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TRANSASIA

ERBA H360
AUTOMATED HEAMATOLOGY ANALYZER

INSTALLATION QUALIFICATION

For

" Shree Mahavir Medical Center, Goregaon
Mumbai "

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

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
Tel: +91 22 4030 9000 Fax: +91 22 2857 3030 Email : transasia@transasia.co.in CIN : U33110MH1985PLC036198

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I. Approval of the IQ procedure:

Both Shree Mahavir Medical Centre. and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer,Model : ERBA – H360, Serial No. K10012148006 in the clinical lab of Shree Mahavir Medical Centre as per the attached protocol.

Protocol Performed By: **Transasia Representative**

Name	:	. Mr. Abhijit Tillu
Signature:		
Title	:	INSTALLATIONQUALIFICATION
Company	:	TRANSASIA BIO-MEDICALS LTD.
Date	:	10-12-2023

Transasia Bio Medicals Ltd. Mumbai

Validation Team from ____ Shree Mahavir Medical Centre.

Name	:	Dr. Sapan Godre
Signature	:	
Designation	:	LAB DIRECTOR
Department	:	Pathology
Date	:	10-12-2023

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
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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 Shree Mahavir Medical Centre 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.

The System is ready for specific usage.

Protocol Performed By: **Transasia Representative**

Name : . Mr. Abhijit Tillu

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre.

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
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III. Scope

This Installation Qualification protocol will be performed on the ERBA Hematology Analyzer, Model H360, Serial No. K10012148006 located in Shree Mahavir Medical Centre, Goregaon East. 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.

Protocol Performed By: **Transasia Representative**

Name	:	. Mr. Abhijit Tillu
Signature:		
Title	:	INSTALLATIONQUALIFICATION
Company	:	TRANSASIA BIO-MEDICALS LTD.
Date	:	10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre.

Name	:	Dr. Sapan Godre
Signature	:	
Designation	:	LAB DIRECTOR
Department	:	Pathology
Date	:	10-12-2023

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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 – 30 °C, relative humidity 30% to 85%, air conditioning facility, non exposure to direct sunlight, non-interference from high frequency radio waves)	Yes / No	Yes	10-12-2023
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	Yes	10-12-2023
3.	DIL-H360; LYSE1 BOTTLE to be placed within a distance of 2 meters :	Yes / No	Yes	10-12-2023
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	Yes	10-12-2023

* Encircle applicable source

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The System is ready for specific usage.

Protocol Performed By: **Transasia Representative**

Name : . Mr. Abhijit Tillu

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre.

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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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	Yes	10-12-2023
2.	Manufacturer's specifications are included	Yes / No	Yes	10-12-2023
3.	Accessories / Consumables are listed	Yes / No	Yes	10-12-2023
4.	Manufacturer's certificate of Compliance attached	Yes / No	Yes	10-12-2023

The System is ready for specific usage.

Protocol Performed By: **Transasia Representative**

Name : . Mr. Abhijit Tillu

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre.

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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V. Installation Qualification

A. Equipment Description

This ERBA H360 is a fully automated three part Hematology analyzer for in vitro diagnostic use in clinical laboratories. The instrument provides accurate and precise test results for (22) parameters including three histograms.

Instrument identification		Verified by	Date
Equipment Name	Automated Hematology	Yes	10-12-2023
Model	H360	Yes	10-12-2023
Manufacturer	Erba Mannheim	Yes	10-12-2023
Marketed By	Transasia	Yes	10-12-2023
Equipment #	H360	Yes	10-12-2023
Serial Number	K10012148006	Yes	10-12-2023
Size (in mm)	W 360 X D 410 X H 475	Yes	10-12-2023
Power	AC 220 V	Yes	10-12-2023
Frequency	50 – 60 Hz	Yes	10-12-2023
Power Consumption	Less Than 250 VA	Yes	10-12-2023

The System is ready for specific usage.

Protocol Performed By: Transasia Representative

Name : . Mr. Abhijit Tillu

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre.

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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B. Accessories / Consumables

No.	Name	Quantity	Unit
1	Auto Hematology Analyzer	1	PCS
2	Power Cable	1	PCS
3	Peripheral Grounding Cable	1	PCS
4	Quick Operation Guide	1	PCS
5	Diluent Adapter Tube	1	PCS
6	Waste Float Adapter Tube	1	PCS
7	Waste Container	1	PCS
8	Inspection Record	1	PCS
9	Reagent Operation Guide for Closed System	1	PCS
10	Data Cable	1	PCS
11	Barcode Scanner	1	PCS
12	Operator's Manual	1	PCS
13	Packing List & QC Certificate	1	PCS

The System is ready for specific usage.
Protocol Performed By: Transasia Representative

Name : . Mr. Abhijit Tillu

Signature:

Title : INSTALLATION QUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre.

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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1 Installation Qualification

Consumables such as H-Clean, DIL H360 & LYSE1 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 Shree Mahavir Medical Centre.

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.

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Protocol Performed By: Transasia Representative

Name : . Mr. Abhijit Tillu

Signature:

Title : INSTALLATION QUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre.

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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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
LOG	Shree Mahavir Medical Centre	Yes	10-12-2023

Sample page of the logbook is attached to this document

Effective date : 10-12-2023

Protocol Performed By: **Transasia Representative**

Name : . Mr. Abhijit Tillu

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre.

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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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 H360 Instruction For Use

2. **Check Before Installation**
   Refer to Page-14 of ERBA H360 Instruction For Use

3. **Grounding**
   Refer to Page-15 of ERBA H360 Instruction For Use

4. **Installation Environment & Space**
   Refer to Page-15 of ERBA H360 Instruction For Use

Protocol Performed By: **Transasia Representative**

Name	:	. Mr. Abhijit Tillu
Signature:		
Title	:	INSTALLATIONQUALIFICATION
Company	:	TRANSASIA BIO-MEDICALS LTD.
Date	:	10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre.

Name	:	Dr. Sapan Godre
Signature	:	
Designation	:	LAB DIRECTOR
Department	:	Pathology
Date	:	10-12-2023

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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

Protocol Performed By: **Transasia Representative**

Name : . Mr. Abhijit Tillu

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from Shree Mahavir Medical Centre.

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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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 .

Protocol Performed By: **Transasia Representative**

Name : . Mr. Abhijit Tillu

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre.

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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TRANSASIA

Erba H360
AUTOMATED HEMATOLOGY ANALYZER

OPERATIONAL QUALIFICATION

For

"Shree Mahavir Medical Center, Goregaon Mumbai"

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

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I. Approval of the OQ procedure:

Both Shree Mahavir Medical Centre. and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer,Model : ERBA – H360, Serial No. Model H360, Serial No. K10012148006 located in Shree Mahavir Medical Centre Miraroad East.

Protocol Performed By: **Transasia Representative**

Name	:	. Mr. Abhijit Tillu
Signature:		A. Tillu
Title	:	INSTALLATIONQUALIFICATION
Company	:	TRANSASIA BIO-MEDICALS LTD.
Date	:	10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name	:	Dr. Sapan Godre
Signature	:	
Designation	:	LAB DIRECTOR
Department	:	Pathology
Date	:	10-12-2023

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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 Shree Mahavir Medical Centre 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.

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III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model H360, Serial No. Model H360, Serial No. K10012148006 located in Shree Mahavir Medical Centre Goregaon East. of Mumbai. This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

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

Protocol Performed By: **Transasia Representative**

Name	:	. Mr. Abhijit Tillu
Signature:		A. Tilly
Title	:	INSTALLATIONQUALIFICATION
Company	:	TRANSASIA BIO-MEDICALS LTD.
Date	:	10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name	:	Dr. Sapan Godre
Signature	:	
Designation	:	LAB DIRECTOR
Department	:	Pathology
Date	:	10-12-2023

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IV. Operational Qualification

a. Instrument Identification

		Verified Date
1. Model Name	H360	10-12-2023
2. Serial Number	K10012148006	

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	10-12-2023
2.	Syringe Assembly	Capacity of Blood Aspiration Diluent Aspiration & Lyse 1 Aspiration	10-12-2023
3.	Liquid Sensing PCB	To verify Liquid sensing Ability Of sensors	10-12-2023

Protocol Performed By: **Transasia Representative**

Name : . Mr. Abhijit Tillu

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from _____ Shree Mahavir Medical Centre

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

Department : Pathology

Date : 10-12-2023

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c. Operational Testing

Test 1

Test Name : Liquid Pump.

Purpose : To test Liquid Pump

Method :Please follow the steps described in Erba H360 "Service Manual"

	PARAMETER	PASS / FAIL
Parameter values for verification :	LIQUID PUMP	PASS

Protocol Performed By: Transasia Representative

Name : . Mr. Abhijit Tillu

Signature: A. Tillu

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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Test 2

Test Name : Syringe Assly

Purpose : To test function

Method : Please follow the steps described in Erba H360 "Service Manual"

	PARAMETER	PASS/ FAIL
Parameter values for verification :	Syringe Assly	PASS

Protocol Performed By: Transasia Representative

Name : . Mr. Abhijit Tillu

Signature: A. Tilly

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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Test 3

Test Name : Liquid sensing PCB

Purpose : To test the liquid sensing operation.

Method : Please follow the steps described in Erba H360 "Service Manual"

	PARAMETER	PASS/ FAIL
Parameter values for verification :	Liquid Sensing	PASS

Protocol Performed By: Transasia Representative

Name : . Mr. Abhijit Tillu

Signature: A-Tillu

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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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.Vikrant Pandurang Bargude. who is certified by Transasia Bio-Medicals Ltd has conducted the training.

Sr.No.	Training Program	Initials	Date
1.	Instrument Setup	VB	10-12-2023
2.	System Operation	VB	10-12-2023
3.	Basic Troubleshooting & Maintenance	VB	10-12-2023

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 Certificate is given.

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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.

Protocol Performed By: **Transasia Representative**

Name	:	. Mr. Abhijit Tillu
Signature:		
Title	:	INSTALLATIONQUALIFICATION
Company	:	TRANSASIA BIO-MEDICALS LTD.
Date	:	10-12-2023

Validation Team from Shree Mahavir Medical Centre

Name	:	Dr. Sapan Godre
Signature	:	
Designation	:	LAB DIRECTOR
Department	:	Pathology
Date	:	10-12-2023

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
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ERBA– H360
AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

For

"Shree Mahavir Medical Center, Goregaon
Mumbai"

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., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
Tel: +91 22 4030 9000 **Fax:** +91 22 2857 3030 **Email :** transasia@transasia.co.in **CIN :** U33110MH1985PLC036198

Table of Contents:

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
Tel: +91 22 4030 9000 Fax: +91 22 2857 3030 Email : transasia@transasia.co.in CIN : U33110MH1985PLC036198

I. Approval of the PQ procedure

Both Shree Mahavir Medical Centre.and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer,Model : ERBA – H360, Serial No. K10012148006 in the clinical lab of
Shree Mahavir Medical Centre. as per the attached protocol.

Protocol Performed By: **Transasia Representative**

Name	:	Mr. Vikrant Bargude
Signature:		
Title	:	INSTALLATIONQUALIFICATION
Company	:	TRANSASIA BIO-MEDICALS LTD.
Date	:	10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name	:	Dr. Sapan Godre
Signature	:	
Designation	:	LAB DIRECTOR
Department	:	Pathology
Date	:	10-12-2023

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
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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 Shree Mahavir Medical Centre. 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.

Protocol Performed By: **Transasia Representative**

Name : Mr. Vikrant Bargude

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model ERBA –H360, Serial No. K10012148006 located in Jagjivan Ram Hospital westren railway Pathology. of Mumbai. This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacture's specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

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

Protocol Performed By: **Transasia Representative**

Name	:	Mr. Vikrant Bargude
Signature:		
Title	:	INSTALLATIONQUALIFICATION
Company	:	TRANSASIA BIO-MEDICALS LTD.
Date	:	10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name	:	Dr. Sapan Godre
Signature	:	
Designation	:	LAB DIRECTOR
Department	:	Pathology
Date	:	10-12-2023

IV. Performance Qualification

a. Instrument Identification

1. Model Name ERBA – H360_
2. Serial Number K10012148006

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	10-12-2023
03	Further Performance Checks	Regular Maintenance	NA

Protocol Performed By: **Transasia Representative**

Name : Mr. Vikrant Bargude

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

nsasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
Tel: +91 22 4030 9000 Fax: +91 22 2857 3030 Email : transasia@transasia.co.in CIN : U33110MH1985PLC036198

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.	5.53 -6.13	5.76	PASS	
2.		5.78		
3.		5.83		
4.		5.83		
5.		5.84		

WBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	18.55 -23.55	21.48	PASS	
2.		21.53		
3.		21.83		
4.		21.93		
5.		21.56		

Hemoglobin:

Test	Control Values	Results Obtained	Pass	Fail
1.	17.8-19.4	18.5	PASS	
2.		18.5		
3.		18.5		
4.		18.5		
5.		18.5		

HCT:

Test	Control Values	Results Obtained	Pass	Fail
1.	53.5 – 61.5	59	PASS	
2.		59.2		
3.		59.6		
4.		59.7		
5.		59.2		

Platelet Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	43.9 – 59.9	288	PASS	
2.		284		
3.		289		
4.		291		
5.		287		

Protocol Performed By: **Transasia Representative**

Name : Mr. Vikrant Bargude

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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

Protocol Performed By: **Transasia Representative**

Name : Mr. Vikrant Bargude

Signature:

Title : INSTALLATIONQUALIFICATION

Company : TRANSASIA BIO-MEDICALS LTD.

Transasia Bio Medicals Ltd. Mumbai

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name : Dr. Sapan Godre

Signature :

Designation : LAB DIRECTOR

Department : Pathology

Date : 10-12-2023

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. Vikrant Pandurang Bargude

Title : PERFORMANCE QUALIFICATION

Signature:

Company: TRANSASIA BIO-MEDICALS LTD.

Date : 10-12-2023

Validation Team from ____ Shree Mahavir Medical Centre

Name	:	Dr. Sapan Godre
Signature	:	
Designation	:	LAB DIRECTOR
Department	:	Pathology
Date	:	10-12-2023

Hematology Analysis Report

First Name: QC1
Last Name:
Sample ID:11
Run Time:
2023-12-10 10:47
Diagnosis:

Parameter	Result	Unit
RBC	5.76	10^6/uL
HGB	18.5	g/dL
HCT	59.0	%
MCV	102.4	fL
MCH	32.1	pg
MCHC	31.4	g/dL
RDW-CV	14.1	%
RDW-SD	59.0	fL
WBC	21.48	10^3/uL
Lym%	14.2	%
Gran%	81.6	%
Mid%	4.2	%
Lym#	3.05	10^3/uL
Gran#	17.53	10^3/uL
Mid#	0.90	10^3/uL
PLT	567	10^3/uL
MPV	9.3	fL
PDW-SD	12.5	fL
PDW-CV	16.6	%
PCT	0.530	%
P-LCR	24.1	%
P-LCC	137	10^3/uL

Hematology Analysis Report

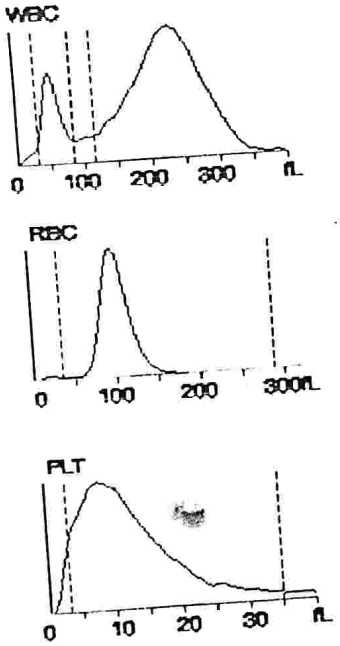
First Name: QC2
Last Name:
Sample ID:12
Run Time:
2023-12-10 10:49
Diagnosis:

Parameter	Result	Unit
RBC	5.78	10^6/uL
HGB	18.7	g/dL
HCT	59.2	%
MCV	102.3	fL
MCH	32.3	pg
MCHC	31.6	g/dL
RDW-CV	14.2	%
RDW-SD	59.4	fL
WBC	21.53	10^3/uL
Lym%	14.4	%
Gran%	81.7	%
Mid%	3.9	%
Lym#	3.10	10^3/uL
Gran#	17.59	10^3/uL
Mid#	0.84	10^3/uL
PLT	576	10^3/uL
MPV	9.4	fL
PDW-SD	11.9	fL
PDW-CV	15.9	%
PCT	0.542	%
P-LCR	23.6	%
P-LCC	136	10^3/uL

...natology Analysis Report

rst Name: QC3
ast Name:
ample ID: 13
un Time:
023-12-10 10:50
lagnosis:

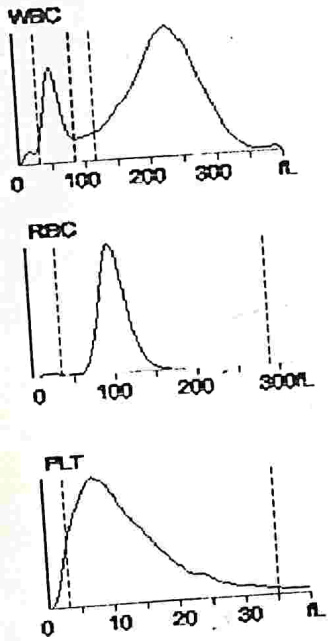
arameter	Result	Unit
:BC	5.83	10^6/uL
IGB	18.7	g/dL
ICT	59.6	%
ICV	102.2	fL
ICH	32.2	pg
ICHC	31.5	g/dL
RDW-CV	14.3	%
RDW-SD	59.8	fL
VBC	21.83	10^3/uL
ym%	14.6	%
Gran%	81.4	%
Mid%	4.0	%
ym#	3.19	10^3/uL
Gran#	17.77	10^3/uL
Mid#	0.87	10^3/uL
PLT	563	10^3/uL
MPV	9.4	fL
PDW-SD	11.8	fL
PDW-CV	15.8	%
PCT	0.531	%
P-LCR	23.9	%
P-LCC	135	10^3/uL



Hematology Analysis Report

First Name: QC4
Last Name:
Sample ID: 14
Run Time:
2023-12-10 10:52
Diagnosis:

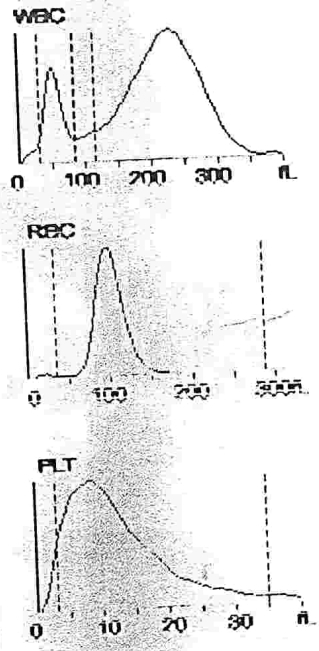
Parameter	Result	Unit
RBC	5.84	10^6/uL
HGB	18.9	g/dL
HCT	59.7	%
MCV	102.4	fL
MCH	32.4	pg
MCHC	31.7	g/dL
RDW-CV	14.2	%.
RDW-SD	59.5	fL
WBC	21.93	10^3/uL
Lym%	14.6	%
Gran%	81.2	%
Mid%	4.2	%
Lym#	3.20	10^3/uL
Gran#	17.81	10^3/uL
Mid#	0.92	10^3/uL
PLT	586	10^3/uL
MPV	9.3	fL
PDW-SD	11.9	fL
PDW-CV	16.1	%
PCT	0.544	%
P-LCR	23.4	%
P-LCC	137	10^3/uL



Hematology Analysis Report

First Name: QC5
Last Name:
Sample ID: 15
Run Time:
2023-12-10 10:53
Diagnosis:

Parameter	Result	Unit
RBC	5.77	10^6/uL
HGB	18.8	g/dL
HCT	58.9	%
MCV	102.0	fL
MCH	32.6	pg
MCHC	31.9	g/dL
RDW-CV	14.2	%
RDW-SD	59.2	fL
WBC	21.56	10^3/uL
Lym%	14.7	%
Gran%	80.9	%
Mid%	4.4	%
Lym#	3.17	10^3/uL
Gran#	17.44	10^3/uL
Mid#	0.95	10^3/uL
PLT	580	10^3/uL
MPV	9.3	fL
PDW-SD	12.3	fL
PDW-CV	16.4	%
PCT	0.541	%
P-LCR	23.7	%
P-LCC	138	10^3/uL



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Date: 10-12-2023
Effective Date: 10-12-2023

Certificate of Calibration

Customer Name: **SHREE MAHAVIR MEDICAL CENTRE GOREGAON**

Model : **Automated Hematology Analyzer H360**

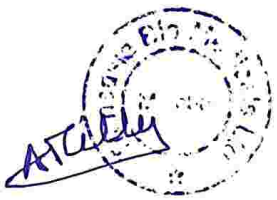
Serial No. : **K10012148006**

Calibration Done Date: **10.12.23**

Next Calibration Due Date On or Before: **10-12-2024**

Lab In-charge: . **DR SAPAN GODRE**

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
Designation
Transasia Bio-Medicals Ltd
Location

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 (East), Mumbai - 400 072
Tel: +91 22 4030 9000 Fax: +91 22 2857 3030 Email : transasia@transasia.co.in CIN : U33110MH1985PLC036198

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Date: 10-12-2023
Effective Date: 10-12-2023

Certificate of Inspection

1. Model: Automated Hematology Analyzer H360

2. Serial No.: K1001214800(

3. Calibration Date: 10-12-2023

4. Material used: H Cal (Lot No. PLUS0124, Expiry date: 10-FEB-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.

Transasia Bio-Medicals Ltd.

Technical Service Department
Transasia Bio-Medicals Ltd

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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

TRANSASIA BIO MED. LTD.

Technical Service Department
Transasia Bio-Medicals Ltd

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Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
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6. PERFORMED ON THE ANALYSER USING A BLOOD SAMPLE BEFORE CALIBRATION (ORIGINALS ATTACHED)

SMP NO	SP1	SP2	SP3	SP4	SP5	SP6	SP7	SP8	SP9	SP10	MEAN	SD	CV%
WBC	5.96	6.05	5.87	5.84	5.8	5.82	5.8	5.98	5.87	6.1	5.87	0.107233	1.826795
LYM%	41.7	42.9	43.8	42.3	43.2	40.4	46.9	45.4	47.3	48.2	43.5	2.613831	6.008806
GRAN%	47.2	41.3	44.1	44.3	45.4	48.2	44.8	48.3	45.1	44.7	44.95	2.110924	4.69616
MID%	11.1	15.8	12.1	13.4	11.4	11.4	8.3	6.3	7.6	7.1	11.25	3.045306	27.06939
LYM#	2.49	2.6	2.57	2.47	2.51	2.35	2.72	2.71	2.78	2.94	2.585	0.174177	6.738005
GRAN#	2.81	2.49	2.59	2.59	2.63	2.81	2.6	2.89	2.64	2.73	2.635	0.126122	4.7864
MID#	0.66	0.96	0.71	0.78	0.66	0.66	0.48	0.38	0.45	0.43	0.66	0.181417	27.48746
RBC	5.62	5.63	5.65	5.69	5.65	5.65	5.75	5.77	5.73	5.85	5.67	0.074304	1.310479
HGB	16.1	16.1	16	16.1	16.1	16	16.4	16.6	16.3	16.4	16.1	0.202485	1.257668
HCT	49.3	49.1	49.1	49.7	49.4	49.3	50.3	50.5	50.01	51	49.55	0.655379	1.322661
MCV	87.6	87.2	87.01	87.4	87.4	87.4	87.5	87.5	87.4	87.2	87.4	0.175401	0.200688
MCH	28.6	28.6	28.3	28.3	28.5	28.3	28.5	28.8	28.5	28.1	28.5	0.201384	0.706611
MCHC	32.6	32.7	32.6	32.4	32.6	32.3	32.6	32.9	32.6	32.3	32.6	0.183787	0.563765
RDW-CV	13.5	13.6	13.4	13.5	13.3	13.9	13.7	13.6	13.6	13.5	13.55	0.164655	1.215163
RDW-SD	47.7	47.8	47.3	47.7	47.01	49.4	48.4	48.2	48.1	47.6	47.75	0.663131	1.388757
PLT	244	262	244	261	253	241	254	267	251	254	253.5	8.517303	3.359883
MPV	10.30	10.20	10.01	10.20	10.01	10.3	10.1	10.1	10.2	10.3	10.2	0.112724	1.105136
PDW-SD	12.10	13.40	13.10	12.50	12.01	12.6	12.5	13.2	13.01	13.1	12.805	0.477861	3.731831
PDW-CV	**14.30**	**15.70**	**15.20**	**14.70**	**14.20**	14.6	14.50%	15.8	14.8	14.9	14.75	4.699446	31.86065
PCT	0.262	0.268	0.244	0.265	0.253	0.248	0.256	0.271	0.256	0.262	0.259	0.00867	3.347441
P-LCR	29.2	29.3	28.4	28.6	27.3	29.6	27.6	29.1	20.01	29.9	28.85	2.894863	10.03419
P-LCC	**74**	**77**	**69**	**75**	**69**	71	70	78	73	76	73.5	3.32666	4.526068

Transasia Bio Medicals Ltd.

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el: +91 22 4030 9000 Fax: +91 22 2857 3030 Email : transasia@transasia.co.in CIN : U33110MH1985PLC036198

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6. PERFORMED ON THE ANALYSER USING A CALIBRATOR (ORIGINALS ATTACHED)

SMP NO	WBC	RBC	HGB	MCV	PLT
1	9.35	4.62	13.1	91.4	241
2	9.46	4.63	13.1	91.4	246
3	9.43	4.65	13.3	91.3	239
4	9.58	4.67	13.3	91.4	247
5	9.74	4.65	13.3	91.2	233
6	9.5	4.64	13.2	91.4	244
7	9.8	4.62	13.3	91.4	240
8	9.73	4.68	13.4	91.5	232
9	9.51	4.64	13.2	91.7	236
10	9.74	4.69	13.4	91.6	236
Mean	9.58	4.65	13.26	91.43	239.40
SD	0.16	0.02	0.11	0.14	5.21
CV%	**1.64**	**0.52**	**0.81**	**0.16**	**2.18**
ceptable 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

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TRACEABILITY

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].

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	9.26	4.65	134	89.9	253
	Relative expansion Uncertainty %	3.1	2.5	2.4	3.7	6.0
H560 (SW A12.2 or higher; version A only)	Calibrator	9.24	4.47	131	92.3	258
	Relative expansion Uncertainty %	3.0	2.6	2.5	3.4	6.5
H560 (SW B1.0 or higher)	Calibrator	9.22	4.57	132	87.7	265
	Relative expansion Uncertainty %	2.9	2.5	2.5	3.3	6.7
ELite 580 (SW A10.4 or higher)	Calibrator	9.54	4.42	133	87.8	259
	Relative expansion Uncertainty %	3.2	2.7	2.5	3.3	6.4

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 05.01.2024

Hematology Analysis Report

First Name:
Last Name:
Sample ID:background
Run Time:
2023-12-10 10:17
Diagnosis:

Parameter	Result	Unit
RBC	0.00	10^6/uL
HGB	0.0	g/dL
HCT	0.0	%
WBC	0.00	10^3/uL
PLT	0	10^3/uL

Hematology Analysis Report

First Name: SP1
Last Name:
Sample ID:1
Run Time:
2023-12-10 10:21
Diagnosis:

Parameter	Result	Unit
RBC	5.62	10^6/uL
HGB	16.1	g/dL
HCT	49.3	%
MCV	87.6	fL
MCH	28.6	pg
MCHC	32.6	g/dL
RDW-CV	13.5	%
RDW-SD	47.7	fL
WBC	5.96	10^3/uL
Lym%	41.7	%
Gran%	47.2	%
Mid%	11.1	%
Lym#	2.49	10^3/uL
Gran#	2.81	10^3/uL
Mid#	0.66	10^3/uL
PLT	254	10^3/uL
MPV	10.3	fL
PDW-SD	12.1	fL
PDW-CV	14.3	%
PCT	0.262	%
P-LCR	29.2	%
P-LCC	74	10^3/uL

Hematology Analysis Report

First Name: SP2
Last Name:
Sample ID:2
Run Time:
2023-12-10 10:24
Diagnosis:

Parameter	Result	Unit
RBC	5.63	10^6/uL
HGB	16.1	g/dL
HCT	49.1	%
MCV	87.2	fL
MCH	28.6	pg
MCHC	32.7	g/dL
RDW-CV	13.6	%
RDW-SD	47.8	fL
WBC	6.05	10^3/uL
Lym%	42.9	%
Gran%	41.3	%
Mid%	15.8	%
Lym#	2.60	10^3/uL
Gran#	2.49	10^3/uL
Mid#	0.96	10^3/uL
PLT	262	10^3/uL
MPV	10.2	fL
PDW-SD	13.4	fL
PDW-CV	15.7	%
PCT	0.268	%
P-LCR	29.3	%
P-LCC	77	10^3/uL

Hematology Analysis Report

First Name: SP3
Last Name:
Sample ID:3
Run Time:
2023-12-10 10:28
Diagnosis:

Parameter	Result	Unit
RBC	5.65	10^6/uL
HGB	16.0	g/dL
HCT	49.1	%
MCV	87.0	fL
MCH	28.3	pg
MCHC	32.6	g/dL
RDW-CV	13.4	%
RDW-SD	47.3	fL
WBC	5.87	10^3/uL
Lym%	43.8	%
Gran%	44.1	%
Mid%	12.1	%
Lym#	2.57	10^3/uL
Gran#	2.59	10^3/uL
Mid#	0.71	10^3/uL
PLT	244	10^3/uL
MPV	10.0	fL
PDW-SD	13.1	fL
PDW-CV	15.2	%
PCT	0.244	%
P-LCR	28.4	%
P-LCC	69	10^3/uL

matology Analysis Report

t Name: SP4
t Name:
nple ID:4
Time:
3-12-10 10:30
gnosis:

meter	Result	Unit
	5.69	10^6/uL
	16.1	g/dL
	49.7	%
	87.4	fL
	28.3	pg
IC	32.4	g/dL
/-CV	13.5	%
/-SD	47.7	fL
	5.84	10^3/uL
%	42.3	%
%	44.3	%
	13.4	%
	2.47	10^3/uL
#	2.59	10^3/uL
	0.78	10^3/uL
	261	10^3/uL
	10.2	fL
-SD	12.5	fL
-CV	14.7	%
	0.265	%
R	28.6	%
	75	10^3/uL

Hematology Analysis Report

First Name: SP5
Last Name:
Sample ID:5
Run Time:
2023-12-10 10:33
Diagnosis:

Parameter	Result	Unit
RBC	5.65	10^6/uL
HGB	16.1	g/dL
HCT	49.4	%
MCV	87.4	fL
MCH	28.5	pg
MCHC	32.6	g/dL
RDW-CV	13.3	%
RDW-SD	47.0	fL
WBC	5.80	10^3/uL
Lym%	43.2	%
Gran%	45.4	%
Mid%	11.4	%
Lym#	2.51	10^3/uL
Gran#	2.63	10^3/uL
Mid#	0.66	10^3/uL
PLT	253	10^3/uL
MPV	10.0	fL
PDW-SD	12.0	fL
PDW-CV	14.2	%
PCT	0.253	%
P-LCR	27.3	%
P-LCC	69	10^3/uL

Hematology Analysis Report

First Name: SP6
Last Name:
Sample ID:6
Run Time:
2023-12-10 10:36
Diagnosis:

Parameter	Result	Unit
RBC	5.65	10^6/uL
HGB	16.0	g/dL
HCT	49.3	%
MCV	87.4	fL
MCH	28.3	pg
MCHC	32.3	g/dL
RDW-CV	13.9	%
RDW-SD	49.4	fL
WBC	5.82	10^3/uL
Lym%	40.4	%
Gran%	48.2	%
Mid%	11.4	%
Lym#	2.35	10^3/uL
Gran#	2.81	10^3/uL
Mid#	0.66	10^3/uL
PLT	241	10^3/uL
MPV	10.3	fL
PDW-SD	12.6	fL
PDW-CV	14.6	%
PCT	0.248	%
P-LCR	29.6	%
P-LCC	71	10^3/uL

Hematology Analysis Report

First Name: SP7
Last Name:
Sample ID:7
Run Time:
2023-12-10 10:38
Diagnosis:

Parameter	Result	Unit
RBC	5.75	10^6/uL
HGB	16.4	g/dL
HCT	50.3	%
MCV	87.5	fL
MCH	28.5	pg
MCHC	32.6	g/dL
RDW-CV	13.7	%
RDW-SD	48.4	fL
WBC	5.80	10^3/uL
Lym%	46.9	%
Gran%	44.8	%
Mid%	8.3	%
Lym#	2.72	10^3/uL
Gran#	2.60	10^3/uL
Mid#	0.48	10^3/uL
PLT	254	10^3/uL
MPV	10.1	fL
PDW-SD	12.5	fL
PDW-CV	14.5	%
PCT	0.256	%
P-LCR	27.6	%
P-LCC	70	10^3/uL

Hematology Analysis Report

First Name: SP8
Last Name:
Sample ID:8
Run Time:
2023-12-10 10:40
Diagnosis:

Parameter	Result	Unit
RBC	5.77	10^6/uL
HGB	16.6	g/dL
HCT	50.5	%
MCV	87.5	fL
MCH	28.8	pg
MCHC	32.9	g/dL
RDW-CV	13.6	%
RDW-SD	48.2	fL
WBC	5.98	10^3/uL
Lym%	45.4	%
Gran%	48.3	%
Mid%	6.3	%
Lym#	2.71	10^3/uL
Gran#	2.89	10^3/uL
Mid#	0.38	10^3/uL
PLT	267	10^3/uL
MPV	10.1	fL
PDW-SD	13.2	fL
PDW-CV	15.8	%
PCT	0.271	%
P-LCR	29.1	%
P-LCC	78	10^3/uL

:matology Analysis Report

st Name: SP9
st Name:
ımple ID:9
ın Tlme:
123-12-10 10:42
agnosis:

ɜrameter	Result	Unit
BC	5.73	10^6/uL
GB	16.3	g/dL
ICT	50.0	%
ICV	87.4	fL
ICH	28.5	pg
ICHC	32.6	g/dL
RDW-CV	13.6	%
RDW-SD	48.1	fL
NBC	5.87	10^3/uL
_ym%	47.3	%
Gran%	45.1	%
Mid%	7.6	%
Lym#	2.78	10^3/uL
Gran#	2.64	10^3/uL
Mid#	0.45	10^3/uL
PLT	251	10^3/uL
MPV	10.2	fL
PDW-SD	13.0	fL
PDW-CV	14.8	%
PCT	0.256	%
P-LCR	29.0	%
P-LCC	73	10^3/uL

Hematology Analysis Report

First Name: SP10
Last Name:
Sample ID:10
Run Time:
2023-12-10 10:43
Diagnosis:

Parameter	Result	Unit
RBC	5.85	10^6/uL
HGB	16.4	g/dL
HCT	51.0	%
MCV	87.2	fL
MCH	28.1	pg
MCHC	32.3	g/dL
RDW-CV	13.5	%
RDW-SD	47.6	fL
WBC	6.10	10^3/uL
Lym%	48.2	%
Gran%	44.7	%
Mid%	7.1	%
Lym#	2.94	10^3/uL
Gran#	2.73	10^3/uL
Mid#	0.43	10^3/uL
PLT	254	10^3/uL
MPV	10.3	fL
PDW-SD	13.1	fL
PDW-CV	14.9	%
PCT	0.262	%
P-LCR	29.9	%
P-LCC	76	10^3/uL

History

13.4

No.	Cal. Time	Cal. Operator	Cal. Method	Cal. Mode	Description
1	2023-12-10...	admin	Calibrator	Whole Blood	PLUS0124(L...

Details

Para.	WBC	RBC	HGB	MCV	PLT
Target	9.26	4.65	13.4	89.9	253
✓ 1	9.35	4.62	13.1	91.4	241
✓ 2	9.46	4.63	13.1	91.4	246
✓ 3	9.43	4.65	13.3	91.3	239
✓ 4	9.58	4.67	13.3	91.4	247
✓ 5	9.74	4.65	13.3	91.2	233
✓ 6	9.50	4.64	13.2	91.4	244
✓ 7	9.80	4.62	13.3	91.4	240
✓ 8	9.73	4.68	13.4	91.5	232
✓ 9	9.51	4.64	13.2	91.7	236
✓ 10	9.74	4.69	13.4	91.6	236
New Cal. Coefficient...	96.62	100.02	101.06	98.33	105.68
Original Cal. Coeffici...	100.00	100.00	100.00	100.00	100.00

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