Transesia Blo - Medicals Ltd., Transesia House, & Chandivali Studio Road, Andheri (E), Mumbal - 400 072 Tel. +91 22 4030 9000 | Fax. +91 22 7857 3030

SYSMEX XN-350 AUTOMATED HEAMATOLOGY ANALYZER

INSTALLATION QUALIFICATION

For

Shruti Clinical Laboratory

Transasia Bio-Medicals Ltd.,

Andheri (E), MUMBAI 400 072

Marketed by:

Transasia House, Chandivali Studio road, Transesia Bio - Medicals Ltd., Transasia House, 8 Chandival: Studio Road, Andheri (E), Mumbai - 400 072 Tel. +91 22 4030 9000 Fax. +91 22 2857 3030

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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

I. Approval of the IQ procedure:

Shruti Clinical Laboratory and Transasia are jointly responsible for the installation of the system SYSMEX HEMATOLOGY Analyzer, Model: XN 350, Serial No. 11473.

Protocol Performed By:

Transasia Representative

Name Title Mr.Rahul Dixit

:

INSTALLATIONQUALIFICATION

Company

TRANSASIA BIO-MEDICALS LTD.

Signature: (Lasal

Date: 18-11-2021

Validation Team from: Shruti Clinical Laboratory

Name

: Mohd Anayatullah Khan

Designation

: Scientific Officer

Department

: Pathology

Signature -

Date 18-11-2021

Customer Authorizations:

Name

Dr. Payal Pandey

INSTALLATION QUALIFICATION

Title Site

Mumbai

Signature:

Date: 18-11(2)021

II. Instructions

1. This document is to be completed at the time the system is shifted to its current location (new) and set up for operation.

2. An authorized TRANSASIA representative will check the system and enter the specific data as outlined in the appropriate Installation Qualification. Each result will be noted and dated.

3. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by the Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team

: Transasia Biomediclas Limited

Name

: Mr. Rahul Dixit

(D. 10)

Designation

: Service Engineer

Signature

.

Date: 25-06-2017



III. Scope

This Installation Qualification protocol will be performed on the SYSMEX-Hematology Analyzer, Model XN-350 Serial No 11473 located in N S Road no. 1, 203, Royal Chambers, Opp Club Millennium, Juhu, Mumbai, Maharashtra 400049. This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacture s specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team: Transasia Buomedicals Ltd

Name : Mr. Rahul Dixit

Designation : Service Engineer

Signature : Paral

Date : 18-11-2021



Transesia Bio - Medicale Ltd., Transasia House, & Chandivali Studio Road, Andrieri (E), Mumbai - 400 072 Tel. +91 22 4030 9000 | Fax: +91 22 2857 3030

IV)Utilities

Sr.No.	Utility		Verified By	Date
1.	Environmental condition as per requirement:	Yes-√ /	Rahul Dixit	18-11-
	(Ambient range of temperature 15 35 °C, air			2022
	conditioning facility, non exposure to direct sunlight, non-interference from high frequency			
	radio waves)			
2.	Adequate space for installation:	Yes-√ /	Rahul Dixit	18-11-
	(Minimum in mm. W 450 X D 660 X H 450)	No		2021
3.	Cellpack DCL, SULFOLYSER, Lysercell WDF,	Yes-√ /	Rahul Dixit	18-11-
	Fluorocell WDF and Cell Clean	No		2021
4.	Power Source Requirements*	Yes-√ /	Rahul Dixit	18-11-
	·	No		2021

√Encircle applicable source

Validation Team: Transasia Biomedicals Ltd

Name

: Mr. Rahul Dixit

Designation

: Service Engineer

Signature

Pala

Date

: 18-11-2021



Transasia Bio - Medicals Ltd., Transasia House. 8 Chandivall Studio Road, Andheri (E). Mumbai - 400 072 Tel. +91 Z2 4330 9000. Fax. +91 Z2 2857 3030.

The instrument has been verified for the following

2.11	Verification		Verified By	Date
Sr.No.		Yes-√ /	Rahul Dixit	18-11-
1.	Instrument is identified	No	Runai Biiii	2021
2	Manufacturer s specifications are included	Yes-√ /	Rahul Dixit	18-11-
2.	Wallufacturer 3 specifications are	No		2021
3.	Accessories / Consumables are listed	Yes-√ / No	Rahul Dixit	18-11- 2021
1	Manufacturer s certificate of Compliance	Yes-√ /	Rahul Dixit	18-11-
4.	attached	No		2021

Validation Team: Transasia Biomedicals Limited

Name

: Mr. RahulDixit

Designation

: Service Engineer

Signature

Date

: 18-11-2021

V. Installation Qualification

A. Equipment Description

This Sysmex XN 350 is a fully automated Hematology analyzer for in vitro diagnostic use in clinical laboratories. The XN-350 provides accurate and precise test results for all parameters.

Instrument identification	011	Verified by	Date
Equipment Name	Automated Hematology		
Model	XN -350		
Manufacturer	Sysmex Corporation		
Marketed By	Transasia		10.11
Equipment #	XN -350	Rahul Dixit	18-11- 2021
Serial Number	11473		
Size (in mm)	W 450 X D 660 X H 450		
Power	AC 220 V		
Frequency	50 60 Hz		
Power Consumption	Less Than 250 VA		

Validation Team: Transasia Biomedicals Ltd

Name

: Mr. Rahul Dixit

Designation

: Service Engineer

Signature

Palal

Date: 18-11-2021



Transeria Bro - Medicals Ltd., Transasia House. & Chandivali Studio Road, Andheri (E), Murabai - 400 072 Tol. +91 22 4030 9030. Faz. +91 22 2857 3030.

B. 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 🗆

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 Shruti Clinical Lab.

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: Transasia Biomedicals Ltd

Name : Mr. Rahul Dixit

Designation : Service Engineer

Signature : 18-11-2021



Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andreti (E.). Mimbai - 400 072 Tel. +91 22 4030 9000 | Fax. +91 22 2857 3030

VI. Installation Procedure

(These had been performed at the time of original installation at the initial location)

- Check Before Installation
 Refer to Chapter 7 of Sysmex XN 350 Service Manual
- 3. Grounding
 Refer to Chapter 1 of Sysmex XN 350 Service Manual
- 4. Installation Environment & Space
 Refer to Chapter 1 of Sysmex XN 350 Service Manual
- 5. Connect Air & Reagent Tubes
 Refer to Chapter 7 of Sysmex XN 350 Service Manual
- 6. Connect Connection Cord & Power Cord
 Refer to Chapter 7 of Sysmex XN 350 Service Manual
- 7. Turn Power On
 Refer to Chapter 7 of Sysmex XN 350 Service Manual

Validation Team: Transasia Biomedicals Ltd

Name

: Rahul Dixit

Designation

: Service Engineer

Signature

- Polar

Date

: 18-11-2021

Transesia Bib - Medicals I.id., Transesia House, & Chandivali Studio Road, Andried (E). Mumbal - 400 972 Tol: +91 22 4030 9010 | Fax. +91 22 7857 3030

VIII. System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this independently Installation 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 : Mr. Rahul Dixit

Title : INSTALLATION QUALIFICATION Signature:

Company: TRANSASIA BIO-MEDICALS LTD. Date : 18-11-2021

Customer Authorizations:

Name : Mohd Anayatullah Khan

Title : INSTALLATION QUALIFICATION Signature: (

Site : Mumbai Date : 18-11-2021

Name: Dr. PayalPandey

Title : INSTALLATION QUALIFICATION Signature:

Site : Mumbai Date : 18-11-2021

Transasia Bio - Medicals Ltd., Transasia Pouse, & Chandivali Studio Road, Ancheri (E), Mumbai - 403 072 Tel +91 22 4030 9000 Fax: +91 22 2857 3000

Date: 18-11-2021

Reagent Check done

Printer checked

Analyzer switched ON at

SELF CHECK performed

RINSE CYCLE completed

Background limits within acceptable range

Analysis start time

Analysis end time

No. of samples analyzed

Shut down procedure done

Analyzer switched OFF at

Recorded by: Rahul Dixit

Checked by:Mohd Anayatullah Khan

SYSMEX XN 350 AUTOMATED HEMATOLOGY ANALYZER

OPERATIONAL QUALIFICATION

For

Shruti Clinical Laboratory "

Marketed by:
Transasia Bio-Medicals Ltd.,
(ISO 13485 CERTIFIED)
Transasia House,
Chandivali Studio road,
Andheri (E),
MUMBAI 400 072

Transasia Bio - Medicals Ltd., Transasia House, & Chandivali Studio Road, Andhen (E), Mumbai - 400 072 Tel: +91 22 4030 9000 Fax +91 22 2857 3030

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Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Anchen (E), Mumbai - 400 072 Tet. +91 22 4030 9000. Fax. +91 22 2857 3030

1. Approval of the OQ procedure:

Shruti Clinical Laboratory and Transasia are jointly responsible for operational check of the HEMATOLOGY Analyzer, Model: XN–350, serial 11473.

Protocol Performed by: Transasia Representative

Name : Rahul Dixit

Signature : Late

Title : OPERATIONAL QUALIFICATION Date: 18-11-2021

2021

Company : TRANSASIA BIO-MEDICALS LTD.

Validation Team from: Shruti Clinical Laboratory

Name : Rahul Dixit

Designation : Service Engineer

Department : Pathology

Customer Authorization:

Name : Dr.Payal Pandey

Signature:

Title : OPERATIONAL QUALIFICATION

Date : 18-11-2021

Site : Mumbai

Transasia Bio - Medicala Ltd., Transasia House, 8 Chandivali Sludio Road, Anchon (E), Mumbai - 400 072 Tel. 491 22 4030 9000 Fax: +91 22 7657 3030

II. Instructions

- 1. The TRANSASIA representative will check each module and enter the specific data as described in the Operational Qualification. Each result will be noted and dated.
- 2. Any test data, which does not meet the specified acceptance criteria, will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.
- 3. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by the Product Manager at Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team: Transasia Biomedicals Ltd.

Name

: Rahul Dixit

Designation

: Service Engineer

Signature

Date

: 18-11-2021

Transasia Bio - Medicals Ltd., Transasia House, & Chandivali Studio Road, Anchen (E), Mumbai - 400 072 Tel. 491 22 4030 9000 Fax. 491 22 2857 3030

III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model XN-350, Serial No. 11473 located in Juhu, Mumbai. This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer s specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team: Transasia Biomedicals Ltd

Name

: Rahul Dixit

Designation

: Service Engineet

Signature

-Pala

Date

: 18-11-2021

Transasia Bin - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Anchen (E), Mimba: - 400 072 Tet +91 22 4030 9000. Fax +91 22 2857 3030

IV. Operational Qualification

a. Instrument Identification

Verified Date

1. Model Name

XN 350

18-11-2021

2. Serial Number

11473

18-11-2021

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

Test <u>No.</u>	Test Name	Test Purpose	Verified Date
1.	Whole Blood (WB)	To check the WB aspiration aspiration motor operation	
2 Motor	Sheath Motor Test.	To check Operation of Sheatl	'n
3.	Diagnostic Test for Auto Sampler and Bar code reader	To Check operation of Auto sampler and Barcode reader.	

Validation Team: Transasia Biomedicals Ltd

Name

Rahul Dixit

Designation

Service Engineer

Signature

Palal

Date

18-11-2021

Transpala Bio - Medicals Ltd., Transpasa House, & Chandivali Shidia Road, Andhan (C), Muntra: -400 672 Tcl. +91 22 4030 9000 | Fax. +91 22 2857 3030

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 chapter 2, page 2.9.1

of Sysmex XN 350 manual

PARAMETER PASS

<u>FAIL</u>

Parameter values for verification : Whold Blood

Aspiration Motor Pass

Test

Test 2

Test Name : Sheath Motor Test

Purpose : To test the Sheath Motor Operation Test.

Method : Please follow the steps described in chapter 2, page 2.9.1

of Sysmex XN 350 s manual No.

<u>PARAMETER</u> <u>PASS</u>

FAIL

Parameter values for verification : Sheath Motor

Motor Test Pass

Transasia Bio - Medicala Ltd. Transas a House, & Chandizal Stu Jio Road, Anchor (E), Munition - 400 072 Tell -91 22 4030 9000. Fax. - 91 22 2857 3030.

Test 3

Test Name : Diagnostics Test for Auto Sampler & Barcode Operation

Purpose : To test the Operation of Auto Sampler & Barcode.

Method : Please follow the steps described in chapter 2, page 2.9.1&4

of Sysmex XN 350 manual No.

PARAMETER

<u>PASS</u>

FAIL

Parameter values for verification: Sampler & Barcode Pass

Test

Transasia Bio - Medicals Ltd., Transasia House, & Chendivali Studio Road, Ancher (E), Mumbus - 408 072 Trl. -91 22 4030 9000. Fax. -91 22 2857 3030

V. System Certification

Study data has determined that the system described in this document either meets all criteria outlined in this Operational 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 : Rahul Dixit

Title : OPERATIONAL QUALIFICATION

Signature:

Company: TRANSASIA BIO-MEDICALS LTD.

Date :18-11-2021

Signature:

Customer Authorizations:

Name : Mohd Anayatullah Khan

Title : OPERATIONAL QUALIFICATION

Site : Mumbai Date : 18-11-2021

Name: Dr. Payal Pandey

Title : OPERATIONAL QUALIFICATION

Site : Mumbai Date : 18-11-2021

Transasia Bio - Medicals Ltd., Transasia Pouse, & Chandivali Shullo Poad, Andheri (E), Mambai - 400 072 Tel +91 27 4030 9030 | Fax +91 27 2857 3030

SYSMEX XN 350 AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

For

Shruti Clinical Laboratory

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



Transasia Bio - Medicats Ltd., Transasia House, 8 Chandivali Studio Road, Andhen (E), Mumbai - 400 072 Tet +91 22 4030 9000 Fax: +91 22 2857 3030

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Transasia Bio - Medicals Ltd., Transasia House, & Chandivali Starbo Road, Ancheri (E), Mumbai - 400 072 Tcl +31 22 4030 9000 | Fax +31 22 2857 3030

I. Approval of the PQ procedure

Both Shruti Clinical Laboratory and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer, SYSMEX Model: XN 350, Serial No. 11473 in the clinical lab of as per the attached protocol.

Protocol Performed By:

Transasia Representative

Name

Rahat Shaikh

Title

PERFORMANCE QUALIFICATION

Signature: Date: 18-11-2021

Company

TRANSASIA BIO-MEDICALS LTD.

Validation Team from : Shruti Clinical Laboratory

Name

: Mohd Anayatullah Khan

Designation

: Scientific Officer

Department

: Pathology

Customer Authorizations:

Name

: Dr.Payal Pandey

Title

PERFORMANCE QUALIFICATION

Site

Mumbai

Signature:

Date:18-11

Transasia Bid - Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai - 400 072 Tct + 91 22 4030 9000 Fax: +91 22 2857 3030

11. Instructions

- 1. An authorized TRANSASIA representative will check for the performance of the instrument and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
- 2. Performance checks on a regular basis described in the Further Performance Checks (vide-infra) will be responsibility of the customer s personnel.
- 3. Employee of (Customer) Shruti Clinical Laboratory will verify each reit's sult and sign in the last page. The members of the validation team will carry this out.
- 4. <u>ALL</u> deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of each PQ protocol. All resolution to such problems will also be noted in the COMMENTS section, and must be resolved prior to issuance of a SYSTEM CERTIFICATION. These will be an additional cost to the purchasing institution (CUSTOMER). However this additional cost will be waived when this test is conducted at time of initial performance check of new instruments.
- 5. Any test data that does not meet the specified acceptance criteria will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.
- 6. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by the Production Manager at Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team: Transasia Biomedicals Ltd

Name : Rahat Shaikh

Designation : Application Manager

Signature Calal

Date : 18-11-2021

Transasia Bio - Medicaly Ltd., Transasia House, & Chandivali Stu lio Road, Anchori (E), Mumbril - 403 072 Tri - +91 22 4030 8000 | Fax - +91 22 2857 3030

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model XN-350, Serial No 11473 located in Juhu, Mumbai. This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacture s specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All documents will be initialed and dated.

Validation Team: Transasia Biomedicals Ltd

Name : Rahat Shaikh

Designation : Application Manager

Signature

Date

: 18-11-2021

Transasia Bio - Medicals Ltd., Transasia House, 8 Chandivan Studio Road, Andhen (E), Mumbai - 400 072 Tel. +91 22 4030 9000 Fax. +91 22 2857 3030

1V. Performance Qualification

a. Instrument Identification

1. Model Name

SYSMEX XN 350

2. Serial Number

11473

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

Test No.	Test Name	Test Purpose	Verified Date
02	Sample Processing	Ability to process san	iples
03	Further Performance Checks	Regular Maintenance	NA

Validation Team: Transasia Biomedicals Ltd

Name

: Rahat Shaikh

Designation

: Application Manager

Signature

t-Calm

Date

: 18-11-2021



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:

18/11/2021

Effective Date: 18/11/2021

Certificate of Calibration

Customer Name: Shruti Clinical Laboratory

Automated Hematology Analyzer Sysmex XNL-350 Model:

Serial No.: 11473-RR

Calibration Done Date: 18.11.21

Next Calibration Due Date On or Before: 17/11/2022

Lab In-charge: . Dr.Payal Pandey

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 Rahul Dixit Service Engineer Transasia Bio-Medicals Ltd Mumbai

Encl:

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



tran Sample, No. a BACKGROUNDCHECK & Chandivali Studio Road, Andheri (E), Mumbai- 400 Doctor:
Battent 10 000 Fax: +91 22 2857 3030 Ward:
Name:
Sample Comment:
Nickna Sex: Nickname: XN-L WDF-CBC WDF SFL WBC 0.00 [10^3/uL] [10^6/uL] RBC 0.00 HGB 0.0 [g/dL] [%] HCT 0.0 MCV. [fL] MCH MCHC [g/dL] [10^3/uL] PLT 0 RDW-SD fL] %] RDW-CV PDW MPV P-LCR PCT NEUT [10^3/uL] LYMPH [10^3/uL] MONO [10^3/uL] [10^3/uL] [10^3/uL] EO . BASO IG [10^3/uL] **RBC**

WBC IP Message

RBC IP Message

PLT IP Message

00-14A 18/11/2021 11:36

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Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Sludio Road, Andhen (E), Mumbai- 400 072
Tel: +91 22 4030 9000 Fax: +91 22 2857 3030
Instrument Nickname: XN-L
Calibration Date: 18/11/2021 10:56:05
Lot No.: 13052101

Logon Name: sysmex

A Comment of the Comm					
CHARLES TO THE STATE OF THE STA	WBC	RBC	HGB	HCT	PLT
Target	7.397	4.394	12.55	36.03	249.1
No. 2	7.31	4.43	12,6	36.1	250
No. 3	7.42	4.38	12.6	35.7	251
No. 4	7.37	4.38	12.6	35.8	240
No. 5	7.42	4.38	12.6	35.8	253
No. 6	7.49	4.43	12.6	36.2	251
No. 7	7.47	4.38	12.6	35.7	254
No. 8	7.57	4.36	12.6	35.6	245
No. 9	7.40	4.38	12.6	35.7	256
No. 10	7.34	4.40	12.6	35.9	257
No. 11	7.49	4.34	12.6	35.4	235
Range Value	0.26	0.09	0.0	0.8	22
Max Range	0.57	0.13	0.2	1.0	26
Mean Value	7.428	4.386	12.60	35.79	249.2
Delta Percent (%)	0.42	0.18	0.40	0.67	0.04
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 (%)	100.7	97.0	100.0	100.6	103.5
New Rate (%)	100.7	97.0	100.0	100.6	103.5

Precision Check Log

TRANSASIA

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Sludio Road, Andheri (E), Mumbai-400 072
Teansasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Sludio Road, Andheri (E), Mumbai-400 072
Execution Date: 18/11/2021 09:48:37

Logon Name:

sysmex

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No. 5	5.89	4.82	14.2	45.3	298		
No. 6	to the same of the	4.86	14.2	45.6	295		
No. 7	5.74			44.9	282		
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No. 9	5,77	4.86		45.4	207	M. P. Carlotte Street,	
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Limit (%)	3.0	1.5	1.0	1.5	4.0		
		11.00	F 12 9.1			the second	

00-14A 18/11/2021 11:34

1/1

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QC Chart

Material Lot No. Exp. Date From To

NN-L Control Level3 QC-12951403 01/02/2022 18/11/2021 18/11/2021 Instrument Nickname XN-L Shift All

UL	SD
Target	Mean
LL	CV (%)

XN-L 0

UL WBC-D	0	n=	1
WBC-D		17.67	
UL		16.36	16.9
NEUT#		15.05	
LL		8.66	
UL		6.06	8.7
LYMPH# LL	0	4.03	
UL		3.10	3.3
MONO#		2.17	
LL		2.34	
UL		1.23	1.40
EO#	•	0.12 3.33	
LL		2.22	2.30
UL BASO#		1.11	
LL L		2.05	
UL		1.15	1.12
IG#	0	0.25	
LL		2.43	
UL		1.82	2.23
NEUT% .		60.8	
LL I		52.9	51.8
	2	45.0	

QC Chart

Shift All	Instrument Nickname	LIGGGI TOT	Lot No.	Exp. Date	Data -	
	XN-L	XN-L Control Level3	QC-12951403	01/02/2022	Date From	То
				02/02/2022	18/11/2021	18/11/2021

L	SD		
arget	Mean		
L	CV (%)		

XN-L

	•		
UL			
LYMPH%	•	n=1	
LL		22.8	
		19.0	19.7
UL MONO%	•	15.2	
		11.3	
LL		7.5;	8.3
UL		3.7	
E0%	•	20.4	
LL		13.6	13.6
UL		6.8	
BASO%	•	12.5	
LL		7.0	
UL		1.5	6.6
IG%		18.6	
LL	•		
		14.9	13.2
	44	11.2	
	11:44		
	# T		
	18/11/2021		
	11/		
	8		

XN-L

0

Shift All

Tankawa			QC Char	t	
Instrument Nickname	Haccital	Lot No.	Exp. Date	Date From	То
VIA- F	XN-L Control Level3	QC-12951403	01/02/2022	18/11/2021	18/11/2021

UL	SD
Target	Mean
LL	(%)

UL		n	=1
MicroR	•	4.0	
LL		2.0	2
UL		0.0	
MacroR		7.4	
LL		4.9	5
UL		2.4	
PLT-I	-	623	1
LL		551	
UL		479	
PDW		9.6	
LL		8.0	
UL		6.4	
PCT		0.63	
LL		0.50	
UL		0.37	
MPV	-	10.4	
LL		7.6	
UL	0	18.6	
P-LCR		12.4	
LL		6.2	
UL UL	•	17.87	
WBC-C LL		16.39	
LL		14.91	

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XN-L

QC Chart

Shift All XN-L
 Material
 Lot No.
 Exp. Date
 Date From
 To

 XN-L Control Level3
 QC-12951403
 01/02/2022
 18/11/2021
 18/11/2021

UL	SD
Target	Mean
LL	CV (%)

		n=1	
UL		5.49	
RBC		5.23	5.25
LL		4.97	
UL		17.5	
HGB		16.8	16.9
LL		16.1	
UL		50.3	
нст	6	45.7	44.8
LL		41.1	
UL		92.5	
MCV LL	e	87.3	85.3
UL		82.1	
MCH		34.7	
LL		32.1	32.2
UL		29.5	~
MCHC	.0	42.0	::::
LL		36.8	37.7
UL		53.8	
RDW-SD	0	46.8	44.4
LL		39.8	
UL		17.1	
RDW-CV	8	14.9	14.5
LL		12.7	14.5
		±2.7	

18/11/2021 11:44

Sample No.: RP 05012 Patient ID: Name: Sample Comment:	Adapter: Ward:	Pos.: 18/11/2021 17:04:16 WB Doctor: Birth: Sex: Nickname: XN-L
Positive Diff. Morph. Count		WDF - CBC ≼[≚[
WBC 11.96 [10^3/uL] RBC 4.37 [10^6/uL] HGB 14.1 [g/dL] HCT 40.4 [%] MCV 92.4 [fL] MCH 32.3 [pg] MCHC 34.9 [g/dL] PLT 159 [10^3/uL] RDW-SD 42.9 [fL] RDW-CV 12.5 [%] PDW 12.8 [fL] MPV 10.5 [fL] P-LCR 29.2 [%] P-LCR 29.2 [%] PCT 0.17 [%] NEUT 6.76 [10^3/uL] LYMPH 3.25 [10^3/uL] MONO 1.64 + [10^3/uL] BASO 0.03 [10^3/uL] IG 1.64 [10^3/uL]	27.2 [%] 13.7 [%] 2.3 [%] 0.3 [%]	RBC PLT

WBC IP Message Monocytosis IG Present

RBC IP Message

PLT IP Message

Performed by! Radhiken Cheek by! Garden.

18/11/2021 17:06:02 WB Adapter: Pos.: Sample No.: RP 05012 Doctor: Ward: Patient ID: Sex: Birth: Name: Nickname: XN-L Sample Comment: WDF-CBC WDF Positive Diff. Morph. Count [10³/uL] 11.91 WBC [10^6/uL] 4.43 **RBC** [g/dL] 14.2 **HGB** 40.8 [%] **HCT** 92.1 fL] MCV 32.1 [pg] MCH 34.8 [g/dL] **MCHC** [10^3/uL] 158 **PLT** [fL] 42.8 RDW-SD 12.4 [%] RDW-CV 12.5 fL] PDW [fL] 10.4 MPV 29.1 P-LCR [%] 0.16 -PCT 57.5 * [%] 6.86 * [10³/uL] **NEUT** 25.7 [10^3/uL] 3.06 LYMPH 1.65 + [10^3/uL] 13.9 MONO 2.6 * [%] 0.31 * [10^3/uL] EO 0.03 [10³/uL] 0.3 **BASO** PLT **RBC** 14.5 * 1.73 * [10^3/uL] IG

WBC IP Message Monocytosis IG Present Left Shift? RBC IP Message

PLT IP Message

Performed by: Rodhikas weeked by forder.

Pos.: 18/11/2021 17:07:35 WB Adapter: Sample No.: RP 05012 Doctor: Ward: Patient ID: Sex: Birth: Name: Nickname: XN-L Sample Comment: WDF-CBC WDF Positive 3 Diff. Morph. Count [10³/uL] 12.06 **WBC** 4.45 [10^6/uL] **RBC** 14.3 [g/dL] HGB 40.8 **HCT** 91.7 [fL] MCV 32.1 [pg] MCH [g/dL] 35.0 MCHC [10^3/uL] 159 **PLT** [fL] 42.3 RDW-SD 12.3 [%] RDW-CV [fL] 13.5 PDW [fL] 10.6 MPV P-LCR 29.9 [%] 0.17 PCT 6.94 * 57.6 * [%] [10³/uL] **NEUT** 26.9 3.25 10^3/uLl LYMPH 12.6 1.52 + [10^3/uL] МОИО 2.5 * 0.30 * [10^3/uL] EO [10³/uL] 0.4 0.05 PLT **BASO RBC** 14.0 * 1.69 * [10^3/uL] IG

WBC IP Message Monocytosis IG Present Left Shift? RBC IP Message

PLT IP Message

Performed by: Radhika Cheek by: gardet

18/11/2021 17:09:00 WB Pos.: Adapter: Sample No.: RP 05012 Doctor: Ward: Sex: Patient ID: Birth: Nickname: XN-L Name: Sample Comment: WDF-CBC WDF Positive Diff. Morph. Count 11.99 [10^3/uL] **WBC** [10^6/uL] 4.30 **RBC** [g/dL] 14.1 HGB [%] 39.4 **HCT** [fL] 91.6 MCV 32.8 [pg] MCH [g/dL] 35.8 MCHC 152 * [10^3/uL] PLT 42.1 [fL] RDW-SD 12.5 [%] RDW-CV 12.3 * [fl] PDW 10.3 * [fL] MPV 28.2 * [%] P-LCR 0.16 * [%] PCT 56.7 * [%] 6.80 * [10^3/uL] NEUT 27.1 [10^3/uL] 3.25 LYMPH 13.2 1.58 + [10³/uL] MONO 2.7 * [%] 0.32 * [10^3/uL] EO PLT 0.3 0.04 [10³/uL] **RBC BASO** 13.7 * [%] 1.64 * [10³/uL] IG

WBC IP Message Monocytosis IG Present Left Shift? RBC IP Message

PLT IP Message PLT Clumps?

Performed by: Radhikad Cheek by: gorden,

18/11/2021 17:10:32 WB Pos.: Adapter: Sample No.: RP 05012 Doctor: Ward: Patient ID: Sex: Birth: Name: Nickname: XN-L Sample Comment: WDF-CBC WDF Positive Diff. Morph. Count [10^3/uL] 12.31 WBC [10^6/uL] 4.39 **RBC** [g/dL] 14.2 HGB [%] 40.1 HCT [fL] 91.3 MCV 32.3 [pg] MCH [g/dL] 35.4 MCHC 10^3/uL] 149 PLT fL] 42.1 RDW-SD [%] 12.3 RDW-CV 12.7 fL] PDW 10.5 [fL] MPV 28.2 P-LCR 0.16 -PCT 56.6 * [%] 6.97 * [10^3/uL] NEUT 27.1 [10^3/uL] 3.33 LYMPH 13.2 1.62 + [10³/uL] MONO 2.8 * [%] 0.35 * [10^3/uL] ΕO PLT 0.3 [10^3/uL] **RBC** 0.04 **BASO** 14.0 * [%] 1.72 * [10³/uL] ΙG

WBC IP Message Monocytosis IG Present Left Shift? RBC IP Message

PLT IP Message

Performed by! Radhithan Cheek by! & gorde!