

**SYSMEX XN-350
AUTOMATED HEAMATOLOGY ANALYZER**

**INSTALLATION
QUALIFICATION**

For

“ Shruti Clinical Laboratory ”

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

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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 : Mr. Rahul Dixit Signature: 
Title : INSTALLATION QUALIFICATION Date: 18-11-2021
Company : TRANSASIA BIO-MEDICALS LTD.

Validation Team from : Shruti Clinical Laboratory

Name : Mohd Anayatullah Khan Signature - 
Designation : Scientific Officer Date 18-11-2021
Department : Pathology


Customer Authorizations:

Name : Dr. Payal Pandey Signature: 
Title : INSTALLATION QUALIFICATION Date: 18-11-2021
Site : Mumbai

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 Biomedicals Limited

Name : Mr. Rahul Dixit 
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 manufacturer'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 : 

Date : 18-11-2021

IV)Utilities

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

√Encircle applicable source

Validation Team : Transasia Biomedicals Ltd

Name : Mr. Rahul Dixit

Designation : Service Engineer

Signature



Date : 18-11-2021

The instrument has been verified for the following

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

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 | | Verified by | Date |
|---------------------------|-----------------------|-------------|------------|
| Equipment Name | Automated Hematology | | |
| Model | XN -350 | | |
| Manufacturer | Sysmex Corporation | | |
| Marketed By | Transasia | | |
| 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



Date : 18-11-2021

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 :



Date

: 18-11-2021

VI. Installation Procedure

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

1. 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 : 

Date : 18-11-2021

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. Payal Pandey

Title : INSTALLATION QUALIFICATION Signature: 

Site : Mumbai Date : 18-11-2021

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

Rahul

Mohd Anayatullah Khan

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

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I. 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 : 

Title : OPERATIONAL QUALIFICATION
2021

Date: 18-11-2021

Company : TRANSASIA BIO-MEDICALS LTD.

Validation Team from : Shruti Clinical Laboratory

Name : Rahul Dixit

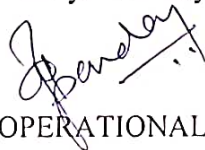
Designation : Service Engineer

Department : Pathology

Customer Authorization:

Name : Dr. Payal Pandey

Signature:



Title : OPERATIONAL QUALIFICATION

Date : 18-11-2021

Site : Mumbai


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

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 Engineer

Signature 

Date : 18-11-2021


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:

| <u>Test No.</u> | <u>Test Name</u> | <u>Test Purpose</u> | <u>Verified Date</u> |
|-----------------|--|--|----------------------|
| 1. | Whole Blood (WB) | To check the WB aspiration aspiration motor operation | |
| 2 Motor | Sheath Motor Test. | To check Operation of Sheath | |
| 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 
Date 18-11-2021

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.****FAIL****PARAMETER****PASS****Parameter values for verification : Sampler & Barcode Pass
Test**


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: 

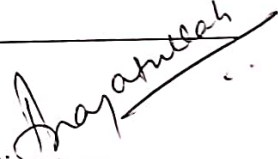
Company: TRANSASIA BIO-MEDICALS LTD.

Date :18-11-2021

Customer Authorizations:

Name : Mohd Anayatullah Khan

Title : OPERATIONAL QUALIFICATION

Signature: 

Site : Mumbai

Date : 18-11-2021

Name : Dr. Payal Pandey

Title : OPERATIONAL QUALIFICATION

Signature: 

Site : Mumbai

Date : 18-11-2021

**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


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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.

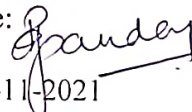
Protocol Performed By: Transasia Representative

Name : Rahat Shaikh Signature: 
Title : PERFORMANCE QUALIFICATION 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 Signature: 
Title : PERFORMANCE QUALIFICATION Date: 18-11-2021
Site : Mumbai


II. 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 result and sign in the last page. The members of the validation team will carry this out.
4. ALL 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 

Date : 18-11-2021

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

Date: 18/11/2021
Effective Date: 18/11/2021

Certificate of Calibration

Customer Name: Shruti Clinical Laboratory

Model : Automated Hematology Analyzer Sysmex XNL-350

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.

R.D

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

Calibrator Calibration History

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
 Instrument Nickname: XN-L
 Material: XN CAL

Calibration Date: 18/11/2021 10:56:05
 Lot No.: 13052101

Logon Name: sysmex

| | 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 Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (E), Mumbai- 400 072
Tel: +91 22 4920-9000 Fax: +91 22 4920-8030

Logon Name: sysmcx

Execution Date: 18/11/2021 09:48:37

| | WBC | RBC | HGB | HCT | PLT |
|------------|-------|-------|-------|-------|-------|
| No. 2 | 5.65 | 4.86 | 14.1 | 46.0 | 292 |
| No. 3 | 5.83 | 4.81 | 14.1 | 45.5 | 283 |
| No. 4 | 5.81 | 4.80 | 14.2 | 45.4 | 289 |
| No. 5 | 5.79 | 4.83 | 14.2 | 45.5 | 285 |
| No. 6 | 5.89 | 4.82 | 14.2 | 45.3 | 298 |
| No. 7 | 5.74 | 4.86 | 14.2 | 45.6 | 295 |
| No. 8 | 5.67 | 4.78 | 14.1 | 44.9 | 282 |
| No. 9 | 5.77 | 4.86 | 14.3 | 45.4 | 289 |
| No. 10 | 5.79 | 4.82 | 14.1 | 45.1 | 287 |
| No. 11 | 5.87 | 4.83 | 14.2 | 45.0 | 284 |
| Mean Value | 5.781 | 4.827 | 14.17 | 45.37 | 288.4 |
| SD | 0.078 | 0.027 | 0.07 | 0.32 | 5.3 |
| CV (%) | 1.3 | 0.6 | 0.5 | 0.7 | 1.8 |
| Limit (%) | 3.0 | 1.5 | 1.0 | 1.5 | 4.0 |

00-14A 18/11/2021 11:34 1/1

Scanned with CamScanner

QC Chart

Shift All

| Instrument Nickname | Material | Lot No. | Exp. Date | Date From | To |
|---------------------|---------------------|-------------|------------|------------|------------|
| XN-L | XN-L Control Level3 | QC-12951403 | 01/02/2022 | 18/11/2021 | 18/11/2021 |

XN-L

0

| | |
|--------|--------|
| UL | SD |
| Target | Mean |
| LL | CV (%) |

| | UL | LL | Mean | SD | CV (%) |
|--------|-------|-------|-------|------|--------|
| WBC-D | 17.67 | 15.05 | 16.36 | 1.31 | 8.01 |
| NEUT# | 11.26 | 8.66 | 9.96 | 1.30 | 13.06 |
| LYMPH# | 4.03 | 3.10 | 3.57 | 0.47 | 13.19 |
| MONO# | 2.34 | 2.17 | 2.26 | 0.09 | 3.98 |
| EO# | 1.23 | 0.12 | 0.68 | 0.56 | 81.94 |
| BASO# | 3.33 | 2.22 | 2.78 | 0.56 | 20.14 |
| IG# | 2.05 | 1.15 | 1.60 | 0.45 | 28.13 |
| NEUT% | 3.04 | 2.43 | 2.74 | 0.30 | 10.95 |
| | 60.8 | 52.9 | 56.85 | 4.00 | 7.04 |
| | 45.0 | | | | |

18/11/2021 11:44

QC Chart

Shift All

| Instrument Nickname | Material | Lot No. | Exp. Date | Date From | To |
|---------------------|---------------------|-------------|------------|------------|------------|
| XN-L | XN-L Control Level3 | QC-12951403 | 01/02/2022 | 18/11/2021 | 18/11/2021 |

XN-L

0

| | |
|--------|--------|
| UL | SD |
| Target | Mean |
| LL | CV (%) |

| | UL | LL | Mean | SD | CV (%) |
|--------|----|----|------|------|--------|
| LYMPH% | UL | LL | 19.7 | 22.8 | 115.2 |
| | UL | LL | 15.2 | 19.0 | 125.0 |
| MONO% | UL | LL | 8.3 | 11.3 | 135.0 |
| | UL | LL | 3.7 | 7.5 | 202.7 |
| EO% | UL | LL | 13.6 | 20.4 | 149.3 |
| | UL | LL | 6.8 | 13.6 | 200.0 |
| BASO% | UL | LL | 6.6 | 12.5 | 189.4 |
| | UL | LL | 1.5 | 7.0 | 466.7 |
| IG% | UL | LL | 13.2 | 18.6 | 141.0 |
| | UL | LL | 11.2 | 14.9 | 133.0 |

18/11/2021 11:44

QC Chart

XN-L

0

Shift All

| Instrument Nickname | Material | Lot No. | Exp. Date | Date From | To |
|---------------------|---------------------|-------------|------------|------------|------------|
| XN-L | XN-L Control Level3 | QC-12951403 | 01/02/2022 | 18/11/2021 | 18/11/2021 |

| | |
|--------|--------|
| UL | SD |
| Target | Mean |
| LL | CV (%) |

| | | | n=1 | |
|--------|----|---|-------|-------|
| MicroR | UL | ● | 4.0 | ---- |
| | LL | | 2.0 | 2.5 |
| MacroR | UL | ● | 0.0 | ---- |
| | LL | | 7.4 | 5.0 |
| PLT-I | UL | ● | 4.9 | ---- |
| | LL | | 2.4 | 554 |
| PDW | UL | ● | 623 | ---- |
| | LL | | 551 | 479 |
| PCT | UL | ● | 9.6 | ---- |
| | LL | | 8.0 | 8.4 |
| MPV | UL | ● | 6.4 | ---- |
| | LL | | 0.63 | 0.51 |
| P-LCR | UL | ● | 0.50 | 0.51 |
| | LL | | 0.37 | ---- |
| WBC-C | UL | ● | 10.4 | ---- |
| | LL | | 9.0 | 9.2 |
| | UL | ● | 7.6 | ---- |
| | LL | | 18.6 | 14.1 |
| | UL | ● | 12.4 | ---- |
| | LL | | 6.2 | 16.98 |
| | UL | ● | 17.87 | ---- |
| | LL | | 16.39 | 16.98 |
| | UL | ● | 14.91 | ---- |
| | LL | | | |

18/11/2021 11:44

QC Chart

XN-L

0

Shift All

| Instrument Nickname | Material | Lot No. | Exp. Date | Date From | To |
|---------------------|---------------------|-------------|------------|------------|------------|
| XN-L | XN-L Control Level3 | QC-12951403 | 01/02/2022 | 18/11/2021 | 18/11/2021 |

| | |
|--------|--------|
| UL | SD |
| Target | Mean |
| LL | CV (%) |

| | | | | n=1 | |
|--------|----|-------|--|------|------|
| RBC | UL | ----- | | 5.49 | ---- |
| | | ----- | | 5.23 | 5.25 |
| | LL | ----- | | 4.97 | ---- |
| HGB | UL | ----- | | 17.5 | ---- |
| | | ----- | | 16.8 | 16.9 |
| | LL | ----- | | 16.1 | ---- |
| HCT | UL | ----- | | 50.3 | ---- |
| | | ----- | | 45.7 | 44.8 |
| | LL | ----- | | 41.1 | ---- |
| MCV | UL | ----- | | 92.5 | ---- |
| | | ----- | | 87.3 | 85.3 |
| | LL | ----- | | 82.1 | ---- |
| MCH | UL | ----- | | 34.7 | ---- |
| | | ----- | | 32.1 | 32.2 |
| | LL | ----- | | 29.5 | ---- |
| MCHC | UL | ----- | | 42.8 | ---- |
| | | ----- | | 36.8 | 37.7 |
| | LL | ----- | | 31.6 | ---- |
| RDW-SD | UL | ----- | | 53.8 | ---- |
| | | ----- | | 46.8 | 44.4 |
| | LL | ----- | | 39.8 | ---- |
| RDW-CV | UL | ----- | | 17.1 | ---- |
| | | ----- | | 14.9 | 14.5 |
| | LL | ----- | | 12.7 | ---- |

18/11/2021 11:44

precision check - 1

Sample No.: RP 05012
Patient ID:
Name:
Sample Comment:

Ward: Adapter:

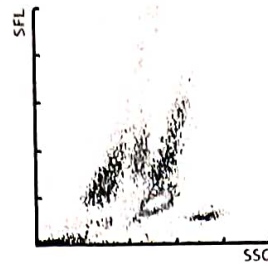
Pos.: 18/11/2021 17:04:16 WB
Doctor:
Birth: Sex:
Nickname: XN-L

Positive

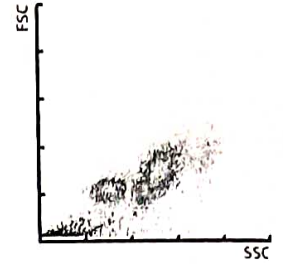
Diff. Morph. Count

| | | | | |
|--------|--------|-----------------------|------|-----|
| 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 | [%] | | |
| PCT | 0.17 | [%] | | |
| NEUT | 6.76 | [10 ³ /uL] | 56.5 | [%] |
| LYMPH | 3.25 | [10 ³ /uL] | 27.2 | [%] |
| MONO | 1.64 + | [10 ³ /uL] | 13.7 | [%] |
| EO | 0.28 | [10 ³ /uL] | 2.3 | [%] |
| BASO | 0.03 | [10 ³ /uL] | 0.3 | [%] |
| IG | 1.64 | [10 ³ /uL] | 13.7 | [%] |

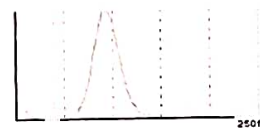
WDF



WDF-CBC



RBC



PLT



WBC IP Message
Monocytosis
IG Present

RBC IP Message

PLT IP Message

Performed by: Radhika

check by: Jagan

Sample No.: RP 05012
Patient ID:
Name:
Sample Comment:

Adapter:
Ward:

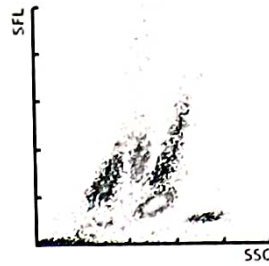
Pos.: 18/11/2021 17:06:02 WB
Doctor:
Birth: Sex:
Nickname: XN-L

Positive

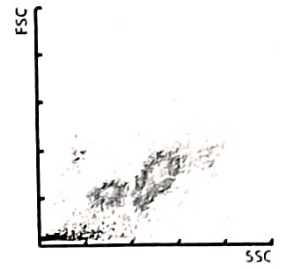
Diff. Morph. Count

| | | | |
|--------|--------|-----------------------|------------|
| WBC | 11.91 | [10 ³ /uL] | |
| RBC | 4.43 | [10 ⁶ /uL] | |
| HGB | 14.2 | [g/dL] | |
| HCT | 40.8 | [%] | |
| MCV | 92.1 | [fL] | |
| MCH | 32.1 | [pg] | |
| MCHC | 34.8 | [g/dL] | |
| PLT | 158 | [10 ³ /uL] | |
| RDW-SD | 42.8 | [fL] | |
| RDW-CV | 12.4 | [%] | |
| PDW | 12.5 | [fL] | |
| MPV | 10.4 | [fL] | |
| P-LCR | 29.1 | [%] | |
| PCT | 0.16 | - [%] | |
| NEUT | 6.86 * | [10 ³ /uL] | 57.5 * [%] |
| LYMPH | 3.06 | [10 ³ /uL] | 25.7 [%] |
| MONO | 1.65 + | [10 ³ /uL] | 13.9 [%] |
| EO | 0.31 * | [10 ³ /uL] | 2.6 * [%] |
| BASO | 0.03 | [10 ³ /uL] | 0.3 [%] |
| IG | 1.73 * | [10 ³ /uL] | 14.5 * [%] |

WDF



WDF-CBC



RBC



PLT



WBC IP Message
Monocytosis
IG Present
Left Shift?

RBC IP Message

PLT IP Message

Performed by: Radhika
checked by gander

Sample No.: RP 05012
 Patient ID:
 Name:
 Sample Comment:

Ward: Adapter:

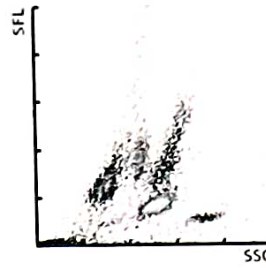
Pos.: 18/11/2021 17:07:35 WB
 Doctor:
 Birth: Sex:
 Nickname: XN-L

Positive

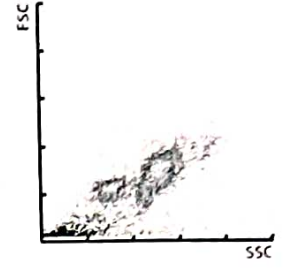
Diff. Morph. Count

| | | | |
|--------|--------|-----------------------|------------|
| WBC | 12.06 | [10 ³ /uL] | |
| RBC | 4.45 | [10 ⁶ /uL] | |
| HGB | 14.3 | [g/dL] | |
| HCT | 40.8 | [%] | |
| MCV | 91.7 | [fL] | |
| MCH | 32.1 | [pg] | |
| MCHC | 35.0 | [g/dL] | |
| PLT | 159 | [10 ³ /uL] | |
| RDW-SD | 42.3 | [fL] | |
| RDW-CV | 12.3 | [%] | |
| PDW | 13.5 | [fL] | |
| MPV | 10.6 | [fL] | |
| P-LCR | 29.9 | [%] | |
| PCT | 0.17 | [%] | |
| NEUT | 6.94 * | [10 ³ /uL] | 57.6 * [%] |
| LYMPH | 3.25 | [10 ³ /uL] | 26.9 [%] |
| MONO | 1.52 + | [10 ³ /uL] | 12.6 [%] |
| EO | 0.30 * | [10 ³ /uL] | 2.5 * [%] |
| BASO | 0.05 | [10 ³ /uL] | 0.4 [%] |
| IG | 1.69 * | [10 ³ /uL] | 14.0 * [%] |

WDF



WDF-CBC



RBC



PLT



WBC IP Message
 Monocytosis
 IG Present
 Left Shift?

RBC IP Message

PLT IP Message

Performed by: Radhika
 Check by: Janday

precision check - 4

XN-L

0

Sample No.: RP 05012
Patient ID:
Name:
Sample Comment:

Ward: Adapter:

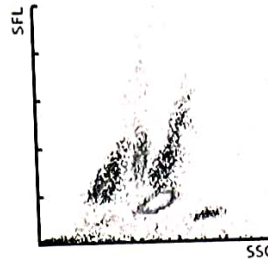
Pos.: 18/11/2021 17:09:00 WB
Doctor:
Birth: Sex:
Nickname: XN-L

Positive

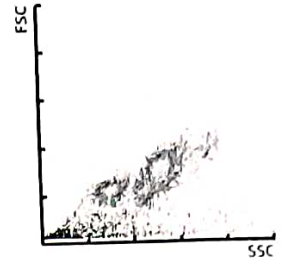
Diff. Morph. Count

| | | | |
|--------|--------|-----------------------|------------|
| WBC | 11.99 | [10 ³ /uL] | |
| RBC | 4.30 | [10 ⁶ /uL] | |
| HGB | 14.1 | [g/dL] | |
| HCT | 39.4 | [%] | |
| MCV | 91.6 | [fL] | |
| MCH | 32.8 | [pg] | |
| MCHC | 35.8 | [g/dL] | |
| PLT | 152 * | [10 ³ /uL] | |
| RDW-SD | 42.1 | [fL] | |
| RDW-CV | 12.5 | [%] | |
| PDW | 12.3 * | [fL] | |
| MPV | 10.3 * | [fL] | |
| P-LCR | 28.2 * | [%] | |
| PCT | 0.16 * | [%] | |
| NEUT | 6.80 * | [10 ³ /uL] | 56.7 * [%] |
| LYMPH | 3.25 | [10 ³ /uL] | 27.1 [%] |
| MONO | 1.58 + | [10 ³ /uL] | 13.2 [%] |
| EO | 0.32 * | [10 ³ /uL] | 2.7 * [%] |
| BASO | 0.04 | [10 ³ /uL] | 0.3 [%] |
| IG | 1.64 * | [10 ³ /uL] | 13.7 * [%] |

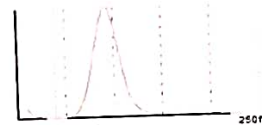
WDF



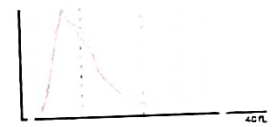
WDF - CBC



RBC



PLT



WBC IP Message
Monocytosis
IG Present
Left Shift?

RBC IP Message

PLT IP Message
PLT Clumps?

Performed by: ~~Redhite~~
Check by: gandey

Sample No.: RP 05012
Patient ID:
Name:
Sample Comment:

Adapter:
Ward:

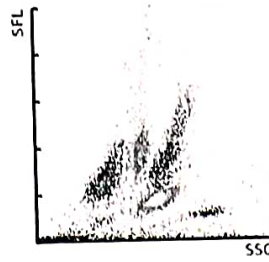
Pos.: 18/11/2021 17:10:32 WB
Doctor:
Birth: Sex:
Nickname: XN-L

Positive

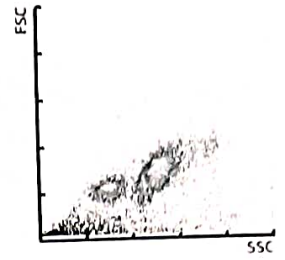
Diff. Morph. Count

| | | | | |
|--------|--------|-----------------------|--------|-----|
| WBC | 12.31 | [10 ³ /uL] | | |
| RBC | 4.39 | [10 ⁶ /uL] | | |
| HGB | 14.2 | [g/dL] | | |
| HCT | 40.1 | [%] | | |
| MCV | 91.3 | [fL] | | |
| MCH | 32.3 | [pg] | | |
| MCHC | 35.4 | [g/dL] | | |
| PLT | 149 | [10 ³ /uL] | | |
| RDW-SD | 42.1 | [fL] | | |
| RDW-CV | 12.3 | [%] | | |
| PDW | 12.7 | [fL] | | |
| MPV | 10.5 | [fL] | | |
| P-LCR | 28.2 | [%] | | |
| PCT | 0.16 | - [%] | | |
| NEUT | 6.97 * | [10 ³ /uL] | 56.6 * | [%] |
| LYMPH | 3.33 | [10 ³ /uL] | 27.1 | [%] |
| MONO | 1.62 + | [10 ³ /uL] | 13.2 | [%] |
| EO | 0.35 * | [10 ³ /uL] | 2.8 * | [%] |
| BASO | 0.04 | [10 ³ /uL] | 0.3 | [%] |
| IG | 1.72 * | [10 ³ /uL] | 14.0 * | [%] |

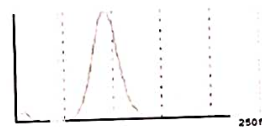
WDF



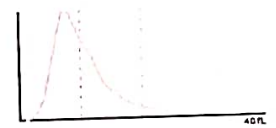
WDF-CBC



RBC



PLT



WBC IP Message
Monocytosis
IG Present
Left Shift?

RBC IP Message

PLT IP Message

Performed by: *Radhika*

check by: *Spandey*