

Ref No: Avantor/Calibration /1713/03

Date: 05/02/2022

CALIBRATION CERTIFICATE

Customer Name	Wellness Diagnostic Pvt. Ltd.
Address	Dharamveer Market 2 nd Floor, Near, Seble Cinema & Metro Station Mathura Road, Badarpur, New Delhi-110044

CALIBRATION Report for

Machine	FULLY AUTO CHEMISTRY ANALYZER
Model	BS 240Pro
Serial Number	BC7-18001351

CALIBRATION Validity

Calibration performed date	05-02-2022
Calibration validity	1 Year
Next Calibration Due on	04-02-2023

CHECKS BEFORE CALIBRATION

PHYSICAL CHECKS:

Outer Casing/Chassis O.K. (No Damage)	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
CPU, Keyboard, Monitor O.K.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
UPS Power supply OK	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Water Unit OK	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>

ENGINEERING CHECKS:

Mechanical fittings O.K.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Screws tightening O.K.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Computer functioning normal	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
On/off switch working normally.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Instrument Switching On normally.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Software checks (All Programs working OK)	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
No abnormal and unusual sound coming.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Lamp switching on & off normal	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Reagent and sample Arm Action correct	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Input Voltage O.K.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Temperature O.K.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Any abnormal noise	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>

CALIBRATION

Sample probe action and movement	CALIBRATED
Reagent probe action and movement	CALIBRATED
Cuvette wash probe action and up/down movement	CALIBRATED
Reaction Cuvette positioning and movement	CALIBRATED
Sample Tray Positioning action and movement	CALIBRATED
Reagent Tray Positioning action and movement	CALIBRATED
Optical Unit	CALIBRATED
Temperature- Heating and Cooling	CALIBRATED
Water Supply Module motor function	CALIBRATED
Wash Unit Motor function	CALIBRATED
Waste Unit Motor Function	CALIBRATED
Mixing Unit Motor function	CALIBRATED
ISE Unit	CALIBRATED

CALIBRATOR NAME	CALIBRATOR LOT	EXPIRY
Multi Sera Calibrator	150121006	2022-12-31

PERFORMANCE CHECKS AFTER CALIBRATION

<p><u>Photometric Unit performance after calibration</u> Wavelength 340, 380, 412,450, 505, 546, 570, 605, 660, 700, 740, 800 <u>Segment wise performance after calibration:</u></p>	<p>GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/></p>
Sample probe action and movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Reagent probe action and movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Cuvette wash probe action and up/down movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Reaction Cuvette positioning and movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Sample Tray Positioning action and movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Reagent Tray Positioning action and movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Optical Unit	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Temperature- Heating and Cooling	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Water Supply Module motor function	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Wash Unit Motor function	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Waste Unit Motor Function	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Mixing Unit Motor function	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
ISE Unit	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
<p><u>Overall performance</u></p>	<p>Satisfactorily <input checked="" type="checkbox"/> Not satisfactorily <input type="checkbox"/></p>

Calibration performed by:



Name: Sanjeev Kumar
Customer Service
Executive Mobile: +91
9811459701
Email: sanjeev.kumar@avantorsciences.com

Signature:
Date: 06/12/2021

PERFORMANCE ANALYSIS

Model: BS-240Pro

Serial no. BC7-18001351

The performance of the analyzer has been verified for the accuracy and precision analysis of the parameters specified below with Bio Red control and human sample.

Quality Control performance

S No.	Chemistry Parameters	Unit	Bio rad level - 1 Lot no. 26491		Bio rad level – 2 Lot no. 26492	
			Mean Value	Results	Mean Value	Results
1	TG	mg/dl	164.2	177.8	75.1	75.2
2	TRP	g/dl	6.1	6.48	3.76	3.89
3	ALP	U/l	121.2	114.5	435.3	417.5
4	D BILL	mg/dl	0.37	0.38	1.64	1.63
5	T BILL	mg/dl	0.92	0.9	4.46	4.39
6	SGPT	U/l	26.1	26	107.6	106.8
7	SGOT	U/l	29.7	29.1	177.9	198.1
8	CHOL	mg/dl	249.3	242.8	104.5	100.8
9	GLU	mg/dl	81.5	84.7	266.9	280.1
10	URIC ACID	mg/dl	4.44	4.53	8.74	8.69
11	ALB	g/dl	3.37	3.82	2.54	2.53
12	UREA	mg/dl	30.9	34.6	92	97.1
13	CREAT	mg/dl	1.93	2.28	4.24	4.7
14	CAL	mg/dl	9.89	10.13	11.45	11.49
15	PHOS	mg/dl	3.12	3.34	7.09	7.49
16	HDL	mg/dl	65.8	68.3	21.4	20.6
17	TRIG	mg/dl	164.2	177.8	75.1	75.2
18	GGT	U/l	59.2	59.6	149.1	151.1

For Avantor Performance Materials India Ltd.

Signature: - 

Name: Sanjeev Kumar
Customer Service
Executive Mobile: +91
9811459701
Email: sanjeev.kumar@avantorsciences.com

Signature:

Date: 06/12/2021

Date:05.02.2022

CALIBRATION CERTIFICATE

To whom So Ever It May Concern

This is to certify that the below mentioned instrument installed Wellness Diagnostic Pvt. Ltd., Dharamveer Market 2nd Floor, Near, Seble Cinema & Metro Station Mathura Road, Badarpur, New Delhi-110044 Has Been Calibrated by Us On 05/02/2022, The Next Calibration is due on before 04/02/2023, The values are falling within the specified range.

The calibration is done by the service team of Avantor performance materials India ltd.

The next calibration is due on 04th Feb. 2023

Validity: -One year for Calibration factor data.

For Avantor Performance Materials India Limited

A handwritten signature in blue ink that reads 'Sanjeev'.

Sanjeev Kumar

Sr. Customer Service Executive

+91 9811459701

Email: sanjeev.kumar@avantorsciences.com



Avantor Performance Materials India Limited

Registered office

17th Floor, Building No. 5, Tower C, DLF Cyber City

Phase-III, Gurgaon - 122002, Haryana, India

Tel: +91-124 - 4656700

Fax: +91-124 - 4656799

Web: www.avantorinc.com

CIN: U24209HR1991PLC048501

MINDRAY BS 240 PRO

BIOCHEMISTRY ANALYSER

INSTALLATION QUALIFICATION (IQ) / OPERATIONAL QUALIFICATION (OQ)

FOR

WELLNESS DIAGNOSTIC PVT. LTD.

BY


AVANTOR PERFORMANCE MATERIALS INDIA LIMITED



CERTIFICATE OF INSTALLATION

INSTRUMENT NAME	MINDRAY BS 240 PRO
SR. NO.	BC7-18001351
CUSTOMER NAME	WELLNESS DIAGNOSTIC PVT. LTD.
ADDRESS	Dharamveer Market 2 nd Floor, Near, Seble Cinema & Metro Station Mathura Road, Badarpur, New Delhi-110044

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE INSTALLATION QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

ENGINEER	
SIGNATURE	
NAME	SANJEEV KUMAR
DESIGNATION	CUSTOMER SERVICE EXECUTIVE
COMPANY	AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

QUALITY MANAGER	
SIGNATURE	
NAME	MR. ARUN KUMAR
DESIGNATION	DIRECTOR
COMPANY	WELLNESS DIAGNOSTIC PVT. LTD.

**INSTALLATION REPORT**

CUSTOMER NAME	Wellness Diagnostic Pvt. Ltd.
PLACE	Dharamveer Market 2 nd Floor, Near, Seble Cinema & Metro Station Mathura Road, Badarpur, New Delhi-110044
DEPARTMENT	Laboratory
CONTACT PERSON	MR. Arun Kumar
INSTRUMENT NAME	MINDRAY BS 240 PRO
SERIAL NUMBER	BC7-18001351
DATE OF INSTALLATION	11/01/2022
WARRANTY EXPIRY	10/01/2027

THE ANALYZER WAS INSTALLED ALONG WITH THE NECESSARY STANDARD ACCESSORIES, ALL BASIC REQUIREMENTS AND ADJUSTMENTS WERE CHECKED AND FOUND TO BE SATISFACTORY. THE PRELIMINARY STANDARDIZATION OF THE ANALYZER AND THE TRAINING WERE PROVIDED TO THE COMPLETE SATISFACTION OF THE CUSTOMER. THE ANALYZER IS FOUND TO BE WORKING SATISFACTORYLY.

FOR AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

A handwritten signature in blue ink that reads 'Sanjeev'.

SANJEEV KUMAR
CUSTOMER SERVICE EXECUTIVE



INSTRUMENT SETUP

INSTALLATION QUALIFICATION

IQ PROTOCOL

1. SYSTEM UNPACKING
2. CHECK FOR ANY PHYSICAL DAMAGE
3. VERIFY ACCESSORIES LIST
4. SPACE REQUIRMENT
5. POWER REQUIREMENT
6. OPERATING ENVIRONMENT

1 SYSTEM UN PACKING / 2 CHECK FOR ANY PHYSICAL DAMAGE

BS 240 PRO WAS UNPACKED AND CHECKED FOR ANY PHYSICAL DAMAGES. FOUND TO BE INTACT

3 VERIFY ACCESSORIES LIST

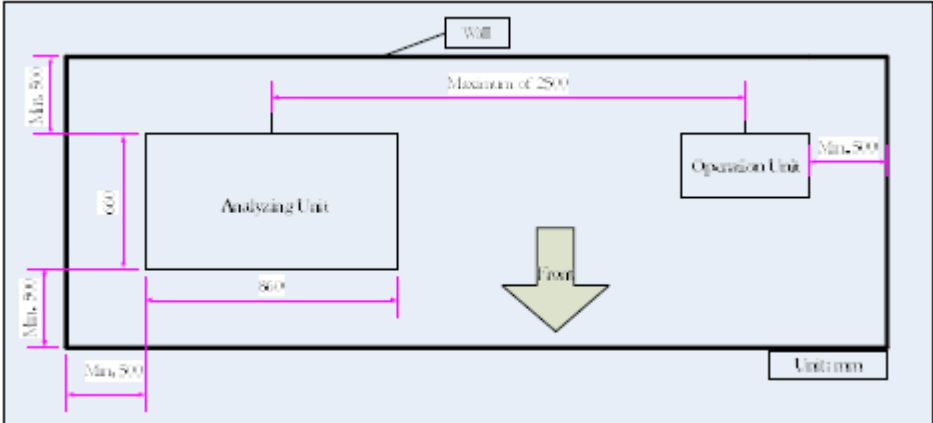
ACCESSORIES LIST WAS COMPARED WITH THE PHYSICALLY AVAILABLE ITEMS AND FOUND TO BE OK

S No	ITEM DESCRIPTION	STATUS
1	COMPUTER UNIT	INSTALLED
2	USER SOFTWARE	INSTALLED
3	INTEGRATED PROBE	INSTALLED
4	MIXER UNIT	INSTALLED
5	DEIONIZED WATER TANK WITH SENSOR	INSTALLED
6	WATER UNIT	INSTALLED
7	DETERGENT CAN WITH SENSOR	INSTALLED
8	H-WASTE CAN WITH SENSOR	INSTALLED
9	PRINTER UNIT	NA



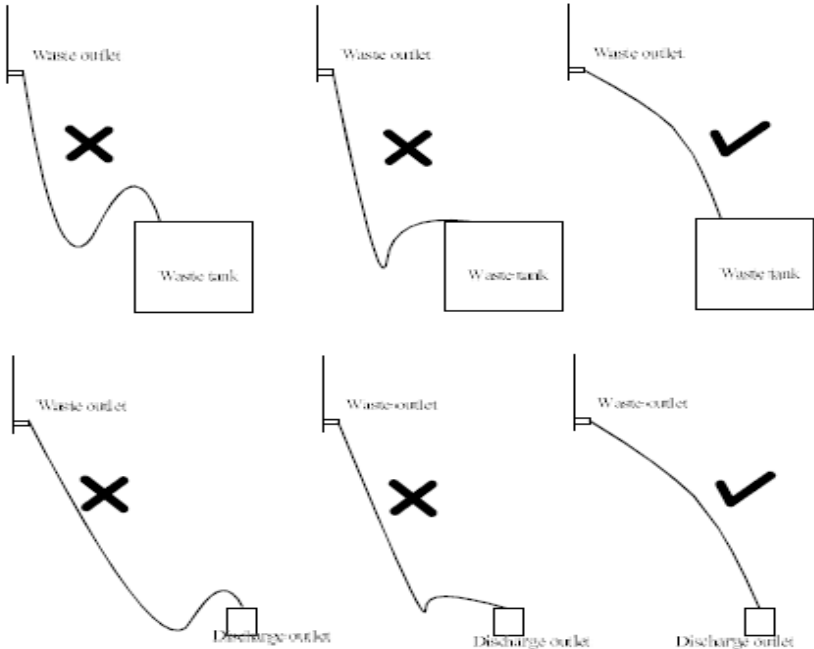
4 SPACE REQUIREMENTS

A: MAIN INSTRUMENT



ALL UNITS IN MM

B: WATER SUPPLY & DRAIN





5 POWER REQUIREMENT / 6 OPERATING ENVIRONMENT

REQUIREMENT	REQUIREMENT	REMARKS
INPUT VOLTAGE	220 ± 10V AC	OK
LINE FREQUENCY	50/60 HZ	OK
AMBIENT TEMPERATURE	15°C - 30°C	OK
UPS	3 KVA ONLINE	OK
GROUNDING	< 5VAC	OK
WATER QUALITY	CONDUCTIVITY - < 1µS/CM	OK

THE INSTALLATION QUALIFICATION POINTS WERE CHECKED AND FOLLOWED AND FOUND TO BE OK AND FURTHER CERTIFIES THE INSTRUMENT TO BE INSTALLED AT THE GIVEN PREMISES

FOR AVANTOR PERFORMANCE MATERIALS INDIA LIMITED


SANJEEV KUMAR
CUSTOMER SERVICE EXECUTIVE



CERTIFICATE OF OPERATION

INSTRUMENT NAME	MINDRAY BS 240 PRO
SR. NO.	BC7-18001351
CUSTOMER NAME	Wellness Diagnostic Pvt. Ltd.
ADDRESS	Dharamveer Market 2 nd Floor, Near, Seble Cinema & Metro Station Mathura Road, Badarpur, New Delhi-110044

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE OPERATION QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

ENGINEER	
SIGNATURE	
NAME	SANJEEV KUMAR
DESIGNATION	CUSTOMER SERVICE EXECUTIVE
COMPANY	AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

QUALITY MANAGER	
SIGNATURE	
NAME	MR. ARUN KUMAR
DESIGNATION	DIRECTOR
COMPANY	WELLNESS DIAGNOSTIC PVT. LTD.



OPERATIONAL QUALIFICATION OF THE INSTRUMENT:

DESCRIPTION	REMARKS
POWER UP	PASSED
LOGIN	PASSED
FLUID PRIME	PASSED
MAINTENANCE RECORD SET UP	DONE
START UP INITIALIZATION	PASSED
IMPORTING & CONFIGURING CHEMISTRY PARAMETERS	NA
SYSTEM PERFORMANCE TEST	PASSED

OPERATIONAL QUALIFICATION VERIFICATION WAS CARRIED OUT AS PER THE PROTOCOL AND INSTRUMENT WAS DEEMED FIT FOR PERFORMANCE QUALIFICATION.

FOR AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

SANJEEV KUMAR
CUSTOMER SERVICE EXECUTIVE

940740584

Running 00 : 05

HOST ServiceUser 09-03 14:14

Levey-Jennings Cumulative Sum Twin-Plot Results Summary QC Setup

Control ALL QC Date 15-12-2021 15-12-2021

Control	Lot No.	Chem	Sample Type	Lot No.	Result	Unit	Set Mean	Set SD	Flag	Run Da
CONTROLL1	059321004	Ca	Serum	1005	8.89	mg/dl	8.83	0.82		15-12-2
CONTROLL1	059321004	T-bil-D II	Serum	1005	1.28	mg/dl	1.22	0.09		15-12-2
CONTROLL1	059321004	D-bil-D II	Serum	1002	1.12	mg/dl	1.11	0.08		15-12-2
CONTROLL1	059321004	ALT	Serum	1006	61.1	U/L	60.9	3		15-12-2
CONTROLL1	059321004	AST	Serum	1008	53.8	U/L	52.2	2.6		15-12-2
CONTROLL1	059321004	ALP	Serum	1005	90.3	U/L	85.2	4.3		15-12-2
CONTROLL1	059321004	TP	Serum	1004	5.1	g/dL	5.13	0.6		15-12-2
CONTROLL1	059321004	TG	Serum	1005	117.3	mg/dl	112	5		15-12-2
CONTROLL1	059321004	TC	Serum	1007	114.5	mg/dl	107	5		15-12-2
CONTROLL1	059321004	UA	Serum	1004	5.20	mg/dl	5.06	0.24		15-12-2
CONTROLL1	059321004	UREA	Serum	1006	42.26	mg/dL	39.9	2		15-12-2
CONTROLL1	059321004	CREAT AV	Serum		1.07	mg/dl	1.07	0.05		15-12-2

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Running

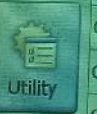
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HOST



ServiceUser

09-03 14:15



Control	Lot No.	Chem	Sample Type	Lot No.	Result	Unit	Set Mean	Set SD	Flag	Run Da
CONTROL-1	059321004	UREA	Serum	1006	42.26	mg/dL	39.9	2		15-12-21
CONTROL-1	059321004	CREAT AV	Serum		1.07	mg/dL	1.07	0.05		15-12-21
CONTROL-1	059321004	GLU AV	Serum		99.9	mg/dL	105	5		15-12-21
CONTROL-1	059321004	ALB II	Serum	1004	3.2	g/dL	3.03	1.6		15-12-21
CONTROL-L2	059421003	Ca	Serum	1005	12.40	mg/dL	12.2	0.5		15-12-21
CONTROL-L2	059421003	T-bil-D II	Serum	1005	4.65	mg/dL	4.51	0.34		15-12-21
CONTROL-L2	059421003	D-bil-D II	Serum	1002	2.70	mg/dL	2.7	0.2		15-12-21
CONTROL-L2	059421003	Al T	Serum	1006	148.0	U/L	145	7		15-12-21
CONTROL-L2	059421003	AST	Serum	1008	160.6	U/L	161	8		15-12-21
CONTROL-L2	059421003	ALP	Serum	1005	226.7	U/L	226	11		15-12-21
CONTROL-L2	059421003	TP	Serum	1004	8.5	g/dL	8.27	0.41		15-12-21
CONTROL-L2	059421003	TG	Serum	1005	215.4	mg/dL	207	10		15-12-21

Levey-Jennings Cumulative Sum Twin-Plot Results Summary QC Setup

Control: ALL QC Date: 15-12-2021 15-12-2021

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940740584

Running 00:04

HOST ServiceUser 09-03 14:15

Levey-Jennings Cumulative Sum Twin-Plot Results Summary QC Setup

Control ALL QC Date 15-12-2021 15-12-2021

Control	Lot No.	Chem	Sample Type	Lot No.	Result	Unit	Set Mean	Set SD	Flag	Run Da
CONTROL-L2	059421003	D-bil-D II	Serum	1002	2.70	mg/dL	2.7	0.2		15-12-2
CONTROL-L2	059421003	ALT	Serum	1006	148.0	U/L	145	7		15-12-2
CONTROL-L2	059421003	AST	Serum	1008	160.6	U/L	161	8		15-12-2
CONTROL-L2	059421003	ALP	Serum	1005	226.7	U/L	226	11		15-12-2
CONTROL-L2	059421003	TP	Serum	1004	8.5	g/dL	8.27	0.41		15-12-2
CONTROL-L2	059421003	TG	Serum	1005	215.4	mg/dL	207	10		15-12-2
CONTROL-L2	059421003	TC	Serum	1007	188.5	mg/dL	179	8		15-12-2
CONTROL-L2	059421003	UA	Serum	1004	10.66	mg/dL	10.5	0.5		15-12-2
CONTROL-L2	059421003	UREA	Serum	1006	128.72	mg/dL	123	6		15-12-2
CONTROL-L2	059421003	CREAT AV	Serum		3.40	mg/dL	3.34	0.21	2.7s	15-12-2
CONTROL-L2	059421003	GLU AV	Serum		237.1	mg/dL	249	13		15-12-2
CONTROL-L2	059421003	ALB II	Serum	1004	4.9	g/dL	4.8	0.24		15-12-2

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Biochemistry Calibration

Reagent Carousel Status

Cal Setup

Chem ALL

Current

History

Cal Date 10-12-2021

15-12-2021

Chem	Flag	Cal Status	Cal Date/Time	RO	K	A
Ca		Cal Time Out	15-12-2021 16:48:49	-0.1857	0.0021	
T-bil-D II		Cal Time Out	15-12-2021 15:37:14	-0.7806	0.0117	
D-bil-D II		Cal Time Out	15-12-2021 15:37:12	-0.2596	0.0017	
ALT		Cal Time Out	15-12-2021 15:31:57	2.1907	0.4924	
AST		Cal Time Out	15-12-2021 15:32:27	-1.3626	0.5401	
ALP		Cal Time Out	15-12-2021 15:32:57	18.4826	0.5068	
TP		Cal Time Out	15-12-2021 16:57:05	20.4636	0.0060	
TP		Calibrated	15-12-2021 15:34:14	15.9515	0.0061	
TG		Cal Time Out	15-12-2021 15:35:57	14.4863	0.0408	
TC		Cal Time Out	15-12-2021 15:32:58	6.1072	0.0447	

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Cal Curve
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Reac Curve
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Biochemistry Calibration

Reagent Carousel Status

Cal Setup

Chem ALL

Current

History

Cal Date 10-12-2021 - 15-12-2021

Chem	Flag	Cal Status	Cal Date / Time	RO	K	A
ALP		Cal Time Out	15-12-2021 15:32:57	18.4826	0.5068	
TP		Cal Time Out	15-12-2021 16:57:05	20.4636	0.0060	
TP		Calibrated	15-12-2021 15:34:14	15.9515	0.0061	
TG		Cal Time Out	15-12-2021 15:35:57	14.4863	0.0408	
TC		Cal Time Out	15-12-2021 15:32:58	6.1072	0.0447	
UA		Cal Time Out	15-12-2021 15:35:27	57.0442	0.0070	
UREA		Cal Time Out	15-12-2021 15:34:27	16.5784	0.1250	
CREAT AV		Calibrated	15-12-2021 15:28:43	10.3068	0.0075	
GLU AV		Calibrated	15-12-2021 15:36:27	146.7802	0.0257	
ALB II		Cal Time Out	15-12-2021 16:52:34	240.7264	0.0004	



Trend

Print

Chem ALL

Current

History

Cal Date: 10-12-2021 - 15-12-2021

Item	Flag	Cal Status	Cal Date/Time	P0	K	A
AST		Cal Time Out	15-12-2021 15:32:27	-1.3626	0.5401	
ALP		Cal Time Out	15-12-2021 15:32:57	18.4826	0.5068	
TP		Cal Time Out	15-12-2021 16:57:05	20.4636	0.0060	
TP		Calibrated	15-12-2021 15:34:14	15.9515	0.0061	
TG		Cal Time Out	15-12-2021 15:35:57	14.4863	0.0408	
TC		Cal Time Out	15-12-2021 15:32:58	6.1072	0.0447	
UA		Cal Time Out	15-12-2021 15:35:27	57.0442	0.0070	
UREA		Cal Time Out	15-12-2021 15:34:27	16.5784	0.1250	
GREAT AV		Calibrated	15-12-2021 15:28:43	10.3068	0.0075	
GLU AV		Calibrated	15-12-2021 15:36:27	146.7802	0.0257	

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