INSTALLATION QUALIFICATION

For

TRANSASIA

ERBA H560
AUTOMATED HEAMATOLOGY ANALYZER

Transasia Bio-Medicals Ltd. Guwahati

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

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	Automated Hematology Analyzer	Instrument ID	K11041952097	

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Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
INSTALLATION QUALIFICATION			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

TRANSASIA® Bio-Medicals Ltd.

I. Approval of the IQ procedure:

Pasteur Institute and Transasia are jointly responsible for the installation of the system ERBA HEMATOLOGY Analyzer, Model: H560, Serial No. K11041952097 in the clinical lab of Pasteur Institute as per the attached protocol.

Protocol Performed By: **Transasia Representative**

Name : Taraknath Chakraborty Signature: TC
Title : **INSTALLATIONQUALIFICATION**
Company : **TRANSASIA BIO-MEDICALS LTD.** Date: 21/9/21

Validation Team from TBM:

Name : Taraknath Chakraborty
Designation : RSM
Department : TSD

Customer Authorizations:

Name :
Title : **INSTALLATION QUALIFICATION**
Site :

Signature :

Date :

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

II. Instructions

1. This document is to be completed at the time the system is shifted to its current location 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 Pasteur Institute 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

III. Scope

This Installation Qualification protocol will be performed on the ERBA Hematology Analyzer, Model H560, Serial No. K11041952097 located in Pasteur Institute, Shillong, Meghalaya. 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
INSTALLATION QUALIFICATION			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

TRANSASIA® Bio-Medicals Ltd.

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 – 30 °C, relative humidity 30% to 85%, 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 360 X D 410 X H 475 for the main unit clearance of around 50 cm from back around 50cm on top and around 50 cm on sides for the main unit)	Yes / No	21/9/21	
3.	DIL-H560; LYSE1 & LYSE2 BOTTLES to be placed within a distance of 2 meters :	Yes / No		
4.	Power Source Requirements* It should have minimum five 5amps plug. It should have proper grounding. In case of online UPS minimum power handling capacity should be minimum 1KVA Line- Neutral voltage:_____ Line –Earth voltage:_____ Neutral-Earth voltage:_____	Yes / No		

* Encircle applicable source

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
INSTALLATION QUALIFICATION			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

TRANSASIA® Bio-Medicals Ltd.

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

c. The instrument has been verified for the following

Sr.No.	Verification		Verified By	Date
1.	Instrument is identified	Yes / No	TC	21/9/21
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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	Automated Hematology Analyzer	Instrument ID	K11041952097	

V. Installation Qualification

A. Equipment Description

This ERBA H560 is a fully automated five part Hematology analyzer for in vitro diagnostic use in clinical laboratories. The instrument provides accurate and precise test results for all parameters including three histograms & one scatter- grams.

Instrument identification		Verified by	Date
Equipment Name	Automated Hematology		
Model	H560		
Manufacturer	Erba Mannheim		
Marketed By	Transasia		
Equipment #	H560		
Serial Number	K11041952097		
Size (in mm)	W 360 X D 410 X H 475		
Power	AC 220 V		
Frequency	50 – 60 Hz		
Power Consumption	Less Than 250 VA		

TC 21/9/21

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
INSTALLATION QUALIFICATION			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

TRANSASIA® Bio-Medicals Ltd.

B. Accessories / Consumables

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
INSTALLATION QUALIFICATION			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

TRANSASIA® Bio-Medicals Ltd.

Installation Qualification

Consumables such as H-Clean, DIL H560, LYSE1 & LYSE2 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. Instructions For use
2. User's Guide

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 Pasteur Institute

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 User Manual.

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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

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.

C. Equipment Logs

Title	Location	Verified by	Date

Sample page of the logbook is attached to this document

Effective date:

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
INSTALLATION QUALIFICATION			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

TRANSASIA® Bio-Medicals Ltd.

H. Installation Procedure

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

1. **Unpacking Checklist**
   Refer to Page-16 of ERBA H560 Instruction For Use

2. **Check Before Installation**
   Refer to Page-14 of ERBA H560 Instruction For Use

3. **Grounding**
   Refer to Page-14 of ERBA H560 Instruction For Use

4. **Installation Environment & Space**
   Refer to Page-14 of ERBA H560 Instruction For Use

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
INSTALLATION QUALIFICATION			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

TRANSASIA® Bio-Medicals Ltd.

COMMENTS:

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
INSTALLATION QUALIFICATION			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

TRANSASIA® Bio-Medicals Ltd.

VII. 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 : Taraknath Chakraborty

Title : **INSTALLATION QUALIFICATION** Signature : TC

Company: **TRANSASIA BIO-MEDICALS LTD.** Date : 21/9/21

Customer Authorizations:

Name :

Title : INSTALLATION QUALIFICATION Signature:

Company : Date :

Name :

Title : INSTALLATION QUALIFICATION Signature:

Company: Date :

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
INSTALLATION QUALIFICATION			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

TRANSASIA® Bio-Medicals Ltd.

Date: 21/9/21

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: TC Checked by

Date: 21/9/21

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	Automated Hematology Analyzer	Instrument ID	K11041952097	

OPERATIONAL QUALIFICATION

For

TRANSASIA

ERBA H560
AUTOMATED HEMATOLOGY ANALYZER

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

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

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Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

I. Approval of the OQ procedure:

Pasteur Institute and Transasia are jointly responsible for operational check of the HEMATOLOGY Analyzer, Model: Erba H560, serial no. K11041952097 in the clinical lab of Pasteur Institute as per protocol attached.

Protocol Performed by: **Transasia Representative**

Name : Taraknath Chakraborty
Title : **OPERATIONAL QUALIFICATION**
Company : **TRANSASIA BIO-MEDICALS LTD.**

Signature : TC
Date : 21/9/21

Validation Team from : TBM

Name : Taraknath Chakraborty
Designation :RSM
Department : TSD

Customer Authorization:

Name :
Title : OPERATIONAL QUALIFICATION
Site :

Signature :
Date :

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

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 Pasteur Institute 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model H560, Serial No. K11041952097 located in Pasteur Institute, Shillong, Meghalaya (city/state or prefecture). 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

IV. Operational Qualification

a. Instrument Identification **Verified Date**

1. Model Name H560
2. Serial Number K11041952097

21/9/21
21/9/21

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

Test No.	Test Name	Test Purpose	Verified Date
1.	Liquid Pump	To verify pressure & vacuum generation	21/9/21
2.	Syringe Assembly	Capacity of Blood Aspiration Diluent Aspiration, Lyse 1& 2 Aspiration	
3.	Liquid Sensing PCB	To verify Liquid sensing ability Of sensors	

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	Automated Hematology Analyzer	Instrument ID	K11041952097	

c. Operational Testing

Test 1

Test Name : Liquid Pump.

Purpose : To test Liquid Pump

Method :Please follow the steps described in Erba H560 "Service Manual"

	PARAMETER	PASS	FAIL
Parameter values for verification :	LIQUID PUMP	✓	

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name	Automated Hematology Analyzer	Instrument ID	K11041952097

TRANSASIA® Bio-Medicals Ltd.

Test 2

Test Name : Syringe Assly

Purpose : To test function

Method : Please follow the steps described in Erba H560 "Service Manual"

	PARAMETER	PASS	FAIL
Parameter values for verification :	Syringe Assly	✓	

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	Automated Hematology Analyzer	Instrument ID	K11041952097	

Test 3

Test Name : Liquid sensing PCB

Purpose : To test the liquid sensing operation.

Method : Please follow the steps described in Erba H560 "Service Manual"

	PARAMETER	PASS	FAIL
Parameter values for verification :	Liquid Sensing	✓	

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/24

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

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. Taraknath Chakraborty 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

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

b. Customer SOP

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

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

COMMENTS:

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

TRANSASIA Bio-Medicals Ltd.

VII. 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 : Taraknath Chakraborty

Title : OPERATIONAL QUALIFICATION Signature : TC

Company : TRANSASIA BIO-MEDICALS LTD. Date : 21/9/22

Customer Authorizations:

Name :

Title : OPERATIONAL QUALIFICATION Signature :

Company : Date :

Name :

Title : OPERATIONAL QUALIFICATION Signature :

Company : Date :

Transasia Bio-Medicals Ltd. Guwahati

ERBA– H560
AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

Transasia Bio-Medicals Ltd. Guwahati

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

Table of Contents:

Transasia Bio-Medicals Ltd. Guwahati

I. Approval of the PQ procedure

Both Pasteur Institute and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer,Model : ERBA – H560, Serial No K11041952097. in the clinical lab of Pasteur Institute as per the attached protocol.

Protocol Performed By: **Transasia Representative**

Name : Taraknath Chakraborty
Title : **PERFORMANCE QUALIFICATION**
Company : **TRANSASIA BIO-MEDICALS LTD.**

Signature: TC
Date: 21/9/21

Customer Authorizations:

Name :
Title : PERFORMANCE QUALIFICATION
Site :

Signature:
Date:

Name :
Title : PERFORMANCE QUALIFICATION
Site :

Signature:
Date:

Transasia Bio-Medicals Ltd. Guwahati

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 Pasteur Institute 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/22

Transasia Bio-Medicals Ltd. Guwahati

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model ERBA -H560, Serial No K11041952097 located in Pasteur Institute Shillong, Meghalaya (city/state or prefecture). 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

IV. Performance Qualification

a. Instrument Identification **Verified Date**

1. Model Name ERBA – H560
2. Serial Number K11041952097

21/9/21
21/9/21

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	21/9/21
03	Further Performance Checks	Regular Maintenance	NA

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

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.				
2.				
3.				
4.				
5.				

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
PERFORMANCE QUALIFICATION			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**

WBC Count:

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

Hemoglobin:

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

HCT:

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

Platelet Count:

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

Transasia Bio-Medicals Ltd. Guwahati

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 21/9/21

Transasia Bio-Medicals Ltd. Guwahati

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 : Taraknath Chakraborty

Title : PERFORMANCE QUALIFICATION Signature: TC

Company: TRANSASIA BIO-MEDICALS LTD. Date: 21/9/21

Customer Authorizations:

Name :

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date :

Name :

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date :

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
PERFORMANCE QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041952097**	

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	Automated Hematology Analyzer	Instrument ID	K11041B2312034	

OPERATIONAL QUALIFICATION

For

TRANSASIA

ERBA H560
AUTOMATED HEMATOLOGY ANALYZER

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

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041B2312034**	

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Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041B2312034**	

I. Approval of the OQ procedure:

Pasteur Institute and Transasia are jointly responsible for operational check of the HEMATOLOGY Analyzer, Model: Erba H560, serial no. K1104B2312034 in the clinical lab of Pasteur Institute as per protocol attached.

Protocol Performed by: **Transasia Representative**

Name : Taraknath Chakraborty
Title : **OPERATIONAL QUALIFICATION**
Company : **TRANSASIA BIO-MEDICALS LTD.**

Signature : TC
Date : 22/10/23

Validation Team from : TBM

Name : Taraknath Chakraborty
Designation :RSM
Department : TSD

Customer Authorization:

Name :
Title : OPERATIONAL QUALIFICATION
Site :

Signature :
Date :

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041B2312034**	

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 Pasteur Institute 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041B2312034**	

III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model H560, Serial No. K1104B2312034 located in Pasteur Institute, Shillong, Meghalaya (city/state or prefecture). 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041B2312034**	

IV. Operational Qualification

a. Instrument Identification **Verified Date**

1. Model Name	H560	22/10/23
2. Serial Number	K1104B2312034	22/10/23

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

Test No.	Test Name	Test Purpose	Verified Date
1.	Liquid Pump	To verify pressure & vacuum generation	22/10/23
2.	Syringe Assembly	Capacity of Blood Aspiration Diluent Aspiration, Lyse 1& 2 Aspiration	
3.	Liquid Sensing PCB	To verify Liquid sensing ability Of sensors	

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	Automated Hematology Analyzer	Instrument ID	K11041B2312034	

c. Operational Testing

Test 1

Test Name : Liquid Pump.

Purpose : To test Liquid Pump

Method :Please follow the steps described in Erba H560 "Service Manual"

	PARAMETER	PASS	FAIL
Parameter values for verification :	LIQUID PUMP	✓	

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED			
PASTEUR INSTITUTE, SHILLONG			
OPERATIONAL QUALIFICATION CHECKLIST			
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041B2312034**

TRANSASIA® Bio-Medicals Ltd.

Test 2

Test Name : Syringe Assly

Purpose : To test function

Method : Please follow the steps described in Erba H560 "Service Manual"

	PARAMETER	PASS	FAIL
Parameter values for verification :	Syringe Assly	✓	

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	Automated Hematology Analyzer	Instrument ID	K11041B2312034	

Test 3

Test Name : Liquid sensing PCB

Purpose : To test the liquid sensing operation.

Method : Please follow the steps described in Erba H560 "Service Manual"

	PARAMETER	PASS	FAIL
Parameter values for verification :	Liquid Sensing	✓	

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041B2312034**	

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. Taraknath Chakraborty 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

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041B2312034**	

b. Customer SOP

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

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041B2312034**	

COMMENTS:

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
OPERATIONAL QUALIFICATION CHECKLIST				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K11041B2312034**	

VII. 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 : Taraknath Chakraborty

Title : OPERATIONAL QUALIFICATION Signature : TC

Company : TRANSASIA BIO-MEDICALS LTD. Date : 22/10/23

Customer Authorizations:

Name :

Title : OPERATIONAL QUALIFICATION Signature :

Company : Date :

Name :

Title : OPERATIONAL QUALIFICATION Signature :

Company : Date :

Transasia Bio-Medicals Ltd. Guwahati

ERBA– H560
AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

Transasia Bio-Medicals Ltd. Guwahati

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

Table of Contents:

Transasia Bio-Medicals Ltd. Guwahati

I. Approval of the PQ procedure

Both Pasteur Institute and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer,Model : ERBA – H560, Serial No K1104B2312034. in the clinical lab of Pasteur Institute as per the attached protocol.

Protocol Performed By: **Transasia Representative**

Name : Taraknath Chakraborty
Title : **PERFORMANCE QUALIFICATION**
Company : **TRANSASIA BIO-MEDICALS LTD.**

Signature:
Date: 22/10/23

Customer Authorizations:

Name :
Title : PERFORMANCE QUALIFICATION
Site :

Signature:
Date:

Name :
Title : PERFORMANCE QUALIFICATION
Site :

Signature:
Date:

Transasia Bio-Medicals Ltd. Guwahati

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 Pasteur Institute 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model ERBA -H560, Serial No K1104B2312034 located in Pasteur Institute Shillong, Meghalaya (city/state or prefecture). 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

IV. Performance Qualification

a. Instrument Identification **Verified Date**

1. Model Name	ERBA – H560	22/10/23
2. Serial Number	K1104B2312034	22/10/23

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	22/10/23
03	Further Performance Checks	Regular Maintenance	NA

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

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.				
2.				
3.				
4.				
5.				

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
PERFORMANCE QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

WBC Count:

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

Hemoglobin:

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

HCT:

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

Platelet Count:

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

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

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 : Taraknath Chakraborty

Title : PERFORMANCE QUALIFICATION Signature: TC

Company: TRANSASIA BIO-MEDICALS LTD. Date: 22/10/23

Customer Authorizations:

Name :

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date :

Name :

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date :

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
PERFORMANCE QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

Transasia Bio-Medicals Ltd. Guwahati

INSTALLATION QUALIFICATION

For

TRANSASIA

ERBA H560
AUTOMATED HEAMATOLOGY ANALYZER

Transasia Bio-Medicals Ltd. Guwahati

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

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

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Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

I. Approval of the IQ procedure:

Pasteur Institute and Transasia are jointly responsible for the installation of the system ERBA HEMATOLOGY Analyzer, Model: H560, Serial No. K1104B2312034 in the clinical lab of Pasteur Institute as per the attached protocol.

Protocol Performed By: **Transasia Representative**

Name : Taraknath Chakraborty Signature: TC
Title : **INSTALLATIONQUALIFICATION**
Company : **TRANSASIA BIO-MEDICALS LTD.** Date: 22/10/23

Validation Team from TBM:

Name : Taraknath Chakraborty
Designation : RSM
Department : TSD

Customer Authorizations:

Name :
Title : **INSTALLATION QUALIFICATION**
Site :

Signature :
Date :

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

II. Instructions

1. This document is to be completed at the time the system is shifted to its current location 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 Pasteur Institute 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

III. Scope

This Installation Qualification protocol will be performed on the ERBA Hematology Analyzer, Model H560, Serial No. K1104B2312034 located in Pasteur Institute, Shillong, Meghalaya. 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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

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 – 30 °C, relative humidity 30% to 85%, 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 360 X D 410 X H 475 for the main unit clearance of around 50 cm from back around 50cm on top and around 50 cm on sides for the main unit)	Yes / No		22/10/23
3.	DIL-H560; LYSE1 & LYSE2 BOTTLES to be placed within a distance of 2 meters :	Yes / No		
4.	Power Source Requirements* It should have minimum five 5amps plug. It should have proper grounding. In case of online UPS minimum power handling capacity should be minimum 1KVA Line- Neutral voltage:_____ Line –Earth voltage:_____ Neutral-Earth voltage:_____	Yes / No		

* Encircle applicable source

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

c. The instrument has been verified for the following

Sr.No.	Verification		Verified By	Date
1.	Instrument is identified	Yes / No	TC 22/10/23	
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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

TRANSASIA Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

V. Installation Qualification

A. Equipment Description

This ERBA H560 is a fully automated five part Hematology analyzer for in vitro diagnostic use in clinical laboratories. The instrument provides accurate and precise test results for all parameters including three histograms & one scatter- grams.

Instrument identification		Verified by	Date
Equipment Name	Automated Hematology		
Model	H560		
Manufacturer	Erba Mannheim		
Marketed By	Transasia		
Equipment #	H560		
Serial Number	K1104B2312034		
Size (in mm)	W 360 X D 410 X H 475		
Power	AC 220 V		
Frequency	50 – 60 Hz		
Power Consumption	Less Than 250 VA		

IC 22/10/23

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature IC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

B. Accessories / Consumables

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

Installation Qualification

Consumables such as H-Clean, DIL H560, LYSE1 & LYSE2 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. Instructions For use
2. User's Guide

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 Pasteur Institute

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 User Manual.

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 : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

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.

C. Equipment Logs

Title	Location	Verified by	Date

Sample page of the logbook is attached to this document

Effective date:

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

H. Installation Procedure

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

1. **Unpacking Checklist**
   Refer to Page-16 of ERBA H560 Instruction For Use

2. **Check Before Installation**
   Refer to Page-14 of ERBA H560 Instruction For Use

3. **Grounding**
   Refer to Page-14 of ERBA H560 Instruction For Use

4. **Installation Environment & Space**
   Refer to Page-14 of ERBA H560 Instruction For Use

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

COMMENTS:

Validation Team : TBM

Name: Taraknath Chakraborty

Designation: RSM

Signature TC

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA® Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

VII. 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 : Taraknath Chakraborty

Title : **INSTALLATION QUALIFICATION** Signature : TC

Company: **TRANSASIA BIO-MEDICALS LTD.** Date : 22/10/23

Customer Authorizations:

Name :

Title : INSTALLATION QUALIFICATION Signature:

Company : Date :

Name :

Title : INSTALLATION QUALIFICATION Signature:

Company: Date :

Transasia Bio-Medicals Ltd. Guwahati

TRANSASIA BIOMEDICALS LIMITED				TRANSASIA Bio-Medicals Ltd.
PASTEUR INSTITUTE, SHILLONG				
INSTALLATION QUALIFICATION				
Instrument Name	**Automated Hematology Analyzer**	**Instrument ID**	**K1104B2312034**	

Date: 22/10/23

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: JC Checked by

Date: 22/10/23

Transasia Bio-Medicals Ltd. Guwahati

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: 22.08.2024
Effective Date: 22.08.2024

Certificate of Calibration

Customer Name: Pasteur Institute

Model : Automated Hematology Analyzer H 560

Serial No. K1104B2312034

Calibration Done Date: 22.08.2024

Next Calibration Due Date On or Before: 21.08.2025

Lab In-charge: . Dr. Eva Shadap

This is to certify that the above-mentioned product has been verified of calibration for CBC 5 parameters (WBC, RBC, HGB, MCV and PLT) according to the standard procedures provided by Erba Lachema s.r.o, Karasek.

Calibration at site performed by
Engineer Name : H.Lalit Kumar Singh
Designation : Sr. Application Specialist
Transasia Bio-Medicals Ltd
Location

Transasia Bio-Medicals Ltd. Guwahati

Encl:
1. Certificate of Inspection
2. Assay Sheet of Hematology Calibrator (H Cal)
3. Printouts
4. Traceability Document

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: 22.08.2024
Effective Date: 22.08.2024

Certificate of Inspection

1. Model: Automated Hematology Analyzer H 560

2. Serial No.: K1104B2312034

3. Calibration Date: 22.08.2024

4. Material used: H Cal (Lot No. PLUS 0824, Expiry date: 10-09-2024)

By comparing your data to the results of the standard counters in Erba Lachema, the calibration for CBC 5 parameters using the measurement standard material (H Cal) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

Technical Service Department
Transasia Bio-Medicals Ltd

Transasia Bio-Medicals Ltd. Guwahati

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

5. BACKGROUND CHECK

PARAMETER	RESULT	Range
WBC	0.0	0.3 x 10^3/Ul or Less
RBC	0.00	0.02 x 10^6/uL or Less
HGB	0.0	0.1 g/dL or Less
PLT	0	10 x 10^3/uL or Less

Technical Service Department
Transasia Bio-Medicals Ltd

Transasia Bio-Medicals Ltd. Guwahati

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: background
Run Time: 2024/08/22 11:38
Age:

Parameter	Result	Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	0.00		10^3/uL				
2 RBC	0.00		10^6/uL				
3 HGB	0.0		g/dL				
4 HCT	0.0		%				
5 PLT	0		10^3/uL				

Sample Type:
Microscopic Description:

Exam. Time:

Submitter:
Sampling Time: 2024/08/22 11:38
Report Time: 2024/08/22 14:25

Operator: admin
Delivery Time: 2024/08/22 11:38
Remarks:

Approver:
Validated Time:

*The Report is responsible for this sample only. If you have any questions,please contact us in 24 hours.

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

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

SMP NO	WBC	RBC	HGB	MCV	PLT
2	6.29	4.58	14.3	91.4	225
3	6.05	4.55	14.1	91.3	226
4	6.13	4.52	14.1	91.4	224
5	6.28	4.53	14	91.2	215
6	6.25	4.56	14.2	91.2	215
7	6.32	4.63	14.4	91.2	222
8	6.22	4.55	14.1	91.4	209
9	6.38	4.61	14.3	91.3	210
10	6.23	4.58	14.1	91.3	216
11	6.32	4.62	14.3	91.3	216
Mean	6.25	4.57	14.19	91.30	217.80
SD	0.10	0.04	0.13	0.08	6.11
CV%	**1.55**	**0.82**	**0.91**	**0.09**	**2.80**
Acceptable CV%	Within 3.5%	Within 2.0%	Within 1.5%	Within 2.0%	Within 6.0%
Result	**PASS**	**PASS**	**PASS**	**PASS**	**PASS**

Technical Service Department
Transasia Bio Medicals Ltd

Transasia Bio-Medicals Ltd. Guwahati

Erba Mannheim

Calibrator

Lot No.: PLUS0824 Exp. Date: 2024/09/10

Cal. Mode: Whole Blood Print Time: 2024/08/22 15:06:09

Para.	WBC	RBC	HGB	MCV	PLT
Target	9.59	4.52	13.2	90.0	255
√1	9.11	4.43	13.1	82.9	241
√2	9.24	4.47	13.1	83.2	242
√3	9.04	4.45	13.1	83.2	245
√4	9.06	4.48	13.1	83.2	236
√5	9.20	4.47	13.1	83.3	232
√6	9.05	4.52	13.2	83.5	240
√7	9.17	4.50	13.2	83.2	234
√8	9.24	4.51	13.2	83.3	238
√9	9.06	4.50	13.2	83.3	233
√10	9.06	4.53	13.2	83.2	236
Mean	9.123	4.486	13.15	83.23	237.7
CV(%)	0.9	0.7	0.4	0.2	1.8
New Cal. Coefficient (%)	105.12	100.76	100.38	108.13	107.28
Original Cal. Coefficient (%)	100.00	100.00	100.00	100.00	100.00

ELite H CAL

Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

Assay values
Atestované hodnoty / Valores de la media

LOT PLUS0824

2024-09-10

CE IVD

Name Název Nombre	Cat. No. Kat.č. No.Cat.	Package volume Objem balení Volumen
ELite H CAL	HEM00027	3 ml

Before using refer to the instruction sheet for mixing directions. Calibration errors may result if instructions are not followed exactly.
Před použitím čtěte návod. Nepřesný postup kalibrace může způsobit chybné výsledky stanovení.
Lea las instrucciones de mezclado antes de usar. Los errores de calibración pueden surgir si no se siguen las instrucciones exactamente.

Instrument Analyzátor Instrumento	Parameter Analyt Analito	Unit Jednotka Unidad	Assigned Value Hodnota Valor	Deviation Odchylka Desviación
ELite 580 (SW A10.4 or higher)	WBC	$x10^9/L$	9.62	± 0.20
	RBC	$x10^{12}/L$	4.57	± 0.08
	HGB	g/L	134	± 2
		g/dL	13.4	± 0.2
	MCV	fL	88.9	± 2.0
	PLT	$x10^9/L$	248	± 12
H560 (SW A12.2 or higher; version A only)	WBC	$x10^9/L$	9.36	± 0.20
	RBC	$x10^{12}/L$	4.54	± 0.08
	HGB	g/L	133	± 2
		g/dL	13.3	± 0.2
	MCV	fL	92.8	± 2.0
	PLT	$x10^9/L$	247	± 12
H560 (SW B1.0 or higher)	WBC	$x10^9/L$	9.59	± 0.20
	RBC	$x10^{12}/L$	4.52	± 0.08
	HGB	g/L	132	± 2
		g/dL	13.2	± 0.2
	MCV	fL	90.0	± 2.0
	PLT	$x10^9/L$	255	± 12
H360	WBC	$x10^9/L$	9.58	± 0.20
	RBC	$x10^{12}/L$	4.79	± 0.08
	HGB	g/L	136	± 2
		g/dL	13.6	± 0.2
	MCV	fL	91.2	± 2.0
	PLT	$x10^9/L$	245	± 12

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ

Date of Issue / Datum vydání / Fecha de emisión: 22. 7. 2024
HEMA/PI/31-A/23/A

Erba Lachema s.r.o.

TRACEABILITY

ELite H CAL
HEM00027

LOT: PLUS0824
EXP.: 2024-09-10

Erba Lachema s.r.o., Karásek 1d, 621 00 Brno hereby certifies the traceability of the assigned values of the product listed below to a reference material.

Assignment of Reference Values to Fresh Whole Blood

Haematology Calibrator values are traceable to standard reference methods.

Haematology analysers in the Quality Assurance Laboratory of the Supplier are whole blood calibrated to values obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analysed within six hours of collection.

The **White Blood Cell (WBC)** and **Red Blood Cell (RBC)** are analysed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

Hemoglobin is measured using the Clinical Laboratory Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method[1]. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations [1].

On some instruments **Mean Cell Volume (MCV)** is the calibrated parameter instead of the HCT. The MCV is calculated from the HCT and RBC using the formula: MCV = HCT × 10/RBC

The **hematocrit** (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document [2]. No correction is made for trapped plasma.

Platelets are assayed using a haemocytometer and phase contrast optics.

Determination of uncertainty

Uncertainty is an estimate of the range in which the true value of a reported result may occur.

The uncertainty associated with the calibration of the H360, H560 and ELite 580 analyser using the ELite H CAL calibrator has been estimated by adding the following sources of uncertainty:

- Uncertainty of the equipment used to determine the reference values: flask, pipette, single aperture impedance counter (WBC, RBC), Haemocytometer by phase-contrast (PLT), spectrophotometer (HGB), and ruler (HCT).
- Uncertainty of the haematology analyser when calibrating with the ELite H CAL.

Table 1: Assignment results and uncertainty of reference method

	Reference	WBC (10^9/L)	RBC (10^{12}/L)	HGB (g/L)	MCV (fL)	PLT (10^9/L)
H360	Calibrator	9.58	4.79	136	91.2	245
	Relative expansion Uncertainty %	3.1	2.9	2.9	3.6	6.9
H560 (SW A12.2 or higher; version A only)	Calibrator	9.36	4.54	133	92.8	247
	Relative expansion Uncertainty %	2.9	2.7	2.5	3.7	6.8
H560 (SW B1.0 or higher)	Calibrator	9.59	4.52	132	90	255
	Relative expansion Uncertainty %	2.7	2.6	2.7	3.5	6.7
ELite 580 (SW A10.4 or higher)	Calibrator	9.62	4.57	134	88.9	248
	Relative expansion Uncertainty %	2.8	2.6	2.4	3.5	6.5

The reported expanded uncertainty in Table 1 is based on a standard uncertainty multiplied by a coverage factor of k=2 providing a level of confidence of approximately 95%.

Technical Product Management

Erba Lachema s.r.o.

Brno 24.07.2024

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 1
Run Time: 2024/08/22 14:27
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	5.99		3.50-9.50	10^3/uL				
2 RBC	4.54		3.80-5.80	10^6/uL				
3 HGB	14.1		11.5-17.5	g/dL				
4 HCT	41.5		35.0-50.0	%				
5 MCV	91.3		82.0-100.0	fL				
6 MCH	30.9		27.0-34.0	pg				
7 MCHC	33.9		31.6-35.4	g/dL				
8 RDW-CV	12.6		11.0-16.0	%				
9 RDW-SD	47.0		35.0-56.0	fL				
10 *Mentzr	20.11							
11 *RDWI	252.73							
12 PLT	226		125-350	10^3/uL				
13 MPV	12.7	↑	6.5-12.0	fL				
14 PDW-SD	19.1	↑	9.0-17.0	fL				
15 PDW-CV	16.4		10.0-17.9	%				
16 PCT	0.287	↑	0.108-0.282	%				
17 P-LCR	56.6	↑	11.0-45.0	%				
18 P-LCC	128	↑	30-90	10^3/uL				

Sample Type:
Microscopic Description:

Exam. Time:

Submitter:
Operator: admin
Approver:
Sampling Time: 2024/08/22 14:27
Delivery Time: 2024/08/22 14:27
Validated Time:
Report Time: 2024/08/22 14:28
Remarks:

The Report is responsible for this sample only. If you have any questions,please contact us in 24 hours.

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 2
Run Time: 2024/08/22 14:28
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	6.29		3.50-9.50	10^3/uL				
2 RBC	4.58		3.80-5.80	10^6/uL				
3 HGB	14.3		11.5-17.5	g/dL				
4 HCT	41.9		35.0-50.0	%				
5 MCV	91.4		82.0-100.0	fL				
6 MCH	31.3		27.0-34.0	pg				
7 MCHC	34.2		31.6-35.4	g/dL				
8 RDW-CV	12.4		11.0-16.0	%				
9 RDW-SD	46.3		35.0-56.0	fL				
10 *Mentzr	19.94							
11 *RDWI	247.42							
12 PLT	225		125-350	10^3/uL				
13 MPV	12.0		6.5-12.0	fL				
14 PDW-SD	17.6	↑	9.0-17.0	fL				
15 PDW-CV	15.9		10.0-17.9	%				
16 PCT	0.271		0.108-0.282	%				
17 P-LCR	53.1	↑	11.0-45.0	%				
18 P-LCC	120	↑	30-90	10^3/uL				

Sample Type:
Microscopic Description:

Exam. Time:

Submitter:
Sampling Time: 2024/08/22 14:28
Report Time: 2024/08/22 14:29

Operator: admin
Delivery Time: 2024/08/22 14:28
Remarks:

Approver:
Validated Time:

***The Report is responsible for this sample only. If you have any questions,please contact us in 24 hours.**

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 3
Run Time: 2024/08/22 14:29
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	6.05		3.50-9.50	10^3/uL				
2 RBC	4.55		3.80-5.80	10^6/uL				
3 HGB	14.1		11.5-17.5	g/dL				
4 HCT	41.5		35.0-50.0	%				
5 MCV	91.3		82.0-100.0	fL				
6 MCH	31.0		27.0-34.0	pg				
7 MCHC	33.9		31.6-35.4	g/dL				
8 RDW-CV	12.2		11.0-16.0	%				
9 RDW-SD	45.4		35.0-56.0	fL				
10 *Mentzr	20.07							
11 *RDWI	244.36							
12 PLT	226		125-350	10^3/uL				
13 MPV	12.5	↑	6.5-12.0	fL				
14 PDW-SD	18.4	↑	9.0-17.0	fL				
15 PDW-CV	15.8		10.0-17.9	%				
16 PCT	0.283	↑	0.108-0.282	%				
17 P-LCR	56.0	↑	11.0-45.0	%				
18 P-LCC	126	↑	30-90	10^3/uL				

Sample Type:
Microscopic Description:

Exam. Time:

Submitter:
Sampling Time: 2024/08/22 14:29
Report Time: 2024/08/22 14:30

Operator: admin
Delivery Time: 2024/08/22 14:29
Remarks:

Approver:
Validated Time:

***The Report is responsible for this sample only. If you have any questions,please contact us in 24 hours.**

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 4
Run Time: 2024/08/22 14:30
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	6.13		3.50-9.50	10^3/uL				
2 RBC	4.52		3.80-5.80	10^6/uL				
3 HGB	14.1		11.5-17.5	g/dL				
4 HCT	41.3		35.0-50.0	%				
5 MCV	91.4		82.0-100.0	fL				
6 MCH	31.3		27.0-34.0	pg				
7 MCHC	34.2		31.6-35.4	g/dL				
8 RDW-CV	12.3		11.0-16.0	%				
9 RDW-SD	46.1		35.0-56.0	fL				
10 *Mentzr	20.23							
11 *RDWI	249.17							
12 PLT	224		125-350	10^3/uL				
13 MPV	12.4	↑	6.5-12.0	fL				
14 PDW-SD	18.8	↑	9.0-17.0	fL				
15 PDW-CV	16.8		10.0-17.9	%				
16 PCT	0.277		0.108-0.282	%				
17 P-LCR	54.6	↑	11.0-45.0	%				
18 P-LCC	122	↑	30-90	10^3/uL				

Sample Type:
Microscopic Description:

Exam. Time:

Submitter:
Sampling Time: 2024/08/22 14:30
Report Time: 2024/08/22 14:31

Operator: admin
Delivery Time: 2024/08/22 14:30
Remarks:

Approver:
Validated Time:

***The Report is responsible for this sample only. If you have any questions,please contact us in 24 hours.**

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 5
Run Time: 2024/08/22 14:32
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	6.28		3.50-9.50	10^3/uL				
2 RBC	4.53		3.80-5.80	10^6/uL				
3 HGB	14.0		11.5-17.5	g/dL				
4 HCT	41.3		35.0-50.0	%				
5 MCV	91.2		82.0-100.0	fL				
6 MCH	31.0		27.0-34.0	pg				
7 MCHC	34.0		31.6-35.4	g/dL				
8 RDW-CV	12.2		11.0-16.0	%				
9 RDW-SD	45.6		35.0-56.0	fL				
10 *Mentzr	20.14							
11 *RDWI	246.44							
12 PLT	215		125-350	10^3/uL				
13 MPV	12.1	↑	6.5-12.0	fL				
14 PDW-SD	17.9	↑	9.0-17.0	fL				
15 PDW-CV	16.2		10.0-17.9	%				
16 PCT	0.261		0.108-0.282	%				
17 P-LCR	53.5	↑	11.0-45.0	%				
18 P-LCC	115	↑	30-90	10^3/uL				

Sample Type:
Microscopic Description:

Exam. Time:

Submitter:
Sampling Time: 2024/08/22 14:32
Report Time: 2024/08/22 14:32

Operator: admin
Delivery Time: 2024/08/22 14:32
Remarks:

Approver:
Validated Time:

***The Report is responsible for this sample only. If you have any questions,please contact us in 24 hours.**

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 6
Run Time: 2024/08/22 14:33
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	**6.25**		**3.50-9.50**	**10^3/uL**				
2 RBC	**4.56**		**3.80-5.80**	**10^6/uL**				
3 HGB	14.2		11.5-17.5	g/dL				
4 HCT	41.5		35.0-50.0	%				
5 MCV	91.2		82.0-100.0	fL				
6 MCH	31.1		27.0-34.0	pg				
7 MCHC	34.1		31.6-35.4	g/dL				
8 RDW-CV	12.1		11.0-16.0	%				
9 RDW-SD	45.0		35.0-56.0	fL				
10 *Mentzr	20.00							
11 *RDWI	241.93							
12 PLT	**215**		**125-350**	**10^3/uL**				
13 MPV	12.1	↑	6.5-12.0	fL				
14 PDW-SD	18.5	↑	9.0-17.0	fL				
15 PDW-CV	16.7		10.0-17.9	%				
16 PCT	0.261		0.108-0.282	%				
17 P-LCR	54.1	↑	11.0-45.0	%				
18 P-LCC	116	↑	30-90	10^3/uL				

Sample Type:
Exam. Time:
Microscopic Description:

Submitter:
Operator: admin
Approver:
Sampling Time: 2024/08/22 14:33
Delivery Time: 2024/08/22 14:33
Validated Time:
Report Time: 2024/08/22 14:34
Remarks:

***The Report is responsible for this sample only. If you have any questions,please contact us in 24 hours.**

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 7
Run Time: 2024/08/22 14:34
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	**6.32**		**3.50-9.50**	**10^3/uL**				
2 RBC	**4.63**		**3.80-5.80**	**10^6/uL**				
3 HGB	14.4		11.5-17.5	g/dL				
4 HCT	42.3		35.0-50.0	%				
5 MCV	91.2		82.0-100.0	fL				
6 MCH	31.0		27.0-34.0	pg				
7 MCHC	34.0		31.6-35.4	g/dL				
8 RDW-CV	12.1		11.0-16.0	%				
9 RDW-SD	45.0		35.0-56.0	fL				
10 *Mentzr	19.69							
11 *RDWI	237.94							
12 PLT	**222**		**125-350**	**10^3/uL**				
13 MPV	12.1	↑	6.5-12.0	fL				
14 PDW-SD	18.3	↑	9.0-17.0	fL				
15 PDW-CV	16.3		10.0-17.9	%				
16 PCT	0.269		0.108-0.282	%				
17 P-LCR	53.6	↑	11.0-45.0	%				
18 P-LCC	119	↑	30-90	10^3/uL				

Sample Type:
Microscopic Description:

Exam. Time:

Submitter:
Operator: admin
Approver:
Sampling Time: 2024/08/22 14:34
Delivery Time: 2024/08/22 14:34
Validated Time:
Report Time: 2024/08/22 14:35
Remarks:

***The Report is responsible for this sample only. If you have any questions,please contact us in 24 hours.**

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 8
Run Time: 2024/08/22 14:35
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	6.22		3.50-9.50	10^3/uL				
2 RBC	4.55		3.80-5.80	10^6/uL				
3 HGB	14.1		11.5-17.5	g/dL				
4 HCT	41.6		35.0-50.0	%				
5 MCV	91.4		82.0-100.0	fL				
6 MCH	31.0		27.0-34.0	pg				
7 MCHC	33.9		31.6-35.4	g/dL				
8 RDW-CV	12.3		11.0-16.0	%				
9 RDW-SD	45.9		35.0-56.0	fL				
10 *Mentzr	20.10							
11 *RDWI	246.99							
12 PLT	209		125-350	10^3/uL				
13 MPV	12.2	↑	6.5-12.0	fL				
14 PDW-SD	17.8	↑	9.0-17.0	fL				
15 PDW-CV	16.0		10.0-17.9	%				
16 PCT	0.255		0.108-0.282	%				
17 P-LCR	53.9	↑	11.0-45.0	%				
18 P-LCC	113	↑	30-90	10^3/uL				

Sample Type:
Microscopic Description:

Exam. Time:

Submitter:
Sampling Time: 2024/08/22 14:35
Report Time: 2024/08/22 14:36

Operator: admin
Delivery Time: 2024/08/22 14:35
Remarks:

Approver:
Validated Time:

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Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 9
Run Time: 2024/08/22 14:37
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	**6.38**		**3.50-9.50**	**10^3/uL**				
2 RBC	**4.61**		**3.80-5.80**	**10^6/uL**				
3 HGB	14.3		11.5-17.5	g/dL				
4 HCT	42.1		35.0-50.0	%				
5 MCV	91.3		82.0-100.0	fL				
6 MCH	31.1		27.0-34.0	pg				
7 MCHC	34.0		31.6-35.4	g/dL				
8 RDW-CV	12.1		11.0-16.0	%				
9 RDW-SD	45.2		35.0-56.0	fL				
10 *Mentzr	19.81							
11 *RDWI	240.20							
12 PLT	**210**		**125-350**	**10^3/uL**				
13 MPV	12.2	↑	6.5-12.0	fL				
14 PDW-SD	18.9	↑	9.0-17.0	fL				
15 PDW-CV	16.4		10.0-17.9	%				
16 PCT	0.255		0.108-0.282	%				
17 P-LCR	54.9	↑	11.0-45.0	%				
18 P-LCC	115	↑	30-90	10^3/uL				

Sample Type:
Microscopic Description:

Exam. Time:

Submitter:
Sampling Time: 2024/08/22 14:37
Report Time: 2024/08/22 14:37

Operator: admin
Delivery Time: 2024/08/22 14:37
Remarks:

Approver:
Validated Time:

***The Report is responsible for this sample only. If you have any questions,please contact us in 24 hours.**

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 10
Run Time: 2024/08/22 14:39
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 **WBC**	**6.23**		**3.50-9.50**	**10^3/uL**				
2 **RBC**	**4.58**		**3.80-5.80**	**10^6/uL**				
3 HGB	14.1		11.5-17.5	g/dL				
4 HCT	41.8		35.0-50.0	%				
5 MCV	91.3		82.0-100.0	fL				
6 MCH	30.9		27.0-34.0	pg				
7 MCHC	33.8		31.6-35.4	g/dL				
8 RDW-CV	12.5		11.0-16.0	%				
9 RDW-SD	46.5		35.0-56.0	fL				
10 *Mentzr	19.93							
11 *RDWI	248.76							
12 **PLT**	**216**		**125-350**	**10^3/uL**				
13 MPV	12.6	↑	6.5-12.0	fL				
14 PDW-SD	18.6	↑	9.0-17.0	fL				
15 PDW-CV	16.7		10.0-17.9	%				
16 PCT	0.272		0.108-0.282	%				
17 P-LCR	55.6	↑	11.0-45.0	%				
18 P-LCC	120	↑	30-90	10^3/uL				

Sample Type:
Exam. Time:
Microscopic Description:

Submitter:
Operator: admin
Approver:
Sampling Time: 2024/08/22 14:39
Delivery Time: 2024/08/22 14:39
Validated Time:
Report Time: 2024/08/22 14:40
Remarks:

***The Report is responsible for this sample only. If you have any questions,please contact us in 24 hours.**

Hematology Analysis Report

First Name:
Last Name:
Gender:
Diagnosis:

Sample Type:
Department:
Patient ID:

Sample ID: PRECESSION 11
Run Time: 2024/08/22 14:40
Age:

Parameter	Result		Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	6.32		3.50-9.50	10^3/uL				
2 RBC	4.62		3.80-5.80	10^6/uL				
3 HGB	14.3		11.5-17.5	g/dL				
4 HCT	42.2		35.0-50.0	%				
5 MCV	91.3		82.0-100.0	fL				
6 MCH	31.0		27.0-34.0	pg				
7 MCHC	34.0		31.6-35.4	g/dL				
8 RDW-CV	12.3		11.0-16.0	%				
9 RDW-SD	45.7		35.0-56.0	fL				
10 *Mentzr	19.76							
11 *RDWI	242.18							
12 PLT	216		125-350	10^3/uL				
13 MPV	12.3	↑	6.5-12.0	fL				
14 PDW-SD	18.3	↑	9.0-17.0	fL				
15 PDW-CV	15.8		10.0-17.9	%				
16 PCT	0.265		0.108-0.282	%				
17 P-LCR	54.8	↑	11.0-45.0	%				
18 P-LCC	118	↑	30-90	10^3/uL				

Sample Type:
Microscopic Description:

Exam. Time:

Submitter:
Sampling Time: 2024/08/22 14:40
Report Time: 2024/08/22 14:41

Operator: admin
Delivery Time: 2024/08/22 14:40
Remarks:

Approver:
Validated Time:

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