

Date: 16-12-2021

Effective Date: 16-12-2021

## Certificate of Calibration

**Customer Name: Dagar Diag. centre , Palwal**

**Model : Automated Hematology Analyzer Sysmex XN-550**

**Serial No. : 11534**

**Calibration Done Date: 16-12-2021**

**Next Calibration Due Date On or Before: 15-12-2022**

**Lab In-charge: . Mr.Joginder Dagar**

*This is to certify that the above-mentioned product has been verified of calibration 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  
Devender singh  
Sr.Service engineer  
Transasia Bio-Medicals Ltd  
Delhi



Encl:

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

## V. Installation Qualification

### A. Equipment Description


This Sysmex XN-L is a fully automated Hematology analyzer for in vitro diagnostic use in clinical laboratories. The XN-L provides accurate and precise test results for (39) parameters.

<b>Instrument identification</b>		<b>Verified by</b>	<b>Date:</b>
<b>Equipment Name:</b> Sunil Kumar Gautam	<b>Automated Hematology</b>	Devender Singh	18.07.2017
<b>Model</b>	<b>XN – L</b>	Devender Singh	18.07.2017
<b>Manufacturer</b>	<b>Sysmex Corporation</b>	Devender Singh	18.07.2017
<b>Marketed By</b>	<b>Transasia</b>	Devender Singh	18.07.2017
<b>Equipment #</b>	<b>XN-L</b>	Devender Singh	18.07.2017
<b>Serial Number</b>	<b>11534</b>	Devender Singh	18.07.2017
<b>Size (in mm)</b>	<b>W 1330 X D 1075 X H 1140</b>	Devender Singh	18.07.2017
<b>Power</b>	<b>AC 220 V</b>	Devender Singh	18.07.2017
<b>Frequency</b>	<b>50 – 60 Hz</b>	Devender Singh	18.07.2017
<b>Power Consumption</b>	<b>Less Than 250 VA</b>	Devender Singh	18.07.2017

Validation Team:

Name: Devender Singh

Designation: Service Engineer

Signature: 

Date: 18.07.2017

## B. Accessories / Consumables


### Accessories

S.no	Item	Qty
1	Sample racks	10
2	Barcode scanner external	01
3	CPU (DELL)	01
4	Monitor (view sonic touch screen)	01
5	Printer(HpP1108)	01
6	All sysmex standard accessories	01

Validation Team:

Name: Devender Singh

Designation: Service Engineer

Signature: 

Date: 18.07.2017

**Consumables:**

Consumables such as Cellpack DCL, SULFOLYSER, Lysercell WDF, Fluorocell WDF and Cell Clean 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. Operator's Manual

**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 **Dagar Dagnostic Centre, Palwal (HARYANA)**


**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 13

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: Devender Singh  
Designation: Service Engineer

Signature: 

Date: 18.07.2017

## F. Spare Parts

Transasia strongly recommends the end user maintain a basic of consumable parts onsite to minimize down time due to minor failures. They have provided a list of such consumable parts and the same is also available in the Operator's Manual no.

## C. Equipment Logs

Title	Location	Verified by	Date: 18.07.2017

Sample page of the logbook is given in operator manual.

Effective Date: 18.07.2017

Validation Team :

Name: Devender Singh

Designation: Service Engineer

Signature



Date: 18.07.2017

#### **IV. Operational Qualification**

##### **a. Instrument Identification**

##### **Verified Date**

1. Model Name	XN-L 350	18.07.2017
2. Serial Number	11534	18.07.2017

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

<b><u>Test No.</u></b>	<b>Test Name</b>	<b>Test Purpose</b>	<b>Verified Date</b>
1.	Whole Blood (WB) X-Aspiration motor operation	to the WB aspiration motor operation	18.07.2017
2	Sheath Motor Test.	To check Operation of Sheath Motor	18.07.2017

Validation Team:

Name: Devender Singh

Designation: Service Engineer

Signature



Date: 18.07.2017

**c. Operational Testing**

**Test 1**

**Test Name** : Whole Blood Aspiration Motor Test  
**Purpose** : To test the Aspiration Motor movement  
**Method** : Please follow the steps described in hand book of Sysmex XN-L 350 operator's manual.

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	Whold Blood Aspiration Motor Test	Pass	

Validation Team:

Name: Devender Singh

Designation: Service Engineer

Signature 

Date: 18.07.2017

**Test 2**

**Test Name** : **Sheath Motor Test**

**Purpose** : **To test the Sheath Motor Operation Test.**

**Method** : **Please follow the steps described in hand book of Sysmex XN-L 350 operator's manual.**

	<u>PARAMETER</u>	<u>PASS</u>	<u>FAIL</u>
Parameter values for verification :	Sheath Motor Motor Test	Pass	

Validation Team:

Name: Devender Singh

Designation: Service Engineer

Signature 

Date: 18.07.2017



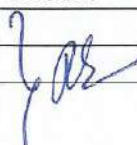
#### d. Operational Procedure

##### a. Certificate of Training

###### 1. Technician Training

This certifies that the technicians listed below have received basic user training in the following categories for the system described in this Installation Qualification.

**Mr.Ravi, Application Specialist** who is certified by Transasia Bio-Medicals Ltd has conducted the training.

Sr.No.	Training Program	Initials	Date
1.	Instrument Setup		18.07.2017
2.	System Operation		18.07.2017
3.	Basic Troubleshooting & Maintenance		18.07.2017

###### 2. Operator Training


The users responsible for the operation of this instrument will be trained in the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filed as indicated below:

Sr.No.	Operators	Location	Initials	Date
1	Mr. Joginder Dagar	Palwal		18.07.2017
2				
3				
4				
5				

Validation Team:

Name: Devender Singh

Designation: Service Engineer

Signature 

Date: 18.07.2017

#### IV. Performance Qualification

##### a. Instrument Identification

Verified Date

1. Model Name                      SYSMEX XN-L 350  
2. Serial Number                  11534

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

<u>Test No.</u>	<u>Test Name</u>	<u>Test Purpose</u>	<u>Verified Date</u>
01	Sample Processing	Ability to process samples	
02	Further Performance Checks	Regular Maintenance	NA

Validation Team:

Name: Ravi Kumar

Designation: Application Specialist

Signature 

Date:

**Hemoglobin:**

Test	Control Values	Results Obtained	Pass	Fail
1.	12.7 - 13.7	13.1	Pass	
2.		13.2	Pass	
3.		13.1	Pass	
4.		13.2	Pass	
5.		13.1	Pass	

**Platelet Count:**

Test	Control Values	Results Obtained	Pass	Fail
1.	203 - 275	227	Pass	
2.		232	Pass	
3.		230	Pass	
4.		238	Pass	
5.		230	Pass	

**Level- III****RBC Count:**

Test	Control Values	Results Obtained	Pass	Fail
1.	4.79 - 5.29	4.98	Pass	
2.		4.94	Pass	
3.		4.95	Pass	
4.		4.92	Pass	
5.		4.92	Pass	

**WBC Count:**

Test	Control Values	Results Obtained	Pass	Fail
1.	15.27 - 18.29	16.77	Pass	
2.		16.72	Pass	
3.		16.27	Pass	
4.		16.33	Pass	
5.		16.70	Pass	

**Hemoglobin:**

Test	Control Values	Results Obtained	Pass	Fail
1.	15.6 - 17.0	16.4	Pass	
2.		16.3	Pass	
3.		16.3	Pass	
4.		16.3	Pass	
5.		16.3	Pass	


**Platelet Count:**

Test	Control Values	Results Obtained	Pass	Fail
1.	490 - 636	538	Pass	
2.		550	Pass	
3.		566	Pass	
4.		561	Pass	
5.		552	Pass	

Validation Team:

Name: Ravi Kumar

Designation: Application Specialist

Signature 

Date:

### Test 3

#### 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 Levy Jennings plots to be updated once in six months

#### Validation Team:

Name: Ravi Kumar

Designation: Application Specialist

Signature 

Date:

Date: 16-12-2021  
Effective Date: 16-12-2021

## Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XN-350
2. Serial No.: 11534
3. Calibration Date: 16-12-2021
4. Material used: XN-CAL (Lot No. 13332101, Expiry date: 02-Jan-2021)

By comparing your data to the results of the standard counters in Sysmex Corporation, the calibration for XN Analyzer parameters using the measurement standard material (XN-CAL) was completed. The calibration result of 10 runs is summarized in the following table. Please refer to the attached sheets for the details.

Technical Service Department  
Transasia Bio-Medicals Ltd

Calibrator Calibration History

Instrument Nickname: XN-L  
Material: XN CAL

Calibration Date: 16/12/2021 15:43:43  
Lot No.: 13332101

Logon Name: lab

	WBC	RBC	HGB	HCT	PLT
Target	7.300	4.300	12.19	35.29	248.0
No. 2	6.91	4.38	12.0	36.5	239
No. 3	7.09	4.40	12.2	36.6	248
No. 4	7.12	4.39	12.0	36.3	243
No. 5	6.89	4.34	12.0	35.9	251
No. 6	6.98	4.40	12.0	36.5	248
No. 7	6.99	4.38	12.1	36.3	249
No. 8	7.07	4.39	12.0	36.4	247
No. 9	7.01	4.30	12.0	35.8	242
No. 10	7.06	4.33	12.0	35.9	245
No. 11	7.12	4.30	12.0	35.7	242
Range Value	0.23	0.10	0.2	0.9	12
Max Range	0.56	0.12	0.2	1.0	26
Mean Value	7.024	4.361	12.03	36.19	245.4
Delta Percent (%)	3.93	1.40	1.33	2.49	1.06
Acceptable Limit (%)	2.27	1.25	0.78	2.64	4.16
Service Limit (%)	14.00	4.00	5.00	5.00	10.00
Current Rate (%)	100.0	102.0	101.7	100.3	102.2
New Rate (%)	103.9	100.6	103.1	99.2	102.2

# Traceability and Uncertainty

## XN CAL Sysmex Calibrator System

### XN-L Series Automated Hematology Analyzer



LOT NO: 1333 2101  
 EXP. DATE: 02-Jan-2022

Parameter	Reference Method	Reference Material	Assigned Value	Uncertainty*	Unit
WBC-C	*1	-	7.825	0.20	10 <sup>9</sup> /L
WBC-D	*1	-	7.337	0.19	10 <sup>9</sup> /L
RBC	*1	-	4.362	0.066	10 <sup>12</sup> /L
RBC-O	*1	-	4.258	0.090	10 <sup>12</sup> /L
PLT	*2	-	248.1	9.7	10 <sup>9</sup> /L
PLT-O	*2	-	250.8	12	10 <sup>9</sup> /L
HGB	*3, *4	-	12.19	0.19	g / dL
HCT	*5	-	35.29	0.60	%

\* : 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 standard"

\*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 haemoglobin cyanide reference preparation (4th ed.)"

\*5: CLSI H7-A3

"Procedure for Determining Packed Cell Volume by the Microhematrit Method – 3rd edition; Approved Standard"



## Precision Check Log

Instrument Nickname: XN-L

Execution Date: 16/12/2021 15:16:20

Logon Name: lab

	WBC	RBC	HGB	HCT	PLT
No. 2	8.80	3.88	14.3	41.3	249
No. 3	8.98	3.90	14.4	41.5	248
No. 4	8.89	3.87	14.2	41.0	250
No. 5	8.81	3.88	14.3	41.1	253
No. 6	8.96	3.86	14.3	40.8	260
No. 7	8.78	3.94	14.5	41.4	258
No. 8	8.75	3.90	14.4	40.9	247
No. 9	8.99	3.92	14.4	41.0	249
No. 10	8.82	3.90	14.4	40.8	252
No. 11	8.70	3.87	14.2	40.5	253
Mean Value	8.848	3.892	14.34	41.03	251.9
SD	0.101	0.025	0.10	0.31	4.3
CV (%)	1.1	0.6	0.7	0.8	1.7
Limit (%)	3.0	1.5	1.0	1.5	4.0