

CELLPACK™

Identification of the IVD reagent CELLPACK™

Intended use

For in vitro diagnostic use only
CELLPACK is a reagent for measuring the numbers and sizes of RBC and platelets by the hydro dynamic focusing (DC Detection). With the addition of the specified lyse reagent for hemoglobin concentration determination, it can also be used to analyze hemoglobin concentration. Also it can be used as a sheath fluid for FCM detector. This reagent is to be used by connecting to an automatic hematology analyzer specified by Sysmex.
Use as a diluent and sheath fluid for hematology analyzer.

Principles of the examination method

The RBC/PLT channel counts red blood cells and platelets using the sheath flow DC (direct current) detection method. A blood sample diluted with CELLPACK is ejected from the nozzle tip and blood cells pass through the specified path at the center of the aperture enclosed in the sheath fluid. As each blood cell passes through the center of the aperture, cell volume information is accurately reflected in the pulse. Based on the histograms derived from the number of pulses and the signal size, it is possible to determine the numbers and volume of RBC and PLT.

Components

Sodium Chloride	6.38 g/L
Boric Acid	1.0 g/L
Sodium Tetraborate	0.2 g/L
EDTA-2K	0.2 g/L

Warnings and precautions

1. Follow the warnings and precautions, as described on the product container, package box, package insert or device's Instructions for Use, to handle the product correctly.
2. Do not use the product if it shows signs of contamination or instability, such as turbidity or discoloration.
3. Never use this product on human body. Avoid direct contact with skin, eyes and mucous membranes. Do not ingest. In case of skin contact, rinse immediately with plenty of water. In case of contact with eyes or mucous membranes, rinse immediately with plenty of water, and seek medical attention. In case of ingestion, seek medical attention immediately.

Examination procedure

1. Remove the cap from the new product container.
2. Register the reagent code (barcode).
3. Gently remove the spout kit from the old product container and insert straight into the new product container.
4. Fasten the spout kit.
5. Refer to the device's Instructions for Use for further information.

Storage and shelf life of unopened product

Store the product at 5-30 °C. When the product is properly stored in its sealed container, it is stable until the expiration date printed on the label.

Storage and shelf life after first opening

Once opened the product is stable for 60 days.

Performance characteristics

Performance should be within device specifications. Refer to the device's Instructions for Use for further information.

Limitations of the examination procedure

1. The reliability of the analysis values cannot be guaranteed if the product is used outside the prescribed intended use.
2. The product must not be used after its expiration date.
3. Do not refill and reuse product containers.
4. Handle the product with care to prevent air bubbles. If air bubbles are present, the performed analysis may be incorrect.
5. If the reagent is removed after it has been connected (i.e. opened), it may become contaminated with bacteria and other particles, causing its performance to deteriorate. Therefore, reconnecting an open reagent is not recommended.
6. If once frozen, mix it well after thawing.
7. The use of this product is validated on specific devices to optimize product performance and meet product specifications. Please refer to the Instructions for Use of your device to confirm that the use of this product is authorized by Sysmex. Sysmex cannot take the responsibility for patient results obtained from the use of Sysmex products on unauthorized devices. It is the responsibility of the user to validate modifications to these instructions or use of the product on devices other than those specified by Sysmex.

Primary sample collection, handling and storage

CELLPACK is intended for use with blood specimens collected either by venipuncture or micro-sampling by skin puncture. Specimens should be collected in EDTA anticoagulant (EDTA-K₂, EDTA-K₃ or EDTA-Na₂).
Note, that the anticoagulant EDTA-Na₂ may not dissolve easily in blood, and thus causing fibrin formation or platelet aggregation in some samples. Thorough mixing is required until all dry anticoagulant is dissolved. Refer to the device's Instructions for Use for further information regarding sample requirements.

Disposal procedures

1. If compressing the container when disposing of fluid, make sure that any remaining liquid has been removed from the container before disposing of the container.
2. Disposal procedures for emptied containers, remaining liquids and waste effluents from the device should meet the requirements of applicable local regulations.

Manufacturer

 **Sysmex Corporation**
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Product information

CELLPACK (PK-30L)	20 L × 1
CELLPACK (CPK-310A)	10 L × 1

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