

Date: 20/04/2024

CALIBRATION CERTIFICATE OF BA200

CUSTOMER NAME – MKAS HEALTHCARE SERVICES PVT LTD

Serial Number = 832001654

Firmware Version = 4.04.26

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	7880	7860	7905
Washing Solution Tank 0	1	-5	5
Washing Solution Tank 50	45	40	60
Washing Solution Tank 100	97	95	105
Waste Tank 0	-2	-5	5
Waste Tank 50	41	40	60
Waste Tank 100	100	95	105
Thermal adjustment of reaction rotor	37.0	36.0	39.0
Thermal adjustment of Wash station	45.0	44	50
Thermal adjustment of reagent tip 1	37.0	36	39
Thermal adjustment of reagent tip 2	37.0	36	39
Main Photometric Dark Current Adjustment	3978	3581	4500

BioSystems

human - centred biotech

Registered office:

BioSystems Diagnostics Pvt. Ltd.,
A4, SIPCOT Industrial Park, Irungattukottai,
Tamil Nadu - 602105. India
Ph: +91 -44 - 30341911 / 12/ 13/14
Email: support@biosystems.in
CIN - U29297TN2003PTC051492

Main Photo Diode Counts 340NM	902403	271781	950000
Main Photo Diode Counts 405NM	900300	826758	950000
Main Photo Diode Counts 505NM	900054	880443	950000
Main Photo Diode Counts 535NM	900834	626023	950000
Main Photo Diode Counts 560NM	899435	679355	950000
Main Photo Diode Counts 600NM	899029	612392	950000
Main Photo Diode Counts 635NM	896434	575332	950000
Main Photo Diode Counts 670NM	899162	702936	950000

Next calibration due on: 19/04/2025

For BIOSYSTEMS DIAGNOSTICS PVT. LTD.,



Authorized Signatory

Date: 20.04.2023

To,
M/s. MKAS HEALTHCARE SERVICES PVT LTD
BA200
Serial No: 832001654

Dear Sir/Madam,

Please find below the traceability details of BioSystems Reagents.

TRACEABLE VALUE

COMPONENT	TRACEABILITY	VAL	UNITS
URIC ACID	SRM 909 b (NIST)		µmol/L
ALBUMINE	SRM 927 c (NIST)		g/L
ALT/GPT	C-RSE/IFCC	-	µkat/L
AST/GOT	C-RSE/IFCC	-	µkat/L
α-AMYLASE	C-RSE/IFCC	-	µkat/L
BILIRUBINE (DIRECT)	SRM 909 b (NIST)		µmol/L
BILIRUBINE (TOTAL)	SRM 909 b (NIST)		µmol/L
CALCIUM	SRM 909 b (NIST)		mmol/L
CK	C-RSE/IFCC	-	µkat/L
CHLORIDES	SRM 909 b (NIST)		mmol/L
CHOLESTEROL	SRM 909 b (NIST)		mmol/L
CREATININE	SRM 909 b (NIST)		µmol/L
ACID PHOSPHATASE	BMC	-	µkat/L
ASO (Turbidimetry)	SRM 97/662 (NIBSC)	-	IU/mL
CRP (Turbidimetry)	ERM-DA472/IFCC	-	mg/L
ALKALINE PHOSPHATASE	C-RSE/IFCC	-	µkat/L
PHOSPHORUS	BMC	-	mmol/L
GLUCOSE	SRM 909 b (NIST)		mmol/L
γ-GT	C-RSE/IFCC	-	µkat/L

IRON	BMC	-	μmol/L
LIPASE	BMC	-	μkat/L
LD/LDH	C-RSE/IFCC	-	μkat/L
MAGNESIUM	SRM 909 b (NIST)		mmol/L
POTASIUUM	SRM 909 b (NIST)		mmol/L
TOTAL PROTEIN	SRM 927 c (NIST)		g/L
SODIUM	SRM 909 b (NIST)		mmol/L
TRIGLYCERIDES	SRM 909 b (NIST)		mmol/L
UREA	SRM 909 b (NIST)		mmol/L
RF (Turbidimetry)	SRM W1066 (ILBS)		IU/mL

NOTES

1. Values for enzymes (U/L y ukat/L) are given for incubation temperature of 37°C
2. C-RSE/IFCC: Traceable to the Reference System reported by the Committee of Enzymes Reference Systems of the IFCC.
3. Values with no traceability have not yet an accepted international reference value. In the meantime value is traceable to intra laboratory studies

For BioSystems Diagnostics Pvt Ltd.,



Authorized Signatory

BA200 – Fully Auto Biochemistry Analyser

Installation Qualification Certificate

For

MKAS HEALTHCARE SERVICES PVT LTD

Balasore

BioSystems Diagnostics Pvt. Ltd

CERTIFICATE OF INSTALLATION

Instrument Name : BA200 Fully Auto Biochemistry Analyzer

Serial Number : 832001654

Customer : MKAS HEALTHCARE SERVICES PVT LTD
Balasore

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

Engineer



Signature :
Name : Mr. Pranawananda Satapathy
Designation : Service Engineer
Company : BioSystems Diagnostics Pvt. Ltd.,

Customer

Signature :
Name : MKAS HEALTHCARE SERVICES PVT LTD
Designation : Lab Incharge
Company : MKAS HEALTHCARE SERVICES PVT LTD, Balasore

INSTALLATION REPORT

Customer Name : MKAS HEALTHCARE SERVICES PVT LTD,
Department : Bio-chemistry
Contact Person : MKAS HEALTHCARE SERVICES PVT LTD
Instrument Model : BA200
Serial Number : 832001654
Date of Installation : 04/04/2023

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.

INSTRUMENT SETUP :

- Instrument and computer installed
- Printer Installed
- User software 5.7.0. 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. Pranawananda Satapathy
Service Engineer

INSTALLATION QUALIFICATION

Customer Name : MKAS HEALTHCARE SERVICES PVT LTD ,
Address : MKAS HEALTHCARE SERVICES PVT LTD ,
Balasore
Instrument Model : BA200
Serial No. : 832001654

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. Pranawananda Satapathy
Service Engineer

BA200 - Fully Auto Biochemistry Analyzer

Operational Qualification

For

MKAS HEALTHCARE SERVICES PVT LTD

Balasore

BioSystems Diagnostics Pvt. Ltd

BA200 – Fully Auto Biochemistry Analyzer

OPERATIONAL QUALIFICATION

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

CERTIFICATE OF OPERATION

Instrument Name : BA200 Fully Auto Biochemistry Analyzer
Serial Number : 832001654
Customer : MKAS HEALTHCARE SERVICES PVT LTD ,
Balasore

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

Engineer



Signature :
Name : Mr. Pranawananda Satapathy
Designation : Service Engineer
Company : BioSystems Diagnostics Pvt. Ltd

Customer

Signature :
Name : MKAS HEALTHCARE SERVICES PVT LTD
Designation : Lab Incharge
Company : MKAS HEALTHCARE SERVICES PVT LTD
Balasore

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:

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. Pranawananda Satapathy

Title : Service Engineer

Company: Biosystems Diagnostics Pvt Ltd

Customer Authorization:

MKAS HEALTHCARE SERVICES PVT LTD

Name: MKAS HEALTHCARE SERVICES PVT LTD

Title : Lab Incharge



ENGINEER SIGNATURE

CUSTOMER SIGNATURE

DATE:

DATE:

BA200 - Fully Auto Bio Chemistry Analyzer

Performance Qualification

For

MKAS HEALTHCARE SERVICES PVT LTD ,

Balasore

BioSystems Diagnostics Pvt. Ltd

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

CERTIFICATE OF PERFORMANCE

Instrument Name : BA200 Fully Auto Biochemistry Analyzer
Serial Number : 832001654
Customer : MKAS HEALTHCARE SERVICES PVT LTD ,
Balasore

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

Engineer



Signature :
Name : Mr. Pranawananda Satapathy
Designation : Service Engineer
Company : BioSystems Diagnostics Pvt Ltd.,

Customer

Signature :
Name : MKAS HEALTHCARE SERVICES PVT LTD
Designation : Lab Incharge
Company : MKAS HEALTHCARE SERVICES PVT LTD
Balasore

Proficiency Certificate

Certified that

Mr. Kanakalata swain

Lab Technician

.....
Has undergone Operator Training Course

April 2023

On
and is qualified to operate the Random
Access Analyzer BA200



.....
Service Manager

.....
Product Manager

Date : **20-04-2023**

BioSystems Diagnostics Pvt. Ltd.

A4,SIPCOT Industrial Park,

Irungattukottai,

Sriperumbudur - 602105

C.Ref : **BDPL/04/2023**

Proficiency Certificate

Certified that

Miss. Marshi das

Lab Technician

.....
Has undergone Operator Training Course

April 2023

On
and is qualified to operate the Random
Access Analyzer BA200



.....
Service Manager

.....
Product Manager

Date : **20-04-2023**

BioSystems Diagnostics Pvt. Ltd.

A4,SIPCOT Industrial Park,
Irungattukottai,
Sriperumbudur - 602105

C.Ref: **BDPL/04/2023**

Proficiency Certificate

Certified that

Mr. Dibyajyoti Dasmahapatra

Lab Technician

.....
Has undergone Operator Training Course

April 2023

On
and is qualified to operate the Random
Access Analyzer BA200



.....
Service Manager

.....
Product Manager

Date : **20-04-2023**

BioSystems Diagnostics Pvt. Ltd.

A4, SIPCOT Industrial Park,

Irungattukottai,

Sriperumbudur - 602105

C.Ref : **BDPL/04/2023**

Proficiency Certificate

Certified that

Mr. Rameshwar Rout
Lab Technician

.....
Has undergone Operator Training Course

April 2023

On
and is qualified to operate the Random
Access Analyzer BA200



.....
Service Manager

.....
Product Manager

Date : **20-04-2023**

BioSystems Diagnostics Pvt. Ltd.
A4, SIPCOT Industrial Park,
Irungattukottai,
Sriperumbudur - 602105

C.Ref : **BDPL/04/2023**