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WRP CHECK™ Product Information

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Intended use
WRP CHECK is used for verification of the reportable range on Sysmex XE, XT, XS, XP, KX-21N and pocH-100i hematology analyzers.

Summary and principle
WRP CHECK is to be used for reportable range and calibration verification. It is not, however, intended for actual calibration of the analyzer. Reportable range verification is normally performed at analyzer installation. Reportable range is defined as the span of test result values over which the laboratory can establish or verify the accuracy of the analyzer's measurement response. The laboratory's reportable range is proven when the mean of the recovered values for each level fall within the assay ranges provided on the enclosed assay sheet. The laboratory's reportable range is the span between the lowest recovered mean value and the highest recovered mean value.

Components
WRP CHECK may contain the following: stabilized red blood cell component(s), stabilized white blood cell component(s) and stabilized platelet component(s) in a preservative medium.

Warnings and precautions
WRP CHECK is for *in vitro* diagnostic use only by laboratory professionals or appropriately trained personnel. Do not inject or ingest. All human source material used to manufacture WRP CHECK was non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed Nucleic Acid Tests (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 assure complete absence of human pathogens, WRP CHECK should be handled with appropriate precautions.

Storage and shelf life of unopened product
WRP CHECK is to be stored closed at 2-8 °C. Avoid freezing this material. When stored properly, the unopened product can be used until the expiration date stated on the label on the vial. Storage outside the recommended temperature range causes damage to the product. Do not use damaged material for verification of reportable range.

Storage and shelf life after first opening
Open vials will retain stability for 5 days if stored at 2-8 °C after being re-capped.

Indications of product deterioration
If WRP CHECK fails to perform within expected results, there may be a problem with WRP CHECK, the reagents or the analyzer in use. Proceed as follows:

1. Check if the reagents are within their expiration dates, not contaminated and have been properly stored.
2. Determine if the analyzer is operating properly and does not require cleaning or maintenance.
3. Verify that WRP CHECK is within the expiration date, has been properly mixed and handled and that the vial has not been frozen or damaged.
4. For assistance, contact the Sysmex Technical Assistance Center or your authorized distributor.

Procedure
See "WRP CHECK pocH-100i, KX-Series and XP-300 Instructions for Use" and "X-Series Instructions for Use".

Performance characteristics and limitations
Analyzer performance is verified when the mean of the recovered values for each level falls within its corresponding assay range. The assay range represents typical analytical performance for the WRP CHECK product, sample concentration and analyzer model.

1. WRP CHECK is intended for use only on Sysmex analyzers using Sysmex reagents. Performance cannot be assured on other analyzers or analyzers using other reagents.
2. Incomplete mixing may invalidate results. Refer to mixing and handling instructions.
3. Increased viscosity of the stabilized RBC product may result in spurious results. Additional aspirations may be required to eliminate outliers.
4. Products are for use as supplied. Combining vials or transferring material to an alternate container may invalidate results.
5. Product viscosity and matrix effects may not allow recovery to span the entire reportable range as stated in the Sysmex Instructions for Use (IFU). The IFU specifications were defined using fresh whole blood prepared and analyzed under research laboratory conditions.

Reference methods
The assigned values for WRP CHECK are determined by analyzers that are calibrated with fresh human blood against international conventional reference measurement procedures:

WBC: Reference method for the enumeration of erythrocytes and leucocytes, ICSH Expert Panel on Cytometry, Clin Lab Haematol. 1994; 16, 131-138. Counts on 1:500 dilutions performed on SCC (Semi-automated Single Channel counter), a volumetric manometer semi-automated electronic impedance cell counter.

RBC: Reference method for the enumeration of erythrocytes and leucocytes, ICSH Expert Panel on Cytometry, Clin Lab Haematol. 1994; 16, 131-138. Counts on 1:500 dilutions performed on SCC (Semi-automated Single Channel counter), a volumetric manometer semi-automated electronic impedance cell counter.

HGB: Recommendation for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specification for international haemiglobincyanide standard (4th edition), ICSH Expert Panel on Haemoglobinometry, J Clin Pathol 1996; 49: 271-274.
CLSI H15-A3: Reference and selected procedures for the quantitative determination of hemoglobin in blood; Approved Standard – Third edition (2000).
Photometry on 1:250 dilutions with appropriate reagent (recommended by van Kampen, Zijlstra).

HCT: Recommendations for Reference Method for the Packed Cell Volume (ICSH Standard 2001), ICSH Expert Panel on Cytometry, Clin Lab Hematol. 2001; 7:148-170.
CLSI H7-A3: Procedure for determining Packed Cell Volume by the Microhematocrit Method; Approved Standard – Third edition (2000).

PLT: Platelet count values are determined by using a Neubauer Improved hemacytometer counting chamber and the bioanalytic GmbH Thrombo-tic PLT counting kit. This method is based on the procedure developed by Brecher and Cronkite.

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. CLSI Document EP17-A Protocol for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline. 2008.
2. CLSI: Evaluation of the Linearity of Quantitative Analytical Methods EP6-P 1986; Clinical Laboratory Technical Procedure Manuals GP2-A2 1992; Performance goals for the Internal QC of Multichannel Hematology Analyzers H26-A 1996.
3. Sysmex XE, XT, XS, XP, KX-21N and pocH-100i Instructions for Use.
4. Bloodborne Pathogen Standard, 29 CFR Part 1910.1030.
5. CLIA 1988 42 CFR Part 493.1201 - 493.1285.

Manufacturer
Sysmex Corporation
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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
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577 Aptakisic Road
Lincolnshire, IL 60069, U.S.A.

Europe, Middle East and Africa:
EC REP Sysmex Europe GmbH
Bornbarch 1, 22848 Norderstedt, Germany

Product information
WRP CHECK 12 × 2.0 mL WBC/RBC/PLT

Date of issue or revision
11/2016, Rev.1

Printed in U.S.A.

REF — Catalogue number

IVD — In vitro diagnostic medical device

Manufacturer

EC REP — Authorised Representative in the European Community

Consult instructions for use

Temperature limitation

Use by

LOT — Batch code

Biological Risks