# XN CHECK ™

EN

### Identification of the IVD reagent
**XN CHECK ™**

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

### Principles of the examination method
XN CHECK is to be used as a haematology control blood for the quality control of the Sysmex X 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 CHECK will provide values within the expected range indicated on the assay sheet.

### Components
XN CHECK includes stabilized human red blood cells, human white blood cells, a platelet and nucleated red blood cell component in a preservative medium.

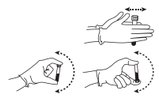
### Warnings and precautions
Do not inject or ingest.
All human source material used to manufacture XN CHECK was non-reactive for antigens to Hepatitis B (HBsAg), negative by tests for antibodies to HIV (HIV-1/HIV-2) and Hepatitis C (HCV), non-reactive for HIV-1 RNA and HCV RNA by licensed NAT, and non-reactive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

### Storage and shelf life of unopened product
XN CHECK is to be stored in a dark place at 2-8 °C. When handled in this manner, XN 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 7 days if stored in a dark place at 2-8 °C after being re-capped.

### Indications of product deterioration
If XN 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 CHECK (i.e. make sure the expiration date, or verify that it has not been frozen).
4. Assay an unopened vial of XN CHECK (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
XN CHECK is intended for only use with
diluents: CELLPACK DCL, CELLPACK DST, CELLPACK DFL.
lysing reagents: Lysercell WNR, Lysercell WDF, Lysercell WDF II*, Lysercell WPC.
Hgb lysing reagent: SULFOLYSER.
staining reagents: Fluorocell WNR, Fluorocell WDF, Fluorocell RET, Fluorocell PLT, Fluorocell WPC.

### 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.
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).
NOTE: If BT-50* is used, refer to the device's instructions for use.

### Performance characteristics
### Limitations of the examination procedure
The mean assay values for each parameter of XN 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 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 CHECK.

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

### 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
7002 S. 109th Street La Vista, NE 68128, U.S.A.


### Authorized representative / Distributors

Asia-Pacific: **Sysmex Asia Pacific Pte Ltd.**
9 Tampines Grande #06-18, Singapore 528735


### Product information
XN CHECK 3.0 mL / vial

### Date of issue or revision
03/2023

*Not available in all countries

Printed in U.S.A.

# XN CHECK ™

ZH-TW

[市售品名]
**XN CHECK ™**

[預期用途]
XN CHECK 用於控制 Sysmex X series 儀器上的完整血液細胞數（CBC）、白血球分類、網狀細胞和有核紅血球（NRBC）參數。

[檢驗方法之原理]
XN CHECK 用作 Sysmex X series 儀器品質控制的血液控制。使用穩定細胞製劑來控制血液儀器為已確立之方法。當處理病患樣本，以及在正確校正過且正常運作儀器的 QC 分析中檢測時，XN CHECK 會提供檢測表上指示的預測範圍內的數值。

[成分]
XN CHECK 含有穩定的人類紅血球、人類白血球、血小板和有核紅血球成分，並存放於保存液中。

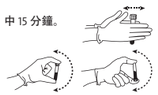
[警告和注意事項]
請勿注射或服用！
所有用於製造 XN CHECK 的人類來源物質皆對 B型肝炎表面抗原（HBsAg）無反應性，HIV (HIV-1 / HIV-2) 及 C 型肝炎 (HCV) 抗體測試結果為陰性，對 NAT 合格的 HIV-1 RNA 和 HCV RNA 無反應性，對採用美國食品和藥物管理局指定技術所進行的梅毒血清測試 (STS) 無反應性。由於目前尚無已知可完全確認試劑中不含所有人類病原體之檢測方法，因此應謹慎處理 XN CHECK 並採取預防措施。

[未開封產品之保存與保存期限]
XN CHECK 應儲存於 2-8 °C 的暗所。在適當儲存情況下，XN CHECK 在包裝和瓶子上註明的到期日之前皆保證穩定。

[開封後的保存方法及保存期限]
已開封的瓶子和從瓶蓋穿孔取樣過的瓶子，蓋回瓶蓋後若保存於 2-8 °C 的暗所，則穩定性可維持 7 天。

[產品變質的指標]
如果 XN CHECK 無法產生檢測表指示的預期結果，則使用的控制血液、試劑或儀器可能有問題。請依照下列程序進行：
1. 檢查儀器是否正常運作，且不需要清潔或維修。
2. 檢查試劑是否過期、遭受污染、正常保存等。
3. 檢查 XN CHECK 是否有效（確認保存期限及是否冷凍過）。
4. 檢查未開封的 XN CHECK 瓶子（確認是否開封超過 7 天）。
5. 向最近的 Sysmex 授權經銷商技術服務人員回報任何問題。

[額外需要的器材]
XN CHECK 僅能與
稀釋劑一起使用： CELLPACK DCL, CELLPACK DST, CELLPACK DFL.
溶解試劑： Lysercell WNR, Lysercell WDF, Lysercell WDF II*, Lysercell WPC.
Hgb 溶解試劑： SULFOLYSER.
染色試劑： Fluorocell WNR, Fluorocell WDF, Fluorocell RET, Fluorocell PLT, Fluorocell WPC.

[檢驗方法]

1. 從冷藏庫中取出瓶子，使用前先放置於室溫（15-30 °C）中 15 分鐘。
2. 在兩個手掌之間滾動每個瓶子 15 秒。
3. 用拇指和手指抓住瓶子的末端，使用手腕非常快速的轉動動作在混勻過程中將瓶子上下翻轉 20 次。
4. 依照使用說明在儀器中分析 QC 試劑。可用瓶蓋上的可穿透隔膜進行取樣分析。
5. 在此測試期間的後續分析可以透過在儀器分析之前將瓶子上下翻轉 5 次來進行。
6. 放回冷藏庫（2-8 °C）儲存。

無論採用何種分析方法（開管、穿蓋、自動採樣或手動採樣），都必須在從冷藏庫中取出樣本後的整個開瓶時間段內重複步驟 1-6。
注意：如果使用BT-50*，請參閱裝置的使用說明。

[效能特性]
[檢驗方法限制]
XN CHECK 每個參數的平均檢測數值是從反覆分析整個血液校正儀器得來的。使用儀器製造廠建議的試劑取得檢測數值。從 XN CHECK 取得的數值應在預期範圍內。檢測表上所列的預期範圍代表每個參數在不同實驗室間的差異預估值。不同實驗室間的差異通常包括儀器校正、維修和操作技巧。因為這個理由，呈現的檢測數值是內部品質控制時有用的參考數字，且不可用於校正。

白色細胞成分經過處理以加強穩定性，因此不會以染色證明細胞典型型態。白血球的顯微鏡分類分析不可與 XN CHECK 一同進行。

在 Sysmex X series 儀器上使用 XN CHECK 僅限於有提供檢測數值的參數。由 Sysmex X series 儀器 QC 分析提供但檢測表未列出的數值，不能有 QC 目標及設為 0 的限值，除非這些數值由操作實驗室產生並接受。

檢測數值和限值透過 Sysmex 試劑專用方式產生，且僅能用於相同 Sysmex 試劑系統的實驗室使用。
控制產品的效能由 X series 儀器的 QC 分析所產生。在臨床實驗室的產品分析應按照儀器使用說明中指示的相同方法分析。

[廢棄物處理程序]
本產品不應丟棄在一般垃圾桶，應與生物感染性醫療廢棄物一同丟棄。建議以焚化方式處理。並符合當地法規的要求。

[參考文獻]

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.


[製造商]

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7002 S. 109th Street La Vista, NE 68128, U.S.A.


[歐洲以外的代理者/經銷商]

亞太: **Sysmex Asia Pacific Pte Ltd.**
9 Tampines Grande #06-18, Singapore 528735


[產品資訊]
XN CHECK 3.0 mL / 瓶

[發行或修改日期]
03/2023

*在所有國家皆無法使用

於美國印製

sysmex

REF — Catalogue number
目錄編碼

IVD — In vitro diagnostic medical device
體外診斷醫療器材

Manufacturer
製造商

Consult instructions for use
請參照使用說明書

Temperature limitation
溫度界線

Use by
保存期限

LOT — Batch code
批號

Biological risks
生化危險

Sysmex Corporation

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