Platelet CHECK™

IVD REF CN464998

Identification of the IVD reagent
Platelet CHECK™

Intended use
Platelet CHECK is a control material for quality control of PLT in the Blood Bank mode of a Sysmex automated hematology analyzer, and is used by healthcare professionals and properly trained personnel. For appropriate use of the product and quality control items, refer to instructions for use of the Blood Bank mode and applicable Sysmex automated hematology analyzers.

Principles of the examination method
Platelet CHECK is to be used as a hematology control material for the quality control of XN-10 analyzers with Blood Bank mode. The use of stabilized cell preparations for controlling hematology instrumentation is an established procedure. When handled according to these instructions and analyzed in QC analysis of a properly calibrated and functioning instrument, Platelet CHECK will provide values within the expected range indicated on the assay sheet.

Components
Platelet CHECK includes a stabilized platelet component in a preservative medium.

Warnings and precautions
Do not inject or ingest.
All human source material used to manufacture Platelet CHECK was non-reactive for antigens to Hepatitis B (HBsAg), negative to antibody tests for HIV (HIV-1/HIV-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed NAT, and non-reactive to Serological Test for Syphilis (STS) using techniques specified by the U.S. Food and Drug Administration. Because no known test method can ensure complete absence of human pathogens, Platelet CHECK should be handled with appropriate precautions.

Storage and shelf life of unopened product
Platelet CHECK is to be stored in a dark place at 2-8 °C. When handled in this manner, Platelet CHECK is stable until the expiration date stated on the package and vials.

Storage and shelf life after first opening
Open vials and vials which have been sampled by cap piercing will retain stability for 7 days if stored in a dark place at 2-8 °C after being re-capped.

Indications of product deterioration
If Platelet CHECK fails to perform within expected results as indicated on the assay sheet, there may be a problem with either the control material, the reagents or the instrument in use. Proceed as follows:
1. Determine if the instrument system is operating properly and does not require cleaning or maintenance.
2. Confirm that the reagent system is within the expiration date, is not contaminated and is stored properly.
3. Assess the validity of Platelet CHECK (i.e. confirm the expiration date or that it has not been frozen).
4. Repeat Platelet CHECK testing with an unopened vial (i.e. verify if the opened vial has been used for more than 7 days).
5. Report any discrepancies to your authorized local Sysmex representative.

Additional required equipment
Automated Hematology Analyzer XN-10 Blood Bank mode
Consult the instructions for use for the specific devices to be used with.

Examination procedure
1. Remove a vial of Platelet CHECK from the refrigerator and keep it at room temperature (18-30 °C) for 15 minutes before use.
2. Mix the vial according to the instructions indicated in the Vial Mixing section of this document.
3. Analyze Platelet CHECK in the instrument QC analysis according to XN-10 analyzer with Blood Bank mode instructions for use. The pierceable septum in the vial cap allows for sampler analysis.
4. Return to refrigerator (2-8 °C) storage.

Vial Mixing
1. Remove the vials from the outer packaging.
2. Roll each vial between the palms of your hands for 15 seconds.

3. Hold the vial at each end between your thumb and finger.
4. Invert end-over-end with a very quick turning motion of the wrist approximately once a second for one minute.

5. Perform a close visual inspection of each vial to confirm that the cell button is completely removed from the bottom of the vial and cellular elements are uniformly suspended with no aggregates.
6. Continue inversions as needed to resuspend the vial contents.

> Note:
> Vials require additional aggressive mixing to break up any microscopic aggregates remaining in the vial.

7. Mechanically vortex each vial for 10 seconds. If a vortex is not available, continue to invert as described in step 4 for one additional minute.
8. Allow vials to sit undisturbed for two minutes to disperse micro-bubbles.
9. Just prior to initial aspiration, remix each vial with 12 gentle end-over-end inversions.

Performance characteristics
Limitations of the examination procedure
The mean assay values for each level of Platelet CHECK are derived from replicate analyses on whole blood calibrated instrumentation. The assay values are obtained using instrument manufacturer's recommended reagents. The values obtained for Platelet CHECK should be within the expected range. The expected ranges listed on the assay sheet represent estimates of inter-laboratory variation for each parameter. Inter-laboratory variation is usually accounted for by instrument calibration, maintenance and operating techniques. For this reason, the given assay values are guide-numbers useful for internal quality control, and shall not be used for calibration.

Assay values and limits have been established through exclusive use of Sysmex reagents, and are valid only with laboratory use of the same Sysmex reagent systems.
Performance of the control product was established through analysis using QC analysis of XN-10 analyzers with Blood Bank mode. The product analysis in the clinical laboratory should follow the same process as indicated in the instrument's instructions for use.

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.

Disposal procedures

This product should not be disposed in general waste but should be disposed with infectious medical waste. Disposal by incineration is recommended. Requirements of applicable local regulations must be considered.

Literature references

1. Henry, J.B. Clinical Diagnostic and Management by Laboratory Methods. Ed.17. W.B. Saunders. Philadelphia, PA 1984
2. Wintrobe, M.M. 'Clinical Hematology', 8th Edition, Lea and Febiger, Philadelphia, 1981.
3. Department of Labor, Occupational Safety and Health Administration. 29 CFR PART 1910. 1030: Occupational Exposure to Bloodborne Pathogens: Final Rule.

Manufacturer

Sysmex Corporation
1-5-1 Wakinohama-Kaigandori,
Chuo-ku, Kobe 651-0073, Japan

"Producer" on OEM-Basis:
STRECK, Inc.
7002 S. 109th Street La Vista, NE 68128, U.S.A.

Authorized representatives

Europe, Middle East and Africa:

EC REP Sysmex Europe SE
Bornbarch 1, 22848 Norderstedt, Germany
Tel +49-40-52726-0 Fax +49-40-52726-100

Product information

Platelet CHECK 3.0 mL / vial

Notice to the user

For a patient or user or third party in the European Union and in countries with identical regulatory regime (Directive 98/79/EC on in vitro diagnostic medical devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative in the European Union and to your national competent authority. Reports to the authorized representative in the European Union, Sysmex Europe SE, must be sent by email to: vigilance@sysmex-europe.com, or by post to Sysmex Europe SE, Bornbarch 1, 22848 Norderstedt, Germany.

Date of issue or revision

11/2022

Revision history

Date of issue or revision	Revised section
11/2022	• Updated: **Authorized representatives** **Notice to the user**