



Certificate of Calibration

Customer Name: IMPULSE DIAGNOSTICS,

Model : Automated Hematology Analyzer Sysmex XY 300

Serial No B6923

Calibration Done Date: 18/08/2021

Next Calibration Due Date On or Before: 17/08/2022

Lab In-charge: . DR RATANDEEP NATH

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
BHOJRAJ SINGH
AREA SERVICE MANAGER
Transasia Bio-Medicals Ltd
Silchar, Assam

Encl:

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



Date: 18/08/2021

Effective Date: 18/08/2021

Certificate of Calibration

1. Model: Automated Hematology Analyzer Sysmex XP – 300
2. Serial No.: B6923
3. Calibration Date: 18/08/2021
4. Material used: SCS-1000 (Lot No. 6257 0525, Expiry date: -21-AUG-2021)

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	0.2	0.3×10^3 /UI or Less
RBC	0.00	0.02×10^6 /uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	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	PLT
1	7.1	3.45	10.3	30.5	387
2	7.1	3.43	10.3	30.6	382
3	7.1	3.43	10.3	30.7	385
4	7.1	3.47	10.3	30.7	392
5	7.10	3.44	10.2	30.4	384
6	7.1	3.47	10.4	30.6	383
7	7	3.45	10.4	30.5	385
8	7.2	3.51	10.4	31.0	381
9	7.2	3.49	10.4	30.8	377
10	7.10	3.50	10.4	31.0	374
Mean	7.11	3.46	10.34	30.68	383.00
SD	0.057	0.029	0.070	0.204	5.033
CV%	0.798	0.830	0.676	0.666	1.314
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
2	7.20	4.48	12.8	34.20	272
3	7.40	4.50	12.8	34.40	265
4	7.40	4.54	12.9	34.80	261
5	7.40	4.53	12.9	34.50	273
6	7.40	4.44	12.7	34.00	262
MEAN	7.36	4.498	12.82	34.38	266.6
Acceptable Limits	7.11-7.75	4.407 - 4.587	12.65 - 12.91	33.68 - 35.20	254.6- 281.4
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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Transasia Bio-Medicals Ltd

TRANSASIA®

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CIN: U33110MH1985PLC036198



SYSMEX XP 300 – HEMATOLOGY ANALYZER

INSTALLATION QUALIFICATION OPERATIONAL QUALIFICATION PERFORMANCE QUALIFICATION (IQ/OQ/PQ)

For, Impulse Diagnostics

Meherpur, Silcher
Assam


Auth. Signatory

Mr Sameer Singh
Transasia Biomedicals Ltd,
New Delhi

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INSTALLATION QUALIFICATION

IQ Protocol

1. System Unpacking
2. System Checking for any Damages
3. All accessories as per checklist verification
4. Space requirement
5. Power requirement
6. Reagent's control, calibrators verification

1. SYSTEM UNPACKING & 2. SYSTEM CHECKING

Sysmex XP300 Haematology Analyzer instrument carefully and check for any physical damage.

3. ACCESSORIES CHECK

Check all accessories as per check list

4. SPACE REQUIREMENT

- Checked site for proper space allocation. At least 100 cm on each side and enough room below the countertop to accommodate the reagent & pneumatic unit and waste containers.

DIMENSIONS	
PARAMETER	ANALYZER OV
Width mm	514
Depth mm	594
Height mm	645
Weight mm	24.5

5. POWER REQUIREMENT

Requirement	Acceptable Range	Observed Ranged
Input voltage	220 +/- 10V	225 v
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15C- 30 C	23



6. Regents, Control, Calibrator's Check

NAME	CHECK	Remark
Diluent	Ok	Ok
Lyse	Ok	Ok
EZ Cleanser	Ok	Ok
Probe Cleanser	Ok	Ok

PRE-INSTALLATION VERIFICATION REPORT

PRE-INSTALLATION VERIFICATION REPORT		
S.NO	PARAMETER	REMARK
1	Unpacking Instrument	Ok
2	System Checking for Damages	Ok
3	Accessories Check	Ok
4	Space Check	Ok
5	Power check	Ok
6	Reagents Check	Ok

OPERATIONAL QUALIFICATION

The operation Qualification procedure specifies the methodology for installation for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OQ Protocol

- System Connections
- Strip and control Preparation
- Customizing the analyzer software
- System Booting, Initializing & Check
- Maintenance Procedures
- Customer Training- Operation & Maintenance



1. SYSTEM CONNECTION

SYSTEM CONNECTION			
S/N	NAME	CHECK	REAMRK
1	Main Unit	Operating Manual	Ok
2	Input Power supply	Connect	Ok

2. Reagent & Waste Connection

REAGENT CONNECTION CHECK		
NAME	CHECK	REMARK
Diluent	Operating Manual	ok
Lyse	Operating Manual	ok
Waste	Operating Manual	ok

3. CUSTOMIZING ANALYZER SOFTWARE

CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Reamrk
1	Date & Time	Operating Manual 2	ok
2	Alarm	Operating Manual 2	ok
3	Reference Ranges	Operating Manual 2	ok
4	Control	Operating Manual 2	ok
5	Printing Format	Operating Manual 2	ok



4. SYSTEM BOOTING, INITIALIZATION CHECK

Power on System and check instrument Initialization Successfully
Check following Parameters.

SYSTEM SETUP				
S/N	Parameter	Actual	Range	Remark
1	Calibration Setup	As per system	As per sheet	Ok
2	Control Setup	Actual	As per sheet	Ok
3	Calibration	1	Auto	Ok
4	Hardware Setup	As per user	As per User	Ok

MAINTENANCE PROCEDURES

MAINTENANCE			
S/N	Parameter	Check	Remark
1	Flush	Operator Manual 3	Ok
2	Enhanced flush	Operator Manual 3	Ok
3	Cleaning	Operator Manual 3	Ok
4	Price chamber	Operator Manual 3	Ok
5	Drain chamber	Operator Manual 3	Ok
6	Touch screen calibration	Operator Manual 3	Ok

ADJUSTMENT			
S/N	Parameter	Check	Remark
1	Control adjustment	Operator Manual 4	Ok
2	Alarm adjustment	Operator Manual 3.3	Ok
3	Limits	Operator Manual 3	Ok



PERFORMANCE QUALIFICATION

LOW CONTROL					
S/N	PARAMETER	Actual	Target	Range	Remark
1	WBC	3.49	3.53	± 1.00	PASS
2	RBC	2.48	2.56	± 0.18	PASS
3	HGB	5.43	5.6	± 4.00	PASS
4	MCV	71.8	72.7	± 5.00	PASS
5	PLT	48	50	± 20.00	PASS
NORMAL CONTROL					
S/N	PARAMETER	Actual	Target	Range	Remark
1	WBC	7.81	7.79	± 1.50	PASS
2	RBC	5.21	5.11	± 0.24	PASS
3	HGB	13.6	13.4	± 6.00	PASS
4	MCV	88.01	87.31	± 5.00	PASS
5	PLT	284	283	± 40.00	PASS
HIGH CONTROL					
S/N	PARAMETER	Actual	Target	Range	Remark
1	WBC	19.1	18.08	± 2.50	PASS
2	RBC	5.71	5.63	± 0.30	PASS
3	HGB	17.1	16.9	± 8.00	PASS
4	MCV	97.01	96.27	± 5.00	PASS
5	PLT	538	532	± 60.00	PASS

IN THIS PQ SECTION I NEED TO ADD CONTROL DATA WITH CONTROL DETAILS AND CALIBRATION FACTORS.