

Blood Cell Staining Solution

Instructions for Use

Product Name

Blood Cell Staining Solution

Type: C101

Specification:

25 pcs/bottle, 50 pcs/bottle

Intended use

It is used to stain cells to observe its morphology and structure, so that the analyzer can perform blood cell classification and counting.

Test Principle

After the quantitative reagent is mixed with the whole blood specimen, a hemolyzing agent lyses the red cells and a staining agent colors the white cells. Place the test card with reagent-treated specimen in analyzer, and the number of cells is counted by the analyzer.

Composition

Methylene blue, saponin, polyethylene glycol octyl phenyl ether (Triton X-100), surfactant.

Storage Conditions and Expiry Date

An unopened vial of staining solution can be stored for 24 months at 2-35°C; once the seal of vial is broken, the staining solution is stable for 30 days at 2-8°C before its expiration date.

Applicable Analyzer

It is applicable to WBC-1, WBC-2, WBC-3, WBC-4, WBC-5, WBC-6 white blood cell analyzer produced by Jiangsu Konsung Bio-Medical Science and Technology Co., Ltd.

Specimen Requirements

- The most suitable specimen is fresh EDTA anticoagulated whole blood.
- Specimen can be stored at 4-8°C for 48 hours.
- If the specimen has been stored in a refrigerator, it will be viscous and the blood should be allowed to warm up to room temperature before mixing.

Test Method

A 10 μ L staining solution was quantified using a micropipette and added to a plastic centrifuge tube.

Change the pipette tip, and a 10 μ L whole blood specimen was quantified using a micropipette and added to a plastic centrifuge tube containing 10 μ L of staining solution.

Use the pipette tip to stir and mix the blood and solution, and simultaneously suck and drain the mixture for at least 10 times and mix the samples thoroughly.

Add 10 μ L of the mixed solution by a micropipettor to the test card specimen tank, and the mixture will evenly spread the inner cavity of the test card. When drawing the mixture, be careful to draw from the bottom to avoid inhaling air bubbles generated by the mixing operation in the upper layer.

Place the filled microcuvette in the microcuvette holder. This must be performed within ten minutes after filling the microcuvette. And gently push the microcuvette holder back into the measuring position. Or press and hold the Confirm button for more than 2 seconds to start a quick test.

The measurement results displays in analyzer after finishing testing.

Positive value/Reference range

Reference range: Adult 3.5-9.5 $\times 10^9$ /L

It is recommended that each laboratory establish its own reference range based on the patient population being tested.

Test Result

The measurement display range is 0.0-32.0 $\times 10^9$ /L.

Higher than the measurement range, the test result displays $> 32.0 \times 10^9$ /L

Limitation of Test Method

Diagnosis and treatment should not rely solely on the test result. Clinical history and other laboratory tests should be considered.

Hyperlipidemia samples can affect the test results. Studies have shown that patient samples with >2% nucleated red blood cells (NRBCs) may give falsely elevated white blood cell count.












Performance Specification

Appearance	Dark blue clear liquid without precipitates, particles and flocs
Blank counting	$\leq 0.3 \times 10^9/L$
Comparability	Relative deviation $\leq \pm 5\%$
Batch difference	$\Delta\lambda_{max}$ (inter-batch difference) $\leq 10nm$

Notes

- This product is for In Vitro Diagnostic use only.
- Use the staining solution prior to the expiration date.
- This product is for single-use only. Always handle blood specimens with care as they may be infectious. Consult local environment authorities for proper disposal.
- Always wear protective gloves when handling blood specimens and test cards with specimen.
- If the solution is accidentally splashed on the surface of the human body such as skin or in the eyes, immediately rinse with plenty of clear water.

Symbol and Explanation

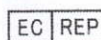
Symbol	Explanation
	In vitro diagnostic medical device
	Consult instructions for use
	Caution
	Batch code
	Date of manufacture
	Manufacturer
	Temperature limits
	Use-by date
	Do not reuse
	CE mark
	Authorized representative in the European community

Bibliography

National Clinical Laboratory Procedures (4th Edition), Shang Hong, Wang Yisan, Shen Ziyu, People's Medical Publishing House



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