

Operation Instruction

【Name】 Sheath

【Model】 URIT 5S 11

【Specifications】 Refer to the packing box or label.

【Microbiological State】 Not applicable.

【Intended Use】 It is used to dilute blood samples to form sheath flow, which is conducive to cell counting and classification by analytical instruments.

【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.

【Component】 Trihydroxymethyl Aminomethane 0.5%, Hydrochloric Acid 0.05%, Triton 0.01%..

【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. Blood samples should be venous and capillary specimens collected in EDTA-K₂ anticoagulant. Coagulated, hemolytic and lipid blood samples cannot be measured.

2 . Blood samples should be stored at 2°C~8°C.

【Operations】

1 . Inject the sheath inlet tubing into the sheath 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 sheath beneath the analyzer.

3 . Avoid direct sunlight, keep away from cooling or heating air outlet, use it at 15°C~30°C.

【Performance Parameter】

1 . pH value: 8.40 ± 0.30 at $(25 \pm 1) ^\circ\text{C}$.

2 . Osmotic concentration (40 ± 20) mOsm / kg.

3 . Blank value: $\text{WBC} \leq 0.2 \times 10^9 / \text{L}$, $\text{HGB} \leq 1\text{g} / \text{L}$.

4 . Accuracy: WBC relative deviation does not exceed $\pm 7.5\%$, HGB relative deviation does not exceed $\pm 3.5\%$.

5 . Batch differences: $\Delta\text{pH value} \leq 0.60$, osmotic concentration $\leq 20\text{mOsm} / \text{kg}$.

【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.

【Limitation】 Not applicable.

【Principle】 Sheath fluid is a buffer fluid that causes cells to form a uniform sheath flow and prevents aggregation between cells. With proper osmotic concentration and ionic strength, it can maintain the integrity and original volume of white blood cells within a few hours. Dissolve on red blood cell permeability, overflow, let the hemoglobin in red blood cell and red blood cells filled with a lot of sheath liquid inside, the red blood cells and then form the shadow cells, because the RBC inclusions is sheath fluid and cells of sheath surrounding fluid, therefore, when red blood cells through the WOC channel,

red blood cells of laser without any light scattering phenomenon, will not influence the leukocyte count and classification; White blood cells were spheroidized and WBC light scattering properties were maintained at WOC detection stage. It also provides adequate humidification to prevent bubble buildup in WOC flow systems.

【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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