TRANSASIA

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai- 400 072
Tel: +91 22 4030 9000 Fax: +91 22 2857 3030

Date: 27/07/2020
Effective Date: 27/07/2020

Certificate of Calibration

Customer Name: SURE DIAGNOSTIC LAB

Model : Automated Hematology Analyzer Sysmex XP-100

Serial No. : B7428

Calibration Done Date: 27.7.20

Next Calibration Due Date On or Before: 27.7.2021

Lab In-charge: . DR SUMEDHA MENGI

This is to certify that the above-mentioned product has been verified of calibration for CBC 5 parameters (WBC, RBC, HGB, HCT and PLT) according to the standard procedures provided by Sysmex Corporation, Japan.

The reference instruments used for value-assignment are managed by the traceability system in Sysmex Corporation and these are traceable to the International Standards, such as ICSH.

Calibration at site performed by
Engineer Name: SUNNY BHAT/ AJAY SINGH
Designation: APP SPECIALIST / ENGINEER
Transasia Bio-Medicals Ltd
Location: JAMMU

Encl:
1. Certificate of Inspection
2. Assay Sheet of Calibrator SCS-1000
3. Printouts
4. Traceability & Uncertainty document

Erba Mannheim

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Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XP – 100

2. Serial No.: B7428

3. Calibration Date: 27/07/2020

4. Material used: SCS-1000 (Lot No. 0196 0525, Expiry date: -16-Aug-2020)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for CBC 5 parameters using the measurement standard material (SCS-1000) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

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5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3 x 10^3/Ul or Less
RBC	0.00	0.02 x 10^6/uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10 x 10^3/uL or Less

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6. PRECISION STUDY PERFORMED ON THE ANALYZER USING A BLOOD SAMPLE (ORIGINALS ATTACHED)

SMP NO	WBC	RBC	HGB	HCT	PLT
1	6.9	4.55	12.7	34.9	248
2	7.1	4.47	12.7	34.9	248
3	6.8	4.62	12.6	35.2	245
4	7	4.62	12.6	35.4	248
5	7.10	4.57	12.8	34.6	253
NA					
NA					
NA					
NA					
NA					
Mean	6.98	4.57	12.68	35.00	248.40
SD	0.130	0.062	0.084	0.308	2.881
CV%	**1.868**	**1.355**	**0.660**	**0.881**	**1.160**
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

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7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
1	6.40	4.40	11.9	32.10	267
2	6.50	4.41	11.9	32.10	273
3	6.50	4.35	12.0	32.30	259
4	6.50	4.35	12.0	32.50	256
5	6.40	4.37	12.0	32.40	247
MEAN	**6.46**	**4.376**	**11.96**	**32.28**	**260.4**
Acceptable Limits	6.34 - 6.91	4.209 - 4.380	11.91 - 12.15	32.09 - 33.54	240.4 - 265.7
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

8. (Traceability System) :
The traceability system of Sysmex Hematology analyzers are shown in attached sheet.

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Hematology Calibrator

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ELite HEM Calibrator

Catalogue No.	Name	Package size
HEM00012	ELite HEM Calibrator	3 ml

INTENDED USE
ELite HEM Calibrator is designed for use in the calibration of hematology analyzers. Please refer to the assay table for specific instrument models.

SUMMARY AND PRINCIPLE
Hematology analyzers require periodic calibration in order to generate accurate patient results. This calibrator is a stable, whole blood preparation that can be used to verify and adjust calibration of select hematology instruments.
Calibrator values for ELite HEM Calibrator are derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. Instruments are calibrated with whole blood using values determined by reference methods.

REAGENTS
ELite HEM Calibrator is an *in vitro* diagnostic reagent composed of human erythrocytes, mammalian leukocytes and mammalian platelets suspended in a plasma like fluid with preservatives.

PRECAUTION
ELite HEM Calibrator is intended for in vitro diagnostic use only by trained personnel.

WARNING:
POTENTIAL BIOHAZARDOUS MATERIAL. For *in vitro* diagnostic use. Each human donor/unit used in the preparation of this product has been tested by a FDA licensed method/test and found to be negative or non-reactive for the presence of HBsAg, Anti--HCV, NAT testing for HIV-1, HCV (RNA) and HIV-1/2. Each unit is also negative by a serological test for Syphilis (RPR or STS). Because no test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

STABILITY AND STORAGE
Store ELite HEM Calibrator upright at 2 - 8° C (35 - 46° F) when not in use. **Protect tubes/vials from overheating and freezing.** Unopened tubes/vials are stable through the expiration date. Opened tubes/vials are stable for 7 days, provided they are handled properly.

INDICATIONS OF DETERIORATION
After mixing, product should be similar in appearance to fresh whole blood. In unmixed tubes/vials, the supernatant may appear cloudy and reddish; this is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration.
Do not use the product if deterioration is suspected.

INSTRUCTIONS FOR USE

A. Mixing and handling directions:
1. Remove tubes/vials from the refrigerator and allow to warm at room temperature (15 - 30°C or 59 - 86°F) for 15 minutes before mixing.
2. To mix, hold a tube/vial horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
   a) Roll the tube/vial back and forth for 20 - 30 seconds; occasionally invert the tube/vial. Mix vigorously but do not shake.
   b) Continue to mix in this manner until the red cells are completely suspended. Tubes/vials stored for a long time may require extra mixing.
   c) Gently invert the tube/vial 8 - 10 times immediately before running each sample.
3. After sampling:
   a) Automatic Sample Handling: Remove the tube/vial from the sample hadler immediately after sampling.
   b) Manual Sample Handling: Carefully wipe the tube/vial rim and cap with a lint-free tissue and replace the cap.
4. Return tubes/vials to refrigerator within 30 minutes of use.

B. Analyze Calibrator:
1. Prime the instrument once by aspirating calibrator sample. Discard the result.
2. Analyze calibrator according to the calibration procedure in the Operator's Manual for your instrument.
3. Compare the mean value for each parameter to the assigned value.
   a) If the difference is within the Range, calibration is optional.
   b) If the difference is not within the Range, calibration may be needed.
4. Ranges given on the assay sheet are intended as guidelines for evaluating instrument calibration. Acceptable ranges should be established by each laboratory. If the calibrator recovered data is outside the range found on the assay sheet with stable control results, interlaboratory QC and/or Proficiency Testing reports that have excellent peer group agreement, this may indicate possible product damage.

Do not use the product if deterioration is suspected.

C. Adjust instrument calibration and verify results:
1. Calibrate the instrument by using the calibration adjustment procedures described in the Operator's Manual for your instrument.
2. Verify calibration by analyzing calibrator and repeat step 3 under "Analyze Calibrator".
3. Confirm calibration by running quality control material.

EXPECTED RESULTS
Verify that the lot number on the tube/vial matches the lot number on the table of assay values. Assay values are determined on well-maintained, properly calibrated instruments using the instrument manufacturer's recommended reagents.

PERFORMANCE METHODS
1. **WBC:** A series of 1:500 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.
2. **RBC:** A series of 1:50,000 dilutions are made with calibrated glassware. Counting is performed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.
3. **HGB:** Hemoglobin value is determined by spectrophotometric procedure according to CLSI Standard H15-A3 and is traceable to ICSH/WHO International Haemiglobincyanide Standard.
4. **HCT:** Packed cell volume (PCV) is measured by the microhematocrit procedure according to CLSI Standard H7 A3. No correction is made for trapped plasma.
5. **PLT:** A series of 1:126 dilutions are made using calibrated glassware in 1% ammonium oxalate. Platelets are counted using a hemocytometer and phase contrast microscopy.

LIMITATIONS
The performance of this product is assured only if it is properly stored and used as described in this insert. Incomplete mixing of a tube/vial prior to use invalidates both the sample withdrawn and any remaining material in the tube/vial.

USED SYMBOLS

REF Catalogue Number | Manufacturer | See Instruction for Use | LOT Lot Number | CE Mark - Device comply with the Directive 98/79/EC

Storage Temperature | Expiry date | IVD In vitro Diagnostics | CONT Content | Biological risks

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