WBC} \leq 0.3 \times 10^9 / \text{L}$, $\text{RBC} \leq 0.05 \times 10^{12} / \text{L}$, $\text{PLT} \leq 10 \times 10^9 / \text{L}$, $\text{HGB} \leq 2\text{g} / \text{L}$.
3. Batch differences: $\Delta\text{PH value} \leq 0.60$.

【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

mix it. 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.

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

【Symbols on Packing Box and Label】

 Use by



Batch code



Keep away from sunlight



Temperature limitation



Date of manufacture



Manufacturer Consult



instructions for use



In Vitro Diagnostic medical device



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.



Wellkang Ltd

Enterprise Hub, NW Business Complex,
1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland,UK



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