

Date: 23.12.20
Effective Date: 23.12.20

Certificate of Calibration

Customer Name: POLO LABS PVT. LTD.

Model : Automated Hematology Analyzer Sysmex XS-800i

Serial No. : 67677

Calibration Done Date: 23.12.20

Next Calibration Due Date On or Before: 22.12.21

Lab In-charge: Dr. SUKSHAM SAMIR

This is to certify that the above-mentioned product has been verified of calibration for CBC 6 parameters (WBC, RBC, HGB, HCT, MCV 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.

21/12/20
Calibration at site performed by
GIAN CHAND
Designation : SR.SERVICE ENGG.
Transasia Bio-Medicals Ltd
Location : JALANDHAR

Encl:


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

Date: 23.12.2020
Effective Date: 23.12.20

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XS-800i
2. Serial No.: 67677
3. Calibration Date: 23.12.20
4. Material used: SCS-1000 (Lot No. 0336 0525, Expiry date: 03-Jan-2021)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for CBC 6 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 | 0.3×10^3 /uL or less |
| RBC | 0.00 | 0.02×10^6 /uL or less |
| HGB | 0.0 | 0.1 g/dL or less |
| PLT | 3 | 10×10^3 /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 | MCV | PLT |
|----------------|-------------|-------------|-------------|-------------|-------------|-------------|
| 102 | 7.92 | 4.60 | 12.10 | 36.6 | 79.6 | 248 |
| 103 | 7.66 | 4.64 | 12.10 | 36.80 | 79.3 | 245 |
| 104 | 7.72 | 4.64 | 12.20 | 36.8 | 79.3 | 251 |
| 105 | 7.75 | 4.61 | 12.20 | 36.4 | 79.0 | 248 |
| 106 | 8.00 | 4.61 | 12.10 | 36.3 | 78.7 | 254 |
| 107 | 7.77 | 4.65 | 12.30 | 36.5 | 78.5 | 257 |
| 108 | 7.6 | 4.65 | 12.20 | 36.4 | 78.3 | 243 |
| 109 | 7.67 | 4.57 | 12.20 | 35.7 | 78.1 | 243 |
| 110 | 7.48 | 4.68 | 12.10 | 36.5 | 78.0 | 249 |
| 111 | 7.61 | 4.66 | 12.20 | 36.2 | 77.7 | 253 |
| Mean | 7.72 | 4.63 | 12.17 | 36.42 | 78.65 | 249.10 |
| SD | 0.153 | 0.033 | 0.067 | 0.319 | 0.636 | 4.701 |
| CV% | 1.988 | 0.709 | 0.555 | 0.876 | 0.809 | 1.887 |
| Acceptable CV% | Within 3.0% | Within 1.5% | Within 1.5% | Within 1.5% | Within 1.5% | Within 4.0% |
| Result | PASS | PASS | PASS | PASS | PASS | PASS |

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7. CALIBRATION DATA

| SMP NO/TIME | WBC | RBC | HGB | HCT | MCV | PLT |
|-------------------|---------------|---------------|---------------|---------------|---------------|---------------|
| 203 | 6.59 | 4.39 | 12.5 | 36.1 | 82.2 | 244 |
| 204 | 6.66 | 4.40 | 12.5 | 36.1 | 82.0 | 254 |
| 205 | 6.58 | 4.36 | 12.3 | 35.8 | 82.1 | 237 |
| 206 | 6.76 | 4.42 | 12.2 | 36.3 | 82.1 | 254 |
| 207 | 6.58 | 4.38 | 12.4 | 36.0 | 82.2 | 256 |
| MEAN | 6.63 | 4.390 | 12.38 | 36.06 | 82.12 | 249.0 |
| Acceptable Limits | 6.472 - 7.005 | 4.328 - 4.464 | 12.30 - 12.49 | 35.42 - 37.02 | 81.35 - 83.45 | 239.3 - 256.8 |
| Result | PASS | PASS | PASS | PASS | PASS | PASS |

8. (Traceability System) :

The traceability system of Sysmex Hematology analyzers are shown in attached sheet.

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