

Registered office:

BioSystems Diagnostics Pvt. Ltd.,
A4, SIPCOT Industrial Park, Irungattukottai,
Thandalam Village, Sriperumbudur - 602105.
Ph: +91 -44 - 30341911 / 12/ 13/14
Email: customersupport@biosystems.in
Website: www.biosystems.in
CIN - U29297TN2003PTC051492



BA200 – Fully Auto Biochemistry Analyser

Installation Qualification Certificate

For

Xtra care Diagnostics

Chembur

BioSystems Diagnostics Pvt. Ltd

Registered office:

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CIN - U29297TN2003PTC051492



CERTIFICATE OF INSTALLATION

Instrument Name : BA200 Fully Auto Biochemistry Analyzer

Serial Number : 832001188

Customer : Xtra care Diagnostics
Next to Safal Ganga, Opposite Shagun Lawans,
R.C.Marg, Chembur, Mumbai-400074

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

Engineer

Signature

Name

Designation

Company

:

: Mr. Pranav Ramesh Dudwadkar

: Senior Service Engineer

: BioSystems Diagnostics Pvt. Ltd.,



Customer

Signature

Name

Designation

Company

:

: Dr. Rishi Mehta(MD)

: Lab In Charge

: Xtra care Diagnostics

Registered office:

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INSTALLATION REPORT

Customer Name : Xtra care Diagnostics
Department : Bio-chemistry
Contact Person : Dr. Rishi Mehta (MD)
Instrument Model : BA200
Serial Number : 832001188
Date of Installation : 3-3-2022

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 5.4.2.0 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

For

A. Pravin



Mr. Pranav Ramesh Dudwadkar
Senior Service Engineer

Registered office:

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INSTALLATION QUALIFICATION

Customer Name : Xtra care Diagnostics

Address : Xtra care Diagnostics
Next to Safal Ganga, Opposite Shagun Lawans,
R.C.Marg, Chembur, Mumbai-400074

Instrument Model : BA200

Serial No. : 832001188

Operational requirement for the Instrument:

Requirement	Acceptable Range	Observed Range
Input Voltage	220 \pm 10 V	231 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

for
A. Pranjayachandran

Mr. Pranav Ramesh Dudwadkar
Senior Service Engineer

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BA200 - Fully Auto Biochemistry Analyzer

Operational Qualification

For

Xtra care Diagnostics

Chembur

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Email: customersupport@biosystems.in
Website: www.biosystems.in
CIN - U29297TN2003PTC051492



BA200 – Fully Auto Biochemistry Analyzer

OPERATIONAL QUALIFICATION

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

Registered office:

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Email: customersupport@biosystems.in
Website: www.biosystems.in
CIN - U29297TN2003PTC051492





CERTIFICATE OF OPERATION

Instrument Name : BA200 Fully Auto Biochemistry Analyzer
Serial Number : 832001188
Customer : Xtra care Diagnostics

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

Engineer
Signature : *for*
Name : Mr. Pranav Ramesh Dudwadkar
Designation : Senior Service Engineer
Company : BioSystems Diagnostics Pvt. Ltd



Customer
Signature : 
Name : Dr. Rishi Mehta (MD)
Designation : Lab In Charge
Company : Xtra care Diagnostics

Registered 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

A handwritten signature in blue ink, consisting of a large, stylized 'A' followed by a vertical line and a horizontal stroke.

Customer Signature:

Registered office:

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Website: www.biosystems.in
CIN - U29297TN2003PTC051492



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. Pranav Ramesh Dudwadkar
Title : Senior Service Engineer
Company: Biosystems Diagnostics Pvt Ltd

Customer Authorization: Xtra care Diagnostics
Name: Dr. Rishi Mehta (MD)
Title : Lab In Charge

for
A. Parthasarathy

ENGINEER SIGNATURE

DATE: 08/04/2022


CUSTOMER SIGNATURE

DATE: 05/04/2022

Registered office:

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BA200 - Fully Auto Bio Chemistry Analyzer

Performance Qualification

For

Xtra care Diagnostics

Chembur

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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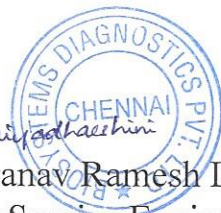
CERTIFICATE OF PERFORMANCE


Instrument Name : BA200 Fully Auto Biochemistry Analyzer
Serial Number : 832001188
Customer : Xtra care Diagnostics

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

Engineer

Signature : 
Name : Mr. Pravin Ramesh Dudwadkar
Designation : Senior Service Engineer
Company : BioSystems Diagnostics Pvt Ltd.,



Customer
Signature : 
Name : Dr. Rishi Mehta (MD)
Designation : Lab In Charge
Company : Xtra care Diagnostics

Registered office:

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Email: customersupport@biosystems.in
Website: www.biosystems.in
CIN - U29297TN2003PTC051492



Date: 03/03/2022

CALIBRATION CERTIFICATE OF BA200

CUSTOMER NAME – XTRA CARE DIAGNOSTICS, CHEMBUR.

Serial Number = 832001188

User Software = 5.4.2.0

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	7893	7860	7905
Thermal adjustment of reaction rotor	34	37	39
Thermal adjustment of Wash station	49	42	50
Thermal adjustment of Sample & Reagent Probe	37	36	39
Photometric Dark Current Adjustment	3923	3300	4500
Main Photo Diode Counts 340NM	899387	600000	950000
Main Photo Diode Counts 405NM	668826	850000	950000
Main Photo Diode Counts 505NM	588264	850000	950000
Main Photo Diode Counts 535NM	788705	850000	950000
Main Photo Diode Counts 560NM	733502	420000	950000
Main Photo Diode Counts 600NM	742420	750000	950000
Main Photo Diode Counts 635NM	681819	850000	950000
Main Photo Diode Counts 670NM	664388	450000	950000

Next calibration due on: 2/3/2023

For BIOSYSTEMS DIAGNOSTICS PVT. LTD.

A. Prayudh aashin

Authorized Signatory

Date: 03/03/2023

CALIBRATION CERTIFICATE OF BA200

CUSTOMER NAME – **Xtra Care Diagnostics**

Serial Number = 832001188

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

[Type here]

BioSystems

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Registered office:

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Tamil Nadu - 602105. India
Ph: +91 -44 - 30341911 / 12/ 13/14
Email: support@biosystems.in
CIN - U29297TN2003PTC051492

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: 02/03/2024

For BIOSYSTEMS DIAGNOSTICS PVT. LTD.,

**KRUNAL
GORDHANBHAI
MADHU**

Digitally signed by KRUNAL
GORDHANBHAI MADHU
DN: cn=KRUNAL GORDHANBHAI
MADHU, c=IN, o=PERSONAL,
email=krunalmadhu@biosystems.in
Date: 2023.05.25 16:50:33 +05'30'

Authorized Signatory

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WORLD CLASS FILING SYSTEM

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First Line

Second Line

First Line

Second Line

QC(Name-Lot)	Test	Target Value	SD Value	QC Range	Result	Test Date
normalyte	GLUC	94	10	75 ~ 113	92	10-08-2023
normalyte	ALB	3.3	0.3	2.7 ~ 3.9	3.5	10-08-2023
normalyte	UREA	33	4	25 ~ 41	37	10-08-2023
normalyte	TP	5.49	0.69	4.11 ~ 6.87	5.02	10-08-2023
normalyte	SGPT	48	5	38 ~ 58	54	10-08-2023
normalyte	CREAT	1.20	0.15	0.90 ~ 1.50	1.19	10-08-2023
normalyte	SGOT	41	4	33 ~ 49	44	10-08-2023
normalyte	UA	4.5	0.5	3.6 ~ 5.4	5.1	10-08-2023
normalyte	HDL - D	44	5	35 ~ 53	46	10-08-2023
normalyte	GGT	26	5	17 ~ 35	28	10-08-2023
normalyte	ALP	100	13	75 ~ 125	105	10-08-2023
normalyte	CALCIUM	7.80	0.60	6.60 ~ 9.00	9.71	10-08-2023
normalyte	CHOL	136	10	116 ~ 156	133	10-08-2023
normalyte	PHOS	3.3	0.3	2.6 ~ 3.9	3.4	10-08-2023
normalyte	TGL	92	7	78 ~ 106	92	10-08-2023
normalyte	BIL D	0.97	0.10	0.77 ~ 1.17	0.80	10-08-2023
normalyte	TBIL	1.72	0.17	1.38 ~ 2.06	1.90	10-08-2023
normalyte	IRON	85.00	11.00	63.00 ~ 107.00	108.77	10-08-2023
patholyte-14123062	GLUC	306	31	244 ~ 368	290	10-08-2023
patholyte-14123062	ALB	5.1	0.5	4.1 ~ 6.2	5.1	10-08-2023
patholyte-14123062	UREA	137	14	110 ~ 164	113	10-08-2023
patholyte-14123062	TP	8.46	0.85	6.76 ~ 10.16	7.36	10-08-2023
patholyte-14123062	SGPT	140	14	112 ~ 168	136	10-08-2023
patholyte-14123062	CREAT	4.55	0.55	3.45 ~ 5.65	4.36	10-08-2023
patholyte-14123062	SGOT	182	18	146 ~ 218	186	10-08-2023
patholyte-14123062	UA	9.3	0.9	7.4 ~ 11.2	9.5	10-08-2023
patholyte-14123062	HDL - D	65	7	52 ~ 78	63	10-08-2023
patholyte-14123062	GGT	93	14	65 ~ 121	93	10-08-2023
patholyte-14123062	ALP	225	23	180 ~ 270	221	10-08-2023
patholyte-14123062	CALCIUM	12.50	1.25	10.00 ~ 15.00	13.17	10-08-2023
patholyte-14123062	CHOL	221	22	177 ~ 265	210	10-08-2023
patholyte-14123062	PHOS	9.8	1.1	7.6 ~ 12.0	6.8	10-08-2023
patholyte-14123062	TGL	205	21	163 ~ 247	192	10-08-2023
patholyte-14123062	BIL D	2.35	0.25	1.85 ~ 2.85	2.33	10-08-2023
patholyte-14123062	TBIL	6.09	0.61	4.87 ~ 7.31	5.75	10-08-2023
patholyte-14123062	IRON	151.00	30.00	91.00 ~ 211.00	224.23	10-08-2023



First Line

Second Line

05-08-2023

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QC(Name-Lot)	Test	Target Value	SD Value	QC Range	Result	Test Date	Stat
normalyte	GLUC	94	10	75 ~ 113	93	05-08-2023	
normalyte	ALB	3.3	0.3	2.7 ~ 3.9	3.5	05-08-2023	
normalyte	UREA	33	4	25 ~ 41	40	05-08-2023	
normalyte	TP	5.49	0.69	4.11 ~ 6.87	4.75	05-08-2023	
normalyte	SGPT	48	5	38 ~ 58	50	05-08-2023	
normalyte	CREAT	1.20	0.15	0.90 ~ 1.50	1.26	05-08-2023	
normalyte	SGOT	41	4	33 ~ 49	46	05-08-2023	
normalyte	UA	4.5	0.5	3.6 ~ 5.4	4.8	05-08-2023	
normalyte	HDL - D	44	5	35 ~ 53	45	05-08-2023	
normalyte	GGT	26	5	17 ~ 35	30	05-08-2023	
normalyte	ALP	100	13	75 ~ 125	101	05-08-2023	
normalyte	CALCIUM	7.80	0.60	6.60 ~ 9.00	8.00	05-08-2023	
normalyte	CHOL	136	10	116 ~ 156	136	05-08-2023	
normalyte	PHOS	3.3	0.3	2.6 ~ 3.9	3.2	05-08-2023	
normalyte	TGL	92	7	78 ~ 106	87	05-08-2023	
normalyte	BIL D	0.97	0.10	0.77 ~ 1.17	0.78	05-08-2023	
normalyte	TBIL	1.72	0.17	1.38 ~ 2.06	1.79	05-08-2023	
normalyte	IRON	85.00	11.00	63.00 ~ 107.00	49.21	05-08-2023	
patholyte	GLUC	270	27	216 ~ 324	265	05-08-2023	
patholyte	ALB	4.2	0.4	3.4 ~ 5.0	4.4	05-08-2023	
patholyte	UREA	120	12	96 ~ 144	122	05-08-2023	
patholyte	TP	7.27	0.75	5.77 ~ 8.77	6.06	05-08-2023	
patholyte	SGPT	105	13	79 ~ 131	110	05-08-2023	
patholyte	CREAT	4.17	0.42	3.33 ~ 5.01	4.40	05-08-2023	
patholyte	SGOT	111	14	83 ~ 139	119	05-08-2023	
patholyte	UA	6.4	0.7	5.1 ~ 7.7	7.0	05-08-2023	
patholyte	HDL - D	56	7	42 ~ 70	58	05-08-2023	
patholyte	GGT	79	12	55 ~ 103	85	05-08-2023	
patholyte	ALP	337	25	286 ~ 388	352	05-08-2023	
patholyte	CALCIUM	10.30	0.80	8.70 ~ 11.90	11.18	05-08-2023	
patholyte	CHOL	172	22	129 ~ 215	170	05-08-2023	
patholyte	PHOS	7.9	0.8	6.3 ~ 9.4	5.4	05-08-2023	
patholyte	TGL	171	21	128 ~ 214	171	05-08-2023	
patholyte	BIL D	2.05	0.21	1.63 ~ 2.47	1.99	05-08-2023	
patholyte	TBIL	4.50	0.57	3.36 ~ 5.64	4.14	05-08-2023	

First Line

Second Line

03-08-

QC(Name-Lot)	Test	Target Value	SD Value	QC Range	Result	Test Date
normalyte	GLUC	94	10	75 ~ 113	97	03-08-2023
normalyte	ALB	3.3	0.3	2.7 ~ 3.9	3.4	03-08-2023
normalyte	UREA	33	4	25 ~ 41	41	03-08-2023
normalyte	TP	5.49	0.69	4.11 ~ 6.87	4.96	03-08-2023
normalyte	SGPT	48	5	38 ~ 58	46	03-08-2023
normalyte	CREAT	1.20	0.15	0.90 ~ 1.50	1.37	03-08-2023
normalyte	SGOT	41	4	33 ~ 49	44	03-08-2023
normalyte	UA	4.5	0.5	3.6 ~ 5.4	4.9	03-08-2023
normalyte	HDL - D	44	5	35 ~ 53	45	03-08-2023
normalyte	GGT	26	5	17 ~ 35	29	03-08-2023
normalyte	ALP	100	13	75 ~ 125	103	03-08-2023
normalyte	CALCIUM	7.80	0.60	6.60 ~ 9.00	8.04	03-08-2023
normalyte	CHOL	136	10	116 ~ 156	136	03-08-2023
normalyte	PHOS	3.3	0.3	2.6 ~ 3.9	6.4	03-08-2023
normalyte	TGL	92	7	78 ~ 106	81	03-08-2023
normalyte	BIL D	0.97	0.10	0.77 ~ 1.17	0.85	03-08-2023
normalyte	TBIL	1.72	0.17	1.38 ~ 2.06	1.87	03-08-2023
normalyte	IRON	85.00	11.00	63.00 ~ 107.00	86.18	03-08-2023
patholyte	GLUC	270	27	216 ~ 324	266	03-08-2023
patholyte	ALB	4.2	0.4	3.4 ~ 5.0	4.4	03-08-2023
patholyte	UREA	120	12	96 ~ 144	127	03-08-2023
patholyte	TP	7.27	0.75	5.77 ~ 8.77	6.42	03-08-2023
patholyte	SGPT	105	13	79 ~ 131	106	03-08-2023
patholyte	CREAT	4.17	0.42	3.33 ~ 5.01	4.67	03-08-2023
patholyte	SGOT	111	14	83 ~ 139	117	03-08-2023
patholyte	UA	6.4	0.7	5.1 ~ 7.7	7.3	03-08-2023
patholyte	HDL - D	56	7	42 ~ 70	58	03-08-2023
patholyte	GGT	79	12	55 ~ 103	84	03-08-2023
patholyte	ALP	337	25	286 ~ 388	347	03-08-2023
patholyte	CALCIUM	10.30	0.80	8.70 ~ 11.90	10.85	03-08-2023
patholyte	CHOL	172	22	129 ~ 215	179	03-08-2023
patholyte	PHOS	7.9	0.8	6.3 ~ 9.4	8.2	03-08-2023
patholyte	TGL	171	21	128 ~ 214	170	03-08-2023
patholyte	BIL D	2.05	0.21	1.63 ~ 2.47	2.05	03-08-2023
patholyte	TBIL	4.50	0.57	3.36 ~ 5.64	4.94	03-08-2023
patholyte	IRON	161.00	20.00	121.00 ~ 201.00	188.65	03-08-2023

