

Sheath reagent for Spincell 5 IVD

INTENDED USE

This product is designed to be used on a Spinreact 5-Part-Diff haematology analyser along with Lyse and Sheath reagents produced by URIT, for testing the cell content in human blood.

FUNCTIONS

Sheath is a buffer solution that allows cells to flow uniformly and avoid aggregation. Its osmotic concentration and ionic strength keeps the integrity and the volume of WBCs. It lyses the RBCs to form ghost cells which would not scatter the laser light to avoid affecting WBC measurement. Sheath spherizes WBCs and optimizes their scattering property. It also has humidifying effect to prevent accumulation of air bubbles in WOC flow system.

INGREDIENTS

Trihydroxymethyl Aminomethane	< 1 g/L
Hydrochloric Acid	< 0.2 g/L
Triton	< 0.1 g/L
2-Phenoxyethanol	< 10 g/L

STORAGE & 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 below 35°C

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. Place the Sheath container beneath the analyzer to avoid direct sunlight. Keep away from cooling or heating air outlet.
2. Use it at 15°C~30°C.
3. Connect Sheath container with the analyzer according to Operation Manual.

TEST RESULT









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.


RESTRICTIONS, PRECAUTIONS & NOTICE

1. Use the reagent under the professional technician's guidance.
2. Make sure that the reagent matches with your analyzer. Any mismatch will lead to misleading results.
3. Avoid contacting with skin and eyes. In case of contact, rinse immediately with plenty of water and seek medical advice.

4. Avoid inhaling the evaporated reagent.
5. Tight up the container's cap to prevent from volatilization and contamination.
6. Once opened, dispose the remains over 60 days.
7. If product has been frozen, let it warm to room temperature, and then gently invert the product to mix it completely. Verify the background results before use.

SYMBOLS ON PACKAGING & LABELS

 Batch code	 Use by	 Consult instructions for use
 Temperature limitations	 Do not reuse	 Manufacturer
 Keep away from sunlight	 Date of manufacture	
<div style="border: 1px solid black; padding: 2px; display: inline-block;">EC REP</div> Authorized representative in the European Community		

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PACKAGING

Ref. 1705681	<div style="border: 1px solid black; padding: 2px; display: inline-block;">Cont</div>	1 x 20 L
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