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: 3.12.2020
Effective Date: 3.12.2020

Certificate of Calibration

Customer Name: PGM DIAGNOSTICS CENTRE

Model : Automated Hematology Analyzer Sysmex XP-100

Serial No. : B6342

Calibration Done Date: 3.12.2020

Next Calibration Due Date On or Before: 2.12.2021

Lab In-charge: .

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 Performed by
Engineer Name:- Sunil Giri
Designation:- Service Engineer
Transasia Bio-Medicals Ltd
Location:- Mumbai

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

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: 3.12.2020
Effective Date: 3.12.2020

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XP – 100

2. Serial No.: B6342

3. Calibration Date: 3.12.2020

4. Material used: SCS-1000 (Lot No. 0308 0525, Expiry date: 06-Dec-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.

Technical Service Department
Transasia Bio-Medicals Ltd

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

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

SMP NO	WBC	RBC	HGB	HCT	PLT
1.	8.6	4.49	14.3	40.3	232
2	8.7	4.47	14.5	40.3	217
3	8.9	4.52	14.5	40.7	226
4	8.8	4.51	14.5	40.7	237
5	8.90	4.54	14.5	40.8	225
6	8.8	4.55	14.5	41.3	223
7	8.9	4.54	14.5	40.9	231
8	8.7	4.52	14.5	40.7	220
9	8.9	4.58	14.6	41.1	215
10	8.90	4.56	14.6	41.1	227
Mean	8.81	4.53	14.50	40.79	225.30
SD	0.110	0.033	0.082	0.328	6.881
CV%	**1.249**	**0.727**	**0.563**	**0.804**	**3.054**
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

Technical Service Department
Transasia Bio-Medicals Ltd

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

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

Technical Service Department
Transasia Bio-Medicals Ltd

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

7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
1	6.90	4.30	12.0	33.80	264
2	6.60	4.20	12.1	33.10	271
3	6.80	4.20	12.1	33.00	259
4	6.60	4.29	12.1	33.60	271
5	6.70	4.29	12.2	33.60	268
MEAN	**6.72**	**4.256**	**12.10**	**33.42**	**266.6**
Acceptable Limits	6.52 - 7.10	4.195 - 4.366	11.90 - 12.14	32.49 - 33.95	250.3 - 276.7
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

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

Technical Service Department
Transasia Bio-Medicals Ltd

Traceability and Uncertainty

SCS-1000 Sysmex Calibrator System

XP-Series, Automated Hematology Analyzer

LOT NO: **03080525**
EXP. DATE: **6-Dec-2020**

Paramter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC	*1	-	6.808	0.16	10^9/L
RBC	*1	-	4.281	0.065	10^{12}/L
PLT	*2	-	263.5	11	10^9/L
HGB	*3, *4	-	12.02	0.12	g / dL
HCT	*5, *6	-	33.22	0.79	%

* : This uncertainty (expanded undertainty: k=2 was calculated in accordance with the "Guide to the expression of Uncertainty in Measurement" (GUM: 1995).

*1: ICSH Expert Panel on Cytometry, Clinical Laboratory Haematology, 16, 131-138, 1994
"Reference method for the enumeration of erythrocytes and leucocytes"

*2: ICSH Expert Panel on Cytometry and International Society of Laboratory Hematology Task Force on Platelet Counting, American Journal of Clinical Pathology, 115, 460-464, 2001
"Platelet Counting by the RBC/Platelet Ratio method – A reference Method"

*3: CLSI, H15-A3
"Reference and selected procedures for the quantitative determination of hemoglobin in blood – 3rd edition; Approved

*4: Journal of Clinical Pathology, 49, 271-274, 1996
"Recommendation for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specification for international haemiglobincyanide reference preparation (4th ed.)"

*5: CLSI H7-A3
"Procedure for Determining Packed Cell Volume by the Microhematcrit Method – 3rd edition; Approved Standard"

*6: Laboratory Hematology, 7, 148-170, 2001
"Recommendations for reference method for the packed cell volume (ICSH Standard 2001)"