Transasia Bio-Medicals Ltd., No. 43, Castle Street, Richmond Road, Opp. Empire Suitess, Asholnagar Bengaluru - 560025
Tel: 080 4430 9000 / 2556 8044 **Email** : sz2@transasia.co.in **CIN** : U33110MH1985PLC036198

TRANSASIA®

UNMATCHED SERVICE
SINCE 1979...

ERBA– H560
AUTOMATED HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

For

DIAGNOSTICA SPAN PVT LTD

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

Erba®

Table of Contents:

I. Approval of the PQ procedure

Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer,Model : ERBA – H560, Serial No.K1104B2142108 in the clinical lab of as per the attached protocol.

Protocol Performed By: Transasia Representative

Name : Sunil kumar kg
Title : PERFORMANCE QUALIFICATION
Company : TRANSASIA BIO-MEDICALS LTD
Date : 30/10/2023

Validation Team from :TRANSASIA BIO-MEDICALS LTD

Name :Mr.Sunilkumar kg

Designation : Application specialist

Signature :

Date :30/10/2023

Customer Authorizations:

Name :Mr.Dilipshetty

Signature:

Title : PERFORMANCE QUALIFICATION

Site :Diagnostica span pvt ltd

Date:30/10/2023

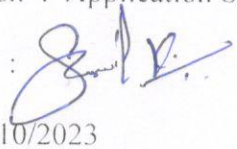
II. Instructions

1. An authorized TRANSASIA representative will check for the performance of the instrument and enter the specific data as outlined in the PerformanceQualification. 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 (Customer) Anand Diagnostic Laboratorywill 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:**TRANSASIA BIO-MEDICALS LTD**

Name : Sunil kumar kg

Designation : Application Specialist

Signature : 

Date :30/10/2023

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model ERBA -H560, Serial No.K1104B2142108, **Diagnostica span pvt ltd**located in Bangalore (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:**TRANSASIA BIO-MEDICALS LTD**

Name : Sunil kumar kg

Designation : Application Specialist

Signature :

Date :30/10/2023

IV. Performance Qualification

a. Instrument IdentificationSl no –K1104B2142108 **Verified Date:**30/10/2023

1. Model Name ERBA – H560

2. Serial N0 K1104B2142108

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

Validation Team:**TRANSASIA BIO-MEDICALS LTD**

Name : Sunil kumar kg

Designation : Application Specialist

Signature :

Date :30/10/2023

c. Performance Testing

Test 1

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.	4.71	4.81	pass	
2.	4.71	4.79	pass	
3.	4.71	4.71	pass	
4.	4.71	4.78	pass	
5.	4.71	4.71	pass	

Validation Team:**TRANSASIA BIO-MEDICALS LTD**

Name : Sunil kumar kg

Designation : Application Specialist

Signature :

Date :30/10/2023

WBC Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	7.96	7970	Pass	
2.	7.96	8090	Pass	
3.	7.96	8100	Pass	
4.	7.96	7800	Pass	
5.	7.96	8270	Pass	

Hemoglobin:

Test	Control Values	Results Obtained	Pass	Fail
1.	13.3	13.4	Pass	
2.	13.3	13.4	Pass	
3.	13.3	13.3	Pass	
4.	13.3	13.3	Pass	
5.	13.3	13.2	Pass	

HCT:

Test	Control Values	Results Obtained	Pass	Fail
1.	40.0	43.9	Pass	
2.	40.0	41.8	Pass	
3.	40.0	41.3	Pass	
4.	40.0	41.7	Pass	
5.	40.0	42.7	Pass	

Platelet Count:

Test	Control Values	Results Obtained	Pass	Fail
1.	268	256	Pass	
2.	268	264	Pass	
3.	268	267	Pass	
4.	268	261	Pass	
5.	268	259	Pass	

Validation Team:**TRANSASIA BIO-MEDICALS LTD**

Name : Sunil kumar kg

Designation : Application Specialist

Signature :

Date :30/10/2023

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

Validation Team:**TRANSASIA BIO-MEDICALS LTD**

Name : Sunil kumar kg

Designation : Application Specialist

Signature :

Date :30/10/2023

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. Sunil kumar kg

Title :PERFORMANCE QUALIFICATION

Company: TRANSASIA BIO-MEDICALS LTD.

Signature:

Date :30/10/2023

Customer Authorizations:

Name :Mr.Dilip Shetty

Title :**Diagnostica span pvt ltd**

Signature:

Date :30/10/2023