Calibration Certificate

This is to certify that Haematology Analyzer **CelQuant-3 Prime** Instrument Serial. No. **CQP30191216** installed at **IVY Hospital, Nawanshahar** has been calibrated by our engineer on **01-May-2021** with appropriate and sophisticated tools. Below parameters are been calibrated:

This calibration includes preventive maintenance, calibration of all moving parts.

TEST ITEMS AND RESULT

Appearance	OK
Test Speed	OK
Suction sample program	OK
Valve and optical application	OK
Motor & valve	OK
Gain adjustment and red, white MCV test	OK
Sample Volume	OK
Diameter Orifice	OK
Hydraulic Unit	OK
Power Consumption	250V 4A
Fuse check	OK
Power Supply and Earthing	230 Volts and Grounding less then 5V

This Calibration Certificate is Valid Up to **30-April-2022.**

Conclusion: All parameter are within range. The Machine is working properly. (As per Meril terms.)

Engineer Name: **Mr. Amit Kumar** Designation: **Service Specialist**

R&D SYSTEMS
614 McKinley Place NE
Minneapolis, MN 55413

Traceability
CBC-ST PLUS Hematology Controls

R&D Systems, Inc Hematology Control and Calibrator values are traceable to standard reference methods.

Hematology analyzers in R&D Systems' Quality Assurance Laboratory are whole blood calibrated to values obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

The **White Blood Cell (WBC)** and **Red Blood Cell (RBC)** are analyzed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

Hemoglobin is measured using the Clinical Laboratory Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method [1]. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations [1].

The **hematocrit** (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document [2]. No correction is made for trapped plasma.

Platelets are assayed using a hemocytometer and phase contrast optics.

1. National Committee for Clinical Laboratory Standards (now Clinical Laboratory Standards Institute.) Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood: Approved Standard-Third Edition. NCCLS document H15-A3. Wayne, PA: NCCLS, 2000.
2. National Committee for Clinical Laboratory Standards (now Clinical Laboratory Standards Institute.) Procedure for Determining Packed Cell Volume by the Microhematocrit Method: Approved Standard, NCCLS document H7-A3. NCCLS, Wayne, PA: NCCLS, 2001.

IVY HOSPITAL

ID:
Date: 01-05-2021 13:33
No. : 217622
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	0	10^3/uL
RBC	0	10^6/uL
HGB	0	g/dL
HCT	*.**	%
MCV	*.**	fL
MCH	*.**	pg
MCHC	*.**	g/dL
PLT	0	10^3/uL
LYM#	*.**	10^3/uL
MXD#	*.**	10^3/uL
NEUT#	*.**	10^3/uL
LYM%	*.**	%
MXD%	*.**	%
NEUT%	*.**	%
RDW-CV	*.**	%
RDW-SD	*.**	fL
PDW	*.**	fL
MPV	*.**	fL
P-LCR	*.**	%
PCT	*.**	%
P-LCC	*.**	10^3/uL

IVY HOSPITAL

ID:
Date: 01-05-2021 10:01
No. : 1
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	5.7	10^3/uL
RBC	3.5	10^6/uL
HGB	↓9.1	g/dL
HCT	↓31.3	%
MCV	89.3	fL
MCH	26	pg
MCHC	↓29.1	g/dL
PLT	418	10^3/uL
LYM#	1.19	10^3/uL
MXD#	0.61	10^3/uL
NEUT#	3.9	10^3/uL
LYM%	20.8	%
MXD%	10.8	%
NEUT%	68.4	%
RDW-CV	↑16.9	%
RDW-SD	50.4	fL
PDW	15.8	fL
MPV	10.3	fL
P-LCR	25.8	%
PCT	↑0.431	%
P-LCC	108	10^3/uL

IVY HOSPITAL

ID:
Date: 01-05-2021 10:05
No. : 2
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	5.73	10^3/uL
RBC	3.51	10^6/uL
HGB	↓9.2	g/dL
HCT	↓31.3	%
MCV	89.2	fL
MCH	26.2	pg
MCHC	↓29.4	g/dL
PLT	402	10^3/uL
LYM#	1.1	10^3/uL
MXD#	0.37	10^3/uL
NEUT#	4.26	10^3/uL
LYM%	19.1	%
MXD%	6.4	%
NEUT%	74.5	%
RDW-CV	↑17	%
RDW-SD	51.3	fL
PDW	↓12.6	fL
MPV	9.7	fL
P-LCR	23.9	%
PCT	↑0.39	%
P-LCC	96	10^3/uL

IVY HOSPITAL

ID:
Date: 01-05-2021 10:07
No. : 3
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	5.47	10^3/uL
RBC	3.51	10^6/uL
HGB	↓9.2	g/dL
HCT	↓31.1	%
MCV	88.7	fL
MCH	26.2	pg
MCHC	↓29.6	g/dL
PLT	391	10^3/uL
LYM#	1.05	10^3/uL
MXD#	0.44	10^3/uL
NEUT#	3.98	10^3/uL
LYM%	19.3	%
MXD%	8	%
NEUT%	72.7	%
RDW-CV	↑16.6	%
RDW-SD	49.5	fL
PDW	↓12.7	fL
MPV	9.8	fL
P-LCR	24.3	%
PCT	↑0.383	%
P-LCC	95	10^3/uL

IVY HOSPITAL

ID:
Date: 01-05-2021 10:09
No. : 4
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	5.7	10^3/uL
RBC	3.58	10^6/uL
HGB	↓9.4	g/dL
HCT	↓31.9	%
MCV	89.2	fL
MCH	26.3	pg
MCHC	↓29.5	g/dL
PLT	412	10^3/uL
LYM#	1.1	10^3/uL
MXD#	↑1.2	10^3/uL
NEUT#	3.4	10^3/uL
LYM%	19.3	%
MXD%	↑21.1	%
NEUT%	59.6	%
RDW-CV	↑17.2	%
RDW-SD	49.5	fL
PDW	16.8	fL
MPV	10.5	fL
P-LCR	26.1	%
PCT	↑0.433	%
P-LCC	108	10^3/uL

IVY HOSPITAL

ID:
Date: 01-05-2021 10:11
No. : 5
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	5.63	10^3/uL
RBC	↓3.49	10^6/uL
HGB	↓9.2	g/dL
HCT	↓31.1	%
MCV	89.1	fL
MCH	26.4	pg
MCHC	↓29.6	g/dL
PLT	411	10^3/uL
LYM#	1.09	10^3/uL
MXD#	0.66	10^3/uL
NEUT#	3.88	10^3/uL
LYM%	19.4	%
MXD%	11.8	%
NEUT%	68.8	%
RDW-CV	↑17	%
RDW-SD	49.5	fL
PDW	16.5	fL
MPV	10.6	fL
P-LCR	26.5	%
PCT	↑0.436	%
P-LCC	109	10^3/uL

IVY HOSPITAL

ID:
Date: 01-05-2021 10:14
No. : 6
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	5.39	10^3/uL
RBC	3.51	10^6/uL
HGB	↓9.1	g/dL
HCT	↓31.1	%
MCV	88.7	fL
MCH	↓25.9	pg
MCHC	↓29.3	g/dL
PLT	418	10^3/uL
LYM#	1.23	10^3/uL
MXD#	↑1.12	10^3/uL
NEUT#	3.04	10^3/uL
LYM%	22.8	%
MXD%	↑20.7	%
NEUT%	56.5	%
RDW-CV	↑16.6	%
RDW-SD	49.5	fL
PDW	16.1	fL
MPV	10.5	fL
P-LCR	26.3	%
PCT	↑0.439	%
P-LCC	110	10^3/uL

IVY HOSPITAL

ID:
Date: 01-05-2021 10:17
No. : 7
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	5.6	10^3/uL
RBC	3.5	10^6/uL
HGB	↓9.2	g/dL
HCT	↓31.1	%
MCV	88.8	fL
MCH	26.3	pg
MCHC	↓29.6	g/dL
PLT	395	10^3/uL
LYM#	1.2	10^3/uL
MXD#	0.8	10^3/uL
NEUT#	3.6	10^3/uL
LYM%	21.5	%
MXD%	14.2	%
NEUT%	64.3	%
RDW-CV	↑16.8	%
RDW-SD	49.5	fL
PDW	15.2	fL
MPV	10.2	fL
P-LCR	25.2	%
PCT	↑0.403	%
P-LCC	100	10^3/uL

IVY HOSPITAL

ID:
Date: 01-05-2021 10:19
No. : 8
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	5.56	10^3/uL
RBC	3.5	10^6/uL
HGB	↓9.2	g/dL
HCT	↓31	%
MCV	88.5	fL
MCH	26.3	pg
MCHC	↓29.7	g/dL
PLT	406	10^3/uL
LYM#	1.21	10^3/uL
MXD#	0.55	10^3/uL
NEUT#	3.8	10^3/uL
LYM%	21.7	%
MXD%	10	%
NEUT%	68.3	%
RDW-CV	↑17.3	%
RDW-SD	50.4	fL
PDW	↓12.8	fL
MPV	9.9	fL
P-LCR	24.7	%
PCT	↑0.402	%
P-LCC	100	10^3/uL

IVY HOSPITAL

ID:
Date: 01-05-2021 10:23
No. : 9
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	5.47	10^3/uL
RBC	3.51	10^6/uL
HGB	↓9.3	g/dL
HCT	↓31.1	%
MCV	88.7	fL
MCH	26.5	pg
MCHC	↓29.9	g/dL
PLT	416	10^3/uL
LYM#	1.16	10^3/uL
MXD#	0.47	10^3/uL
NEUT#	3.84	10^3/uL
LYM%	21.1	%
MXD%	8.6	%
NEUT%	70.3	%
RDW-CV	↑16.8	%
RDW-SD	49.5	fL
PDW	16	fL
MPV	10.3	fL
P-LCR	25.8	%
PCT	↑0.428	%
P-LCC	107	10^3/uL

IVY HOSPITAL

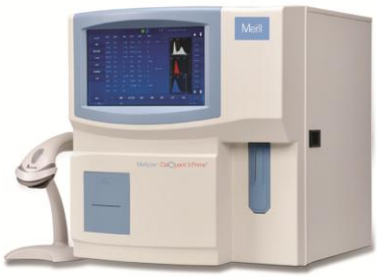
ID:
Date: 01-05-2021 10:29
No. : 10
Mode: WB
Patient:
Sex: Age: Years
Bed No:
Dept:
Case No:

Item:	Result:	
WBC	5.5	10^3/uL
RBC	3.53	10^6/uL
HGB	↓9.3	g/dL
HCT	↓31.3	%
MCV	88.8	fL
MCH	26.3	pg
MCHC	↓29.7	g/dL
PLT	393	10^3/uL
LYM#	1.09	10^3/uL
MXD#	0.49	10^3/uL
NEUT#	3.92	10^3/uL
LYM%	19.8	%
MXD%	8.9	%
NEUT%	71.3	%
RDW-CV	↑17	%
RDW-SD	48.7	fL
PDW	16.4	fL
MPV	10.6	fL
P-LCR	26.8	%
PCT	↑0.417	%
P-LCC	105	10^3/uL

MERIL DIAGNOSTICS

CELQUANT PRIME
3-PDA HEAMATOLOGY ANALYZER

INSTALLATION QUALIFICATION



Marketed by:
MERIL DIAGNOSTICS.
MUMBAI

I. Approval of the IQ procedure:

Ivy Diagnostic Laboratory and MERIL DIAGNOSTICS are jointly responsible for the installation of the system HEMATOLOGY Analyzer, Model: CELQUANT PRIME, Serial No. **CQP3O191216** in the clinical lab of **Ivy Diagnostic Laboratory** as per the attached protocol.

Protocol Performed By: **MERIL DIAGNOSTICS Representative**

Name	:	**IVY Diagnostic Laboratory**	Signature:
Title	:	**INSTALLATIONQUALIFICATION**	
Company	:	**MERIL DIAGNOSTICS LTD.**	Date:03-May-2019

Validation Team from:

Name	: SANDEEP SHINDE
Designation	: MANAGER- TECHNICAL SERVICE
Department	: SERVICE

Customer Authorizations:

Name	:	Mr Ravi Kumar	Signature :
Title	:	**INSTALLATION QUALIFICATION**	
Site	:		Date:03-May-2019

II. Instructions

1. This document is to be completed at the time the system is shifted to its current location (new) and set up for operation.

2. An authorized 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 **IVY Diagnostic Laboratory (Mr Ravi Kumar)**will verifies 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.

III. Scope

This Installation Qualification protocol will be performed on the Hematology Analyzer, Model CELQUANT PRIME, Serial No. **CQP3O191216** located in Inside IVY Hospital Chandigarh road Nawa Shahar. 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.

IV. Ancillary Information.

Utilities

Sr.No.	Utility		Verified By	Date
1.	Environmental condition as per requirement: (Ambient range of temperature 15 – 30 °C, relative humidity 45% to 85%, air conditioning facility, non exposure to direct sunlight, non-interference from high frequency radio waves)	Yes / No	Mr Daljeet Singh	3-05-19
2.	Adequate space for installation : 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	Mr Daljeet Singh	3-05-19
3.	ALL REAGENTS placed within a distance of 2 meters :	Yes / No	Mr Daljeet Singh	3-05-19
4.	Power Source Requirements* It should have minimum one 5amps plug. It should have proper grounding. In case of online UPS minimum power handling capacity should be minimum 1KVA Line- Neutral voltage:_____ Line –Earth voltage:_____ Neutral-Earth voltage:_____	Yes / No	Mr Daljeet Singh	3-05-19

c. The instrument has been verified for the following

Sr.No.	Verification		Verified By	Date
1.	Instrument is identified	Yes / No	Mr Daljeet Singh	3-05-19
2.	Manufacturer's specifications are included	Yes / No	Mr Daljeet Singh	3-05-19
3.	Accessories / Consumables are listed	Yes / No	Mr Daljeet Singh	3-05-19
4.	Manufacturer's certificate of Compliance attached	Yes / No	Mr Daljeet Singh	3-05-19

V. Installation Qualification

Equipment Description:

This Hematology Analyzer CELQUANT PRIME is an automated 3-PDA Hematology analyzer for in vitro diagnostic use in clinical laboratories. The CelQuant provides accurate and precise test results for (20) parameters including three histograms.

Instrument identification		Verified by	Date
Equipment Name	3-PDA Hematology	Mr Daljeet Singh	3-05-19
Model	CELQUANT PRIME	Mr Daljeet Singh	3-05-19
Manufacturer	MERIL DIAGNOSTICS	Mr Daljeet Singh	3-05-19
Marketed By	MERIL DIAGNOSTICS	Mr Daljeet Singh	3-05-19
Equipment #	CELQUANT Prime	Mr Daljeet Singh	3-05-19
Serial Number	CQP3O191216	Mr Daljeet Singh	3-05-19
Size (in mm)	W 335 X L 475 X H 445	Mr Daljeet Singh	3-05-19
Power	AC 220 V	Mr Daljeet Singh	3-05-19
Frequency	50 – 60 Hz	Mr Daljeet Singh	3-05-19
Power Consumption	Less Than 250 VA	Mr Daljeet Singh	3-05-19

Installation Qualification:

Consumables such as **Standard Accessory** were supplied along with instrument.

Currently a sufficient stock of the same is being maintained Yes □ No □

C. List of Manuals, Certificates and Drawings

MERIL DIAGNOSTICS 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 MERIL DIAGNOSTICS and **IVY Diagnostic Laboratory**.

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 Instruction For use.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period MERIL DIAGNOSTICS 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.

Spare Parts

MERIL DIAGNOSTICS 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:

H. Installation Procedure

(These had been performed at the time of original installation at the initial location)

1. **Unpacking Checklist**
   CELQUANT PRIME Instruction for Use

2. **Check Before Installation**
   CELQUANT PRIME Instruction for Use

3. **Grounding**
   CELQUANT PRIME Instruction for Use

4. **Installation Environment & Space**
   CELQUANT PRIME Instruction for Use

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 : MERIL DIAGNOSTICS Representative

Name : SANDEEP SHINDE.

Title : **INSTALLATION QUALIFICATION** Signature :

Company : **MERIL DIAGNOSTICS.** Date :

Customer Authorizations:

Name :

Title : INSTALLATION QUALIFICATION Signature:

Customers name: Date :

1) Reagent Check: -

2) Printer checked:-

3) Analyzer switched ON

4) SELF CHECK performed

5) RINSE CYCLE completed

6) Background limits within acceptable range

7) Analysis start time

8) Analysis end time

9) No. of samples analyzed

10) Shut down procedure done

11) Analyzer switched OFF at

Recorded by: Checked by:

MERIL DIAGNOSTICS

3-PDA HEMATOLOGY ANALYZER
CELQUANT PRIME

OPERATIONAL QUALIFICATION

Marketed by:
MERIL DIAGNOSTICS

I. Approval of the OQ procedure:

IVY Diagnostic Laboratoryand MERIL DIAGNOSTICS are jointly responsible for operational check of the HEMATOLOGY Analyzer, Model: CELQUANT PRIME serial No. **CQP3O191216** in the clinical lab of Inside ivy hospital, Chandigarh road, Nawa shahar , Punjab as per protocol attached.

Protocol Performed by: MERIL DIAGNOSTICS **Representative**

Name	:	Mr Daljeet Singh	Signature:
Title	:	**OPERATIONAL QUALIFICATION**	Date: 03-May-2019
Company	:	MERIL DIAGNOSTICS.	
Designation	:	Area Service Manager	
Department	:	SERVICE	

Customer Authorization:

Name	:	Mr Ravi Kumar	Signature:
Title	:	OPERATIONAL QUALIFICATION	Date: 03-May-2019
Site	:		

II. Instructions

5. The MERIL DIAGNOSTICS representative will check each module and enter the specific data as described in the Operational Qualification. Each result will be noted and dated.
6. Employee of the **IVY Diagnostic Laboratory, (Mr Ravi Kumar)** will verify each result and sign in the last page. The member/s of the validation team will be responsible for the same.
7. Any deviations from the acceptance criteria detailed in this document will be noted in the _____**(COMMENT)** 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 IVY Diagnostic Laboratory. However this additional cost will be waived when this test is conducted at time of initial performance check of new instruments.
8. 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.

III. Scope

This Operational Qualification protocol will be performed on the Hematology Analyzer, CELQUANT PRIME, Serial No.**CQP3O191216** located in **IVY Diagnostic Laboratory, Nawa Shaher, Punjab** 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.

IV. Operational Qualification

a. Instrument Identification		**Verified Date**
1. Model Name	CELQUANT PRIME	03-5-2019
2. Serial Number	CQP3O191216	03-5-2019

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.	Vacuum Pump	To verify pressure & Vacuum generation	03-05-2019
2.	Arm Motor	Capacity of performing Arm functions.	
3.	Hgb Lamp	To check HGB result	
4.	Solenoide valve	To test & verify function of Solenoide valves	
5.	Display Unit	To test & verify Screen & Touch	

c. Operational Testing

Test 1

Test Name : Vacuum Pump.

Purpose : To test Vacuum Pump

Method : Service Menu

		PARAMETER	PASS	FAIL
Parameter values for verification	:	Vacuum PUMP		

Test 2

Test Name : Arm Motor

Purpose : To test Arm Motor function

Method : Service Menu

		PARAMETER	PASS	FAIL
Parameter values for verification	:	Arm Motor		

Test 3

Test Name : Hgb Lamp

Purpose : To test Hgb Gain.

Method : Diagnostic Menu

		PARAMETER	PASS	FAIL
Parameter values for verification	:	Hgb Lamp Test		

Test 4

Test Name : Solenoide Valve

Purpose : To test the Solenoide valves operation.

Method : Diagnostic Menu

	PARAMETER	PASS	FAIL
Parameter values for verification :	Solenoide Valve Test		

Test 5

Test Name : Display

Purpose : To test functioning of touch and screen functioning

Method : Manual

	PARAMETER	PASS	FAIL
Parameter values for verification :	Display Test		

Operational Procedure

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.Ravi Kumar who is certified by MERIL DIAGNOSTICS 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

Customer SOP

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

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 : Meril Diagnostics **Representative**

Name : SANDEEP SHINDE

Title : OPERATIONAL QUALIFICATION Signature:

Company: MERIL DIAGNOSTICS LTD. Date :03-05-2019

Designation: MANGER-TECHNICAL SERVICE.

Customer Authorizations:

Name : Mr Ravi Kumar

Title : OPERATIONAL QUALIFICATION Signature:

Company: Date :03-05-2019

MERIL DIAGNOSTICS
CELQUANT PRIME

3-PDA HEMATOLOGY ANALYZER

PERFORMANCE QUALIFICATION

Marketed by:

MERIL DIAGNOSTICS

MUMBAI

I. Approval of the PQ procedure :

Both **IVY Diagnostic Laboratory**and **MERIL DIAGNOSTICS** are jointly responsible for conducting the **Performance Check** of the **Hematology Analyzer, CELQUANT PRIME Serial No.CQP3O191216** in the clinical lab of **IVY Diagnostic Laboratory**as per the attached protocol.

Protocol Performed By : MERIL DIAGNOSTICS Representative

Name	:	Mr Daljeet Singh	Signature :
Title	:	**PERFORMANCE QUALIFICATION**	Date :03-05-2019
Company	:	MERIL DIAGNOSTICS	
Designation	:	Area Service Manager.	
Department	:	SERVICE	

Customer Authorizations:

Name	:	Mr Ravi Kumar	Signature :
Title	:	PERFORMANCE QUALIFICATION	Date :03-05-19
Site	:		

II. Instructions

9. An authorized MERIL DIAGNOSTICS 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.
10. Performance checks on a regular basis described in the Further Performance Checks (vide-infra) will be responsibility of the customer's personnel.
11. Employee of **IVY Diagnostic Laboratory**will verify each result and sign in the last page. The members of the validation team will carry this out.
12. 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 **IVY Diagnostic Laboratory.** However this additional cost will be waived when this test is conducted at time of initial performance check of new instruments.

13. 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.

III. Scope

This Performance Qualification protocol will be performed on the Hematology Analyzer, **CELQUANT PRIME, Serial No . CQP3O191216** located in Nawa Shaher , Punjab. 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.

IV. Performance Qualification

a. Instrument Identification **Verified Date**

1. Model Name CELQUANT PRIME _____
2. Serial Number _____

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

Test No.	Test Name	Test Purpose	Verified Date
01	Precision Tests	Establishing Reproducibility	_____
02	Accuracy Checks	Ability of Sample processing	_____

c. Performance Testing

Test 1

Test Name: Precision Testing

Purpose: To comply with specification and find out deviation if any. If required to apply correction

Method: To run normal sample 06 times consecutively and identify SD, CV and to establish that it lies as per the manufacturer's specs. To omit first run and to consider rest 05 runs and to calculate SD & CV

Run sequence	WBC	RBC	HGB	HCT	MCV	PLT
2						
3						
4						
5						
Mean						
SD						
CV%						
Status PASS/FAIL						

c. Accuracy Testing

Test 2

Test Name : Accuracy Check

Purpose: Ability to Process Samples

Method: To Run Normal Level control five times

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

Parameters Values for Verification: Control Level: "N" Lot no:
Exp dt:

WBC Count:

Sr. No.	Control Values	Results Obtained	Pass	Fail
1				
2.				
3.				
4.				
5.				

RBC Count:

Sr. No.	Control Values	Results Obtained	Pass	Fail
1				
2.				
3.				
4.				
5.				

HGB:

Test	Control Values	Results Obtained	Pass	Fail

1.				
2.				
3.				
4.				
5.				

MCV:

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

Platelet Count:

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

C. List of Manuals, Certificates and Drawings

MERIL DIAGNOSTICS provides the following with the instrument.

3. Instruction For Use
4. 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 **MERIL DIAGNOSTICS** and **IVY Diagnostic Laboratory.**

E. Maintenance

The instrument listed within this document will be placed under the control of the purchasing institution with respect to proper maintenance procedures.

A trained analyst using the manuals provided with the instrumentation can perform simple maintenance. Upon expiration of the warranty period MERIL DIAGNOSTICS 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.

VII. 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 : MERIL DIAGNOSTICS Representative

Name : SANDEEP SHINDE Signature:

DESIGNATION: MANAGER-TECHNICAL SERVICE

Title : PERFORMANCE QUALIFICATION

Company : MERIL DIAGNOSTICS Date :03-05-19

Customer Authorizations:

Name : Mr Ravi Kumar Signature :

DESIG : Lab Manager

Title : PERFORMANCE QUALIFICATION

Company : Date :03-05-19