Transasia Bio-Medicals Ltd., 516, Kamalalaya Centre, 156A, Lenin Sarani, Kolkata - 700013
Tel: 033-2215-3898 Email : ez@transasia.co.in
CIN : U33110MH1985PLC036198

UNMATCHED SERVICE
SINCE 1979...

*July 09, 2024*

## *Calibration Certificate for H560 Hematology Analyser*

*This is to certify that the H560 Hematology Analyser (Sl.No. K1104B2211039) installed at Diagnostics,* 190B, Rash Behari Ave, Golpark, Hindustan Park, Gariahat, Kolkata, West Bengal 700029, *has been calibrated, checked and found well within the limit.*

*This calibration is valid till July 08, 2025.*

*For Transasia Bio-Medicals Ltd.*

*Arijit Dey*
*Area Service Manager*

# TRANSASIA

# ERBA H560
# AUTOMATED HEAMATOLOGY ANALYZER

## INSTALLATION
## QUALIFICATION
For
DIAGNOSTICS
(KOLKATA)

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

ransasia Bio-Medicals Ltd., 518, Kamalalaya Centre, 156A, Lenin Sarani, Kolkata - 700013
el: 033-22153898/22157839 Fax: 033-22158035 Email : ez@transasia.co.in
CIN : U33110MH1985PLC036198

TRANSASIA®

UNMATCHED SERVICE SINCE 1979...

Diagnostics
H560 IQ OQ PQ

ADCO
dt. 9/2/23

Table of Contents

I. Approval of the IQ procedure:

DIAGNOSTICS and Transasia are jointly responsible for the installation of the system ERBA HEMATOLOGY Analyzer, Model: **H560** **SN: K1104B2211039** in the clinical lab of DIAGNOSTICS as per the attached protocol.

Protocol Performed By: Transasia Representative

Name : MR.ARIJIT DEY
Title : INSTALLATIONQUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

Signature:
Date: 13/2/23

Validation Team from _____:

Name :
Designation :
Department :

Customer Authorizations:

Name :
Title : INSTALLATION QUALIFICATION
Site :

Signature :
Date :

## II. Instructions

1. This document is to be completed at the time the system is shifted to its current location (KOLKATA) 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 DIAGNOSTICS will verify each result and sign in the last page. The members of the validation team will carry this out.

4. ALL deviations from normal specification to include any problems with installation will be noted under COMMENTS. All resolution to such problems will also be noted in the COMMENTS section. Additional space is provided at the end of this protocol for the same.

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

Validation Team :

Name

Designation

Signature

Date

## III. Scope

This Installation Qualification protocol will be performed on the ERBA Hematology Analyzer, Model **H560** **SN: K1104B2211039** located in KOLKATA This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacture's specifications and intended use. Successful completion of this protocol will verify that the instrument identified has been installed in accordance with the intended usage.

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

Trained, knowledgeable personnel will perform qualification studies.

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

Validation Team:

Name:

Designation:

Signature:

Date:

## 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 : 13/2/23

### 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 ✓ | | 13/2/23 |
| 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 ✓ | | |
| 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<br>Line- Neutral voltage: 220<br>Line –Earth voltage: 219<br>Neutral-Earth voltage: 1 | Yes / No | | 13/2/23 |

* Encircle applicable source

c. The instrument has been verified for the following

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

Validation Team :

Name

Designation

Signature

Date

## 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 (29) 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 # | | | |
| Serial Number | | | |
| 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 | | |

Validation Team:

Name

Designation

Signature

Date

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 DIAGNOSTICS.

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 :

Name

Designation

Signature

Date

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 :

Name

Designation

Signature

Date

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 :

Name

Designation

Signature

Date

## 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 : MR.ARIJIT DEY

Title : INSTALLATION QUALIFICATION Signature :

Company: TRANSASIA BIO-MEDICALS LTD. Date : 3/2/23

Customer Authorizations:

Name :

Title : INSTALLATION QUALIFICATION Signature:

Company : Date :

Name :

Title : INSTALLATION QUALIFICATION Signature:

Company: Date :

Date:

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

OK

Dani
13/2/23

Recorded by: Checked by:

Date:

TRANSASIA

Erba H560
AUTOMATED HEMATOLOGY ANALYZER

# OPERATIONAL QUALIFICATION

For

**DIAGNOSTICS**
( KOLKATA)

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

Table of Contents

I. Approval of the OQ procedure:

DIAGNOSTICS and Transasia are jointly responsible for operational check of the HEMATOLOGY Analyzer, Model: Erba **H560** **SN: K1104B2211039** in the clinical lab of DIAGNOSTICS as per protocol attached.

Protocol Performed by: Transasia Representative

Name : MR.ARIJIT DEY
Title : OPERATIONAL QUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD.

Signature :
Date : 13/2/23

Validation Team from _____

Name :
Designation :
Department :

Customer Authorization: _____

Name :
Title : OPERATIONAL QUALIFICATION
Site :

Signature :
Date :

II. Instructions

1. The TRANSASIA representative will check each module and enter the specific data as described in the Operational Qualification. Each result will be noted and dated.
2. Employee of DIAGNOSTICS willl 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 (DIAGNOSTICS). However this additional cost will be waived when this test is conducted at time of initial performance check of new instruments.
4. Any test data, which does not meet the specified acceptance criteria, will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.
5. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by the Product Manager at Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team:

Name

Designation

Signature

Date

## III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, Model **H560** **SN: K1104B2211039** located in , KOLKATA. Clinical laboratory of DIAGNOSTICS. This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

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

Validation Team:

Name

Designation

Signature

Date

## IV. Operational Qualification

a. Instrument Identification

Verified Date

1. Model Name H560
2. Serial Number K110482211039

13/2/23

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 | |
| 2. | Syringe Assembly | Capacity of Blood Aspiration Diluent Aspiration, Lyse 1& 2 Aspiration | 13/2/23 |
| 3. | Liquid Sensing PCB | To verify Liquid sensing ability Of sensors | |

Validation Team:

Name

Designation

Signature

Date

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 :

Name

Designation

Signature

Date

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 :

Name

Designation

Signature

Date

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 :

Name

Designation

Signature

Date

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. Atanu Biswas 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 :

Name

Designation

Signature

Date

b. Customer SOP

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

Validation Team :

Name

Designation

Signature

Date

## 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 : MR. ARIJIT DEY

Title : OPERATIONAL QUALIFICATION Signature :

Company : TRANSASIA BIO-MEDICALS LTD. Date : 13/2/23

Customer Authorizations:

Name :

Title : OPERATIONAL QUALIFICATION Signature :

Company : Date :

Name :

Title : OPERATIONAL QUALIFICATION Signature :

Company : Date :

# ERBA– H560
# AUTOMATED HEMATOLOGY ANALYZER

## PERFORMANCE QUALIFICATION

For

## DIAGNOSTICS (KOLKATA)

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

**Table of Contents:**

## I. Approval of the PQ procedure

Both DIAGNOSTICS and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer, Model : ERBA – **H560** **SN:K1104B2211039**in the clinical lab of BEST DIAGNOSTICS as per the attached protocol.

**Protocol Performed By:** **Transasia Representative**

Name : ATANU BISWAS
Title : **PERFORMANCE QUALIFICATION**
Company : **TRANSASIA BIO-MEDICALS LTD.**

Signature:
Date: A Biswas 13/2/22

**Validation Team from**

Name :
Designation :
Department :

Name :
Designation :
Department :

**Customer Authorizations:**

Name : PERFORMANCE QUALIFICATION
Title :
Site :

Signature:
Date:

Name : PERFORMANCE QUALIFICATION
Title :
Site :

Signature:
Date:

## 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 DIAGNOSTICS 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 DIAGNOSTICS. However this additional cost will be waived when this test is conducted at time of initial performance check of new instruments.
5. Any test data that does not meet the specified acceptance criteria will be submitted to the appropriate laboratory personnel for solution. All steps taken subsequently will be documented.
6. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by the Production Manager at Transasia Bio-Medicals Ltd., Transasia House, Mumbai.

Validation Team:

Name

Designation

Signature

Date

**III. Scope**

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model ERBA-H560 SN:K1104B2211039located in KOLKATA. This Protocol will define the documentation that will be used to evaluate the instruments installation in accordance with the manufacture's specifications and intended use. Successful completion of this protocol will verify that the instrument identified is performing in accordance with the intended usage.

Trained, knowledgeable personnel will perform qualification studies.

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

Validation Team:

Name

Designation

Signature

Date

## IV. Performance Qualification

**a. Instrument Identification** **Verified Date**

ABISWAS 13/2/23

1. Model Name ERBA – H560
2. Serial Number **K1104B2211039**

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 | 13/2/23 |
| 03 | Further Performance Checks | Regular Maintenance | NA |

Validation Team:

Name

Designation

Signature

Date

**c. Performance Testing**

**Test 1**

**Test Name:** **Sample Processing**

**Purpose:** **Ability to Process Samples**

**Method:**

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

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

**Parameters Values for Verification:**

**RBC Count:**

| Test | Control Values | Results Obtained | Pass | Fail |
|---|---|---|---|---|
| 1. | 4.41 – 4.89 | 4.59 | √ | |
| 2. | 4.41 – 4.89 | 4.56 | √ | |
| 3. | 4.41 – 4.89 | 4.57 | √ | |
| 4. | 4.41 – 4.89 | 4.58 | √ | |
| 5. | 4.41 – 4.89 | 4.50 | √ | |

Validation Team:

Name

Designation

Signature

Date

**WBC Count:**

| Test | Control Values | Results Obtained | Pass | Fail |
|---|---|---|---|---|
| 1. | 7.1 – 9.1 | 7.95 | √ | |
| 2. | 7.1 – 9.1 | 8.13 | √ | |
| 3. | 7.1 – 9.1 | 8.09 | √ | |
| 4. | 7.1 – 9.1 | 7.91 | √ | |
| 5. | 7.1 – 9.1 | 7.76 | √ | |

**Hemoglobin:**

| Test | Control Values | Results Obtained | Pass | Fail |
|---|---|---|---|---|
| 1. | 12.5 – 13.7 | 13.2 | √ | |
| 2. | 12.5 – 13.7 | 13.2 | √ | |
| 3. | 12.5 – 13.7 | 13.2 | √ | |
| 4. | 12.5 – 13.7 | 13.2 | √ | |
| 5. | 12.5 – 13.7 | 13 | √ | |

**MCV:**

| Test | Control Values | Results Obtained | Pass | Fail |
|---|---|---|---|---|
| 1. | 83.3 -93.3 | 85.9 | √ | |
| 2. | 83.3 -93.3 | 85.7 | √ | |
| 3. | 83.3 -93.3 | 85.7 | √ | |
| 4. | 83.3 -93.3 | 85.9 | √ | |
| 5. | 83.3 -93.3 | 85.6 | √ | |

**Platelet Count:**

| Test | Control Values | Results Obtained | Pass | Fail |
|---|---|---|---|---|
| 1. | 217 - 297 | 268 | √ | |
| 2. | 217 - 297 | 279 | √ | |
| 3. | 217 - 297 | 278 | √ | |
| 4. | 217 - 297 | 287 | √ | |
| 5. | 217 - 297 | 287 | √ | |

Validation Team:

Name

Designation

Signature

Date

**Test 2**

**Test Name:**

1. Linearity,Carryover for checking the performance of the instruments during analysis
2. Tests for checking long term performance of the instrument

Purpose:

The purpose of the above checks is to ensure the reliability of the results being obtained.

Method:

1. During Sample analysis:

To run control samples each time the instrument is used for sample analysis and verification of the results of the controls to be within the reference range to be established by performance of the precision experiments.

2. Long term Performance

This is to be checked by Levy Jennings plots to be updated once in six months

Validation Team:

Name

Designation

Signature

Date

**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 :ATANU BISWAS

Title : PERFORMANCE QUALIFICATION Signature: A Biswas

Company: TRANSASIA BIO-MEDICALS LTD. Date : 13/4/23

Customer Authorizations:

Name :

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date :

Name :

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date :