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**ERBA– H560
AUTOMATED HEMATOLOGY ANALYZER**

**PERFORMANCE
QUALIFICATION**

For

“ ERBA H-560 ”

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

Table of Contents:

Sr. No.	Contents	Page No.
I	Approval of the PQ procedure	3
II	Instructions	4
III	Scope	5
IV	Performance Qualification	6
V	System Certification	10


I. Approval of the PQ procedure

Both RARI and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer, Model: ERBA – H560, Serial No. K1104B2211056 in the clinical lab of the Hospital as per the attached protocol.

Protocol Performed By: Transasia Representative

Name: MR. AJAY SINGH
Title: PERFORMANCE QUALIFICATION
Company: TRANSASIA BIO-MEDICALS LTD.

Date:

Signature: 
9/1/23

Validation Team from :

Name :
Designation :
Department :

Name :
Designation :
Department :

Customer Authorizations:

Name: DR. MEENAKSHI SURI ✓
Title: PERFORMANCE QUALIFICATION
Site : RARI, Jammy

Signature: 

Date: 09/01/2023

Name :
Title: PERFORMANCE QUALIFICATION
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 the responsibility of the customer's personnel.
3. Employee of (Customer) RARI, Jammu Laboratory will verify each result and sign on 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 resolutions to such problems will also be noted in the COMMENTS section and must be resolved prior to the 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 the time of the 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 the 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

Mr. Ajay Singh

Designation

Sr. Service Engg.

Signature



Date

9/1/23

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model ERBA -H560, Serial No K1104B2211056 located in the clinical laboratory of RARI Jammu. This Protocol will define the documentation that will be used to evaluate the instrument's 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

Mv. Ajay Singh .

Designation

Sr. Service Engg .

Signature



Date

9/1/23

IV. Performance Qualification

a. Instrument Identification

Verified Date

1. Model Name ERBA - H560
2. Serial Number K1104B2211056

9/1/23
11

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

Test No.	Test Name	Test Purpose	Verified Date
02	Sample Processing	Ability to process samples	✓
03	Further Performance Checks	Regular Maintenance	NA

Validation Team:

Name

Mr. Ajay Singh

Designation

Sr. Service Engg.

Signature

[Signature]

Date

9/1/23

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.	2.31	2.23	PASS	
2.	2.31	2.23	PASS	
3.	2.31	2.22	PASS	
4.	2.31	2.21	PASS	
5.	2.31	2.24	PASS	

Validation Team:

Name

Mr. Ajay Singh

Designation

Sr. Service Engg

Signature.

[Handwritten Signature]

Date

9/1/23

WBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	3.42	3.42	PASS	
2.	3.42	3.41	PASS	
3.	3.42	3.38	PASS	
4.	3.42	3.32	PASS	
5.	3.42	3.60	PASS	

Hemoglobin:

Test	Control Values	Results Obtained	Pass	Fail
1.	5.7	5.7	PASS	
2.	5.7	5.7	PASS	
3.	5.7	5.6	PASS	
4.	5.7	5.7	PASS	
5.	5.7	5.7	PASS	

HCT:

Test	Control Values	Results Obtained	Pass	Fail
1.	17.3	18.1	PASS	
2.	17.3	18.1	PASS	
3.	17.3	18.1	PASS	
4.	17.3	17.9	PASS	
5.	17.3	18.2	PASS	

Platelet Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	67	71	PASS	
2.	67	72	PASS	
3.	67	68	PASS	
4.	67	66	PASS	
5.	67	67	PASS	

Validation Team: TRANSASIA BIO-MEDICALS LTD

Name. MR. AJAY SINGH

Designation SR. SERVICE ENGG.

Signature



9/1/23

Date

Test 2

Test Name:

1. Tests for checking the performance of the instruments during analysis
2. Tests for checking the long-term performance of the instrument

Purpose:

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

Method:

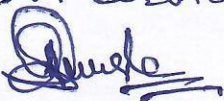
1. During Sample analysis:

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 the 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 Mr. Ajay Singh .
Designation Sr. Service Engg .
Signature 
Date 9/1/23

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. AJAY SINGH

Title: PERFORMANCE QUALIFICATION

Company: TRANSASIA BIO-MEDICALS LTD.

Signature:



9/1/23

Date:

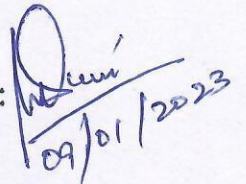
Customer Authorizations:

Name: DR. MEENAKSHI SURI

Title: PERFORMANCE QUALIFICATION

Site: JAMMU

Signature:



09/01/2023

Date:

Name:

Title: PERFORMANCE QUALIFICATION

Site:

Signature:

Date: