EIGHTCHECK™-3WP-N, EIGHTCHECK™-3WP-L, EIGHTCHECK™-3WP-H

EN

Identification of the IVD reagent

EIGHTCHECK™-3WP-N, EIGHTCHECK™-3WP-L, EIGHTCHECK™-3WP-H

Intended use

For in vitro diagnostic use only
EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H are hematology control materials primarily for intralaboratory quality control of automated, semiautomated and manual procedures that measure components of blood. Additionally, EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H can be used in external quality assessment. Do not use EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H to calibrate the instrument.

Principles of the examination method

EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H are to be used as hematology controls blood for the quality control of Sysmex automated 3-part differential instruments. Use of stabilized cell preparations for controlling hematology instrumentation is an established procedure. When handled like a patient sample and assayed in the Quality Control Mode of a properly calibrated and functioning instrument, EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H will provide values within the expected range indicated on the assay sheet.

Components

The product EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H includes stabilized human red blood cells, fixed mammalian white blood cells and a platelet component in a preservative medium.

Warnings and precautions

Do not inject or ingest.
All human source material used to manufacture this product 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 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, this product should be handled with appropriate precautions.

Storage and shelf life of unopened product

EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H are to be stored closed at 2-8 °C. When handled in this manner, EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H are guaranteed 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 at 2-8 °C after being re-capped. EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H have been tested and found to provide stable parameter values after at least 12 hours at room temperature (25 °C).

Indications of product deterioration

If EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L, and EIGHTCHECK-3WP-H fail to perform within expected results as indicated on the assay sheet, there may be a problem with either the control blood, 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. Check if the reagent system is within the expiration date, if the reagent system is not contaminated, if the reagent has not been frozen, and etc.
3. Determine validity of EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H (i.e. make sure the expiration date, or verify that it has not been frozen).
4. Assay an unopened vial of EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H (i.e. verify if the opened vial is used over the period of 7 days).
5. Report any discrepancies to Technical Services of the nearest Sysmex authorized distributor.

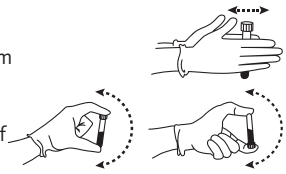
Additional required equipment

EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H are intended for only use with

diluent:	CELLPACK.
WBC lysing reagents:	STROMATOLYSER-WH, STROMATOLYSER-3WP.
Hgb lysing reagents:	SULFOLYSER, STROMATOLYSER-WH, QUICKLYSER V.

Sysmex platelet isotonic diluent with CD (Centrifuge Dilution) method: CELLKIT-CD.

Examination procedure



1. Remove the vial from the refrigerator and equilibrate to room temperature (15-30 °C) for 15 minutes before use.
2. Roll each vial between the palms of your hands for 15 seconds.
3. Holding the vial by the ends between the thumb and finger, invert the vial 20 times end-to-end using a very quick turning motion of your wrist during mixing (http://www.sysmex-europe.com/media-center/sysmex-qc-material-preparation-26847.html).
4. Analyze the QC reagent in the instrument according to the Instructions for Use. The pierceable septum in the vial cap allows sampler analysis.
5. Subsequent analyses during this test period may be performed by inverting the vial 5 times prior to instrument analysis.
6. Return to refrigerator (2-8 °C) storage.

Steps 1-6 must be repeated upon removing the sample from the refrigerator for the entire open-vial time period regardless of the method of analysis (open tube, cap piercing, auto sample or manual sample).

Performance characteristics

Limitations of the examination procedure

The mean assay values for each parameter of EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H are derived from replicate analyses on whole blood calibrated instrumentation. The assay values are obtained using instrument manufacturer's recommended reagents. The values obtained on EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H prior to expiration should be within the expected range. The expected ranges listed represent estimates of inter-laboratory variation for each parameter. Inter-laboratory variation is usually accounted for by instrument calibration, maintenance and operating technique. For this reason, the assay values given are guide-numbers useful for control, and are not absolute assays for calibration. The user must establish values and expected ranges for parameters not listed on the assay sheet. It is recommended that at least 5 consecutive analyses be performed on a properly calibrated instrument to establish the "assay" mean and standard deviation. The white cell components have been treated to enhance their stability; therefore, they will not stain to demonstrate typical cell morphology. A microscopic differential analysis of white blood cells cannot be accomplished with EIGHTCHECK-3WP-N, EIGHTCHECK-3WP-L and EIGHTCHECK-3WP-H.

The intended use of this product with Sysmex automated 3-part differential instruments are limited to those parameters for which assay values are provided. Values provided in QC analysis by the Sysmex automated 3-part differential instruments but not listed on the assay sheet should have their QC target and limit values set to 0 (zero) unless these values are established and accepted by the operating laboratory. 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 system. Performance of the control product was established through analysis using the Quality Control Mode of operation of the Sysmex automated 3-part differential instruments. Analysis of the product in the clinical laboratory should follow the same process as indicated in the instrument Instructions for Use. Slight variations in recovered values may occur between Open Mode and Closed Mode of instrument operation (see instrument Instructions for Use). Therefore, if the user chooses to use the product for control of both modes of analysis the results should be filed separately. Combining Open and Closed Mode data may widen the range of SD and CV performance.

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.

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

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Authorized representatives

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Product information

EIGHTCHECK-3WP-N	1.5 mL / vial, 4.6 mL / vial
EIGHTCHECK-3WP-L	1.5 mL / vial, 4.6 mL / vial
EIGHTCHECK-3WP-H	1.5 mL / vial, 4.6 mL / vial

Date of issue or revision

08/2023

Catalogue number

In vitro diagnostic medical device


Manufacturer


Consult instructions for use


Temperature limitation


Use by

Batch code


Biological risks