

CALIBRATION CERTIFICATE OF BA200

**CUSTOMER NAME - PCR Healthcre pvt.ltd
DELHI**

Serial Number -

WS-18004021

User Software = V 5.4.2

Initialization Motor

Vertical Motors - S /R1 /R2 in Home

Polar Motors - S /R1 /R2 in Home

Reaction Rotor in home

Sample /Reagent rotor in Home

Ceramic Dispensing pump - S/ R1 /R2 in Home

Optics Initialization: Ok

Auto adjustment of the probe is done

Peltier cells and drivers test

Rotor Peltier/ Reagent Rotor peltier driver test: Ok

Temperature system initialized

LED test: ok

Hardware completely initialized

Parameters	Current value	Minimum	Maximum
Reading reference Position - Well 1	7896	7860	7905
Washing Solution Tank 0	0	-5	5
Washing Solution Tank 50	46	40	60
Washing Solution Tank 100	98	95	105
Waste Tank 0	-1	-5	5
Waste Tank 50	43	40	60
Waste Tank 100	100	95	105
Thermal adjustment of reaction rotor	37.0	36.0	39.0
Thermal adjustment of Wash station	44.9	44	50
Thermal adjustment of reagent tip 1	37.0	36	39

Thermal adjustment of reagent tip 2	37.0	36	39
Photometric Dark Current Adjustment	3885	3941	4500
Main Photo Diode Counts 340NM	8,82,490	2,16,086	950000
Main Photo Diode Counts 405NM	8,99,288	7,40,174	950000
Main Photo Diode Counts 505NM	9,01,338	7,03,853	950000
Main Photo Diode Counts 535NM	8,89,214	5,97,627	950000
Main Photo Diode Counts 560NM	8,99,482	7,10,590	950000
Main Photo Diode Counts 600NM	9,01,891	5,82,890	950000
Main Photo Diode Counts 635NM	9,00,649	5,91,854	950000
Main Photo Diode Counts 670NM	8,99,062	7,39,773	950000

Next calibration due on: 02/11/2024

For PCR Healthere Pvt.Ltd
DELHI

KRUNAL
GORDHANBHAI
MADHU

Digitally signed by KRUNAL
GORDHANBHAI MADHU
DN: cn=GORDHANBHAI MADHU,
ou=PCR HEALTHERE PRIVATE
LIMITED, email=gordhanbhai@pcrhealthere.com,
Date: 2023.05.25 10:51:23 +05'30'

Authorized Signatory

Maintenance Cal Blank Maintenance Log

SPAN

MANUAL SPAN

AUTO SPAN

Wavelength

Gain

Cur: 01

Gain Value

OK

Out of Range

340	405	505	545	570	600	650	700
613	495	472	505	499	955	720	521

START

WASH

WASH MAINTENANCE COMMANDS

- CUVETTE RINSE
- WATER SAVE
- AUTO WASH
- PHOSE WASH
- PRIME WASH

START

DEAD VOLUME CALIBRATION

SELECT CONTAINER TYPE

- Sample 1 (Pre-Flow) Pos: 3
- Sample 2 (Pre-Flow) Pos: 2
- Sample 1 (Pre-Flow) Pos: 1
- Sample 2 (Pre-Flow) Pos: 1
- Sample 1 (Pre-Flow) Pos: 1
- Sample 2 (Pre-Flow) Pos: 1

CALIBRATE

DEF-QUIT

STOP

AUTO MAINTENANCE

START

STOP

START

MAINTENANCE ERRORS

S.N. ERROR MESSAGE

Exit(F2)

Cal Parameter(F3)

Profiles / Cal(F4)

Calibration(F5)

Consumables(F6)

Status Monitor(F7)

Search(F8)

Reports(F9)

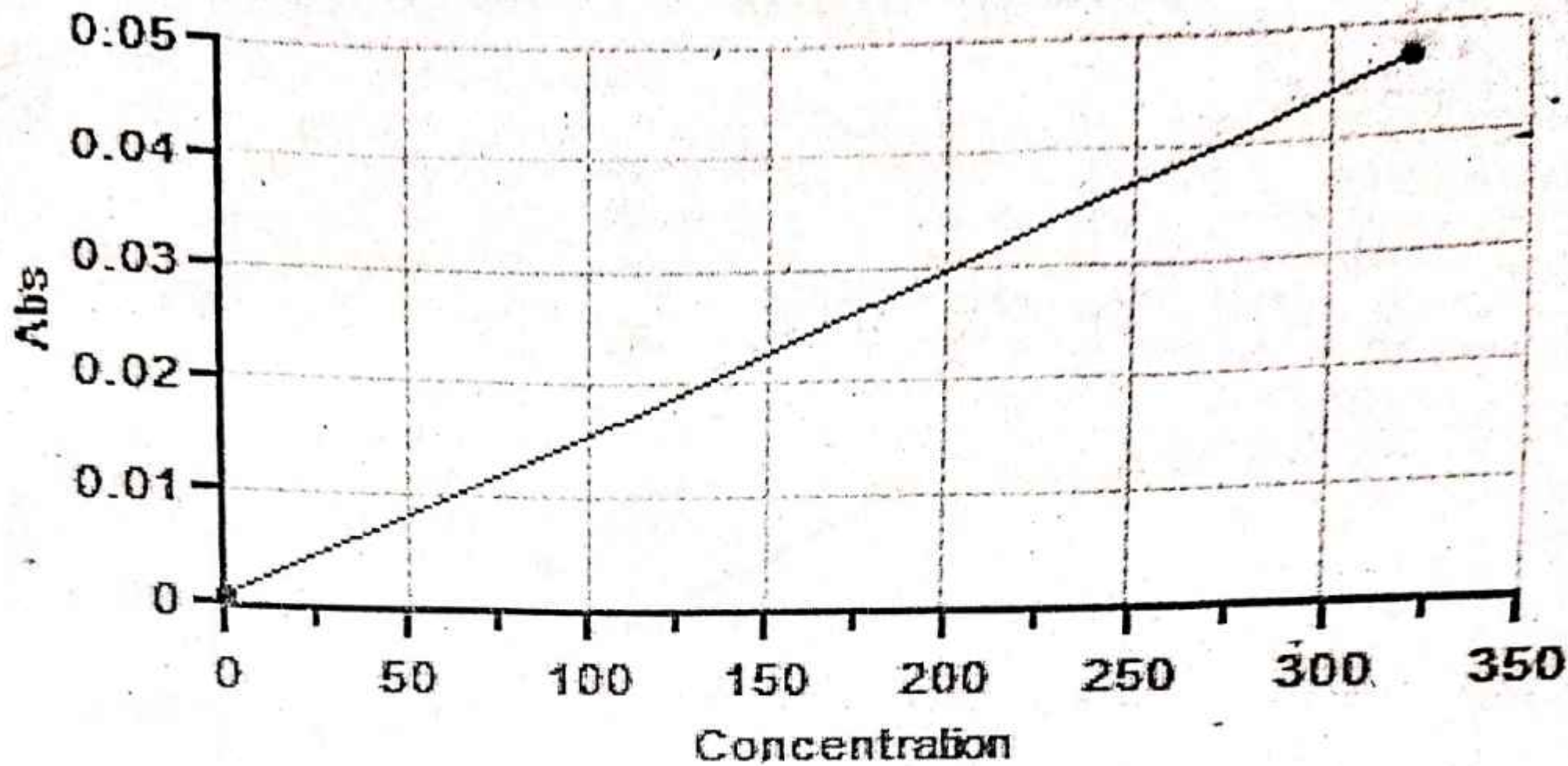
Master

Utility(F11)

Service Check

Settings

Start Down



Test : ALPU

Curve Type : Linear

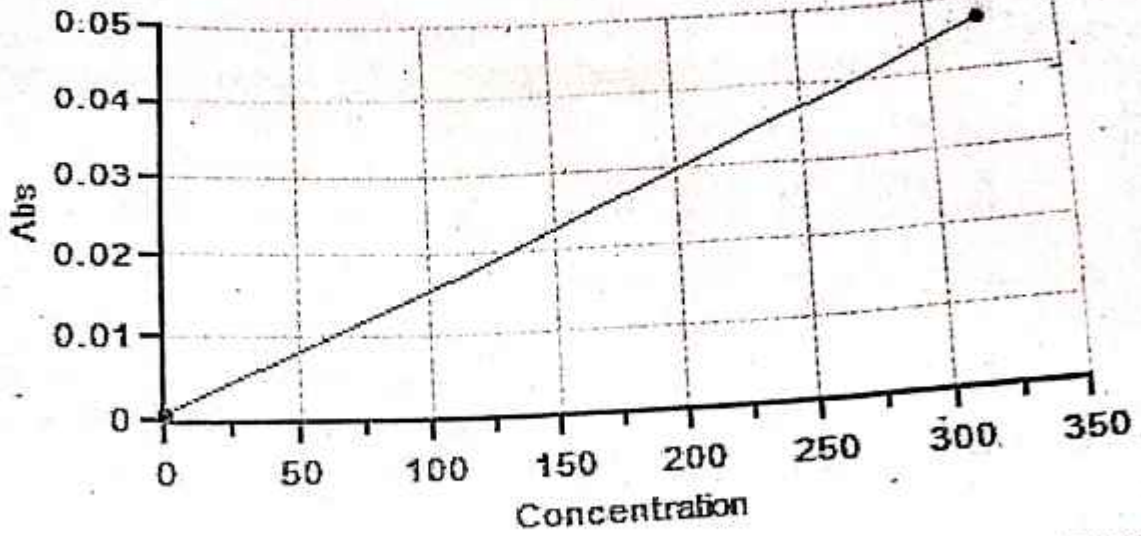
Calibration Date : 03-Nov-2023 17:13:21

Last Calibration Date : 03-Nov-2023 17:13:21

Revision : <A-200-ALPU-3 01.03.2016>

R1 Lot No : B092232-237

R2 Lot No : B092232-237



Pos	Consumable	LotNo.	Conc	Delta Abs/Min	Factor
I-1	BLANK	1234	0.000	0.0008	0.0000
I-2	MULTICAL	2309047A	320.000	0.0472	6,903.9912

Print Date : 03-Nov-2023

Curve Type : Linear

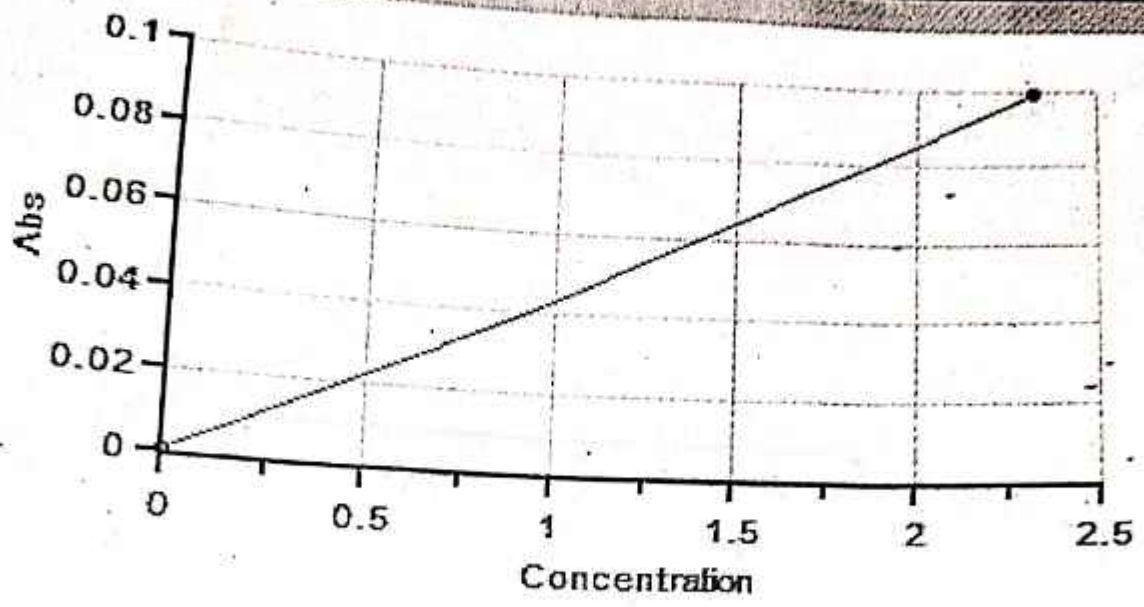
Revision : <A-200-BIDD-4 10.04.2018>

Calibration Date : 03-Nov-2023 17:15:10

R1 Lot No : S052320-320

Last Calibration Date : 03-Nov-2023 17:15:10

R2 Lot No : S052320-320



Pos	Consumable	LotNo.	Conc	Abs	Factor
1-1	BLANK	1234	0.000	0.0009	0.0000
2	MULTICAL	2309047A	2.320	0.0991	23.6373

Test : BIT

Revision : <A-200-BIT-2 26.09.2013>

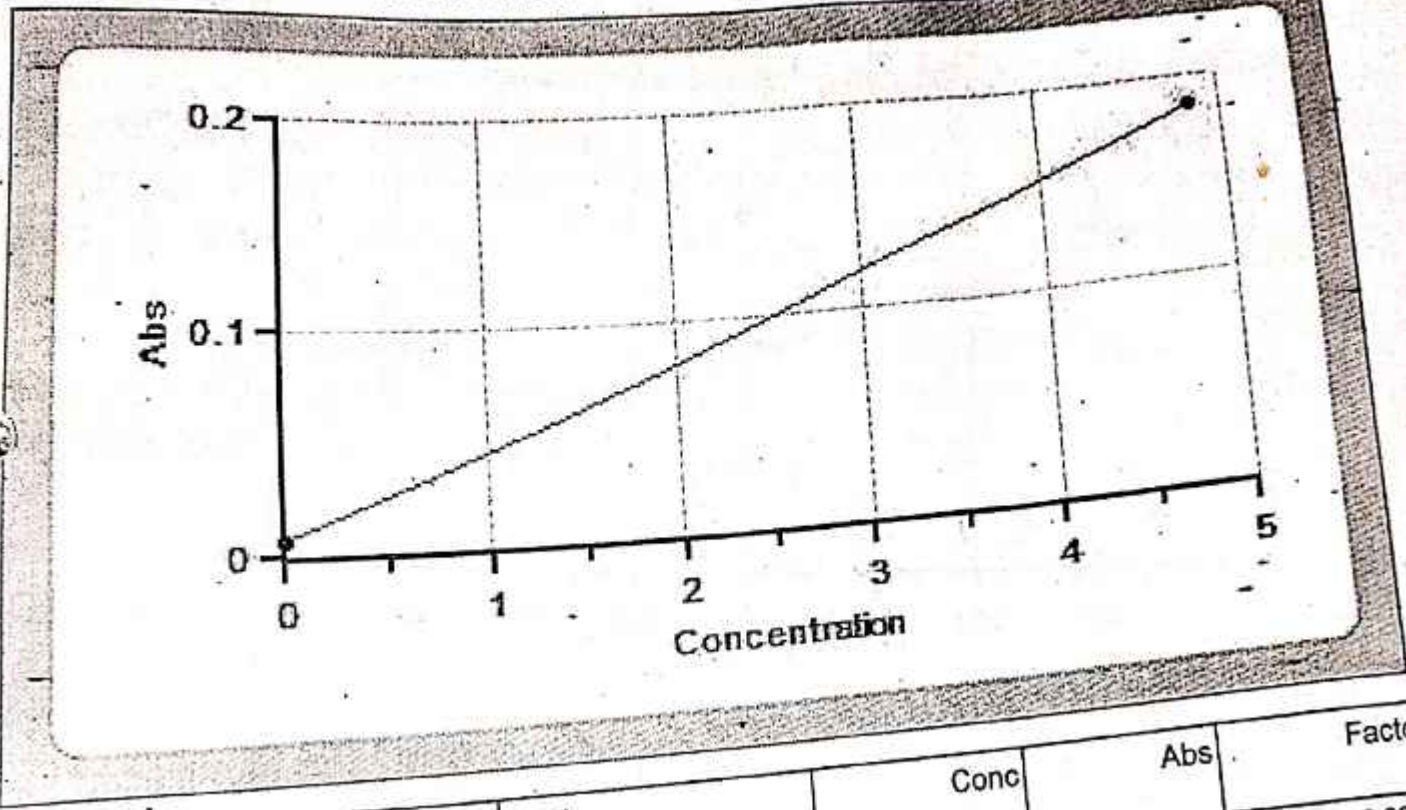
Curve Type : Linear

R1 Lot No : S042350-315

Calibration Date : 03-Nov-2023 17:16:58

R2 Lot No : S042350-315

Last Calibration Date : 03-Nov-2023 17:16:58



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	BLANK	1234	0.000	0.0074	0.0000
I-2	MULTICAL	2309047A	4.830	0.1840	27.3499

Test : CHOL

Revision : <A-200-CHOL-1 20.08.2013>

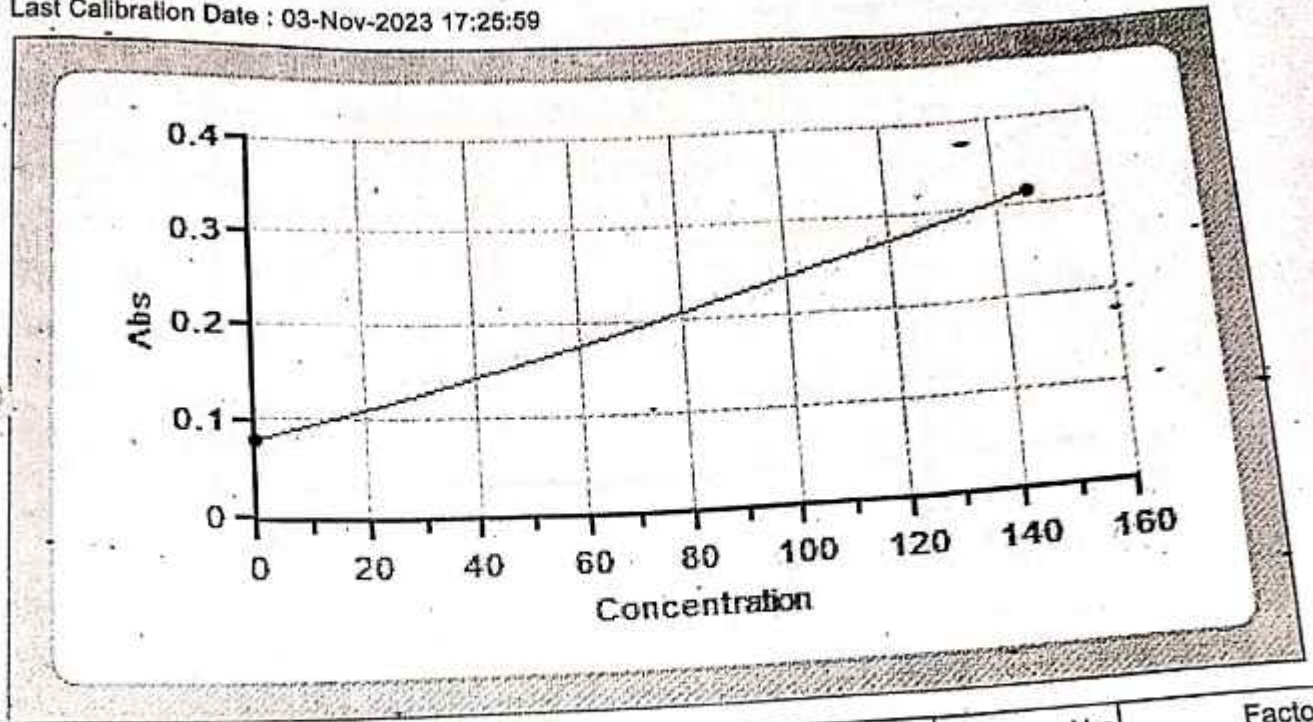
Curve Type : Linear

R1 Lot No : S072326-328

Calibration Date : 03-Nov-2023 17:25:59

R2 Lot No : --

Last Calibration Date : 03-Nov-2023 17:25:59



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	BLANK	1234	0.000	0.0784	0.0000
I-2	MULTICAL	2309047A	146.000	0.3158	615.1254

Print Date : 03-Nov-2023

Curve Type : Linear

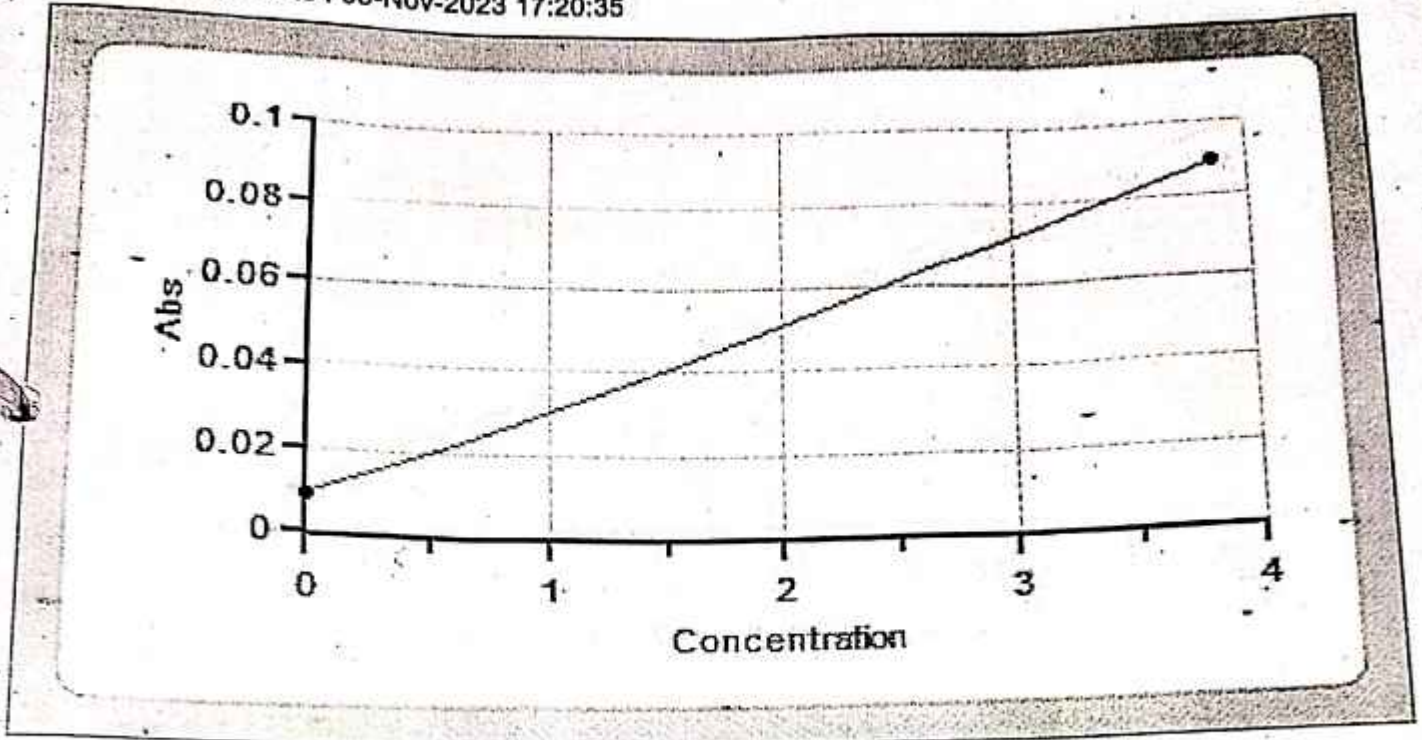
Calibration Date : 03-Nov-2023 17:20:35

Last Calibration Date : 03-Nov-2023 17:20:35

Revision : <A-200-CREZ-1 01.08.2014>

R1 Lot No : T012313-305

R2 Lot No : T012313-305



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	BLANK	1234	0.000	0.0095	0.0000
I-2	MULTICAL	2309047A	3.850	0.0891	48.3668

Test : GLU

Curve Type : Linear

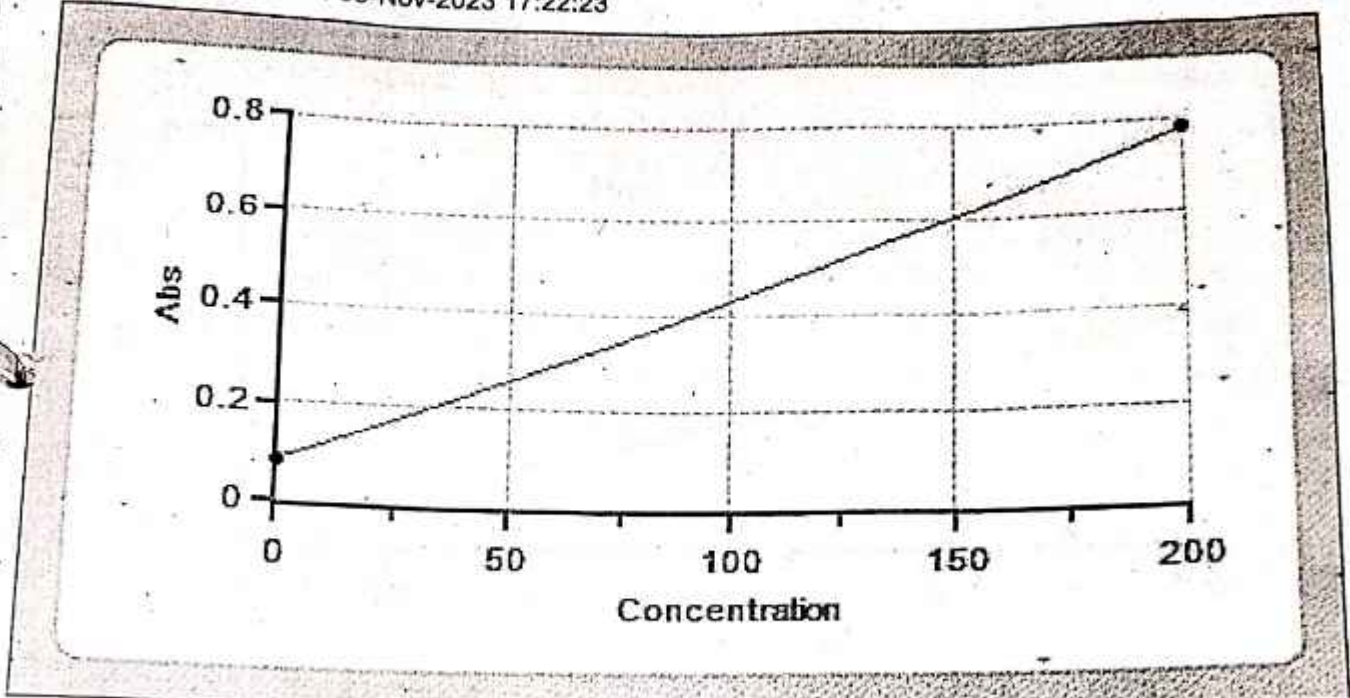
Calibration Date : 03-Nov-2023 17:22:23

Last Calibration Date : 03-Nov-2023 17:22:23

Revision : <A-200-GLU-1 20.08.2013>

R1 Lot No : B052209-219

R2 Lot No : ---



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	BLANK	1234	0.000	0.0864	0.0000
I-2	MULTICAL	2309047A	200.000	0.7803	288.2052

Calibration - EM 200

Test : GLU

Curve Type : Linear

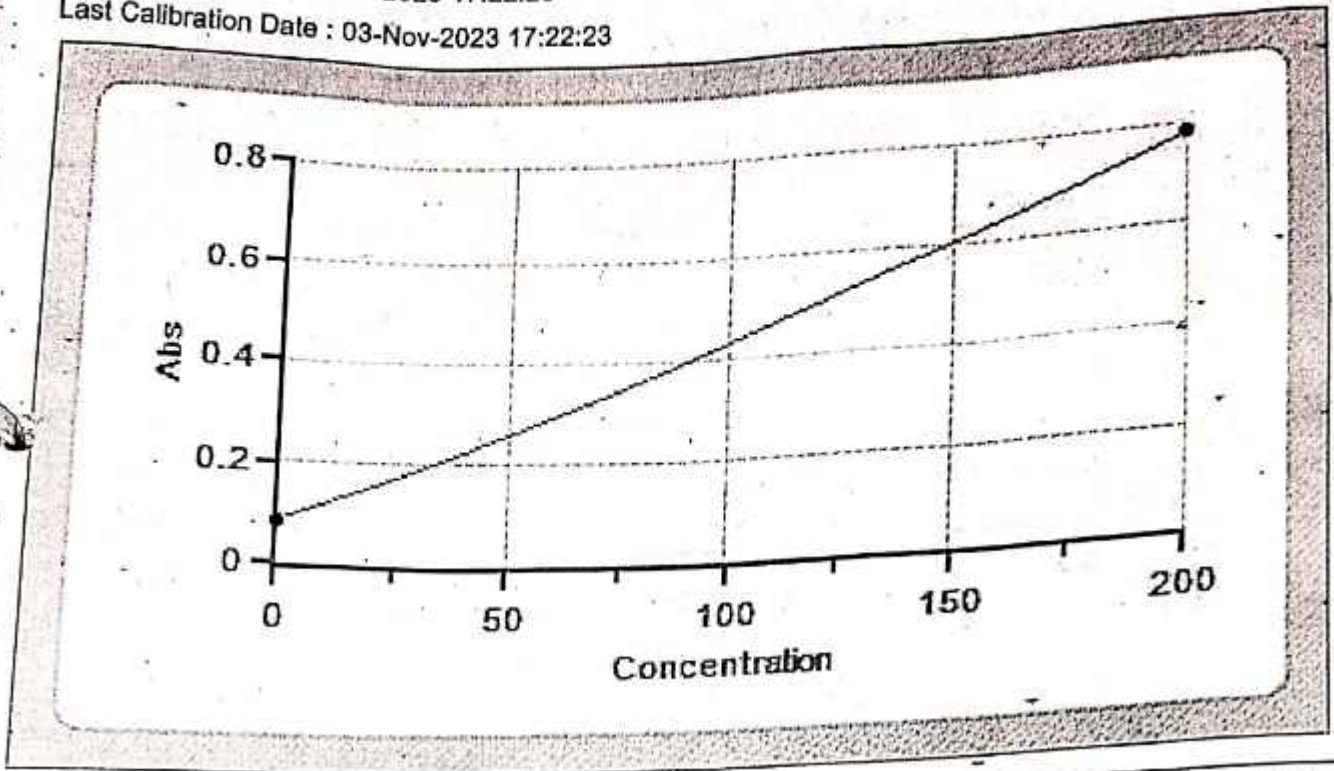
Calibration Date : 03-Nov-2023 17:22:23

Last Calibration Date : 03-Nov-2023 17:22:23

Revision : <A-200-GLU-1 20.08.2013>

R1 Lot No : B052209-219

R2 Lot No : ---



Pos	Consumable	LotNo.	Conc	Abs	Factor
I-1	BLANK	1234	0.000	0.0864	0.0000
I-2	MULTICAL	2309047A	200.000	0.7803	288.2052

Test Statistics

Test BIT
Date From 03-Nov-2023
Report Type Patients
Date To 03-Nov-2023

Sample ID	PREASIOSAN	Patient Name	PREASIOSAN	Age
Sr#	Result Unit	Flag	Result Date	Curve # Used Calibration
1	5.82 mg/dl	H	03-Nov-2023 16:48:19	59698 15-May-2024 15:30:05
2	5.79 mg/dl	H	03-Nov-2023 16:48:01	59697 15-May-2024 15:30:05
3	5.86 mg/dl	H	03-Nov-2023 16:47:43	59696 15-May-2024 15:30:05
4	5.83 mg/dl	H	03-Nov-2023 16:47:25	59695 15-May-2024 15:30:05
5	5.90 mg/dl	H	03-Nov-2023 16:47:07	59694 15-May-2024 15:30:05

Computed Ranges And Statistical Values

Reference Range 3
 Above Reference Range 6
 Below Reference Range 0
 Default Range 0
 Total Test(s) 9

Sr# From - To -

5
 Mean 5.84
 SD 0.04
 %CV 0.72
 Range 0.11

03-Nov-2023

Test Statistics

Test CA
Date From 03-Nov-2023
Report Type Patients
Date To 03-Nov-2023

Sample ID	*PREASIOSAN		Patient Name	PREASIOSAN	Age
Sr#	Result	Unit	Flag	Result Date	Curve # Used Calibration
1	12.0	mg/dl	H	03-Nov-2023 16:52:50	59713 17-May-2024 11:09:30
2	11.8	mg/dl	H	03-Nov-2023 16:52:32	59712 17-May-2024 11:09:30
	12.3	mg/dl	H	03-Nov-2023 16:52:14	59711 17-May-2024 11:09:30
4	12.1	mg/dl	H	03-Nov-2023 16:51:56	59710 17-May-2024 11:09:30
5	12.0	mg/dl	H	03-Nov-2023 16:51:38	59709 17-May-2024 11:09:30

Computed Ranges And Statistical Values

Reference Range 0
 Above Reference Range 5
 Below Reference Range 0
 Default Range 0
 Total Test(s) 5

Sr# From 1 To 5

Mean 12.0
 SD 0.18
 %CV 1.51
 Range 0.5

03-Nov-2023

Test Statistics

Test PRO **Report Type** Patients
Date From 03-Nov-2023 **Date To** 03-Nov-2023

Sample ID	PREASIOSAN	Patient Name	PREASIOSAN	Age
Sr#	Result Unit	Flag	Result Date	Curve # Used Calibration
1	8.78 g/dl	H	03-Nov-2023 16:54:20	59718 17-May-2024 11:11:18
2	8.75 g/dl	H	03-Nov-2023 16:54:02	59717 17-May-2024 11:11:18
3	8.77 g/dl	H	03-Nov-2023 16:53:44	59716 17-May-2024 11:11:18
4	8.75 g/dl	H	03-Nov-2023 16:53:26	59715 17-May-2024 11:11:18
5	8.86 g/dl	H	03-Nov-2023 16:53:08	59714 17-May-2024 11:11:18

Computed Ranges And Statistical Values

Reference Range 3
 Above Reference Range 5
 Below Reference Range 1
 Default Range 0
 Total Test(s) 9

Sr# From - To -

Mean 8.78
 SD 0.05
 %CV 0.52
 Range 0.11

03-Nov-2023

Test Statistics

Test PRO
Date From 03-Nov-2023
Report Type Patients
Date To 03-Nov-2023

Sample ID	PREASIOSAN	Patient Name	PREASIOSAN	Age
Sr#	Result Unit	Flag	Result Date	Curve # Used Calibration
1	8.78 g/dl	H	03-Nov-2023 16:54:20	59716 17-May-2024 11:11:18
2	8.75 g/dl	H	03-Nov-2023 16:54:02	59717 17-May-2024 11:11:18
	8.77 g/dl	H	03-Nov-2023 16:53:44	59716 17-May-2024 11:11:18
4	8.75 g/dl	H	03-Nov-2023 16:53:26	59715 17-May-2024 11:11:18
5	8.86 g/dl	H	03-Nov-2023 16:53:08	59714 17-May-2024 11:11:18

Computed Ranges And Statistical Values

Reference Range	3
Above Reference Range	5
Below Reference Range	1
Default Range	0
Total Test(s)	9

Sr# From - To -

	5
Mean	8.78
SD	0.05
%CV	0.52
Range	0.11

03-Nov-2023

Test Statistics

Test SGOTD
Date From 03-Nov-2023
Report Type Patients
Date To 03-Nov-2023

Sample ID	PREASIOSAN	Patient Name	PREASIOSAN	Age
Sr#	Result Unit	Flag	Result Date	Curve # Used Calibration
1	139.7 U/L	H	03-Nov-2023 16:46:49	59893 15-May-2024 15:24:40
2	142.2 U/L	H	03-Nov-2023 16:46:31	59892 15-May-2024 15:24:40
	138.4 U/L	H	03-Nov-2023 16:46:13	59891 15-May-2024 15:24:40
4	140.0 U/L	H	03-Nov-2023 16:45:55	59890 15-May-2024 15:24:40
5	142.4 U/L	H	03-Nov-2023 16:45:37	59889 15-May-2024 15:24:40

Computed Ranges And Statistical Values

Reference Range 3
 Above Reference Range 6
 Below Reference Range 0
 Default Range 0
 Total Test(s) 9

Sr# From - To -

Mean 140.5
 SD 1.72
 %CV 1.22
 Range 4.0

03-Nov-2023

Test Statistics

Test UREA **Report Type** Patients
Date From 03-Nov-2023 **Date To** 03-Nov-2023

Sample ID	PREASIOSAN	Patient Name	PREASIOSAN	Age
Sr#	Result Unit	Flag	Result Date	Curve # Used Calibration
1	101.9 mg/dl	H	03-Nov-2023 16:49:49	59703 15-May-2024 15:31:53
2	101.6 mg/dl	H	03-Nov-2023 16:49:31	59702 15-May-2024 15:31:53
	105.1 mg/dl	H	03-Nov-2023 16:49:13	59701 15-May-2024 15:31:53
4	102.1 mg/dl	H	03-Nov-2023 16:48:56	59700 15-May-2024 15:31:53
5	103.3 mg/dl	H	03-Nov-2023 16:48:37	59699 15-May-2024 15:31:53

Computed Ranges And Statistical Values

Reference Range 0
 Above Reference Range 5
 Below Reference Range 0
 Default L Range 0
 Total Test(s) 5

Sr# From 1 To 5

Mean 102.8
 SD 1.44
 %CV 1.40
 Range 3.5

03-Nov-2023

TRACEABILITY

XL MULTICAL
Product Code: XSYS0034
Lot: 2206133A

Analyt	Reference Methods / Reference Material	Calibrator value	Uncertainty ¹	Unit
Albumin	CRM 470	3.52	0.044	g/dl
ALP	Original formulation IFCC	262	1.59	U/l
ALT/SGPT	Original formulation IFCC (1985)	88.8	1.24	U/l
AST/SGOT	Original formulation IFCC (1985)	100	0.86	U/l
Amylase	Original formulation IFCC (1998)	184	1.68	U/l
Bilirubin Direct (Walter & Gerarde)	Reference method accor. Jendrassik-Gróf	2.13	0.012	mg/dl
Bilirubin Direct (DCA)	Reference method accor. Jendrassik-Gróf	2.29	0.013	mg/dl
Bilirubin Total (Walter & Gerarde)	Reference method accor. Jendrassik-Gróf	4.54	0.095	mg/dl
Bilirubin Total (DCA)	Reference method accor. Jendrassik-Gróf	4.30	0.090	mg/dl
Calcium	Atomic absorption	10.3	0.064	mg/dl
Chloride	Coulometrie	100	4.64	mmol/l
Cholesterol	ID-MS	155	1.61	mg/dl
CK	Original formulation IFCC (1991)	333	1.82	U/l
CK MB	Original formulation IFCC with immunoinhibition (2002)	429	23.2	U/l
Creatinine (Jaffé)	ID-MS	3.91	0.038	mg/dl
Creatinine (Enz.)	ID-MS	3.84	0.037	mg/dl
GGT	Original formulation Persijn v.d. Slik (1976)	111	1.05	U/l
Glucose	ID-MS	200	1.57	mg/dl
LDH-P	Reference method	517	3.83	U/l
Lipase	Original formulation IFCC	99.4	1.88	U/l
Magnesium	Atomic absorption	2.72	0.021	mg/dl
Phosphorus	Primary reference material	5.49	0.057	mg/dl
Total Protein	SRM 927e	5.04	0.044	g/dl
Triglycerides (single reagent)	SRM 909c	141	1.37	mg/dl
Triglycerides (two reagents)	SRM 909c	140	1.36	mg/dl
Urea	SRM 909c	100	1.04	mg/dl
Uric Acid	ID-MS	5.43	0.034	mg/dl

¹ Expanded uncertainty, k = 2

² CRM = Certified reference material, European

³ SRM = Standard reference material

⁴ ID-MS = Isotope dilution - mass spectrometry

Date: 05.12.2022

Erba Lachema s.r.o., Karlošek 2219/1d, 621 00 Brno, Czech Republic
 Identification number: 269 18 846. Tax identification number: CZ26918846
 Incorporated in the Commercial Register maintained by the Regional Court in Brno, Section C, insert 45458
 Tel. +420 517 077 111, e-mail: diagnostics@erbalachema.com, www.erbalachema.com

Test Statistics

Test CHOL
Date From 03-Nov-2023
Report Type Patients
Date To 03-Nov-2023

Sample ID	PREASIOSAN	Patient Name	PREASIOSAN	Age
Sr#	Result Unit	Flag	Result Date	Curve # Used Calibration
1	242 mg/dl	H	03-Nov-2023 18:51:19	59706 15-May-2024 15:39:06
2	241 mg/dl	H	03-Nov-2023 18:51:01	59707 15-May-2024 15:39:06
3	240 mg/dl	H	03-Nov-2023 16:50:43	59706 15-May-2024 15:39:06
4	237 mg/dl	H	03-Nov-2023 16:50:25	59705 15-May-2024 15:39:06
5	244 mg/dl	H	03-Nov-2023 16:50:07	59704 15-May-2024 15:39:06

Computed Ranges And Statistical Values

Reference Range	1
Above Reference Range	5
Below Reference Range	0
Default Range	0
Total Test(s)	6

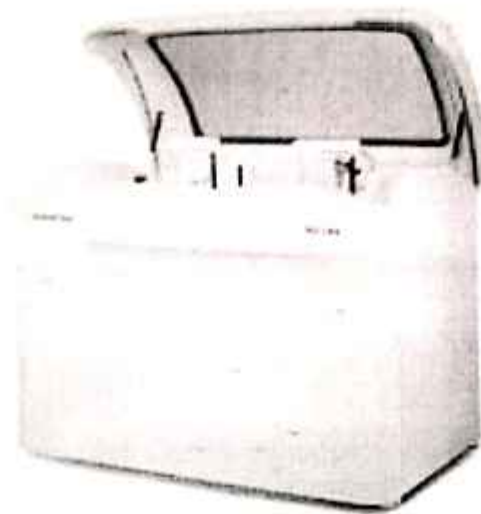
Sr# From - To -

	5
Mean	241
SD	2.59
%CV	1.07
Range	7

03-Nov-2023

BS-380

Automated Clinical Chemistry Analyzer



Qualification Manual:

Installation Qualification/Operation Qualification/Performance Qualification

IQ/OQ/PQ-BS380

INSTALLATION QUALIFICATION

INSTRUCTIONS:

1. This document is to be completed at the time the system is unpacked and set up for operation.
2. An authorized Mindray representative will check out each module and verify the alignment.
3. All deviations from normal specification to include any problems with installation will be noted in the comments section.
4. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by Mindray.

INSTALLATION QUALIFICATION PROTOCOL:

This Installation Qualification protocol will be performed on the instrument installed at,

PCR Healthcare Pvt. Ltd
DELHI

This protocol will define the documentation that will be used to evaluate the instrument documented in accordance with manufacture's specifications and identified use.

Installation checks will be performed to verify that the instrumentation has been installed with proper connections and utilities.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated & appropriate course of action will be determined.

IQ/OQ/PQ-B5380

INSTALLATION QUALIFICATION

SYSTEM CERTIFICATION:

Study data has determined that the system described in this document meets all criteria outlined 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 specified usage.


Protocol performed by: **AVANTOR REPRESENTATIVE**

Name: Mr. Amol Patil
Title: Area Service Manager
Company: Avantor

Signature: 

Customer Authorization:

PCR Healthcare Pvt. Ltd
DELHI

Signature: 



IQ/OQ/PQ-BS380

CERTIFICATION OF INSTALLATION-REPORT

Analyzer Name: **BS-380**


Serial Number: **BS-380 & S. No: WS-18004021**

CUSTOMER NAME & ADDRESS:

PCR Healthcare Pvt. Ltd
DELHI

The undersigned performer certifies that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

Authorized Engineer,

Signature: 


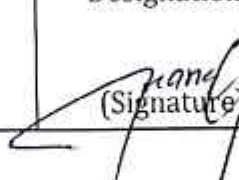

Name: Mr. Amol Patil
Designation: Area Service
Manager Company: **Avantor**

IQ/OQ/PQ-BS380

INSTALLATION VERIFICATION REPORT

This is to certify that the following checks mentioned in the installation verification protocol have been performed and found to be satisfactory.

1. PRE-INSTALLATION CHECK	REMARK
A) Carton arrival	Checked
B) Spare and accessibility	Checked & Cleared
C) Electrical input	Checked & Passed
D) Ambient temperature and Humidity	Passed
E) Ventilation	Passed
F) Drainage	NA
2. UNPACKING & INSTALLING THE CONSOLE	Passed
3. INSTALLING THE ELECTRICAL CABLES	Checked & Passed
4. UNPACKING & INSTALLING THE ANALYTICAL UNIT	Passed
5. SETTING THE ANALYTICAL UNIT	Success
6. ALIGNMENT VERIFICATION	Success

<p>Mr. Amol Patil</p> 	<p>MR. MANOJ KUMAR</p> <p>Designation: ADMIN</p>  
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IQ/OQ/PQ-BS380

Installation Qualification Notes & Attachments:

OPERATIONAL QUALIFICATION

SYSTEM CERTIFICATION:

Study date has determined that the system described in this document meets all criteria outlined in this Operational Qualification protocol. All exceptional conditions if any have been addressed. The system is ready for specified usage.

Protocol performed by: **AVANTOR REPRESENTATIVE**

Name: Mr. Amol Patil

Area Service Manager

Company: AVANTOR

Customer Authorization:

PCR Healthcre pvt.ltd
DELHI

Authorized Engineer's Signature

Date: 08.11.2022


Customer's Signature

Date: 08.11.2022




IQ/OQ/PQ-BS380

OPERATIONAL QUALIFICATION - SYSTEM VERIFICATION REPORT

This is to certify that the following checks mentioned in the operational verification protocol have been performed and found to be satisfactory.

<u>OPERATIONAL QUALIFICATION PROTOCOL</u>	<u>REMARKS</u>
1] CHECKING THE ANALYTICAL UNIT	
A] SOFTWARE BOOTING & INITIALIZATION	Success
B] BASIC SYSTEM CHECKS & VERIFICATION	Verified
2] IMPORTING & CALIBRATING THE CHEMISTRIES	Success
3] RUNNING CONTROLS	Success
4] TRAINING THE OPERATORS	Completed

Mr. Amol Patil	MR MANOJ KUMAR Designation: ADMIN  (Signature)
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IQ/OQ/PQ-BS380

OPERATIONAL QUALIFICATION PROCEDURES

The Operational Qualification procedure specifies the methodology for the installation of the specified system after successful Installation qualification. Successful completion of the specified protocols and is ready for operation and subsequent performance analysis.

OO PROCEDURES:

1. System software loading.
2. System Booting and Initialization
3. Basic System Checks.
4. Importing Chemistries & Calibrating Chemistries.
5. Running Controls.
6. Operators Training Schedule.

References:

1. *Operation Manual - BS240Pro*
2. *Service Manual - BS240Pro*

Operational Qualification Notes:

PERFORMANCE QUALIFICATION

SYSTEM CERTIFICATION:

Study data has determined that the system described in this document 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.

Protocol performed by: AVANTOR REPRESENTATIVE

Name: Viraj Kale
Title: Manager-
Technical IVD-
Automation

Company: AVANTOR

Customer Authorization:

PCR Healthcare Pvt. Ltd
DELHI

Authorized Engineer's Signature

Date: 08.11.2022



IQ/OQ/PQ-BS380


Customer's Signature

Date: 08.11.2022

PERFORMANCE QUALIFICATION VERIFICATION REPORT

This is to certify that the following checks mentioned in the performance verification protocol have been performed and found to be satisfactory.

<p>Viraj Kale</p> <p>Manager- Technical IVD- Automation</p> 	<p>MR MANOJ KUMAR</p> <p>Designation: ADMIN</p> <p> Signature</p> 
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IQ/OQ/PQ-BS380

PERFORMANCE ANALYSIS

Avantor™

Tests Validated - Glucose, Urea, Creatinine, Total Cholesterol, Triglycerides, Total Protein, Uric Acid, SGPT, SGOT, Albumin, Total Bilirubin, Direct Bilirubin, Alkaline Phosphatase, LDH.

Analyzer Model & Serial No	BS-380 & S. No: WS-18004021
Date of Validation	08.11.2023
Method	Photometry at 37°C
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd
Name of LABORATORIES	PCR Healthcare Pvt. Ltd
Department	Laboratory

Within run precision report protocol:

20 replicates each of BIORAD chemistry control Level 3 analyzed on BS 380 bearing the serial number WS-18004021 continuously to verify the precision

Summary:

S.No	Parameter	Manufacturer's CV%	Observed CV%
1	Glucose (mg/dl)	$\leq 3.0\%$	1.1%
2	Urea (mg/dl)	$\leq 4.0\%$	0.7%
3	Creatinine (mg/dl)	$\leq 3.0\%$	0.9%
4	Total Cholesterol (mg/dl)	$\leq 3.0\%$	0.0%
5	Triglycerides (mg/dl)	$\leq 3.0\%$	0.6%
6	Total Protein (g/dl)	$\leq 3.0\%$	0.8%
7	Uric Acid (mg/dl)	$\leq 3.0\%$	0.3%
8	SGPT (U/L)	$\leq 3.5\%$	0.9%
9	SGOT (U/L)	$\leq 3.5\%$	0.5%
10	Albumin (g/dl)	$\leq 3.0\%$	0.4%
11	Total Bilirubin (mg/dl)	$\leq 5.0\%$	0.6%
12	Direct Bilirubin (mg/dl)	$\leq 4.0\%$	0.8%

Conclusion:

Within run precision of the parameters involving the modes, endpoint & fixed-time kinetic with various sample volume, reagent volume, wavelengths were completed & tabulated.

The Percentage coefficient variation (CV %) of all the parameters obtained are well within the acceptable limits (Manufacturer's CV %) on BS-380

Reported By

Name

Kale Designation

Technical Company

-Viraj

- Manager

- Avantor

IQ/OQ/PQ-BS380



Accuracy:

Equipmentname& SerialNo	B5-380 &S. No: WS-18004021
Validatedduring	08.11.2023
Method	Photometryat37°C
Manufacturer	Shenzhen MindrayBio-Medical Electronics Co., Ltd
NameofLaboratory/Hospital	PCR Healthcre pvt.ltd
Department	Laboratory

TESTSVALIDATED—Glucose,Urea,Creatinine,TotalCholesterol,Triglycerides,SGOT,SGPT,
Albumin, Total Protein, Albumin, Total Protein, Total Billrubin,Direct
Billrubin,Calcium

Accuracyprotocol:

The accuracy of B5-380 &S. No: WS-18004021 been verified by analyzing Multi-Sera Calibrator LOT
No:150121008.

S. No	Parameter	ValueObtained	CalibratorConcentration
1	Glucose(mg/dl)	191	190
2	Urea (mg/dl)	102	102
3	Creatinine(mg/dl)	4.05	4.53
4	TC(mg/dl)	160	164
5	TGL(mg/dl)	132	131
6	SGOT(U/L)	108	110
7	SGPT(U/L)	103	103
8	Ca(mg/dl)	11	10.57
9	UA(mg/dl)	5.80	5.76
10	Albumin(g/dl)	3.6	3.68
11	TP(g/dl)	5.70	5.82
12	T.BILI(mg/dl)	4.88	4.72
13	D.BILI(mg/dl)	2.57	2.75

Conclusion

WS-18004021 has been verified by analyzing the Multi-Sera Calibrator the results obtainedwere satisfactory

ReportedBy



Viraj Kale
Manager-
TechnicalIVD-
Automation
+91-9930033581