SCS™-1000

EN

Identification of the IVD reagent
SCS™-1000

Intended use
The SCS-1000 is a calibrator for Sysmex haematology analysers. It is designed for the calibration and calibration verification of WBC, RBC, HGB, HCT/MCV, PLT and RET*.

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.

Components
SCS-1000 contains stabilised human red blood cells, fixed mammalian white blood cells, and a platelet component in a medium containing preservatives.

Storage and shelf life of unopened product
SCS-1000 vials should be stored 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 of 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.

Additional required equipment
SCS-1000 is intended only for use on Sysmex instruments and reagents. The SCS-1000 acceptable limits were established by solely using Sysmex instruments and reagents and are thus comparable only with values likewise established.

Calibration procedure
Precalibration validation
1. Do not use SCS-1000 if the ambient room temperature exceeds 30 °C.
2. Instrument power should be on for at least 30 minutes prior to calibration.
3. Please make sure that you have entered the lot numbers and expiration dates of all reagents used on the analyzer in the instrument's log.
4. Verify that maintenance of the instrument has been performed according to the manufacturer's recommendations.
5. Perform Auto Rinse and verify that backgrounds are within specified limits.
6. Review the recent internal quality control data to ensure that the analyser performance is stable.
7. Verify that the lot number and expiration date on the SCS-1000 vials match the data provided on the assay sheet.

Analyser precision verification
1. Analyse a normal fresh whole blood sample in the open whole blood mode 11 consecutive times. Discard the first result and calculate the Coefficient of Variation (CV%) for all parameters being calibrated using results two (2) to eleven (11).
2. Verify that the instrument performs within “precision limits” as stated in the instructions for use.

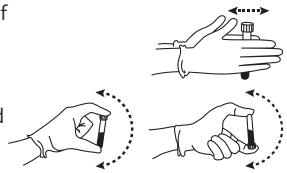
Selection of the mode
Select the following mode dependant upon the instrument type.

Instrument	Mode		
	Whole blood Mode	Maintenance Mode / Special Mode / Control Blood Mode	Maintenance Mode / Special Mode / Calibrator Mode
K-800	X		
K-1000	X		
K-4500	X		
KX-21/XP-Series			X
pocH-100i			X
XS-Series		X (CTR3)	
XT-Series			X
XE-Series			X
XQ-Series*	Refer to the device's instructions for use.		

Preparation of the calibrator
Since SCS-1000 calibrator is a product containing minimal stabilised cells, utmost care is to be exercised in handling the material. Slight haemolysis indicated by a slightly coloured supernatant is normal. A strong coloured supernatant is an indication for excessive haemolysis which could be the result of exposure to temperature extremes. In this case the product should be discarded.

Please follow the following procedure exactly, because it is critical for the correct calibration and calibration verification.

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 Calibrator reagent in the instrument according to the instructions for use.
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, auto sample or manual sample).

Calculate mean and check data
1. Discard the first of the 6 results.
2. Calculate the mean of remaining 5 results for each parameter and check if the mean (analyser mean) lies within the acceptable limits.

Evaluation of results
Analyser 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 (Sysmex IQAS, 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.

Calculate new calibration settings

1. Calculate new calibration settings using this formula:

$$\text{New calibration factor} = \text{Current calibration factor} \times \frac{\text{Assay Target}}{\text{Analyser Mean}}$$

2. After calibration settings have been changed, verify the changes by repeating the calibration procedure. Analyser mean values which lie within the acceptable limits confirm the accurate calibration status of the instrument.

Metrological traceability

The assigned values for SCS-1000 are determined by multiple analyses on Sysmex haematology analysers 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: Recommendations for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specifications 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).

Limitations of the examination procedure

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.

Manufacturer

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Product information

SCS-1000 2.0 mL x 1

Date of issue or revision

08/2023

*Not available in all countries

REF	Catalogue number
IVD	In vitro diagnostic medical device
	Manufacturer
	Consult instructions for use
	Temperature limitation
	Use by
LOT	Batch code
	Biological risks