

# Transit Bio Medicals

Ref.

Date:

06/09/2022

Effective Date:

06/09/2022.....

## Certificate of Calibration

**Customer Name: CITILAB HEALTHCARE INDIA PVT LTD**

**Model : Automated Hematology Analyzer Sysmex XP-100**

**Serial No. : A7125**

**Calibration Done Date: 6.9.22**

**Next Calibration Due Date On or Before: 09/05/2023**

**Lab In-charge: . Tabrez Alam**

*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 Donald Joy Thomas

Designation Service Engineer

Transasia Bio-Medicals Ltd

Location Bangalore

Encl:

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



*Haritha*



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Date: 06/09/2022  
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## Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XP – 100
2. Serial No.: A7125
3. Calibration Date: 06/09/2022
4. Material used: SCS-1000 (Lot No. 22210525, Expiry date: 11-Sep-2022)

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.



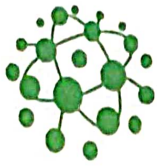
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**6. PRECISION STUDY PERFORMED ON THE ANALYZER USING A BLOOD SAMPLE  
(ORIGINALS ATTACHED)**

SMP NO	WBC	RBC	HGB	HCT	PLT
01	5.6	4.07	12.3	36.4	219
02	5.6	4.09	12.3	36.4	220
03	5.9	4.08	12.3	36.5	224
04	5.6	4.10	12.3	36.3	220
05	5.70	4.12	12.3	36.6	220
06	5.7	4.09	12.4	36.2	211
07	5.7	4.13	12.3	36.8	236
08	5.8	4.07	12.5	36.2	228
09	5.7	4.12	12.4	36.5	214
10	5.80	4.15	12.4	36.6	225
Mean	5.71	4.10	12.35	36.45	221.70
SD	0.099	0.027	0.071	0.190	7.072
CV%	1.742	0.658	0.573	0.521	3.190
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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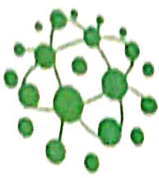
Date .....

## 5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	$0.3 \times 10^3/\text{UI}$ or Less
RBC	0.00	$0.02 \times 10^6/\text{uL}$ or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	$10 \times 10^3/\text{uL}$ or Less



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## 7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
01	7.20	4.32	12.1	33.60	264
02	7.10	4.35	12.1	33.90	273
03	7.40	4.35	12.2	33.90	280
04	7.20	4.36	12.2	33.90	275
05	7.30	4.41	12.2	34.30	278
<b>MEAN</b>	<b>7.24</b>	<b>4.358</b>	<b>12.16</b>	<b>33.92</b>	<b>274.0</b>
Acceptable Limits	6.91 - 7.53	4.265 - 4.439	12.03 - 12.28	32.98 - 34.47	254.1 - 280.9
<b>Result</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>	<b>PASS</b>

## 8. (Traceability System) :

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



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