

Instructions for Hematology Analyzer Reagent Kit (Diluent and Lyse)



Product Name

Hematology Analyzer Reagent Kit (Diluent and Lyse)

Model

PTD-1

Packaging Specifications

25 tests/kit, 50 tests/kit

Intended Use

Diluent (R1): it is used for blood cell analysis, sample dilution and cell suspension preparation.

Lyse (R2): it is used to destroy red blood cells, lyse out hemoglobin, and maintain the shape of the cells to be tested before blood cell analysis, thereby facilitating cell differential count or quantitative determination of hemoglobin.

Principle

The diluent (R1) is a solution with certain ion strength and conductivity, which can dilute the blood and form the sheath flow, providing a stable environment for blood cell count.

The lyse (R2), by lysing red blood cells, reacts with the released hemoglobin for HGB concentration measurement, WBC count, and WBC differential.

Components

The product consists of reagent kit, TIP, Capillary blood tube (optional) and RF card. The diluent (R1) and lyse (R2) are packed in the reagent kit.

Main components of the diluent (R1): sodium chloride, sodium sulphate, buffer, antibacterial agent, and preservative.

Main components of the lyse (R1): surfactant, buffer, and antibacterial agent.

RF card: includes reagent batch No., date of manufacture, and expiry date.

The two packaging specifications are as follows:

Specification	Content
25 tests/kit	25 × (R1: 4.5 ml, R2: 0.3 ml), 30 TIPs
50 tests/kit	50 × (R1: 4.5 ml, R2: 0.3 ml), 55 TIPs

Storage and Stability

The product can be stably stored for 2 years at 2°C~30°C.

The product is for single use at 15°C~30°C.

Applicable Analyzers

The product is applicable to the following auto hematology analyzers produced by Dymind: DP-H10, DP-H12, DP-H13, DP-H15, DP-H16, and DP-H17.

How to Use

1. Open a new reagent kit:

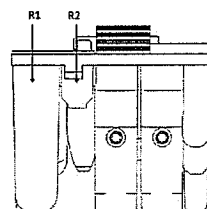
When opening a new reagent kit, you need to put the RF card in the kit to the designated place of the device to read the information of the RF card into the device. You only need to read the card once for each kit.

2. Sample test:

- Take one test kit from the reagent kit for each test, and restore it to the using temperature.
- Open the test kit, and put the test tube (with blood) and a TIP

into the corresponding place of the test kit.

- Place the test kit into the analyzer as instructed by the analyzer operator's manual for test.



Performance Characteristics

- Appearance: the product is a clear liquid without sediment, particles or floccules.
- Diluent (R1): particle volume ≥ 2.5 fL, particle count $\leq 2.5 \times 10^5/L$
- Lyse (R2): blank count: WBC $\leq 0.3 \times 10^5/L$, HGB $\leq 2g/L$

Precautions

- Do not ingest. Avoid contact with skin and eyes. Once in contact, rinse immediately with plenty of water. If accidentally taken or splashed into eyes, please seek medical attention immediately.
- If it is frozen, thaw it at room temperature, mix well, and make sure that the background results are within the range required by the device before use.
- Please dispose of waste, waste liquid and remaining reagents according to local regulations and relevant environmental-protection requirements.
- The following elements will interfere with the test: the reagent is expired or invalid; dust in the air contaminates the reagent; sample processing is not clean.

Interpretation of symbols



Temperature limitation



Date of manufacture



In Vitro diagnostic medical device



Manufacturer



Do not re-use



Batch code



Use-by date



European CE declaration of conformity

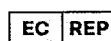


Consult instructions for use



Authorized representative in the European Community

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