

Registered Office:

BioSystems Diagnostics Pvt. Ltd.,
A4, SIPCOT Industrial Park, Irungattukottai,
Thandalam Village, Sriperumbudur - 602105.
Ph: +91 - 44 - 3034 1911 / 12 /13
E-mail: customersupport@biosystems.in
Website: www.biosystems.in
CIN - U29297TN2003PTC051492



Date: 11/01/2021

CALIBRATION CERTIFICATE OF BA200

CUSTOMER NAME – OM Sai Pathology Laboratory

Serial Number = 832000211

User Software = 5.1.3

Initialization Motor

Vertical Motors – Sample and reagent in Home

Polar Motors – Sample and reagent in Home

Reaction Rotor in home

Sample and Reagent rotor in Home

Ceramic Dispensing pump – Sample and reagent in Home

Optics Initialization: Ok

Peltier cells and drivers test

Rotor Peltier and Sample Reagent Rotor peltier driver test: Ok

Temperature system initialized

LED test: ok

Hardware completely initialized

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Parameters	Current value	Minimum	Maximum
Reading reference Position - Well 1	7895	7860	7905
Thermal adjustment of reaction rotor	36.9	37	39
Thermal adjustment of Wash station	50	42	50
Thermal adjustment of Sample & Reagent Probe	37	36	39
Photometric Dark Current Adjustment	4028	3300	4500
Main Photo Diode Counts 340NM	904307	600000	950000
Main Photo Diode Counts 405NM	740189	850000	950000
Main Photo Diode Counts 505NM	404592	850000	950000
Main Photo Diode Counts 535NM	900564	850000	950000
Main Photo Diode Counts 560NM	801157	420000	950000
Main Photo Diode Counts 600NM	415560	750000	950000
Main Photo Diode Counts 635NM	851520	850000	950000
Main Photo Diode Counts 670NM	828257	450000	950000

Next calibration due on: 10/01/2022

For BIOSYSTEMS DIAGNOSTICS PVT. LTD.

Authorized Signatory



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BA200 – Fully Auto Biochemistry Analyser


Installation Qualification Certificate

For

Omsai Pathology Laboratory ,Latur

BioSystems Diagnostics Pvt. Ltd

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A circular logo for ISO 13485 certification is located in the bottom right corner. It consists of a large, light-colored circle with a smaller, white circle inside it, partially overlapping the larger one. The text "ISO 13485" is printed in a black, sans-serif font within the white circle.

ISO 13485

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CERTIFICATE OF INSTALLATION

Instrument Name : BA200 Fully Auto Biochemistry Analyzer

Serial Number : 832000211

Customer : Omsai Pathology Laboratory ,Latur,
Central Bus Stand Gate no. 1 Latur -413512

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

Engineer
Signature : 
Name : Mr.Nitin Phadatare
Designation : Service Engineer
Company : BioSystems Diagnostics Pvt. Ltd.,



Customer
Signature :
Name : Dr. Kapil Dhumure
Designation : Lab Incharge
Company : Omsai Pathology Laboratory ,Latur,

Corporate Office:

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INSTALLATION REPORT

Customer Name : Omsai Pathology Laboratory ,Latur,
Department : Bio-chemistry
Contact Person : Dr. Kapil Dhumure
Instrument Model : BA200
Serial Number : 832000211
Date of Installation : 01/12/2018

The System was installed along with the necessary accessories. All basic requirements and adjustments were checked and are found to be satisfactory. Preliminary customer training was provided and standardization of all parameters was done. The Instrument is found to be working satisfactorily.

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INSTRUMENT SETUP :

- Instrument and computer installed
- Printer Installed
- User software 5.1.3.0 installed
- All necessary cable connections given

OPERATION INSPECTION :

- No air bubbles found in the Tubing
- Temperature of the Needles/Reaction & Rotor Chamber are within range
- No unusual noises produced in the system
- Warm up procedure within time limit
- Internal Dosing of all Needle's were fine
- External Dosing of all Wash Station is perfect
- Conditioning of Machine with Air/Wash solution/Distilled water done

For Biosystems Diagnostics Pvt. Ltd

Mr. Nitin Phadatore
Service Engineer



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INSTALLATION QUALIFICATION

Customer Name : Omsai Pathology Laboratory ,Latur,
Address : Omsai Pathology Laboratory ,Latur,
Central Bus Stand Gate no. 1 Latur -413512
Instrument Model : BA200
Serial No. : 832000211

Operational requirement for the Instrument:

Requirement	Acceptable Range	Observed Range
Input Voltage	220 \pm 10 V	228 V
Line Frequency	50 or 60 Hz	50 Hz
Ambient Temperature	18 – 30 deg. C	25 deg. C
Distill Water	Type II NCCLS	Available

For Biosystems Diagnostics Pvt. Ltd


Mr. Nitin Phadatare
Service Engineer



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BA200 - Fully Auto Biochemistry Analyzer

Operational Qualification


For

Omsai Pathology Laboratory ,Latur

BioSystems Diagnostics Pvt. Ltd

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ISO 13485

The ISO 13485 certification logo is located in the bottom right corner. It consists of a stylized, circular graphic with overlapping lines in shades of purple and grey, resembling a globe or a molecular structure. The text "ISO 13485" is printed in a small, black, sans-serif font within the lower right portion of the graphic.

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BA200 – Fully Auto Biochemistry Analyzer

OPERATIONAL QUALIFICATION

1. System Performance check procedures.
2. System operational certificate.

Corporate Office:

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ISO 13485

Registered Office:

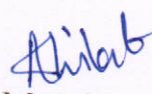
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Website: www.biosystems.in
CIN - U29297TN2003PTC051492



CERTIFICATE OF OPERATION

Instrument Name : BA200 Fully Auto Biochemistry Analyzer
Serial Number : 832000211
Customer : Omsai Pathology Laboratory ,Latur,
Central Bus Stand Gate no. 1 Latur -413512

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

Engineer
Signature : 
Name : Mr. Nitin Phadatar
Designation : Service Engineer
Company : BioSystems Diagnostics Pvt. Ltd



Customer
Signature :
Name : Dr. Kapil Dhumure
Designation : Lab Incharge
Company : Omsai Pathology Laboratory, Latur.

Corporate Office:

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SYSTEM PERFORMANCE CHECK PROCEDURE

SYSTEM CHECK	PERFORMANCE
LED Photometric Check	Done
Warm Up	Done
Mechanical Adjustments	Done
Temperature Check	Done
Internal/External Dosing Check	Done

Customer Signature:

Corporate Office:

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OPERATIONAL QUALIFICATION

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.

Protocol Performed By :

BioSystems Diagnostics Pvt Ltd

Name : Mr.Nitin Phadatare

Title : Service Engineer

Company: Biosystems Diagnostics Pvt Ltd

Customer Authorization:

Omsai Pathology Laboratory, Latur.

Name: Dr. Kapil Dhumure

Title: Lab Incharge

ENGINEER SIGNATURE

DATE:



CUSTOMER SIGNATURE

DATE:

Corporate Office:
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BA200 - Fully Auto Bio Chemistry Analyzer

Performance Qualification

For

Omsai Pathology Laboratory ,Latur

BioSystems Diagnostics Pvt. Ltd

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BA200 Fully Auto Biochemistry Analyzer

PERFORMANCE QUALIFICATION:

The following parameters were checked and found to be within acceptable limits.

Parameter	Check
Vertical Motors – Sample and reagent in Home	Done
Polar Motors – Sample and reagent in Home	Done
Reaction Rotor in home	Done
Sample and Reagent rotor in Home	Done
Ceramic Dispensing pump – Sample and reagent in Home	Done
Optics Initialization: Ok	Done
Peltier cells and drivers test	Done
Rotor Peltier and Sample Reagent Rotor peltier driver test: Ok	Done
Temperature system initialized	Done
LED test: ok	Done
Hardware completely initialized	Done

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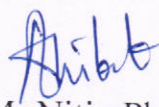
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CERTIFICATE OF PERFORMANCE

Instrument Name : BA200 Fully Auto Biochemistry Analyzer
Serial Number : 832000211
Customer : Omsai Pathology Laboratory ,Latur,
Central Bus Stand Gate no. 1 Latur -413512

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

Engineer
Signature : 
Name : Mr.Nitin Phadatare
Designation : Service Engineer
Company : BioSystems Diagnostics Pvt Ltd.,



Customer
Signature :
Name : Dr. Kapil Dhumure
Designation : Lab Incharge
Company : Omsai Pathology Laboratory ,Latur.

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Patient ID		Precision test				
Tests	Type	No. Abs.	Conc.	Unit	Ref. ranges	Date
ALBUMIN	SER	0.2007	3.11	g/dL		12/1/2018 5:52 PM
		1 0.2003	3.10	g/dL		12/1/2018 5:49 PM
		2 0.2012	3.13	g/dL		12/1/2018 5:49 PM
		3 0.2008	3.12	g/dL		12/1/2018 5:50 PM
		4 0.2020	3.14	g/dL		12/1/2018 5:50 PM
		5 0.2003	3.10	g/dL		12/1/2018 5:50 PM
		6 0.2005	3.11	g/dL		12/1/2018 5:51 PM
		7 0.1987	3.06	g/dL		12/1/2018 5:51 PM
		8 0.2012	3.13	g/dL		12/1/2018 5:51 PM
		9 0.2014	3.13	g/dL		12/1/2018 5:52 PM
		10 0.2004	3.11	g/dL		12/1/2018 5:52 PM
ALT-GPT	SER	0.0517	163	U/L		12/1/2018 5:39 PM
		1 0.0526	166	U/L		12/1/2018 5:37 PM
		2 0.0522	164	U/L		12/1/2018 5:37 PM
		3 0.0517	163	U/L		12/1/2018 5:37 PM
		4 0.0518	163	U/L		12/1/2018 5:37 PM
		5 0.0514	162	U/L		12/1/2018 5:38 PM
		6 0.0511	161	U/L		12/1/2018 5:38 PM
		7 0.0518	163	U/L		12/1/2018 5:38 PM
		8 0.0514	162	U/L		12/1/2018 5:39 PM
		9 0.0509	160	U/L		12/1/2018 5:39 PM
		10 0.0517	163	U/L		12/1/2018 5:39 PM
AST-GOT	SER	0.0563	158	U/L		12/1/2018 5:42 PM
		1 0.0559	157	U/L		12/1/2018 5:40 PM
		2 0.0563	158	U/L		12/1/2018 5:40 PM
		3 0.0566	159	U/L		12/1/2018 5:40 PM
		4 0.0566	159	U/L		12/1/2018 5:40 PM
		5 0.0568	159	U/L		12/1/2018 5:41 PM
		6 0.0570	160	U/L		12/1/2018 5:41 PM
		7 0.0563	158	U/L		12/1/2018 5:41 PM
		8 0.0565	158	U/L		12/1/2018 5:42 PM
		9 0.0559	157	U/L		12/1/2018 5:42 PM
		10 0.0553	155	U/L		12/1/2018 5:42 PM
BILIRUBIN TOTAL	SER	0.1145	6.2	mg/dL		12/1/2018 5:31 PM
		1 0.1140	6.2	mg/dL		12/1/2018 5:28 PM
		2 0.1117	6.1	mg/dL		12/1/2018 5:28 PM
		3 0.1140	6.2	mg/dL		12/1/2018 5:29 PM
		4 0.1154	6.3	mg/dL		12/1/2018 5:30 PM
		5 0.1168	6.3	mg/dL		12/1/2018 5:30 PM
		6 0.1155	6.3	mg/dL		12/1/2018 5:30 PM

					12/1/2018 5:13 PM	
		7	0.1137	6.2	mg/dL	12/1/2018 5:31 PM
		8	0.1146	6.2	mg/dL	12/1/2018 5:31 PM
		9	0.1145	6.2	mg/dL	12/1/2018 5:31 PM
		10	0.1151	6.3	mg/dL	12/1/2018 5:31 PM
CHOLESTEROL	SER		0.4836	301	mg/dL	12/1/2018 5:47 PM
		1	0.4857	303	mg/dL	12/1/2018 5:44 PM
		2	0.4831	301	mg/dL	12/1/2018 5:44 PM
		3	0.4818	300	mg/dL	12/1/2018 5:45 PM
		4	0.4884	304	mg/dL	12/1/2018 5:45 PM
		5	0.4802	299	mg/dL	12/1/2018 5:45 PM
		6	0.4813	299	mg/dL	12/1/2018 5:46 PM
		7	0.4852	302	mg/dL	12/1/2018 5:46 PM
		8	0.4802	299	mg/dL	12/1/2018 5:46 PM
		9	0.4837	301	mg/dL	12/1/2018 5:46 PM
		10	0.4862	303	mg/dL	12/1/2018 5:47 PM
CREATININE	SER		0.0983	3.81	mg/dL	12/1/2018 5:43 PM
		1	0.1012	3.93	mg/dL	12/1/2018 5:40 PM
		2	0.0956	3.70	mg/dL	12/1/2018 5:40 PM
		3	0.0968	3.75	mg/dL	12/1/2018 5:40 PM
		4	0.0991	3.84	mg/dL	12/1/2018 5:41 PM
		5	0.1000	3.88	mg/dL	12/1/2018 5:41 PM
		6	0.0954	3.69	mg/dL	12/1/2018 5:41 PM
		7	0.1013	3.93	mg/dL	12/1/2018 5:42 PM
		8	0.0974	3.77	mg/dL	12/1/2018 5:42 PM
		9	0.0974	3.77	mg/dL	12/1/2018 5:42 PM
		10	0.0985	3.82	mg/dL	12/1/2018 5:43 PM
GLUCOSE	SER		0.9954	267	mg/dL	12/1/2018 5:34 PM
		1	0.9773	262	mg/dL	12/1/2018 5:32 PM
		2	1.0039	270	mg/dL	12/1/2018 5:32 PM
		3	0.9928	266	mg/dL	12/1/2018 5:32 PM
		4	1.0031	269	mg/dL	12/1/2018 5:33 PM
		5	1.0092	271	mg/dL	12/1/2018 5:33 PM
		6	0.9945	267	mg/dL	12/1/2018 5:33 PM
		7	0.9884	265	mg/dL	12/1/2018 5:34 PM
		8	0.9933	266	mg/dL	12/1/2018 5:34 PM
		9	0.9970	267	mg/dL	12/1/2018 5:34 PM
		10	0.9943	267	mg/dL	12/1/2018 5:34 PM
PROTEIN TOTALBIR	SER		0.2520	4.72	g/dL	12/1/2018 5:50 PM
		1	0.2512	4.70	g/dL	12/1/2018 5:47 PM
		2	0.2466	4.57	g/dL	12/1/2018 5:47 PM
		3	0.2518	4.72	g/dL	12/1/2018 5:48 PM
		4	0.2535	4.77	g/dL	12/1/2018 5:48 PM
		5	0.2556	4.83	g/dL	12/1/2018 5:48 PM

					12/1/2018 5:13 PM	
		6	0.2555	4.82	g/dL	12/1/2018 5:49 PM
		7	0.2503	4.67	g/dL	12/1/2018 5:49 PM
		8	0.2508	4.69	g/dL	12/1/2018 5:49 PM
		9	0.2525	4.74	g/dL	12/1/2018 5:49 PM
		10	0.2519	4.72	g/dL	12/1/2018 5:50 PM
TRIGLYCERIDES	SER		0.3875	261	mg/dL	12/1/2018 5:53 PM
		1	0.3769	252	mg/dL	12/1/2018 5:50 PM
		2	0.3872	261	mg/dL	12/1/2018 5:51 PM
		3	0.3854	259	mg/dL	12/1/2018 5:51 PM
		4	0.3882	262	mg/dL	12/1/2018 5:51 PM
		5	0.3893	263	mg/dL	12/1/2018 5:52 PM
		6	0.3913	264	mg/dL	12/1/2018 5:52 PM
		7	0.3905	264	mg/dL	12/1/2018 5:52 PM
		8	0.3918	265	mg/dL	12/1/2018 5:52 PM
		9	0.3873	261	mg/dL	12/1/2018 5:53 PM
		10	0.3867	260	mg/dL	12/1/2018 5:53 PM
UREA-BUN-UV	SER		0.1509	108	mg/dL	12/1/2018 5:45 PM
		1	0.1533	110	mg/dL	12/1/2018 5:43 PM
		2	0.1546	111	mg/dL	12/1/2018 5:43 PM
		3	0.1503	108	mg/dL	12/1/2018 5:43 PM
		4	0.1471	105	mg/dL	12/1/2018 5:43 PM
		5	0.1508	108	mg/dL	12/1/2018 5:44 PM
		6	0.1446	103	mg/dL	12/1/2018 5:44 PM
		7	0.1591	114	mg/dL	12/1/2018 5:44 PM
		8	0.1512	108	mg/dL	12/1/2018 5:45 PM
		9	0.1497	107	mg/dL	12/1/2018 5:45 PM
		10	0.1486	106	mg/dL	12/1/2018 5:45 PM

BA200

Customer - OM Sai Path Lab, Latur

S/N. - 832000211

SOFTWA

RE VER. 5.1.3

Precision Studies of Material Quality -

Runs	ALBUMIN	ALT	AST	BILI T	CREAT	UREA	GLU	CHOL	TP	TG
1	3.1	166	157	6.2	3.93	110	262	303	4.7	252
2	3.13	164	158	6.1	3.7	111	270	301	4.57	261
3	3.12	163	159	6.2	3.75	108	266	300	4.72	259
4	3.14	163	159	6.3	3.84	105	269	304	4.77	262
5	3.1	162	159	6.3	3.88	108	271	299	4.83	263
6	3.11	161	160	6.3	3.69	103	267	299	4.82	264
7	3.06	163	158	6.2	3.93	114	265	302	4.67	264
8	3.13	162	158	6.2	3.77	108	266	299	4.69	265
9	3.13	160	157	6.2	3.77	107	267	301	4.74	261
10	3.11	163	155	6.3	3.82	106	267	303	4.72	260
MEAN	3.11	162.70	158.00	6.23	3.81	108.00	267.00	301.10	4.72	261.10
SD	0.02	1.64	1.41	0.07	0.09	3.13	2.58	1.85	0.08	3.73
CV	0.74	1.01	0.90	1.08	2.28	2.90	0.97	3.70	2.80	1.43