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: 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

Sample No.: PRE-CHK-01
Patient ID:
Name:
Sample Comment:

Ward:

Adapter:

Pos.:

16/12/2021 15:02:43 WB

Doctor:

Birth:

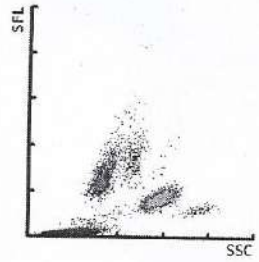
Sex:

Nickname: XN-L

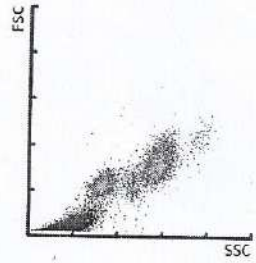
Negative

WBC	8.85	[10^3/uL]		
RBC	3.89	[10^6/uL]		
HGB	14.2	[g/dL]		
HCT	41.5	[%]		
MCV	106.7	[fL]		
MCH	36.5	[pg]		
MCHC	34.2	[g/dL]		
PLT	257	[10^3/uL]		
RDW-SD	55.4 +	[fL]		
RDW-CV	14.0	[%]		
PDW	15.1	[fL]		
MPV	12.0	[fL]		
P-LCR	41.6	[%]		
PCT	0.31	[%]		
NEUT	5.63	[10^3/uL]	63.6	[%]
LYMPH	2.71	[10^3/uL]	30.6	[%]
MONO	0.33	[10^3/uL]	3.7	[%]
EO	0.14	[10^3/uL]	1.6	[%]
BASO	0.04	[10^3/uL]	0.5	[%]
IG	0.02	[10^3/uL]	0.2	[%]

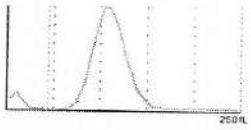
WDF



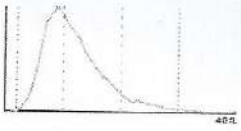
WDF-CBC



RBC



PLT



WBC IP Message

RBC IP Message

PLT IP Message

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.

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

Validation Team:

Name: Devender Singh

Designation: Service Engineer

Signature: Devender

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

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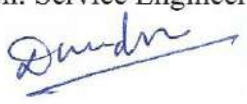
b. Following is a list of tests to be performed and verified:

Test No.	Test Name	Test Purpose	Verified Date
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.**

		PARAMETER	PASS	FAIL
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.**

		PARAMETER	PASS	FAIL
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:

Test No.	**Test Name**	**Test Purpose**	**Verified Date**
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: