



INSTALLATION QUALIFICATION

For

AUTOMATED HEMATOLOGY ANALYZER

MODEL : BC 3000 PLUS

AGAPPE DIAGNOSTICS LTD.

ADL/DO/SER/IOP/0069/21-22

AGAPPE DIAGNOSTICS LTD.

ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

CORPORATE OFFICE / REAGENT PLANT
Agappe Hills, Pattimattom (PO), Dist. Ernakulam, Kerala - 683 562, India.
Tel: +91 484 286 7000 | Email: agappe@agappe.in

MUMBAI (REGISTERED OFFICE)
401 & 402, 4th Floor, Jaishigh Business Centre, 119,
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Tel: +91 22 4300 8000 | Email: mumbaioffice@agappe.in

EQUIPMENT PLANT
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DELHI OFFICE
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New Delhi - 110 015, India.
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KOLKATA OFFICE
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BANGALORE OFFICE
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Bangalore - 560 001. Tel: +91 80 2228 8288
Email: bangaloreoffice@agappe.in

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AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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I. APPROVAL OF THE INSTALLATION QUALIFICATION PROCEDURE

Both SHREE PATH LAB, REWARI and AGAPPE DIAGNOSTICS LTD are jointly responsible for the installation of BC 3000 PLUS with serial number RJ-99128744 at "Shree Path Lab, 1st Floor, Ratan Ultrasound Centre, Opposite Government Girls School, Circular Road, Rewari" as per the attached INSTALLATION Qualification Protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.



Name	: SURAJ KUMAR	Signature :	<i>[Signature]</i>
Designation	: Manager - Customer Service		
Title Company	: AGAPPE DIAGNOSTICS LTD	Date	: 25/AUG/2020

Validation Team from SHREE PATH LAB, REWARI

Name	: <i>Dr. Kamal Kant</i>	Signature :	<i>[Signature]</i>
Designation	: Dr. Kamal Kant M.B.B.S., M.D. DMC - 58271		
Department	: Shree Path Lab	Date	: 25/08/2020

Customer Authorizations:

Name : *Dr. Kamal Kant* **Dr. Kamal Kant
M.B.B.S., M.D.
DMC - 58271
Shree Path Lab**

Title : INSTALLATION QUALIFICATION **Signature** : *[Signature]*

Site : *Rewari* **Date** : 25/08/2020



II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Installation Qualification. Each result will be noted and dated.
2. The concerned employees of **SHREE PATH LAB, REWARI** will verify each result and sign in each page. The member of the validation team will carry this out.
3. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the IQ 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.

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III. SCOPE

This Installation Qualification protocol will be performed on the **BC 3000 PLUS** at **SHREE PATH LAB, REWARI**. This Installation 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 has been installed 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.

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IV. INSTALLATION QUALIFICATION

A. Instrument Identification

Verified Date : 25/AUG/2020

Model Name : BC 3000 PLUS

Serial Number : RJ-99128744

Following is a list of accessories /consumables verified:

S No.	Component	Present (Yes/No)	Verified By	Comments
01	Analyzer Main unit	Yes	SURAJ KUMAR	OK
02	Power cord	Yes	SURAJ KUMAR	OK
03	Waste can	Yes	SURAJ KUMAR	OK
04	Diluent Connector	Yes	SURAJ KUMAR	OK
05	Lyse connector tube	Yes	SURAJ KUMAR	OK
06	Rinse connector tube	Yes	SURAJ KUMAR	OK
07	Waste tube	Yes	SURAJ KUMAR	OK
08	Pre – dilution cups	Yes	SURAJ KUMAR	OK
09	Paper roll	Yes	SURAJ KUMAR	OK
10	Air filter	Yes	SURAJ KUMAR	OK

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1. INSTALLATION CHECKS

Purpose: To make sure that the instrument is received with all the major components necessary for operation

S No.	Component	(Yes/No)	Verified By	Comments
1	Major components and accessories are present	Yes	SURAJ KUMAR	OK
2	There is no physical damage to the components	Yes	SURAJ KUMAR	OK
3	Ambient temperature is available	Yes	SURAJ KUMAR	OK
4	Instrument is installed in the table leveled properly	Yes	SURAJ KUMAR	OK
5	Power supply is correct	Yes	SURAJ KUMAR	OK
6	Electric connections are tight, weatherproof & earthed	Yes	SURAJ KUMAR	OK
7	Analyzer unit installed as per the manufacturers recommendations	Yes	SURAJ KUMAR	OK

Summary:

The information is recorded against each data and the deviations if any is justified / explained properly.

Acceptance criteria:

PARAMETER


 PASS


 FAIL



2. INSTRUMENT INSTALLATION

Date of Installation : 25/AUG/2020

Installed by : SURAJ KUMAR

S No.	Parameter	Done by	Comments
01	Installation of the main unit	SURAJ KUMAR	OK
02	Connecting the lyze tubing	SURAJ KUMAR	OK
03	Connecting the Diluent tubing	SURAJ KUMAR	OK
04	Connecting the Rinse tubing	SURAJ KUMAR	OK
05	Connecting the waste tubing	SURAJ KUMAR	OK
06	Releasing the sample probe tie	SURAJ KUMAR	OK
07	Connecting the earth wire	SURAJ KUMAR	OK

Acceptance criteria System should be "Ready" after daily maintenance without any error

PARAMETER PASS FAIL

Parameter values for verification: System found "Ready" after daily maintenance



3. Startup check

Purpose: To make the instrument READY for operation

Summary: Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Check the room temperature and switch on the Air Conditioner
- Check the UPS.
- Switch on the BC 3000 plus system by pressing the main switch.
- Wait for the instrument to get ready after initialization
- The machine is ready for next step if it displays "READY" on the Status Area
- If not, initialize by pressing the initialize again after solving the error displayed
- Follow instructions provided for the error message

Acceptance criteria:

- No error Messages displayed

PARAMETER **PASS** **FAIL**

Parameter values for verification: No Error Messages

4. Priming

Purpose: To check the internal tubing's and flow of liquids

S No	Activity	Done By	Date
01	Do wash using the maintenance screen	SURAJ KUMAR	25/AUG/2020

Acceptance criteria:

- No error message or air bubbles in the internal tubing's
- All the dilutor working well without air bubbles / leakage

PARAMETER **PASS** **FAIL**

Parameter values for verification: No Error Messages



VI. SYSTEM CERTIFICATION

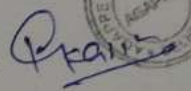
Study data has determined that the system described in this document either meets all criteria outline in this Installation Qualification Protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any, have been addressed. The system is ready for Operational Qualification.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : SURAJ KUMAR

Designation : Manager - Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

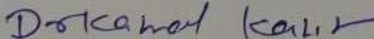
Signature : 

Date

: 25/AUG/2020

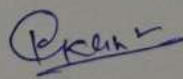


Customer Authorizations: **SHREE PATH LAB, REWARI**

Name : 

Designation : **Dr. Kamal Kant
M.B.B.S., M.D.**

Company : **DMC - 58271
Shree Path Lab**

Signature : 

Date

: 25/08/2020

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AGAPPE

OPERATIONAL QUALIFICATION

For

AUTOMATED HEMATOLOGY ANALYZER

MODEL : BC 3000 PLUS

AGAPPE DIAGNOSTICS LTD.

ADL/DO/SER/IOP/0069/21-22

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I. APPROVAL OF THE OPERATIONAL QUALIFICATION PROCEDURE

Both SHREE PATH LAB, REWARI and AGAPPE DIAGNOSTICS LTD are jointly responsible for the installation of BC 3000 PLUS with serial number RJ-99128744 at "Shree Path Lab, 1st Floor, Ratan Ultrasound Centre, Opposite Government Girls School, Circular Road, Rewari" as per the attached OPERATIONAL Qualification protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.



Name	: SURAJ KUMAR	Signature :	
Designation	: Manager - Customer Service		
Title Company	: AGAPPE DIAGNOSTICS LTD	Date	: 25/AUG/2020

Validation Team from SHREE PATH LAB, REWARI

Name	: <i>Dr. Kamal Kant</i> Dr. Kamal Kant	Signature :	<i>[Signature]</i>
Designation	: M.B.B.S., M.D. DMC - 53271 Shree Path Lab		
Department	: <i>Hematology</i>	Date	: 25/08/2020

Customer Authorizations:

Name : *Dr kamal kant* **Dr. Kamal Kant**
M.B.B.S., M.D.
DMC - 58271
Shree Path Lab

Title : OPERATIONAL QUALIFICATION *[Signature]*

Site : *Rewari* Date : 25/08/2020

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III. SCOPE

This Operational Qualification protocol will be performed on the BC 3000 PLUS, Serial No. **RJ-99128744** at **SHREE PATH LAB, REWARI**. This Installation 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 has been installed in accordance with the intended usage.

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IV. OPERATIONAL QUALIFICATION

A. Instrument Identification

Verified Date: 25/AUG/2020

Model Name : BC 3000 PLUS

Serial Number : RJ-99128744

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

Test No.	Test Name	Test purpose	Verified By and date
01	Start up	To make the equipment ready for operation	SURAJ KUMAR 25/AUG/2020
02	Daily maintenance	To clean appropriate modules	SURAJ KUMAR 25/AUG/2020
03	Calibration	To calibrate the system	SURAJ KUMAR 25/AUG/2020
04	QC check	To confirm that the system is calibrated and working within specifications	SURAJ KUMAR 25/AUG/2020
05	Reproducibility check	To check the precision [CV %] after calibration	SURAJ KUMAR 25/AUG/2020
06	Sample programming and Analysis	To run the samples	SURAJ KUMAR 25/AUG/2020
07	Shut down procedure	To shut down the system	SURAJ KUMAR 25/AUG/2020

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Test 01: Starting the system

Purpose: To make the instrument READY for operation

Summary:

Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Check the room temperature and switch on the Air Conditioner
- Check the UPS.
- Switch on the BC 3000 plus system by pressing the main switch.
- Wait for the instrument to get ready after initialization
- The machine is ready for next step if it displays "READY" on the Status Area
- If not, initialize by pressing the initialize again after solving the error displayed
- Follow instructions provided for the error message

Acceptance criteria: System to display READY status

PARAMETER

 PASS

~~FAIL~~

Parameter values for verification: "READY" on Status Area



Test 02: Daily Maintenance

Purpose: To clean appropriate modules so as per the daily maintenance protocol

Method:

Refer detailed procedure for Daily Maintenance

S No.	Activity	Done by	Date
01	Empty waste container	SURAJ KUMAR	25/AUG/2020
02	Check Diluents	SURAJ KUMAR	25/AUG/2020
03	Check Lyse	SURAJ KUMAR	25/AUG/2020
04	Check Rinse	SURAJ KUMAR	25/AUG/2020
05	Clean Wipe Block	SURAJ KUMAR	25/AUG/2020
06	Clean out side area	SURAJ KUMAR	25/AUG/2020
07	Load supplies and remove outdated and empty reagents	SURAJ KUMAR	25/AUG/2020
08	Check startup screen	SURAJ KUMAR	25/AUG/2020
09	Perform Quality Control	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: System should be "Ready" after daily maintenance without any error

PARAMETER

PASS

FAIL

Parameter values for verification: System found "Ready" after daily maintenance

Test: 5: Calibration of the system

Purpose: To calibrate the system*

Procedure:

S No.	Activity	Done By	Date
01	Preparation of the calibration material	SURAJ KUMAR	25/AUG/2020
02	Performing Calibration with calibration programming screen	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: "Calibration Successful" should come on screen

PARAMETER **PASS** ~~FAIL~~

Parameter values for verification:

- ▲ The system is pre calibrated and the calibration details are displayed on the screen.
We recommend on site calibration once in a year

Test 7: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

Procedure:

S No	Activity	Done By	Date
01	Preparing control material	SURAJ KUMAR	25/AUG/2020
02	Creating QC file	SURAJ KUMAR	25/AUG/2020
03	QC sample programming and analysis	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER **PASS** ~~FAIL~~

Parameter values for verification: QC values within $\pm 2SD$

Test 08: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	SURAJ KUMAR	25/AUG/2020
02	Running triplicates	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: Results CV within specified limits

PARAMETER PASS FAIL

Parameter values for verification: CV% within the limits

Test 09: Sample programming and Analysis

Purpose: To run the samples

Procedure:

S No.	Activity	Done By	Date
01	Preparing and Processing of samples	SURAJ KUMAR	25/AUG/2020
02	Programming samples	SURAJ KUMAR	25/AUG/2020
03	Aspirating the samples	SURAJ KUMAR	25/AUG/2020
04	Viewing samples in process	SURAJ KUMAR	25/AUG/2020
05	Review results: Monitoring results	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: Samples Analysis without any error

PARAMETER PASS FAIL

Parameter values for verification: Sample analysis without any error

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Test 10: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	SURAJ KUMAR	25/AUG/2020
02	Following the on screen instructions	SURAJ KUMAR	25/AUG/2020
03	Switch off the instrument when prompted	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: Shut down without any error

PARAMETER

PASS

FAIL

Parameter values for verification: Shut down without any error

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C. Operational procedure:

a. Certificate of Training

1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

S No.	Training program	Initials	Date
1.	Instrument Setup	OK	25/AUG/2020
2.	System Operation	OK	25/AUG/2020
3.	Basic trouble shooting and Maintenance	OK	25/AUG/2020

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
1	Prem Singh	Hematology	PS	25/08/2020
2	Manish Kumar	Hematology	MK	25/08/2020
3				
4				

VI. SYSTEM CERTIFICATION


Study data has determined that the system described in this document either meets all criteria outline 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 Performance Qualification.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : SURAJ KUMAR

Designation : Manager - Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature : 

Date : 25/AUG/2020

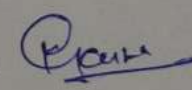


Customer Authorizations: **SHREE PATH LAB, REWARI**

Name : *Dr. Kamal Kant*

Designation : **Dr. Kamal Kant
M.B.B.S., M.D.**

Company : **DMC - 58271
Shree Path Lab**

Signature : 

Date : 25/08/2020

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PERFORMANCE QUALIFICATION

For

AUTOMATED HEMATOLOGY ANALYZER

MODEL: BC 3000 PLUS

AGAPPE DIAGNOSTICS LTD.

ADL/DO/SER/IOP/0069/21-22

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I. APPROVAL OF THE PERFORMANCE QUALIFICATION PROCEDURE

Both SHREE PATH LAB, REWARI and AGAPPE DIAGNOSTICS LTD are jointly responsible for the installation of BC 3000 PLUS with serial number RJ-99128744 at "Shree Path Lab, 1st Floor, Ratan Ultrasound Centre, Opposite Government Girls School, Circular Road, Rewari" as per the attached PERFORMANCE Qualification protocol.

Protocol Performed By: Representative of AGAPPE DIAGNOSTICS LTD.



Name	: SURAJ KUMAR	Signature :	
Designation	: Manager - Customer Service		
Title Company	: AGAPPE DIAGNOSTICS LTD	Date	: 25/AUG/2020

Validation Team from SHREE PATH LAB, REWARI

Name	: Dr. Kamal Kant Dr. Kamal Kant	Signature :	
Designation	: M.B.B.S., M.D. DMC - 58271		
Department	: Hematology	Date	: 25/08/2020

Customer Authorizations:

Dr. Kamal Kant
M.B.B.S., M.D.
DMC - 58271
Shree Path Lab

Name : Dr. Kamal Kant
Title : PERFORMACNE QUALIFICATION
Site : Rewari

Signature :
Date : 25/08/2020

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II. INSTRUCTIONS

1. An authorized **AGAPPE DIAGNOSTICS LTD.** representative will check and enter the specific data as outlined in the Performance Qualification. Each result will be noted and dated.
2. The concerned employees of **SHREE PATH LAB, REWARI** verify each result and sign in each page. The member of the validation team will carry this out.
3. ALL deviations from the acceptance criteria detailed in this document will be noted in the COMMENTS section at the end of the 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.



III. SCOPE

This Performance Qualification protocol will be performed on the **BC 3000 PLUS** at **SHREE PATH LAB, REWARI**. This Performance 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 has been installed 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.



IV PERFORMANCE QUALIFICATION

A. Instrument Identification

Verified Date: 25/AUG/2020

1. Model Name : BC 3000 PLUS

B. Serial Number : RJ-99128744

Following is a list of tests to be performed and verified

Test No.	Test Name	Test purpose	Verified By and date	
01	Start up	To make the equipment ready for operation	SURAJ KUMAR	25/AUG/2020
03	Back ground Count	To check the background	WBC≤0.3	SURAJ KUMAR 25/AUG/2020
			RBC≤0.03	SURAJ KUMAR 25/AUG/2020
			PLT≤10	SURAJ KUMAR 25/AUG/2020
			HB≤1	SURAJ KUMAR 25/AUG/2020
			HCT≤0.5	SURAJ KUMAR 25/AUG/2020
04	Inventory of reagents /consumables	To check the reagent	SURAJ KUMAR	25/AUG/2020
05	Calibration Check	To calibrate the system when required	SURAJ KUMAR	25/AUG/2020
06	QC check	To confirm that system and reagents are acceptable and working within specifications	SURAJ KUMAR	25/AUG/2020
07	Reproducibility check	To check the precision [CV %]	WBC≤ 2%	SURAJ KUMAR 25/AUG/2020
			RBC≤ 2%	SURAJ KUMAR 25/AUG/2020
			PLT≤ 4%	SURAJ KUMAR 25/AUG/2020
			HB≤ 1.5%	SURAJ KUMAR 25/AUG/2020
			MCV≤ 1.0%	SURAJ KUMAR 25/AUG/2020
08	Sample programming and Analysis	To run the samples	SURAJ KUMAR	25/AUG/2020
09	Shut down procedure	To shut down the system	SURAJ KUMAR	25/AUG/2020

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Test 01: Starting the system

Purpose : To make the instrument READY for operation

Summary :

Instrument checks functioning of different parts of the instrument automatically; if there is an error code, initialize the system and follow corrective action instructions provided for the error message.

Procedure:

- Check the room temperature and switch on the Air Conditioner
- Check the UPS.
- Switch on the BC 3000 plus system by pressing the main switch.
- Wait for the instrument to get ready after initialization
- The machine is ready for next step if it displays "READY" on the Status Area
- If not, initialize by pressing the initialize again after solving the error displayed
- Follow instructions provided for the error message

Acceptance criteria: System to display "READY" status

PARAMETER

PASS

FAIL

Parameter values for verification: "READY" on Status Area

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Test 02: Daily Maintenance

Purpose: To clean appropriate modules so as per the daily maintenance protocol.

Method:

Refer detailed procedure for Daily Maintenance

S No.	Activity	Done by	Date
01	Empty waste container	SURAJ KUMAR	25/AUG/2020
02	Check Diluents	SURAJ KUMAR	25/AUG/2020
03	Check Lyse	SURAJ KUMAR	25/AUG/2020
04	Check Rinse	SURAJ KUMAR	25/AUG/2020
05	Clean Wipe Block	SURAJ KUMAR	25/AUG/2020
06	Clean out side area	SURAJ KUMAR	25/AUG/2020
07	Load supplies and remove outdated and empty reagents	SURAJ KUMAR	25/AUG/2020
08	Check startup screen	SURAJ KUMAR	25/AUG/2020
09	Perform Quality Control	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: System should be "Ready" after daily maintenance without any error

PARAMETER PASS

~~FAIL~~

Parameter values for verification: System found "Ready" after daily maintenance

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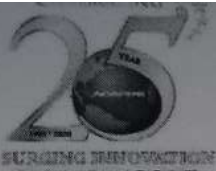
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Test 03: Back ground Count

Purpose: To check the relative background of installed BC 3000 plus

Procedure:

S No.	Activity	Done By	Date
01	Checking the blank pulse	SURAJ KUMAR	25/AUG/2020
	WBC		
	RBC		
	PLT		
	HGB		
	HCT		

Acceptance criteria:

- No error Messages displayed
- All reagents should show acceptance

PARAMETER PASS FAIL

Parameter values for verification: No Error Messages

Test 04: Inventory of reagents /Consumables

Purpose: To check the quality of reagents

S No	Activity	Done By	Date
01	Diluent	SURAJ KUMAR	25/AUG/2020
02	Rinse	SURAJ KUMAR	25/AUG/2020
03	Lyse	SURAJ KUMAR	25/AUG/2020

Acceptance criteria:

- No cloudiness or background abnormal message
- All reagents should show acceptance

PARAMETER PASS FAIL

Parameter values for verification: No Error Messages

Test 03: Calibration of the system

Purpose: To calibrate the system

Procedure:

S No.	Activity	Done By	Date
01	Preparation of the cal material	SURAJ KUMAR	25/AUG/2020
02	Performing Calibration with calibration programming screen	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: Calibration data shows concordance values in triplicate measurement

PARAMETER PASS FAIL

Parameter values for verification: No error message in the printout

Test 04: QC check

Purpose: To confirm that systems, reagents and consumables are acceptable & working within specifications for each assay used.

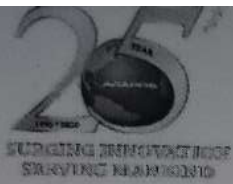
Procedure:

S No.	Activity	Done By	Date
01	Preparing control material	SURAJ KUMAR	25/AUG/2020
02	Creating QC file	SURAJ KUMAR	25/AUG/2020
03	QC sample programming and analysis	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: QC results within specified limits mentioned on the control product insert

PARAMETER PASS FAIL

Parameter values for verification: QC values within $\pm 2SD$



Test 05: Reproducibility Check

Purpose: To check the reproducibility of instrument

S No.	Activity	Done By	Date
01	Preparing control material/ sample	SURAJ KUMAR	25/AUG/2020
02	Running triplicates	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: Results CV within specified limits

PARAMETER PASS ~~FAIL~~

Parameter values for verification: CV% within the limits

Test 06: Sample programming and Analysis

Purpose: To run the samples

Procedure:

S No.	Activity	Done By	Date
01	Preparing and Processing of samples	SURAJ KUMAR	25/AUG/2020
02	Programming samples	SURAJ KUMAR	25/AUG/2020
03	Aspirating the samples	SURAJ KUMAR	25/AUG/2020
04	Viewing samples in process	SURAJ KUMAR	25/AUG/2020
05	Review results: Monitoring results	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: Samples Analysis without any error

PARAMETER PASS ~~FAIL~~

Parameter values for verification: Sample analysis without any error



Test 07: Shut down

Purpose: To shut down the system

Procedure:

S No.	Activity	Done By	Date
01	Preparing the system for shut down	SURAJ KUMAR	25/AUG/2020
02	Following the on screen instructions	SURAJ KUMAR	25/AUG/2020
03	Switch off the instrument when prompted	SURAJ KUMAR	25/AUG/2020

Acceptance criteria: Shut down without any error

PARAMETER PASS FAIL

Parameter values for verification: Shut down without any error

AGAPPE DIAGNOSTICS LTD. ISO 9001:2015 | EN ISO 13485:2016 CERTIFIED COMPANY | CIN : U24239MH1998PLC115413

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C. Operational procedure:

a. Certificate of Training


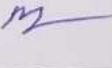
1. Technician Training

This certifies that the technicians have received basic user training in the following categories for the system described in this Operational Qualification.

S No.	Training program	Initials	Date
1.	Instrument Setup	OK	25/AUG/2020
2.	System Operation	OK	25/AUG/2020
3.	Basic trouble shooting and Maintenance	OK	25/AUG/2020

2. Operator Training

The users responsible for the operation of this equipment have been trained in the proper usage of the system. Training focused on the basic operation and maintenance of the system.

S No.	Operators	Department	Initials	Date
1	Prem Singh	Hematology		25/08/2020
2	Mathil Kerman	Hematology		25/08/2020
3				
4				

VI. SYSTEM CERTIFICATION

Study data has determined that the system described in this document either meets all criteria outline 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 Performance Qualification.

Report Performed By: **AGAPPE DIAGNOSTICS LTD.** Representative

Name : SURAJ KUMAR

Designation : Manager - Customer Service

Company : AGAPPE DIAGNOSTICS LTD.

Signature :



Date

: 25/AUG/2020

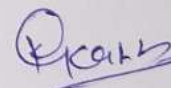
Customer Authorizations: **SHREE PATH LAB, REWARI**

Name : *Dr. Kamal Kant*

Designation : **Dr. Kamal Kant
M.B.B.S., M.D.**

Company : **DMC - 58271
Shree Path Lab**

Signature :



Date

:



CERTIFICATE OF CALIBRATION

Customer Name : Shree Path Lab

Address of the customer : Opposite Government Girls School, Circular Road, Rewari

Instrument Model : BC 3000 Plus - 3 Part Hematology Analyzer

Serial No. : RJ-99128744

Date of Installation : 25/08/2020

Date of Calibration : 03/01/2022

This is to certify that the above-mentioned product has been calibrated for CBC parameters (WBC, RBC, HGB, MCV, PLT) according to the standard operating procedure given by the MINDRAY

The reference instruments used for value assignment are managed by the traceability system in Shenzhen Mindray Bio – Medical Electronics Co., Ltd, and these are traceable to the International Standards such as ICSH/WHO, NCCLS.

For Agappe Diagnostics Ltd.,



Suraj
Authorized Signatory
Name: Suraj Kumar
Designation: Manager Customer Service

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**AGAPPE**DETAILS OF CONTROL RUN

Instrument Model : BC 3000 PLUS - 3 Part Hematology Analyzer
 Serial No : RJ-99128744
 Date of Control Run : 07/05/2022
 Control Used : D-checkKD
 Lot No : 102201
 Expiry : 05/06/2022

The results of repeatability test are summarized in the following table. Refer the attached control sheets for details.

Sample No	WBC K/ μ L	RBC M/ μ L	HGB g/dL	MCV fL	PLT K/ μ L
1	2.4	2.57	7.2	75.8	86
2	7.4	4.66	14.5	83.3	240
3	16.2	5.61	18.0	84.2	501
Instrument Mean	7.17	4.28	12.20	81.07	226
Range	0.2 - 99.9	0.20 - 8.00	10 - 250	40 - 150	10 - 999
CV %	2.5%	2%	1.5%	0.5%	5%

This is to certify that the above-mentioned product has been calibrated for CBC parameters (WBC, RBC, HGB, MCV, PLT) according to the standard operating procedure given by the Mindray

The control run after calibration shows good repeatability and precision

Next Calibration due on **02/07/2022**

For Agappe Diagnostics Ltd.,



Suraj
 Authorized Signatory

Name: Suraj Kumar

Designation: Manager Customer Service

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SHREE PATH LAB,REWARI

EQAS CAPA CHECKLIST

Date and time:- 12/04/2022

EQAS sample detail:- AIIMS EQAS 153-K

Result detail:- ALL RESULTS ARE ACCEPTABLE EXCEPT VALUE OF WBC COUNT OF SAMPLE-1.

Outlier detail:- AIIMS EQAS SAMPLE 153-K. NO TRANSCRIPTIONAL ERROR DURING RESULT SUBMISSION ON THE PORTAL. ALL RESULTS FOUND IN ACCEPTABLE RANGE EXCEPT WBC COUNT OF SAMPLE-1.

Root cause analysis checklist:-

1.	Check for typographical error	OK
2.	Check instrument print for flag or alarm	OK
3.	Check technical staff status	OK
4.	IQC status for any outlier	OK
5.	Sample run procedure step according to SOP	OK
6.	Storage condition of EQAS sample	OK
7.	IQC send for outlier parameter to verify current status	OK
8.	IQC result interpretation	OK

Analysis comment:-

CHECKLIST COMPLETED AND A RANDOM SAMPLE SENT OUTSIDE LAB FOR VERIFICATION. RESULT WAS FOUND OUT TO BE SATISFACTORY.

Corrective action taken and preventive action:-

HEMATOLOGY ANALYSER RC-3070 PLUS CALIBRATED
AND IQC SAMPLE RESULT VERIFICATION DONE
FOR CURRENT STATUS.

Follow up status:-

IQC TO BE MONITOR FOR ANY SHIFT
OR ANY OUTLIER.

(K) Rawl
Department in-charge

Psen
Technical Staff

ajp
Prepared by

(K) Rawl
Approved by



PROFICIENCY TESTING REPORT
ISHTM-AIIMS EXTERNAL QUALITY ASSURANCE PROGRAMME
 NABL accredited program as per ISO/IEC 17043:2010 standard
 Organized By Department of Hematology, AIIMS, New Delhi-110029



Duration of stability testing - minimum upto 8 days at ambient temp. after dispatch of specimens

EQAP CODE No. : 4249

Distribution No.: 154-K

Month/Year: January/2022

Instrument ID: RJ-99128744

Name & Contact No. of PT Co-ordinator: Dr. Seema Tyagi (Prof.), Hematology, AIIMS, Delhi,
 Tel: 9013085730 , E-Mail : accuracy2000@gmail.com

Date of issue & status of the report: 28-03-2022[Final].

CBC and Retic Assessment

Test Parameters	S.No.	Among Lab (Accuracy Testing)						Within Lab (Precision Testing)			
		Your Result 1	Your Result 2	Your Results Sum of 2 Value	Consensus result sum of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score	Yours Results Diff. of 2 Values	Consensus Result Diff. of 2 values (Assigned Value)	Uncertainty of Assigned Values	Z Score
WBC x10 ³ /µl	1	7.7	7.5	15.2	16.96	0.0760	-0.93	0.2	0.17	0.0130	0.20
RBC x10 ⁶ /µl	1	4.08	4.07	8.15	8.89	0.0130	-2.38	0.01	0.04	0.0030	-0.58
Hb g/dl	1	11.5	11.3	22.8	21.9	0.0310	1.21	0.2	0.1	0.0090	0.67
HCT%	1	31.7	31.4	63.1	71.7	0.1730	-1.97	0.3	0.4	0.0270	-0.27
MCV-fl	1	77.9	77.1	155	161.8	0.3460	-0.77	0.8	0.2	0.0220	2.02
MCH-Pg	1	28.2	27.6	55.8	49.3	0.0870	3.10	0.6	0.2	0.0160	1.80
MCHC-g/dl	1	36.2	35.9	72.1	60.9	0.1530	2.91	0.3	0.3	0.0190	0.00
Plt. x10 ³ /µl	1	355	336	691	811	3.57	-1.37	19	10	0.70	0.87
Retic %	2	1.1	0.7	1.8	7	0.16	-1.12	0.4	0.3	0.02	0.45

P.S . Assesment

YOUR REPORT			CONSENSUS REPORT		
DLC%	3	Nrbcs=8.00 , Poly=50.00 L=15.00, E=4.00, Mono/Promono= , B1=3.00 P.M.=2.00, Mye=6.00, Meta=18.00, Other=	Poly: 55 - 69, Myelo: 4 - 10, Meta: 4 - 9; Lympho/Promyelo: 1 - 10; Blast/nRBC/Eos/Baso/Mono: 0 - 5		
RBC Morphology	3	NORMOCYTIC NORMOCHROMIC	Predominantly: Normocytic/Normochromic; Moderate: Anisocytosis, Microcytosis, Hypochromia; Mild: Macrocytosis, Poikilocytosis		
Diagnosis	3	CHROINC MYELOID LEUKEMIA-CHRONIC PHASE	Chronic Myeloid Leukemia (CML)		

COMBINED DATA VALUES OF TOTAL PARTICIPANTS

Test parameters	S.No.	Total participants covered in the current dist. 154--K	Total No. responded	% of Labs with Z Score 0-2		% of Labs with Z Score 2-3		% of Labs with Z Score >3	
				Among labs	Within lab	Among labs	Within lab	Among labs	Within lab
WBC x10³/µl	1	268	266	83.46	87.97	4.14	4.51	12.4	7.52
RBC x10⁶/µl	1	268	268	87.31	91.04	7.46	3.36	5.23	5.6
Hb g/dl	1	268	268	89.55	91.79	6.34	4.1	4.11	4.11
HCT%	1	268	265	92.83	91.32	3.77	3.4	3.4	5.28
MCV-fl	1	268	264	93.94	94.32	1.52	2.65	4.54	3.03
MCH-Pg	1	268	264	89.02	90.91	6.82	3.41	4.16	5.68
MCHC-g/dl	1	268	265	92.83	91.32	4.15	4.53	3.02	4.15
Plt. x10³/µl	1	268	265	92.83	89.43	3.4	5.66	3.77	4.91
ReticCount%	2	268	268	92.16	83.96	3.36	6.34	4.48	9.7
PS Assessment	3	268	233	Satisfactory :85.03%, Borderline Sat. :12.35%, Unsatisfactory :2.62%					

***Comments:**

1). **Among Lab (EQA) : Results acceptable.**

2). **Within Lab (IQA) : Precision acceptable.**

Note-1: EQA (External Quality Assurance) : Your Performance among various of participating labs in PT, to determine the accuracy of your results.

IQA (Internal Quality Assurance) : Your Performance of comparison of two consecutive measurement values within your lab to test the precision of your autoanalyzer.

Note-2: Z score among & within lab were calculated, as per to ISO/IEC 13528:2015 standard. Z score among lab (EQA)= (Your Result Sum of two values - Consensus Result sum of two values)/(Normalised IQR)

Z score within lab (IQA)= (Your Result Difference of two values - Consensus Result difference of two values)/(Normalised IQR)

IQR = Quartile 3 - Quartile 1 of participant data, Normalised IQR = 0.7413 x IQR

Note-3: Z score 0 to ± 2 : Acceptable, Z score ± 2 to ± 3 :Warning Signal, Z score $> \pm 3$: Unacceptable [As per ISO/IEC 13528:2015 standard]

Note-4: Z score value between "0 to ± 2 " are texted in green colour. Z score value between " ± 2 to ± 3 " are texted in orange colour. Z score value $> \pm 3$ are texted in red colour.

Note-5: Homogeneity and stability testing of PT sample were done as per ISO 13528:2015 standard. To pass homogeneity test, between sample SD (Ss) should be smaller than the check value (0.3*SDPA). To pass the stability test, average difference in measurement values of first and last day sample ($\bar{x}-\bar{y}$) should be smaller than the check value (0.3*SDPA).

Note-6: ISHTM-AIIMS-EQAP does not subcontract any task of its scheme

Note-7: Participants are free to use methods/analyzer of their own choice.

Note-8: Proficiency testing (PT) samples are sent quarterly to each participant.

Note-9: All the necessary details regarding design and implementation of PT, are provided in the instruction sheet as well as on programme's website www.ishtmaiimseqap.com.

Report authorized by,



Dr. Seema Tyagi (Prof.)

PT Co-ordinator: ISHTM-AIIMS-EQAP

Department of Hematology, AIIMS, New Delhi

-----End Of Report-----