



## ELITE 580 AUTOMATED HEMATOLOGY ANALYZER

### PERFORMANCE QUALIFICATION

For

“ REDCLIFFE LIFETECH PVT LTD ”  
PLOT NO.: 144/C, GROUND FLOOR, CHANDRASEKHARPUR,  
BHUBANESWAR-751016

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

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## I. Approval of the PQ procedure

Both REDCLIFFE LIFETECH PVT LTD and Transasia are jointly responsible for conducting the Performance Check of the Hematology Analyzer, Model : ERBA – ELIE 580, Serial No. K11052124025 in the clinical lab of REDCLIFFE LIFETECH PVT LTD as per the attached protocol.

### Protocol Performed By: Transasia Representative

Name : SUDIPTA JANA  
Title : PERFORMANCE QUALIFICATION  
Company : TRANSASIA BIO-MEDICALS LTD.

Signature:  
Date:

*S JANA*  
29.10.21

### Validation Team from :

Name :  
Designation :  
Department :

Name :  
Designation :  
Department :

### Customer Authorizations:

Name :  
Title : PERFORMANCE QUALIFICATION  
Site :

Signature:

Date:

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 responsibility of the customer's personnel.
3. Employee of REDCLIFFE LIFETECH PVT LTD 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 (REDCLIFFE LIFETECH PVT LTD). 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

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### III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, Model ERBA – ELIE 580, Serial No.: K11052124025 located in BHUBANESWAR. 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:

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## IV. Performance Qualification

### a. Instrument Identification

Verified Date

1. Model Name ERBA – ELIE 580  
2. Serial Number K11052124025

29/10/2011

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

<u>Test No.</u>	<u>Test Name</u>	<u>Test Purpose</u>	<u>Verified Date</u>
01	Accuracy Testing	Performance check	
02	Precision Check	Performance check	
03	Carry over Test	Performance check	

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## 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 (L1) Values	Results Obtained	Status	Control (L2) Values	Results Obtained	Status	Control (L3) Values	Results Obtained	Status
1.	2.15 – 2.51	2.36	Pass	4.24 – 4.72	4.47	Pass	4.92 – 5.92	5.53	Pass
2.	2.15 – 2.51	2.36	Pass	4.24 – 4.72	4.41	Pass	4.92 – 5.92	5.37	Pass
3.	2.15 – 2.51	2.37	Pass	4.24 – 4.72	4.46	Pass	4.92 – 5.92	5.41	Pass
4.	2.15 – 2.51	2.38	Pass	4.24 – 4.72	4.48	Pass	4.92 – 5.92	5.37	Pass
5.	2.15 – 2.51	2.36	Pass	4.24 – 4.72	4.34	Pass	4.92 – 5.92	5.35	Pass

Validation Team: TSD.

Name SUDIPTA JANA

Designation APPLICATION MANAGER .

Signature

Date

*[Signature]*  
29.10.21



## WBC Count:

Test	Control (L1) Values	Results Obtained	Status	Control (L2) Values	Results Obtained	Status	Control (L3) Values	Results Obtained	Status
1.	2.85 – 3.85	3.38	Pass	7.12 – 9.12	8.09	Pass	15.2 – 20.28	18.19	Pass
2.	2.85 – 3.85	3.58	Pass	7.12 – 9.12	8.08	Pass	15.2 – 20.28	18.41	Pass
3.	2.85 – 3.85	3.52	Pass	7.12 – 9.12	8.05	Pass	15.2 – 20.28	18.00	Pass
4.	2.85 – 3.85	3.46	Pass	7.12 – 9.12	8.10	Pass	15.2 – 20.28	18.16	Pass
5.	2.85 – 3.85	3.51	Pass	7.12 – 9.12	8.08	Pass	15.2 – 20.28	18.36	Pass

## Hemoglobin:

Test	Control (L1) Values	Results Obtained	Status	Control (L2) Values	Results Obtained	Status	Control (L3) Values	Results Obtained	Status
1.	5.3 – 6.1	5.9	Pass	12.5 – 13.6	13.2	Pass	16.1 – 17.7	17.0	Pass
2.	5.3 – 6.1	5.9	Pass	12.5 – 13.6	13.1	Pass	16.1 – 17.7	16.9	Pass
3.	5.3 – 6.1	5.8	Pass	12.5 – 13.6	13.1	Pass	16.1 – 17.7	16.9	Pass
4.	5.3 – 6.1	5.8	Pass	12.5 – 13.6	13.3	Pass	16.1 – 17.7	16.9	Pass
5.	5.3 – 6.1	5.8	Pass	12.5 – 13.6	13.2	Pass	16.1 – 17.7	16.9	Pass

## MCV:

Test	Control (L1) Values	Results Obtained	Status	Control (L2) Values	Results Obtained	Status	Control (L3) Values	Results Obtained	Status
1.	72.7 – 82.7	80.2	Pass	84.5 – 94.5	90.0	Pass	88.4–100.4	95.5	Pass
2.	72.7 – 82.7	80.6	Pass	84.5 – 94.5	90.3	Pass	88.4–100.4	95.2	Pass
3.	72.7 – 82.7	80.2	Pass	84.5 – 94.5	90.0	Pass	88.4–100.4	95.2	Pass
4.	72.7 – 82.7	80.5	Pass	84.5 – 94.5	90.3	Pass	88.4–100.4	95.2	Pass
5.	72.7 – 82.7	80.2	Pass	84.5 – 94.5	89.9	Pass	88.4–100.4	95.1	Pass

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29.10.21

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## Platelet Count:

Test	Control (L1) Values	Results Obtained	Status	Control (L2) Values	Results Obtained	Status	Control (L3) Values	Results Obtained	Status
1.	34 - 74	57	Pass	228 - 308	257	Pass	460 - 580	519	Pass
2.	34 - 74	60	Pass	228 - 308	250	Pass	460 - 580	508	Pass
3.	34 - 74	57	Pass	228 - 308	255	Pass	460 - 580	496	Pass
4.	34 - 74	58	Pass	228 - 308	263	Pass	460 - 580	509	Pass
5.	34 - 74	60	Pass	228 - 308	254	Pass	460 - 580	509	Pass


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## Test 2

**Test Name : Precision Check**

**Run the samples 10 times consecutively - Data Attached**

## Test 3

**Test Name : Carry over Test**

**Run High & Low sample run consecutively - Data Attached**

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

  
29/1/21



## 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

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Name : Sudipta Jana

Title : PERFORMANCE QUALIFICATION Signature:

Company: TRANSASIA BIO-MEDICALS LTD. Date :

*S. Jana*  

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*29/1/14*

Customer Authorizations:

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Name :

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date :

Name :

Title : PERFORMANCE QUALIFICATION Signature:

Site : Date :

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