

**INSTALLATION QUALIFICATION OPERATIONAL
QUALIFICATION
&
PERFORMANCE QUALIFICATION**

BeneSphera A10 Supreme

HbA1c Analyzer

Installation Qualification

For

Wellness Diagnostic Pvt. Ltd.

By


Avantor Performance Materials India Limited

CERTIFICATE OF INSTALLATION

INSTRUMENT NAME : BeneSphera A10 Supreme
SERIAL NUMBER : OIAD18800142
CUSTOMER NAME : WELLNESS DIAGNOSTIC PVT. LTD.
ADDRESS : Dharamveer Market 2nd 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

TECHNICAL MANAGER

Signature :
Name : Mr. Arun Kumar
Designation : Director
Organization : WELLNESS DIAGNOSTIC PVT. LTD.

INSTALLATION REPORT

CUSTOMER NAME : Wellness Diagnostic Pvt. Ltd.
PLACE : Dharamveer Market 2nd Floor,
Near, Seble Cinema & Metro
Station Mathura Road,
Badarpur, New Delhi-110044
DEPARTMENT : Laboratory
CONTACT PERSON : MR. Arun Kumar
INSTUMENT NAME : BeneSphera A10 Supreme
SERIAL NUMBER : OIAD18800142
INSTALLATION DATE : 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 WORKINGSATISFACTORILY.

For Avantor Performance Materials India Limited

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

Sanjeev Kumar
Customer Service Executive

INSTRUMENT SETUP

S No	ITEM DESCRIPTION	STATUS
1	SOFTWARE	INSTALL E D
2	A ELUENT TUBE	INSTALL E D
3	B ELUENT TUBE	INSTALL E D
4	C ELUENT TUBE	INSTALL E D
5	HEMOLYSING AGENT TUBE	INSTALL E D
6	WASTE CAN TUBE	INSTALL E D
7	AUTO LOADER	INSTALL E D
8	BARCODE SCANNER	INSTALL E D

OPERATION INSPECTION

- POWER SUPPLY CHECKED.
- NO UNUSUAL NOISES PRODUCED IN THE SYSTEM.

For Avantor Performance Materials India Ltd



Sanjeev Kumar
Customer Service Executive

INSTALLATION QUALIFICATION

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Station Mathura Road, Badarpur, New Delhi-110044
INSTRUMENT NAME : BeneSphera A10 Supreme
SERIAL NUMBER : OIAD18800142

INSTALLATION REQUIREMENTS FOR THE INSTRUMENT:

ANALYZER	VOLTAGE	FREQUENCY	INPUT POWER
BeneSphera A10 Supreme	a.c.100 V~240 V	50/60 Hz	≤150 VA

For Avantor Performance Materials India Limited

Sanjeev Kumar
Customer Service Executive

BeneSphera A10 Supreme

HbA1c Analyzer

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TECHNICAL MANAGER

Signature :
Name : Mr. Arun Kumar
Designation : Director
Organization : WELLNESS DIAGNOSTIC PVT. LTD.

OPERATIONAL QUALIFICATION OF THE INSTRUMENT:

DESCRIPTION	STATUS	REMARKS
POWER SUPPLY UNIT	SELF TEST	PASSED
ELECTRONICS	SELF TEST	PASSED
HARDWARE	SELF TEST	PASSED
BARCODE	NORMAL & SENSING	PASSED
AUTO LOADER	SELF TEST	PASSED
TOUCH SCREEN	NORMAL & SENSING	PASSED
WASTE TUBE	NORMAL & DRAINING	PASSED
A ELUENT TUBE	NORMAL & ASPIRATING	PASSED
B ELUENT TUBE	NORMAL & ASPIRATING	PASSED
C ELUENT TUBE	NORMAL & ASPIRATING	PASSED
HAEMOLYTIC REAGENT TUBE	NORMAL & ASPIRATING	PASSED
THERMAL PRINTER	NORMAL & PRINTING	PASSED

For Avantor Performance Materials India Limited



 Sanjeev Kumar
 Customer Service Executive

BeneSphera A10 Supreme

HbA1c Analyzer

Performance Qualification

For

Wellness Diagnostic Pvt. Ltd.

By


Avantor Performance Materials India Limited

CERTIFICATE OF PERFORMANCE

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Organization : WELLNESS DIAGNOSTIC PVT. LTD.

PERFORMANCE ANALYSIS

Model: BeneSphera A10 Supreme Serial

Number: OIAD18800142

The performance of the analyzer has been verified for the precision analysis of the parameter specified below with given sample

20 replicates of the given sample have been run and a statistical analysis has been performed on the data.

Parameter: HbA1c

S.No	Replicates
1	5.5 %
2	5.7 %
3	5.6 %
4	5.6 %
5	5.6 %
6	5.7 %
7	5.7 %
8	5.7 %
9	5.6 %
10	5.5 %
11	5.6 %
12	5.6 %
13	5.5 %
14	5.6 %
15	5.5 %
16	5.5 %
17	5.6 %
18	5.6 %
19	5.5 %
20	5.6 %
Mean	5.59
SD	0.072
CV%	1.28

Conclusion:

Within run precision of the tabulated parameters were completed. The percentage coefficient of variation for all the parameters falls within acceptable limits.

CV% Obtained: 1.28

Mean: 5.59%

SD: 0.072

For Avantor Performance Materials India Limited

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

Sanjeev Kumar
Customer Service Executive

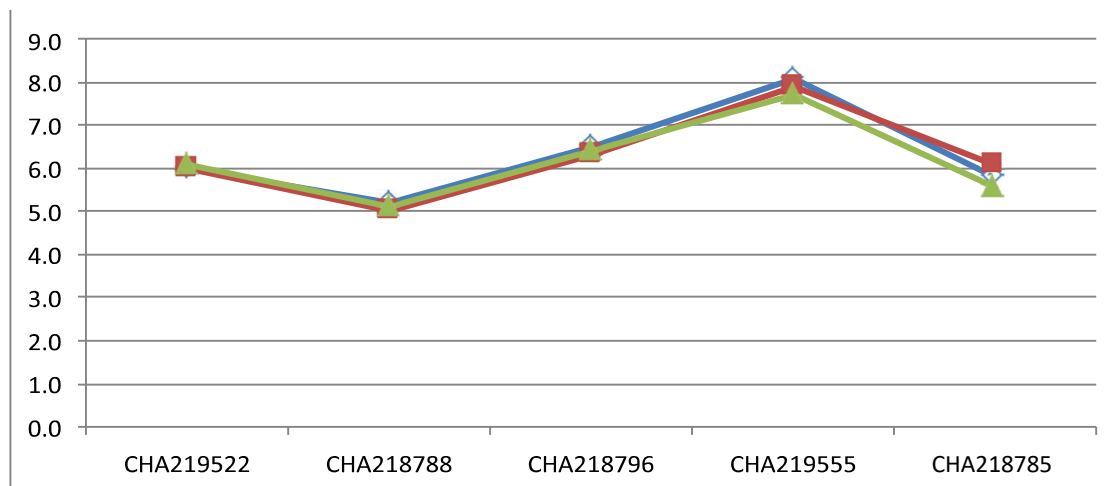
PERFORMANCE ANALYSIS

Model: BeneSphera A10 Supreme Serial

Number: OIAD18800142

Five different samples have been analysed for HbA1c in BIO-RAD Variant II & the same were analysed for HbA1c on two consecutive days for the recovery & correlation

ANALYZER BIO-RAD Variant II			BeneSphera A10 Supreme	
			Day 1	Day 2
S.No.	Sample ID	08-01-2022	09-01-2022	11-01-2022
1	CHA219522	6.0 %	6.0 %	6.1 %
2	CHA218788	5.2 %	5.0 %	5.1 %
3	CHA218796	6.5 %	6.3 %	6.4 %
4	CHA219555	8.1 %	7.9 %	7.7 %
5	CHA218785	5.8 %	6.1 %	5.6 %



Conclusion:

The correlation & recovery of HbA1c results obtained from BeneSphera A10 Supreme on day 1 & day 2 & satisfactory

Model: BeneSphera A10 Supreme Serial

Number: OIAD18800142

A regression analysis between BIO-RAD VARIANT II & BeneSphera A10 Supreme for 20 different samples & a statistical data have been established based on the results obtained

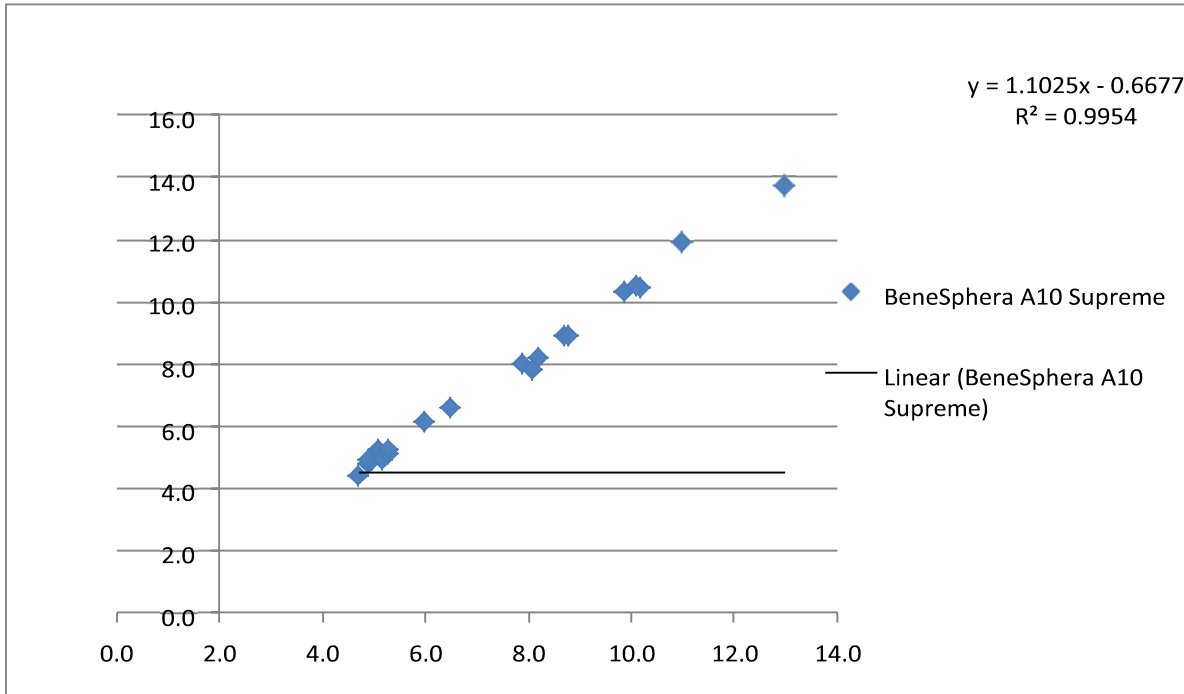
S.No	Sample ID	BIO-RAD Variant II	BeneSphera A10 Supreme
1	CHA254582	5.1 %	5.2 %
2	H0921320	9.9 %	10.3 %
3	H0814990	5.0 %	4.9 %
4	CHA219549	10.2 %	10.4 %
5	H1462194	4.7 %	4.4 %
6	H0976397	11.0 %	11.9 %
7	CHA2667908	4.9 %	4.8 %
8	CHA219522	6.0 %	6.1 %
9	CHA2682179	4.9 %	4.9 %
10	H0746025	13.0 %	13.7 %
11	CHA218796	6.5 %	6.6 %
12	H0924378	8.2 %	8.2%
13	CHA218788	5.2 %	4.9 %
14	H1044921	7.9 %	8.0 %
15	CHA219555	8.1 %	7.8 %
16	H0746026	10.1 %	10.5 %
17	H0746030	5.3 %	5.1 %
18	H0743185	8.7 %	8.9 %
19	H0956352	5.3 %	5.2 %
20	H0994103	8.8 %	8.9 %

For Avantor Performance Materials India Limited



Sanjeev Kumar
Customer Service Executive

BeneSphera A10 Supreme



Conclusion

A regression analysis between BIO-RAD VARIANT II & BeneSphera A10 Supreme for 20 different samples & the R^2 obtained is 0.9954.

For Avantor Performance Materials India Limited



Sanjeev Kumar
Customer Service Executive

CALIBRATION CERTIFICATE	
PCLP/CAL/2022/001	August 15, 2018
NAME OF THE CUSTOMER	MANUFACTURER
Wellness Diagnostic Pvt. Ltd	Lifotronics, CHINA
Dharamveer Market 2 nd Floor, Near, Seble Cinema & Metro Station Mathura Road, Badarpur, New Delhi-110044	
PRODUCT	SERIAL No:
BeneSphera A10 Supreme	IA2D18800142

This is to Certify that the **BeneSphera A10 Supreme** has been inspected and Calibrated as per the protocol on 11.01.2022. The Equipment is working satisfactorily. This Calibration is valid through 10.01 23.

S. No	TEST PARAMETERS	MEASURED/CALIBRATED	REMARKS
01	INPUT VOLTAGE	230V	PASSED
02	POWER CONSUMPTION	100-240VA	PASSED
03	INPUT FREQUENCY	50/60 HZ	PASSED
04	OPERATING TEMPERATURE	10 - 30°C	PASSED

S. No	TEST PARAMETERS	STATUS TEST	REMARKS
01	COUNTING TIME	PASSED	WORKING
02	SYRINGE MODULES	PASSED	WORKING
03	EVACUATION VALVE TEST	PASSED	WORKING
04	VACUUM - -40, -85	-44.1, -73.0	PASSED
05	PRESSURE - 250, 160, 70	240.8, 147, 73.1	PASSED
06	VALVES CHECK	PASSED	WORKING
07	A/D INPUT CHECK	PASSED	WORKING
08	AUTO LOADER CHECK	STEPS	PASSED
09	ELUENT A TUBE CHECK	DISPENSE	PASSED
10	ELUENT B TUBE CHECK	DISPENSE	PASSED
11	ELUENT C TUBE CHECK	DISPENSE	PASSED
12	LYSE L TUBE CHECK	DISPENSE	PASSED
13	WASTE TUBE CHECK	DRAINING	PASSED

The Next Calibration is due on 10.01. 2022

Signature: - 

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 Customer Service Executive
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