e-CHECK™(XS)

EN

Identification of the IVD reagent
e-CHECK™(XS)

Intended use
For in vitro diagnostic use only
e-CHECK(XS) is a hematology control material primarily for intralaboratory quality control of automated, semiautomated and manual procedures that measure components of the blood. Additionally, e-CHECK(XS) can be used in external quality assessment.
Do not use e-CHECK(XS) to calibrate the instrument.

Principles of the examination method
e-CHECK(XS) is to be used as a hematology control blood for the quality control of the XS-Series instrument system. 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, e-CHECK(XS) will provide values within the expected range indicated on the assay sheet.

Components
e-CHECK(XS) contains stabilized human red blood cells, human 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.

Examination procedure

1. Remove a vial of e-CHECK(XS) from refrigerator, and equilibrate to room temperature (18-30°C) for 15 minutes before use.
2. Place the vial between the palms, and roll it back and forth 10 times as shown.
3. Turn the vial upside down, and roll 10 more times.
4. Repeat step (2) and (3) eight more times, or for a total of two minutes. Examine the bottom of the vial and assure the mixing is complete by confirming that there is no pellet of cells adhering to the bottom of the vial.
5. Analyze e-CHECK(XS) in the instrument Quality Control Mode according to the XS-Series Instruction for Use. The pierceable septum in the vial cap allows closed tube analysis.
6. If the vial has been opened for use in the Open Mode of analysis, wipe the threads of both vial and cap with clean lint-free tissue or gauze before replacing cap after sampling.
7. Recap the vial tightly and return to refrigerator (2-8°C) storage.

Storage and shelf life of unopened product
e-CHECK(XS) is to be stored closed at 2-8°C. When handled in this manner, e-CHECK(XS) is 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 14 days if stored at 2-8°C.

Indications of product deterioration
If e-CHECK(XS) fails 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 e-CHECK(XS) (i.e. make sure the expiration date, or verify that it has not been frozen).
4. Assay an unopened vial of e-CHECK(XS) (i.e. verify if the opened vial is used over the period of 14 days).
5. Report any discrepancies to Technical Services of the nearest Sysmex authorized distributor.

Performance characteristics
Limitations of the examination procedure
The mean assay values for each parameter of e-CHECK(XS) 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 e-CHECK(XS) 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 for each level.
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 e-CHECK(XS).
The intended use of this product with Sysmex XS-Series instruments is limited to those parameters for which assay values are provided. Values provided in QC analysis by the XS-Series 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 XS-Series instruments. Analysis of the product in the clinical laboratory should follow the same process as indicated in the analyzer's Instruction 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.

Additional required equipment
e-CHECK(XS) is intended for only use with

diluent:	CELLPACK,
lysing reagent:	STROMATOLYSER-4DL,
Hgb lysing reagent:	SULFOLYSER,
staining reagent:	STROMATOLYSER-4DS.

Disposal procedures
This product should not be disposed in general waste but should be disposed with infectious medical waste. Disposal by incineration is recommended.

Manufacturer
Sysmex Corporation
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Product information
e-CHECK(XS) 1.5 mL/vial

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.

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