XN-L CHECK ™

EN

Identification of the IVD reagent
XN-L CHECK ™

Intended use
XN-L CHECK is intended to be used as a control for complete blood cell count (CBC), white blood cell differential and reticulocyte parameters on Sysmex XN-L series instruments.

Principles of the examination method
XN-L CHECK is to be used as a haematology control blood for the quality control of the Sysmex XN-L series instrument system. Use of stabilized cell preparations for controlling haematology instrumentation is an established procedure. When handled like a patient sample and assayed in the QC Analysis of a properly calibrated and functioning instrument, XN-L CHECK will provide values within the expected range indicated on the assay sheet.

Components
XN-L CHECK includes stabilized human red blood cells, white blood cells and a platelet component in a preservative medium.

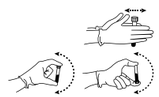
Warnings and precautions
Do not inject or ingest.
All human source material used to manufacture XN-L CHECK was non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed NAT, and non-reactive 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, XN-L CHECK should be handled with appropriate precautions.

Storage and shelf life of unopened product
XN-L CHECK is to be stored in a dark place at 2-8 °C. When handled in this manner, XN-L CHECK 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 15 days if stored in a dark place at 2-8 °C after being re-capped.

Indications of product deterioration
If XN-L CHECK 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 reagents are stored properly, and etc.
3. Determine validity of XN-L CHECK (i.e. make sure the expiration date, or verify that it has not been frozen).
4. Assay an unopened vial of XN-L CHECK (i.e. verify if the opened vial is used over the period of 15 days).
5. Report any discrepancies to Technical Services of the nearest Sysmex authorized distributor.

Additional required equipment
XN-L CHECK is intended for only use with
diluents: CELLPACK DCL, CELLPACK DST, CELLPACK DFL.
lysing reagents: Lysercell WDF.
Hgb lysing reagent: SULFOLYSER.
staining reagents: Fluorocell WDF, Fluorocell RET.

Examination procedure


1. Remove the vial from the refrigerator and equilibrate to room temperature (15-35 °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.
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 XN-L 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 on XN-L 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 technique. For this reason, the assay values given are guide-numbers useful for internal quality control, and shall not be used for calibration.

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 XN-L CHECK.

The intended use of XN-L CHECK with Sysmex XN-L series instruments is limited to those parameters for which assay values are provided. Values provided in QC analysis by the Sysmex XN-L series 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 QC Analysis of operation of the XN-L series instruments. Analysis of the product in the clinical laboratory should follow the same process as indicated in the instrument 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
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Authorized representative / Distributors

Asia-Pacific: **Sysmex Asia Pacific Pte Ltd.**
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Product information
XN-L CHECK 3.0 mL / vial

Date of issue or revision
03/2023

Printed in U.S.A.

REF — Catalogue number

IVD — In vitro diagnostic medical device

Manufacturer

Consult instructions for use

Temperature limitation

Use by

LOT — Batch code

Biological risks