Date: 06-08-2021
Effective Date: 06-08-2021

Certificate of Calibration

Customer Name: **"MAEER'S VishwaRaj Hospital Laboratory, Loni Kalbhor, Pune"**

Model : **Automated Hematology Analyzer Sysmex XS-800i**

Serial No. : **67641**

Calibration Done Date: **06-08-2021**

Next Calibration Due Date On or Before: **06-08-2022**

Lab In-charge: . **Dr. Aniruddha Garud**

This is to certify that the above-mentioned product has been verified of calibration for CBC 6 parameters (WBC, RBC, HGB, HCT, MCV and PLT).

Calibration at site performed by
Er Name : Er. Khurshid M. Kazi
Designation : Technical Director
Soha Biomedical Engineers, Pune

Signature

SOHA BIOMEDICAL ENGINEERS

Encl:
1. Assay Sheet of Calibrator.
2. Printouts

A402, Sahil-Sarvda, SR#38/5B, Opp. Maruti Sai Service Centre, A/P : Kondhwa-Khurd, Pune-411048 Dist: Pune, Maharashtra, India.
Phone: 8484 84 5154, Email: kmkazi@rediffmail.com

Date: 06-08-2021
Effective Date: 06-08-2021

Certificate of Inspection

1. Model: Automated Hematology Analyzer Sysmex XS-800i

2. Serial No.: 67641

3. Calibration Date: 06-08-2021

4. Material used: SCS-1000 (Lot No. 11940525, Expiry date: 15-Aug-2021)

Calibration for CBC 6 parameters using the measurement standard material (SCS-1000) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

Soha Biomedical Engineers, Pune

SOHA BIOMEDICAL ENGINEERS PUNE

A402, Sahil-Sarvda, SR#38/5B, Opp. Maruti Sai Service Centre, A/P : Kondhwa-Khurd, Pune-411048 Dist: Pune, Maharashtra, India.
Phone: 8484 84 5154, Email: kmkazi@rediffmail.com

SOHA BIOMEDICAL ENGINEERS

5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3×10^3/uL or less
RBC	0.00	0.02×10^6/uL or less
HGB	0.0	0.1 g /dL or less
PLT	4	10×10^3/uL or less

SOHA BIOMEDICAL ENGINEERS PUNE

A402, Sahil-Sarvda, SR#38/5B, Opp. Maruti Sai Service Centre, A/P : Kondhwa-Khurd, Pune-411048 Dist: Pune, Maharashtra, India.
Phone: 8484 84 5154, Email: kmkazi@rediffmail.com

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

SMP NO	WBC	RBC	HGB	HCT	MCV	PLT
P01	5.55	5.20	13.00	39.8	76.5	292
P02	5.6	5.29	13.00	40.40	76.4	285
P03	5.66	5.19	12.80	39.7	76.5	293
P04	5.87	5.22	12.90	39.8	76.2	285
P05	5.56	5.19	12.80	39.6	76.3	287
P06	5.72	5.24	12.80	40.0	76.3	281
P07	5.58	5.26	12.80	40.0	76.0	295
P08	5.62	5.22	12.80	39.7	76.1	291
P09	5.65	5.30	13.00	40.2	75.8	290
P10	5.67	5.29	13.00	40.1	75.8	296
Mean	5.65	5.24	12.89	39.93	76.19	289.50
SD	0.094	0.043	0.099	0.254	0.260	4.859
CV%	**1.671**	**0.815**	**0.771**	**0.636**	**0.341**	**1.678**
Acceptable CV%	Within 3.0%	Within 1.5%	Within 1.5%	Within 1.5%	Within 1.5%	Within 4.0%
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

SOHA BIOMEDICAL ENGINEERS PUNE

SOHA BIOMEDICAL ENGINEERS

7. CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	MCV	PLT
C00	7.22	4.51	12.4	37.0	82.0	248
C01	7.15	4.53	12.4	36.2	79.9	245
C02	7.53	4.51	12.4	36.1	80.0	235
C03	7.14	4.54	12.5	36.3	80.0	240
C04	7.19	4.58	12.5	36.7	80.1	246
MEAN	**7.25**	**4.534**	**12.44**	**36.46**	**80.40**	**242.8**
Acceptable Limits	7.046 - 7.626	4.499 - 4.639	12.29 - 12.48	35.79 - 37.40	79.08 - 81.11	240.0 - 257.6
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

SOHA BIOMEDICAL ENGINEERS PUNE

A402, Sahil-Sarvda, SR#38/5B, Opp. Maruti Sai Service Centre, A/P : Kondhwa-Khurd, Pune-411048 Dist: Pune, Maharashtra, India.
Phone: 8484 84 5154, Email: kmkazi@rediffmail.com

CE

SCS-1000

sysmex

For Asian Pacific

LOT 11940525

15-Aug-2021

Sysmex Calibrator System Assay Sheet

	XE-Series		XT-Series		XS-Series*	
Parameter	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.752	7.446 - 8.059	7.979	7.664 - 8.294	7.336	7.046 - 7.626
RBC M/uL	4.587	4.516 - 4.657	4.482	4.413 - 4.551	4.569	4.499 - 4.639
HGB g/dL	12.49	12.40 - 12.59	12.30	12.21 - 12.40	12.39	12.29 - 12.48
HCT %	35.94	35.14 - 36.73	34.47	33.71 - 35.23	36.60	35.79 - 37.40
MCV fL	78.35	77.35 - 79.34	76.90	75.92 - 77.88	80.09	79.08 - 81.11
PLT K/uL	248.9	240.1 - 257.7	247.7	239.0 - 256.5	248.8	240.0 - 257.6

	K-4500 / K-1000 / K-800		pocH-100i**		KX-21		XP-Series	
Parameter	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits	Assay Target	Acceptable Limits
WBC K/uL	7.76	7.42 - 8.09	7.46	7.14 - 7.78	7.72	7.39 - 8.05	7.12	6.82 - 7.43
RBC M/uL	4.530	4.440 - 4.621	4.565	4.474 - 4.657	4.524	4.433 - 4.614	4.485	4.395 - 4.575
HGB g/dL	12.39	12.26 - 12.51	12.10	11.98 - 12.22	12.50	12.38 - 12.63	12.07	11.95 - 12.19
HCT %	33.34	32.60 - 34.07	35.64	34.85 - 36.43	33.87	33.12 - 34.62	33.69	32.94 - 34.43
MCV fL	73.59	72.78 - 74.40	78.07	77.21 - 78.92	74.87	74.05 - 75.69	75.10	74.28 - 75.93
PLT K/uL	256.0	243.2 - 268.8	244.9	232.6 - 257.1	275.9	262.1 - 289.7	268.5	255.0 - 281.9

SCS-1000 ASSAY TERM DEFINED

Assay Target – This is the assigned value for calibration.

Acceptable Limits – These limits represent the interval around the Assay Target that can be attributed to the expanded uncertainty of the total traceability chain. A calibrator mean (n=5) that falls within these limits indicates an accurately calibrated instrument.

* **XS-1000i/XS-800i** – Assay target for WBC only for operation in CBC+Diff mode

** **pocH-100i** – Assay Target for WBC only for systems operating under software version 00–18 and following

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Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

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SYSMEX XS-800I
AUTOMATED HEAMATOLOGY ANALYZER

INSTALLATION QUALIFICATION

For

" MAEER's Vishwaraj Hospital Laboratory"

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

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

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Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

I. Approval of the IQ procedure:

MAEER's Vishwaraj Hospital Laboratory and Transasia are jointly responsible for the installation of the system SYSMEX – HEMATOLOGY Analyzer, Model: XS-800I, Serial No. 67641 in the clinical lab of MAEER's Vishwaraj Hospital Laboratory as per the attached protocol.

Protocol Performed By: Transasia Representative

Name : Mr. Swapnil Kamarikar Signature:
Title : INSTALLATIONQUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD. Date: 6/8/21

TRASASIA BIO MEDICALS LTD.

Validation Team from _____:

Name :
Designation :
Department :

Customer Authorizations:

Name : Dr. Aniruddha Ganed Signature:
Title : INSTALLATION QUALIFICATION
Site : Date:

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

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. Employee of MAEER's Vishwaraj Hospital 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 normal specification to include any problems with installation will be noted under COMMENTS. All resolution to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this protocol for the same.

5. 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:

Name Swapnil Kamerikar

Designation Service Eng.

Signature

Date 6/8/21

TRANSASIA BIO MEDICALS LTD.

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

III. Scope

This Installation Qualification protocol will be performed on the SYSMEX-Hematology Analyzer, Model XS-800I Serial No. 67641 located in MAEER's Vishwaraj Hospital Laboratory 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:

Name: Swapnil Kamarikar

Designation: Service Engg.

Signature:

Date: 6/8/21

LTD. * TRASASIA BIO MEDICALS

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IV. Ancillary Information.

a. Certification of Purchase Order Compliance

I certify to the best of my knowledge, the instrument is purchased under Purchase order No._____, Dt._____ sent against Quotation number _____ dt._____ is in compliance with the specifications of the Purchase order.

Verified By :_____ Date :_____

b. Utilities

Sr.No.	Utility		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	✓	
2.	Adequate space for installation : (Minimum in mm. W 450 X D 660 X H 450)	Yes / No	✓	
3.	Cellpack DCL, SULFOLYSER,,Lysercell WDF, Fluorocell WDF and Cell Clean	Yes / No	✓	
4.	Power Source Requirements*	Yes / No	✓	

* Encircle applicable source

Validation Team :

Name Swapnil Kanamkar

Designation Service Engg.

Signature

Date 6/8/21

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c. The instrument has been verified for the following

Sr.No.	Verification		Verified By	Date
1.	Instrument is identified	Yes / No	✓	
2.	Manufacturer's specifications are included	Yes / No	✓	
3.	Accessories / Consumables are listed	Yes / No	✓	
4.	Manufacturer's certificate of Compliance attached	Yes / No	✓	

Validation Team:

Name Swapnil Kamaikar

Designation Service Engg

Signature

Date 6/8/21

TRASASIA BIO MEDICALS LTD.

Erba® Mannheim

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

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

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V. Installation Qualification

A. Equipment Description

This Sysmex XS-800I is a fully automated Hematology analyzer for in vitro diagnostic use in clinical laboratories. The XS-800I provides accurate and precise test results for ( ) parameters.

Instrument identification		Verified by	Date
Equipment Name	Automated Hematology	✓	
Model	XS800i	✓	
Manufacturer	Sysmex Corporation	✓	
Marketed By	Transasia	✓	
Equipment #		✓	
Serial Number	67641	✓	
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:

Name Swapnil Komaitkar.

Designation Service Engg.

Signature

Date 6/8/21

TRANSASIA BIO MEDICALS LTD.

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B. Accessories / Consumables

Accessories

Validation Team :

Name Swapnil Kamerkar

Designation Service Eng.

Signature

Date 6/8/21

TRANSASIA BIO MEDICALS LTD.

Consumables:

Consumables such as Cellpack SULFOLYSER, Stromatlyser 4DL, Stroamtolyser 4DS 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 MAEER's Vishwaraj Hospital Laboratory.

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 Swapnil Kamaitkar

Designation Service Engr.

Signature

Date 6/8/21

TRANSASIA BIO MEDICALS LTD.

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

Sample page of the logbook is attached to this document

Effective date:

Validation Team:

Name Swapnil Khemnar.

Designation Service Engg.

Signature

Date 6/8/21

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
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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 XS800i Service Manual

3. **Grounding**
   Refer to Chapter 1 of Sysmex XS800i Service Manual

4. **Installation Environment & Space**
   Refer to Chapter 1 of Sysmex XS800i Service Manual

5. **Connect Air & Reagent Tubes**
   Refer to Chapter 7 of Sysmex XS800i Service Manual

6. **Connect Connection Cord & Power Cord**
   Refer to Chapter 7 of Sysmex XS800i Service Manual

7. **Turn Power On**
   Refer to Chapter 7 of Sysmex XS800i Service Manual

Validation Team:

Name Swapnil Kanerikar

Designation Service Eng

Signature

Date 6/8/24

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Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 **Fax**: +91 20 2616 2658 **Email**: wz3@transasia.co.in **CIN**: U33110MH1985PLC036198

VII. COMMENTS:

Validation Team:

Name Swapnil Kamanikar

Designation

Signature

Date 6/8/21

TRANSASIA BIO MEDICALS LTD.

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. Swapnil Kamarikar

Title : **INSTALLATION QUALIFICATION** Signature:

Company: **TRANSASIA BIO-MEDICALS LTD.** Date : 6/8/21

Customer Authorizations:

Name : Dr. Aniruddha Kamal

Title : INSTALLATION QUALIFICATION Signature:

Site : Date :

Name : Dr. Aniruddha Kamal

Title : INSTALLATION QUALIFICATION Signature:

Site : Date :

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Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

Date: 6/8/21

Reagent Check done	OK
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: Mr. Kiran Pandit Checked by: Dr. Aniruddha Garud,

Date: 6/8/21

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SYSMEX XS800i
AUTOMATED HEMATOLOGY ANALYZER

OPERATIONAL QUALIFICATION

For

"MAEER's Vishwaraj Hospital Laboratory"

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

Erba® Mannheim

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

Table of Contents

I. Approval of the OQ procedure:

MAEER's Vishwaraj Hospital Laboratory and Transasia are jointly responsible for operational check of the HEMATOLOGY Analyzer, Model: XS800i, serial# 67641 in the clinical lab of MAEER's Vishwaraj Hospital Laboratory as per protocol attached.

Protocol Performed by: Transasia Representative

Name : Mr. Swapnil Kamarikar
Title : OPERATIONAL QUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

Signature:
Date: 6/8/21

Validation Team from _____

Name :
Designation :
Department :

Customer Authorization:

Name : Dr. Aniruddha Ganed
Title : OPERATIONAL QUALIFICATION
Site :

Signature:
Date:

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. Employee of MAEER's Vishwaraj Hospital Laboratory will verify each result and sign in the last page. The member/s of the validation team will be responsible for the same.
3. Any deviations from the acceptance criteria detailed in this document will be noted in the **COMMENTS** section of the OQ 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. This 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.
4. 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.
5. 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:

Name Swapnil Kamanikar

Designation Service Engg.

Signature

Date 6/8/21

TRANSASIA BIO MEDICALS LTD.

III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model XS-800I, Serial No:67641 located in MAEER's Vishwaraj Hospital Laboratory. 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:

Name Swapnil Kamerikar

Designation Service Engg.

Signature

Date 6/8/21

TRANSASIA BIO MEDICALS LTD.

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

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IV. Operational Qualification

a. Instrument Identification **Verified Date**

1. Model Name XS800i
2. Serial Number 67641 _____

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	_____
2	Sheath Motor Test.	To check Operation of Sheath Motor	_____
3.	Diagnostic Test for Auto Sampler and Bar code reader	To Check operation of Auto sampler and Barcode reader.	_____

Validation Team:

Name Swapnil Kamerkar

Designation Service Eng.

Signature

Date 6/8/21

TRASASIA BIO MEDICALS LTD.

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	FAIL
Parameter values for verification	:	**Whold Blood Aspiration Motor Test**	✓	

Validation Team:

Name Swapnil Kamanikar

Designation Service Engg.

Signature

Date 6/8/21

TRANSASIA BIO MEDICALS LTD.

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 XS800i's manual No.**

		PARAMETER	PASS	FAIL
Parameter values for verification	:	**Sheath Motor Motor Test**	✓	

Validation Team:

Name Swapnil Kamaikar

Designation Service Engg.

Signature

Date 6/8/21

BIO MEDICALS LTD. * TRANSASIA

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 **Fax**: +91 20 2616 2658 **Email**: wz3@transasia.co.in **CIN**: U33110MH1985PLC036198

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 XS800i manual No.**

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

Validation Team:

Name Swapnil Kamaikar

Designation Service Eng.

Signature

Date 6/8/21

TRANSASIA BIO MEDICALS LTD.

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. Vijay Shahu who is certified by Transasia Bio-Medicals Ltd has conducted the training.

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

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	Kiran Pandit	VRH		
2	Sachin Bankar	VRH		
3	Krishna Kendre	VRH		

Validation Team:

Name Swapnil Kamanikar

Designation Service Engr

Signature

Date 6/8/21

TRANSASIA BIO MEDICALS LTD.

b. Customer SOP

Title	Number	Revision #	Effective Date	Location	Verified By	Date
Operating Procedure		NA				

Validation Team:

Name Swapnil Khomenkar

Designation Service Engg

Signature

Date 6/8/21

TRASASIA BIO MEDICALS LTD.

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 **Fax**: +91 20 2616 2658 **Email**: wz3@transasia.co.in **CIN**: U33110MH1985PLC036198

COMMENTS:

Validation Team:

Name Swapnil Kamerikar

Designation Service Engg.

Signature

Date 6/8/21

TRASASIA BIO MEDICALS LTD.

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 : Mr. Swapnil Kamarikar

Title : OPERATIONAL QUALIFICATION Signature:

Company: TRANSASIA BIO-MEDICALS LTD. Date : 6/8/2(

TRANSASIA BIO MEDICALS LTD.

Customer Authorizations:

Name : Dr. Aniruddha Ganed

Title : OPERATIONAL QUALIFICATION Signature:

Site : Date :

Name : Dr. Aniruddha Ganed

Title : OPERATIONAL QUALIFICATION Signature:

Site : Date :

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

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SYSMEX XS800i
AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

For

"MAEER's Vishwaraj Hospital Laboratory"

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

Erba® Mannheim

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 **Fax**: +91 20 2616 2658 **Email**: wz3@transasia.co.in **CIN**: U33110MH1985PLC036198

Table of Contents:

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

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I. Approval of the PQ procedure

MAEER's Vishwaraj Hospital Laboratory and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer, SYSMEX Model : XS800i, Serial No.67641 in the clinical lab of MAEER's Vishwaraj Hospital Laboratory as per the attached protocol.

Protocol Performed By: Transasia Representative

Name : Mr. Vijay Shahu
Title : PERFORMANCE QUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

Signature: Vijay
Date: 6/8/21

TRANSASIA BIO MEDICALS LTD.

Validation Team from :

Name :
Designation :
Department :

Name :
Designation :
Department :

Customer Authorizations:

Name : Dr Aniruddha Kamat
Title : PERFORMANCE QUALIFICATION
Site : Pune

Signature:
Date: 6/8/21

Name : Dr Aniruddha Kamat
Title : PERFORMANCE QUALIFICATION
Site : Pune

Signature:
Date: 6/8/21

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

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 MAEER's Vishwaraj Hospital 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:

Name Vijay Sahu

Designation Vijr. App Spl.

Signature

Date 6/8/21

TRASASIA BIO MEDICALS LTD.

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model XS-800I, Serial No 67641 located in MAEER's Vishwaraj Hospital Laboratory. 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:

Name Vijay Sahu

Designation App spl.

Signature Vij

Date 6/8/21

TRASASIA BIO MEDICALS LTD.

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

IV. Performance Qualification

a. Instrument Identification

Verified Date

1. Model Name SYSMEX XS800i _____
2. Serial Number 67641 _____

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 samples	_____
03	Further Performance Checks	Regular Maintenance	NA

Validation Team:

Name Vijay Sahu

Designation Appl.

Signature Vsj.

Date 6/8/21

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c. Performance Testing

Test 1

Test Name: **Sample Processing**

Purpose: **Ability to Process Samples**

Method:

1. **Run the control samples five times consecutively**

Acceptance Criteria: Each of the results obtained above should be within the range as specified in the control chart.

Parameters Values for Verification:

RBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	4.2	4.1	✓	
2.	4.2	4.2	✓	
3.	4.2	4.2	✓	
4.	4.2	4.2	✓	
5.	4.2	4.2	✓	

Validation Team:

Name Vijay sahu

Designation App Spl.

Signature Vij

Date 6/8/21

TRASASIA BIO MEDIC T.O.

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

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

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WBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	6·1	6·2	✓	
2.	6·1	5·9	✓	
3.	6·1	6·0	✓	
4.	6·1	6·1	✓	
5.	6·1	6·1	✓	

Hemoglobin:

Test	Control Values	Results Obtained	Pass	Fail
1.	12·1	11·9	✓	
2.	12·1	12·0	✓	
3.	12·1	12·0	✓	
4.	12·1	12·0	✓	
5.	12·1	12·0	✓	

Platelet Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	350	340	✓	
2.	350	345	✓	
3.	350	343	✓	
4.	350	333	✓	
5.	350	352	✓	

Validation Team:

Name vijay sahu

Designation Appl. spl.

Signature Vij

Date 6/8/21

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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 Levy Jennings plots to be updated once in six months

Validation Team:

Name Vijay Sahu

Designation Appl. Spl.

Signature VJ

Date 6/8/21

TRASASIA BIO MEDICALS

Transasia Bio - Medicals Ltd., Akshay Complex, B Wing, Gala No. 214, Tadiwala Road, Pune - 411001
Tel: +91 20 2616 2658 Fax: +91 20 2616 2658 Email: wz3@transasia.co.in CIN: U33110MH1985PLC036198

V. 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 : Mr. Vijay Shahu

Title : PERFORMANCE QUALIFICATION Signature: Vij

Company: TRANSASIA BIO-MEDICALS LTD. Date : 6/8/21

TRANSASIA BIO MEDICALS LTD.

Customer Authorizations:

Name : Dr. Arvindkumar Gamel

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date : 6/8/21

Name : Dr. Arvindkumar Gamel

Title : PERFORMANCE QUALIFICATION Signature:

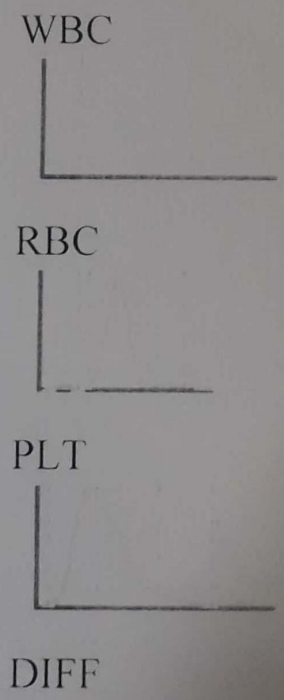
Site : Date : 6/8/21

Item

Sample No. P00 Rack: Tube: 2021/08/06 20:57:35

Ward: Dr.:

WBC	5.75	[10^3/uL]		
RBC	5.17	[10^6/uL]		
HGB	12.9	[g/dL]		
HCT	39.7	[%]		
MCV	76.8	[fL]		
MCH	25.0	[pg]		
MCHC	32.5	[g/dL]		
PLT	290	[10^3/uL]		
RDW-SD	34.4	[fL]		
RDW-CV	12.6	[%]		
PDW	12.5	[fL]		
MPV	11.2	[fL]		
P-LCR	34.9	[%]		
PCT	0.33	[%]		
NEUT	3.60	[10^3/uL]	62.6	[%]
LYMPH	1.84	[10^3/uL]	32.0	[%]
MONO	0.21	[10^3/uL]	3.7	[%]
EO	0.06	[10^3/uL]	1.0	[%]
BASO	0.04	[10^3/uL]	0.7	[%]

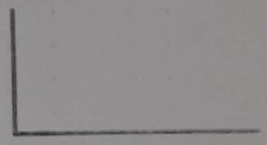


Sample No. P01 Rack: Tube: 2021/08/06 20:59:03

Ward: Dr.:

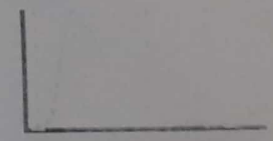
WBC	5.55	[10^3/uL]		
RBC	5.20	[10^6/uL]		
HGB	13.0	[g/dL]		
HCT	39.8	[%]		
MCV	76.5	[fL]		
MCH	25.0	[pg]		
MCHC	32.7	[g/dL]		
PLT	292	[10^3/uL]		
RDW-SD	34.2	[fL]		
RDW-CV	12.4	[%]		
PDW	13.3	[fL]		
MPV	11.3	[fL]		
P-LCR	35.2	[%]		
PCT	0.33	[%]		
NEUT	3.44	[10^3/uL]	62.0	[%]
LYMPH	1.81	[10^3/uL]	32.6	[%]
MONO	0.21	[10^3/uL]	3.8	[%]
EO	0.06	[10^3/uL]	1.1	[%]
BASO	0.03	[10^3/uL]	0.5	[%]

WBC



RBC

PLT

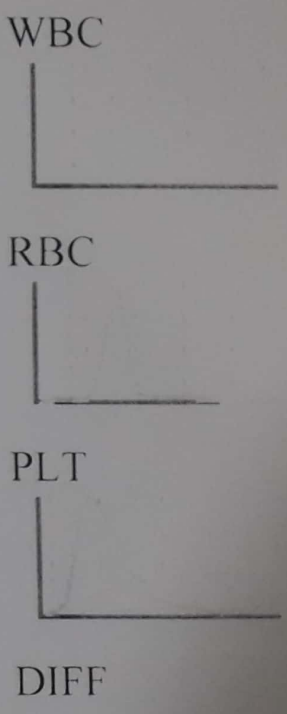


DIFF

Sample No. P02 Rack: Tube: 2021/08/06 21:00:10

Ward: Dr.:

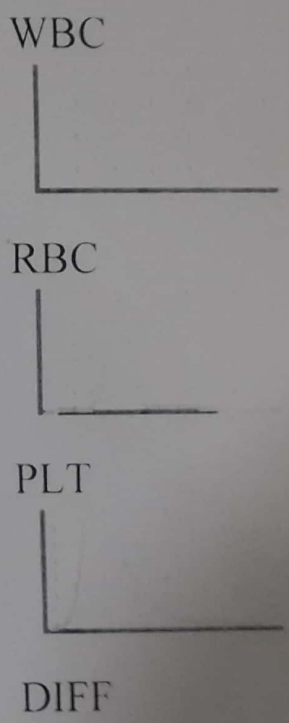
WBC	5.60	[10^3/uL]		
RBC	5.29	[10^6/uL]		
HGB	13.0	[g/dL]		
HCT	40.4	[%]		
MCV	76.4	[fL]		
MCH	24.6	[pg]		
MCHC	32.2	[g/dL]		
PLT	285	[10^3/uL]		
RDW-SD	34.2	[fL]		
RDW-CV	12.4	[%]		
PDW	13.3	[fL]		
MPV	11.3	[fL]		
P-LCR	35.3	[%]		
PCT	0.32	[%]		
NEUT	3.46	[10^3/uL]	61.8	[%]
LYMPH	1.79	[10^3/uL]	32.0	[%]
MONO	0.22	[10^3/uL]	3.9	[%]
EO	0.08	[10^3/uL]	1.4	[%]
BASO	0.05	[10^3/uL]	0.9	[%]



Sample No. P03 Rack: Tube: 2021/08/06 21:01:10

Ward: Dr.:

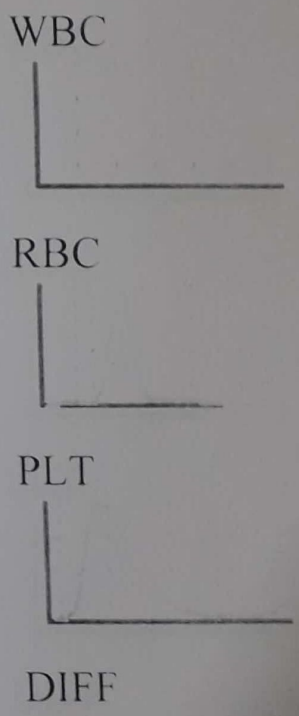
WBC	5.66	[10^3/uL]		
RBC	5.19	[10^6/uL]		
HGB	12.8	[g/dL]		
HCT	39.7	[%]		
MCV	76.5	[fL]		
MCH	24.7	[pg]		
MCHC	32.2	[g/dL]		
PLT	293	[10^3/uL]		
RDW-SD	34.1	[fL]		
RDW-CV	12.4	[%]		
PDW	13.8	[fL]		
MPV	11.4	[fL]		
P-LCR	36.1	[%]		
PCT	0.33	[%]		
NEUT	3.54	[10^3/uL]	62.6	[%]
LYMPH	1.81	[10^3/uL]	32.0	[%]
MONO	0.21	[10^3/uL]	3.7	[%]
EO	0.07	[10^3/uL]	1.2	[%]
BASO	0.03	[10^3/uL]	0.5	[%]



Sample No. P04 Rack: Tube: 2021/08/06 21:02:18

Ward: Dr.:

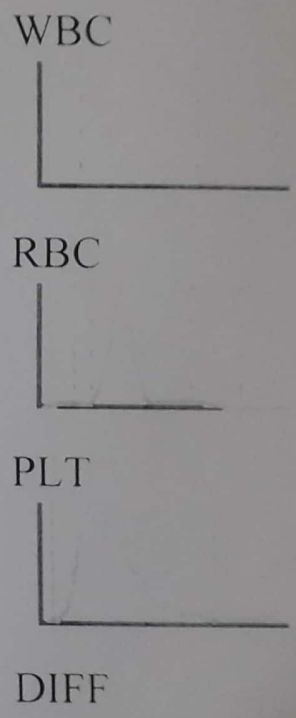
WBC	5.87	[10^3/uL]		
RBC	5.22	[10^6/uL]		
HGB	12.9	[g/dL]		
HCT	39.8	[%]		
MCV	76.2	[fL]		
MCH	24.7	[pg]		
MCHC	32.4	[g/dL]		
PLT	285	[10^3/uL]		
RDW-SD	33.8	[fL]		
RDW-CV	12.3	[%]		
PDW	13.3	[fL]		
MPV	11.2	[fL]		
P-LCR	34.2	[%]		
PCT	0.32	[%]		
NEUT	3.60	[10^3/uL]	61.3	[%]
LYMPH	1.92	[10^3/uL]	32.7	[%]
MONO	0.22	[10^3/uL]	3.7	[%]
EO	0.08	[10^3/uL]	1.4	[%]
BASO	0.05	[10^3/uL]	0.9	[%]



Sample No. P05 Rack: Tube: 2021/08/06 21:03:26

Ward: Dr.:

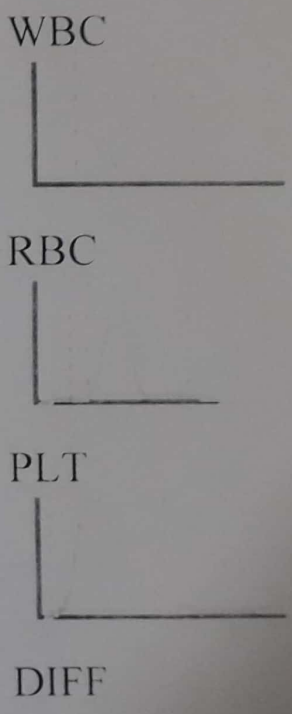
WBC	5.56	[10^3/uL]		
RBC	5.19	[10^6/uL]		
HGB	12.8	[g/dL]		
HCT	39.6	[%]		
MCV	76.3	[fL]		
MCH	24.7	[pg]		
MCHC	32.3	[g/dL]		
PLT	287	[10^3/uL]		
RDW-SD	34.1	[fL]		
RDW-CV	12.4	[%]		
PDW	13.1	[fL]		
MPV	11.2	[fL]		
P-LCR	35.6	[%]		
PCT	0.32	[%]		
NEUT	3.38	[10^3/uL]	60.8	[%]
LYMPH	1.85	[10^3/uL]	33.3	[%]
MONO	0.22	[10^3/uL]	4.0	[%]
EO	0.08	[10^3/uL]	1.4	[%]
BASO	0.03	[10^3/uL]	0.5	[%]



Sample No. P06 Rack: Tube: 2021/08/06 21:04:29

Ward: Dr.:

WBC	5.72	[10^3/uL]		
RBC	5.24	[10^6/uL]		
HGB	12.8	[g/dL]		
HCT	40.0	[%]		
MCV	76.3	[fL]		
MCH	24.4	[pg]		
MCHC	32.0	[g/dL]		
PLT	281	[10^3/uL]		
RDW-SD	34.4	[fL]		
RDW-CV	12.5	[%]		
PDW	12.9	[fL]		
MPV	11.2	[fL]		
P-LCR	35.4	[%]		
PCT	0.31	[%]		
NEUT	3.55	[10^3/uL]	62.2	[%]
LYMPH	1.82	[10^3/uL]	31.8	[%]
MONO	0.22	[10^3/uL]	3.8	[%]
EO	0.10	[10^3/uL]	1.7	[%]
BASO	0.03	[10^3/uL]	0.5	[%]

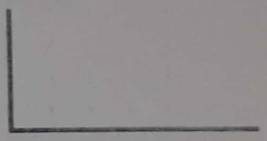


Sample No. P07 Rack: Tube: 2021/08/06 21:05:40

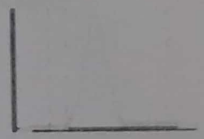
Ward: Dr.:

WBC	5.58	[10^3/uL]		
RBC	5.26	[10^6/uL]		
HGB	12.8	[g/dL]		
HCT	40.0	[%]		
MCV	76.0	[fL]		
MCH	24.3	[pg]		
MCHC	32.0	[g/dL]		
PLT	295	[10^3/uL]		
RDW-SD	34.2	[fL]		
RDW-CV	12.4	[%]		
PDW	13.9	[fL]		
MPV	11.4	[fL]		
P-LCR	36.1	[%]		
PCT	0.33	[%]		
NEUT	3.44	[10^3/uL]	61.7	[%]
LYMPH	1.78	[10^3/uL]	31.9	[%]
MONO	0.24	[10^3/uL]	4.3	[%]
EO	0.08	[10^3/uL]	1.4	[%]
BASO	0.04	[10^3/uL]	0.7	[%]

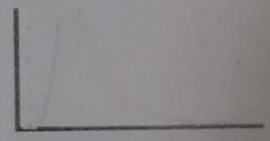
WBC



RBC



PLT

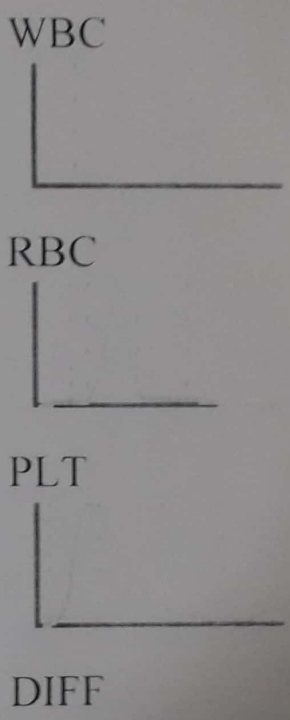


DIFF

Sample No. P08 Rack: Tube: 2021/08/06 21:06:44

Ward: Dr.:

WBC	5.62	[10^3/uL]		
RBC	5.22	[10^6/uL]		
HGB	12.8	[g/dL]		
HCT	39.7	[%]		
MCV	76.1	[fL]		
MCH	24.5	[pg]		
MCHC	32.2	[g/dL]		
PLT	291	[10^3/uL]		
RDW-SD	34.0	[fL]		
RDW-CV	12.4	[%]		
PDW	13.4	[fL]		
MPV	11.3	[fL]		
P-LCR	35.6	[%]		
PCT	0.33	[%]		
NEUT	3.48	[10^3/uL]	62.0	[%]
LYMPH	1.75	[10^3/uL]	31.1	[%]
MONO	0.25	[10^3/uL]	4.4	[%]
EO	0.10	[10^3/uL]	1.8	[%]

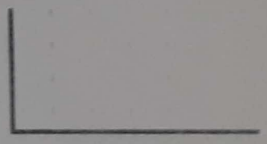


Sample No. P09 Rack: Tube: 2021/08/06 21:07:57

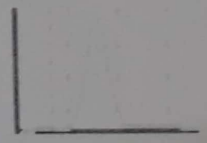
Ward: Dr.:

WBC	5.65	[10^3/uL]		
RBC	5.30	[10^6/uL]		
HGB	13.0	[g/dL]		
HCT	40.2	[%]		
MCV	75.8	[fL]		
MCH	24.5	[pg]		
MCHC	32.3	[g/dL]		
PLT	290	[10^3/uL]		
RDW-SD	34.0	[fL]		
RDW-CV	12.5	[%]		
PDW	13.3	[fL]		
MPV	11.2	[fL]		
P-LCR	34.9	[%]		
PCT	0.33	[%]		
NEUT	3.44	[10^3/uL]	60.9	[%]
LYMPH	1.84	[10^3/uL]	32.6	[%]
MONO	0.24	[10^3/uL]	4.2	[%]
EO	0.09	[10^3/uL]	1.6	[%]
BASO	0.04	[10^3/uL]	0.7	[%]

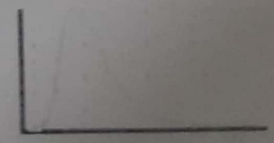
WBC



RBC



PLT



DIFF

Sample No. P10 Rack: Tube: 2021/08/06 21:08:59

Ward: Dr.:

WBC	5.67	[10^3/uL]		
RBC	5.29	[10^6/uL]		
HGB	13.0	[g/dL]		
HCT	40.1	[%]		
MCV	75.8	[fL]		
MCH	24.6	[pg]		
MCHC	32.4	[g/dL]		
PLT	296	[10^3/uL]		
RDW-SD	34.3	[fL]		
RDW-CV	12.5	[%]		
PDW	13.0	[fL]		
MPV	11.4	[fL]		
P-LCR	35.5	[%]		
PCT	0.34	[%]		
NEUT	3.46	[10^3/uL]	61.0	[%]
LYMPH	1.81	[10^3/uL]	31.9	[%]
MONO	0.23	[10^3/uL]	4.1	[%]
EO	0.12	[10^3/uL]	2.1	[%]
BASO	0.05	[10^3/uL]	0.9	[%]