



Date: 16-07-2021  
Effective Date: 16-07-2021

## Certificate of Calibration

**Customer Name:** DIAGNOSTIC POINT

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

**Serial No. :** A7677

**Calibration Done Date:** 16.7.21

**Next Calibration Due Date On or Before:** 15-07-2022

**Lab In-charge: .** Dr Atul Kapila

*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  
Sr. ASM  
Transasia Bio-Medicals Ltd  
DELHI

Encl:

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

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Transasia Bio-Medicals Ltd., 109-110, 1st FloorB, Deep Shikha Building, Rajendra Place, New Delhi - 110 008  
Tel.: 011 - 25732223 Fax: 011-25785451 Email: nz1@transasia.co.in CIN: U33110MH1985PLC036198



**Installation Qualification for XP-100**

**Customer Name** : DIAGNOSTIC POINT PATHLAB

**Address** : 109 , Aggarwal Tower , Pocket O and P Market , Dilshad garden , Delhi

**Instrument Name** : Sysmex XP-100

**Serial Number** : A7677

**Initial Inspection of the unit carried out and the details are as follows:**

**System Condition Report:**

Found the System to have been delivered in satisfactory condition and no external physical damaged observed on the same. The Tilt-indicator and the Shock-indicators on the Packaging were found to be in Good Condition, indicating the System has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

Installation Procedure & Checklist Attached for records.

**External Requirements for Installation:**

1. Input voltage of 220V-240V / 50Hz or 60Hz.
2. Recommended Operating Temperature is 15-30 °C, with Relative Humidity 30-85% and Atmospheric Pressure 70-106 kPa.

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**Installation Report for**

**Customer Name** : DIAGNOSTIC POINT PATHLAB

**Department** : Pathology

**Contact Person** : Dr. Atul Kapila

**Instrument Model** : Sysmex XP-100

**Serial Number** : A7677

**Date of Installation:** 16-11-2015

The instrument was installed and was found to be working satisfactorily. Preliminary Customer Training was provided and standardization of some parameters were done. The results were found to be within the expected range and System found to be working satisfactorily.

TBM, Technical Services Department

CUSTOMER  
**Diagnostic point Pathlab**

Name: Bhoraj Singh  
Designation: ASM

Contact Person : Dr. Atul Kapila  
Designation : PATHOLOGIST

Signature :  
Date: 04-08-2020

Signature  
Date : 04-08-2020

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**Installation Qualifications for XP-100**

Carried out all the Installation Procedures as per the Installation Procedure & Checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Carried out Priming and Cleaning Operations

Checked the counts by running the samples and found OK.

Performed all due maintenance activities.

Handed over the Instrument for Operators Training & Qualifications

**For TBM, Technical Services Department**

**Name:** Boraj Singh

**Designation:** ASM

**Date:**04-08-2020

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....., Mumbai - 400 072,



**Installation Certificate for XP-100**

This is to certify that the XP-100 Instrument Serial No. A7677 is successfully installed and Commissioned at TBM, Delhi and the Installation Protocol / checklist has been successfully completed for the above instrument.

**TBM, Technical Services Department**

**Name** : Boraj Singh

**Designation** : ASM

**Date** :04-08-2020



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#### **Instrument Setup**

1. Assembled the instrument accessories.
2. Removed the rubber caps of the reagent connection nipples.
3. Connected all the reagent tubes and waste collection unit.
4. Mounted the printer paper.
5. Placed the control adapter at the sample position

#### **Operational Inspection**

1. Performed Solenoid Valves, Motors and Syringes test and found OK.
2. Checked Pressure and Vacuum status and found OK.
3. Checked counts and found OK.

#### **TBM, Technical Services Department**

**Name** : Boraj Singh

**Designation:** ASM

**Date:** 04-08-2020

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**Operations Qualifications for Sysmex XP-100 Sr. No. A7677**

- |  |        |
|--|--------|
| 1. Verified all the reagent connections                      | : Done |
| 2. verified all Solenoid Valve, Motors<br>And Syringes tests | : Done |
| 3. Verified Pressure and Vacuum status                       | : Done |
| 4. Verified Blank Counts                                     | : Done |

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TRANSASIA  
SYSMEX XP-100  
AUTOMATED HEMATOLOGY ANALYZER

OPERATIONAL  
QUALIFICATION

Marketed by:  
Transasia Bio-Medicals Ltd.,  
(ISO 9002 CERTIFIED)  
Transasia House,  
Chandivali Studio road,  
Andheri (E),  
MUMBAI - 400 072

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HO : Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 400 072.





**Operational Qualification:**

**System Certification:**

Study data has determined that the System described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any, have been addressed.

**The System is ready for specific usage.**

Protocol Performed By: TBM, Delhi

Name: Borhaj Singh

Designation: ASM

Customer Authorization: **DIAGNOSTIC POINT PATHLAB**

Name: Dr Atul Kapila

Designation: PATHOLOGIST

Company Representative Name & Sign

Customer Name & Sign

Date: 04-08-2020

Date:04-08-2020

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**TRANSASIA**  
**SYSMEX XP-100**  
**AUTOMATED HEMATOLOGY ANALYZER**

**PERFORMANCE**  
**QUALIFICATION**

Marketed by:  
Transasia Bio-Medicals Ltd.,  
(ISO 9002 CERTIFIED)  
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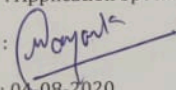
## I. Performance Qualification

a. Instrument Identification		Verified Date
1. Model Name	Sysmex XP100	04-08-2020
2. Serial Number	A7677	04-08-2020

### b. Following is a list of tests to be performed and verified:

Test No.	Test Name	Test Purpose	Verified Date
01	Precision Tests	Establishing Reproducibility	04-08-2020
02	Accuracy Checks	Ability of Sample processing	04-08-2020

### Validation Team:

Name : MAYANK TANWAR  
Designation : Application Specialist  
Signature :   
Date : 04-08-2020

**c. Performance Testing****Test 1****Test Name:** Precision Testing**Purpose:** To comply with specification and find out deviation if any. If required to apply correction**Method:** To run normal sample 10 times consecutively and identify SD, CV and to establish that it lies as per the manufacturer's specs. To omit first run and to consider rest 10 runs and to calculate SD & CV

Sample No.	WBC	RBC	HGB	HCT	PLT
1	17.5	3.4	8.2	25	170
2	17.8	3.42	8.4	25.2	178
3	17.8	3.43	8.5	25.1	169
4	17.8	3.43	8.4	25.1	174
5	17.5	3.45	8.5	25.3	175
6	17.9	3.41	8.4	25	166
7	17.7	3.46	8.4	25.2	170
8	17.8	3.45	8.5	25.1	170
9	18	3.47	8.4	25.3	174
10	18	3.44	8.5	25.1	187
<b>Mean</b>	<b>17.78</b>	<b>3.44</b>	<b>8.42</b>	<b>25.14</b>	<b>173.30</b>
<b>SD</b>	<b>0.18</b>	<b>0.02</b>	<b>0.09</b>	<b>0.11</b>	<b>5.95</b>
<b>CV%</b>	<b>0.98</b>	<b>0.65</b>	<b>1.09</b>	<b>0.43</b>	<b>3.43</b>



## Test 2

### Test Name:

1. Tests for checking the performance of the instruments during analysis
2. Tests for checking long term performance of the instrument

### Purpose:

The purpose of the above checks is to ensure the reliability of the results being obtained.

### Method:

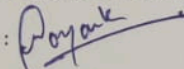
#### 1. During Sample analysis:

To run control samples each time the instrument is used for sample analysis and verification of the results of the controls to be within the reference range to be established by performance of the precision experiments.

#### 2. Long term Performance

This is to be checked by levey Jennings plots to be updated once in six months

### Validation Team:

Name : MAYANK TANWAR  
Designation : Application Specialist  
Signature :   
Date : 04-08-2020





## Consumable List

Consumables such as Cell clean, Cell Pack, Stromatolyser were supplied along with instrument.

Currently a sufficient stock of the same is being maintained Yes  No

## C. List of Manuals, Certificates and Drawings

Transasia provides the following with the instrument.

1. Instruction For Use
2. User's Guide

## D. Change Control Procedure

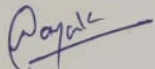
The instrument will not be altered, enhanced, modified or substituted for another system until a formal Change Control Authorization is approved from Transasia Bio-Medicals Ltd. and **Diagnostic point Pathlab** (lab name).

## E. Maintenance

The instrument listed within this document will be placed under the control of the purchasing institution with respect to proper maintenance procedures as detailed in the operations manual chapter 9


A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period Transasia offers several levels of Maintenance Agreements and Performance Testing services to assist you in maintaining GLP/GMP compliance. Contacting your local representative and requesting the additional Service Agreement can supply additional information.

## Validation Team:

Name : MAYANK TANWAR  
Designation : Application Specialist  
Signature :   
Date : 04-08-2020

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

SMP NO	WBC	RBC	HGB	HCT	PLT
Precision 1	10	4.77	12.8	39.1	253
Precision 2	9.8	4.74	12.9	38.9	257
Precision 3	10.2	4.71	13.0	38.5	241
Precision 4	10	4.78	12.9	38.9	268
Precision 5	9.90	4.77	12.9	39.0	263
Precision 6	9.9	4.79	13.0	38.9	253
Precision 7	10.3	4.79	13.0	38.9	249
Precision 8	10	4.77	12.9	38.8	272
Precision 9	9.9	4.84	13.0	39.2	259
Precision 1	10.10	4.74	12.9	38.7	253
Mean	10.01	4.77	12.93	38.89	256.80
SD	0.152	0.035	0.067	0.197	9.151
CV%	1.522	0.740	0.522	0.506	3.563
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

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**VII. System Certification**

Study data has determined that the system described in this document either meets all criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for specified usage.

Report Performed By: Transasia Representative

Name : MAYANK TANWAR

Title : PERFORMANCE QUALIFICATION

Company: TRANSASIA BIO-MEDICALS LTD.

Signature:

Date: 04-08-2020

Customer Authorizations:

Name : Dr Atul Kapila

Title : PERFORMANCE QUALIFICATION

Company: TRANSASIA BIO-MEDICALS LTD.

Signature:

Date: 04-08-2020

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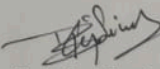


## 7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
2	7.70	4.44	12.4	33.10	271
3	7.70	4.41	12.5	32.90	267
4	7.60	4.38	12.5	32.70	277
5	7.60	4.39	12.5	32.80	262
6	7.30	4.34	12.3	32.40	266
<b>MEAN</b>	<b>7.58</b>	<b>4.392</b>	<b>12.44</b>	<b>32.78</b>	<b>268.6</b>
Acceptable Limits	7.41 - 8.07	4.297 - 4.473	12.26 - 12.51	32.36 - 33.83	257.1 - 284.2
<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.

  
Technical Service Department  
Transasia Bio-Medicals Ltd





# Traceability and Uncertainty

## SCS-1000 Sysmex Calibrator System

### XP-Series, Automated Hematology Analyzer

LOT NO: 93650525  
 EXP. DATE: 2-Feb-2020

Parameter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC	*1	-	6.882	0.19	10 <sup>9</sup> /L
RBC	*1	-	4.345	0.068	10 <sup>12</sup> /L
PLT	*2	-	265.8	12	10 <sup>9</sup> /L
HGB	*3, *4	-	12.22	0.13	g / dL
HCT	*5, *6	-	33.09	0.78	%

\* : This uncertainty (expanded uncertainty: 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 haemoglobinocyanide reference preparation (4th ed.)"
- \*5: CLSI H7-A3  
 "Procedure for Determining Packed Cell Volume by the Microhematrit Method – 3rd edition; Approved Standard"
- \*6: Laboratory Hematology, 7, 148-170, 2001  
 "Recommendations for reference method for the packed cell volume (ICSH Standard 2001)"