# XN CAL ™

EN

**Identification of the IVD reagent**
**XN CAL ™**

**Intended use**
XN CAL is a calibrator for Sysmex X series. It is designed for the calibration and calibration verification of WBC, RBC, HGB, HCT, PLT and RET.

**Principles of the examination method**
XN CAL is to be used as a calibrator of the Sysmex X series instrument system. Use of stabilized cell preparations for monitoring the calibration status of haematology instrumentation is an established procedure. When handled like a patient sample and assayed in the Calibrator Mode of a properly calibrated and functioning instrument, XN CAL will provide values indicated on the assay sheet.

**Warnings and precautions**
Do not inject or ingest. All human source material used to manufacture XN CAL 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 CAL should be handled with appropriate precautions.

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

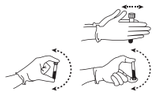
**Storage and shelf life of unopened product**
XN CAL is to be stored in a dark place at 2-8 °C. Avoid freezing this material. When stored properly the unopened product can be used until the expiration date stated on the label on the vial. Storage outside the recommended temperature range causes damage to the product. Do not use damaged material for calibration and calibration verification.

**Storage and shelf life after first opening**
Opened vials should be used within 4 hours. Afterwards opened vials should be discarded.

**Indications of product deterioration**
If XN CAL fails to perform within expected results as indicated on the assay sheet, there may be a problem with either the calibrator, 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 CAL (i.e. make sure the expiration date, or verify that it has not been frozen).
4. Assay an unopened vial of XN CAL (i.e. verify if the opened vial is used over the period of 4 hours).
5. Report any discrepancies to Technical Services of the nearest Sysmex authorized distributor.

**Additional required equipment**
XN CAL is intended only for use on Sysmex X series and its reagents. Acceptable limits of XN CAL were established by solely using Sysmex X series and its reagents and are thus comparable only with values likewise established.

**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 Calibrator reagent in the instrument according to the instructions for use. The pierceable septum in the vial cap allows closed tube 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).

**Preparation of the calibrator**
Since XN CAL is containing minimal stabilized cells, utmost care is to be exercised in handling the material.

**Calibration procedure**
See instrument instructions for use (Chapter 12).

**Evaluation of results**
Analyzer mean values deviating from the acceptable limits indicate the need for recalibration. However, before changing calibration settings the results of the internal quality control (using Sysmex control bloods) and of the external quality control (SNCS-IQAS ONLINE or external third-party inter-laboratory test) have to be taken into account. If results are contradicting it is to be checked that the calibrator is intact. The justification for recalibration shall be given careful consideration.

**Metrological traceability and literature references**
The assigned value for XN CAL is determined by X series who are calibrated with fresh human blood against the following 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 1:50,000 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: CLSI H7-A3: Procedure for determining Packed Cell Volume by the Microhematocrit Method; Approved Standard – Third edition (2000).
PLT: Platelet counting by the RBC/Platelet Ratio Method – A Reference method, ICSH Expert Panel on Cytometry and ISLH Task Force on Platelet Counting, Am J Clin Pathol 2001; 115, 460-464.
Determined from the RBC/PLT ratio performed by fluorescence flow cytometry with platelets labeled with monoclonal antibodies.
RET: Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline – Second Edition Manual method CLSI H44-A2 (2004).

**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
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 CAL 3.0 mL / vial

**Date of issue or revision**
03/2023 Printed in U.S.A.

# XN CAL ™

ZH-TW

[市售品名]
**XN CAL ™**

[預期用途]
XN CAL 是 Sysmex X series 的校正液。用於 WBC, RBC, HGB, HCT, PLT 和 RET 的校正及校正驗證。

[檢驗方法之原理]
XN CAL 是用作 Sysmex X series 儀器的校正液。使用穩定細胞製劑來監測血液儀器的校正狀態為已確立之方法。當處理病患樣本，以及在正確校正過且正常運作儀器的校正模式中檢測時，XN CAL 會提供檢測表上指示的數值。

[警告和注意事項]
請勿注射或服用！所有用於製造 XN CAL 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 CAL 並採取預防措施。

[成分]
XN CAL 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。

[未開封產品之保存與保存期限]
XN CAL 應儲存於 2-8 °C 的暗所。本產品請勿冷凍。在適當儲存情況下，未開封產品在瓶外標籤註明的到期日之前皆可使用。若儲存溫度超過建議範圍則產品會受損。請勿使用受損之產品以進行校正及校正驗證。

[開封後的保存方法及保存期限]
產品開封後應於 4 小時內使用。開封超過 4 小時請丟棄。

[產品變質的指標]
如果 XN CAL 無法產生檢測表指示的預期結果，則使用的校正液、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 CAL 是否有效（確認保存期限及是否冷凍過）。
4. 檢查未開封的 XN CAL 瓶子（確認是否開封超過 4 小時）。
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 CAL 僅用於 Sysmex X series 及其試劑。XN CAL 的可接受限制為僅使用 Sysmex X series 及其試劑的限制，因此僅能與相同限制的數值做比較。

[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校正液試劑。可用瓶蓋上的可穿透隔膜進行封閉式試管分析。
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。

[準備校正液]
由於 XN CAL 含有極小的穩定細胞，處理時須非常謹慎。

[校正方法]
請參閱儀器使用說明（第 12 章）。

[結果評估]
分析儀的平均值超出可接受範圍，須重新校正。但是在變更校正設定前，必須考慮內部品質控制（使用 Sysmex 控制血液）和外部品質控制（SNCS-IQAS ONLINE 或外部第三方實驗室間測試）的結果。如果結果牴觸，則必須檢查校正液是否正常。應該謹慎考量重新校正的必要性。

[度量衡學之可追蹤性與參考文獻]
XN CAL 的指定值是由採新鮮人血並對照下列國際慣例的參考測量方法進行校正的 X series所決定：

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.
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CLSI H15-A3: Reference and selected procedures for the quantitative determination of hemoglobin in blood; Approved Standard – Third edition (2000).
以 1:250 比例稀釋適當試劑（Kampen, Zijlstra 所推薦）進行光度檢測。
HCT: CLSI H7-A3: Procedure for determining Packed Cell Volume by the Microhematocrit Method; Approved Standard – Third edition (2000).
PLT: Platelet counting by the RBC/Platelet Ratio Method – A Reference method, ICSH Expert Panel on Cytometry and ISLH Task Force on Platelet Counting, Am J Clin Pathol 2001; 115, 460-464.
以螢光流式細胞儀及標示為單株抗體的血小板所執行的 RBC/PLT 比率所決定。
RET: Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline – Second Edition Manual method CLSI H44-A2 (2004).

[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，並符合於當地法規的要求。

[製造商]
**Sysmex Corporation**
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

OEM "製造商": STRECK
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 CAL 3.0 mL / 瓶

[發行或修改日期]
03/2023 於美國印製

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