



Calibration Certificate

Following values have been checked & adjusted on BS 240 (Sr.No- YX-64000027) at Dham's Diagnostic Centre 3856/23, Reghar pura, Arya Samaj Road, Karol Bagh, New Delhi-110005

System voltages are in the specified range –Checked by Digital Multimeter are as below:

S.No.	Module	Observed Value	Acceptable Range
1	24 Voltage Supply	24.3 VDC	24.0 +/- 1.0 VDC
2	12 Voltage Supply	12.2 VDC	12.0 +/- 0.5 VDC
3	5 Voltage Supply	5.01 VDC	5.00 +/- 0.1 VDC
4	Liquid Level Sensor Board Supply	4.0 VDC	4.0 +/- 0.1 VDC

System Temperature values are in the specified range –Checked by Digital Thermometer are as below:

S.No.	Module	Observed Value	Acceptable Range
1	Reagent Preheater Temp.	45 °C	45 +/- 0.5 °C
2	Reaction Disk Temp.	37 °C	37 +/- 0.4 °C
3	Reagent Compartment Temp.	10 °C	8 to 12 °C

Photometer Adjustment Values are within range as recommended:

S.No.	Module	Observed Value	Acceptable Range
1	Background Count for all Wavelength	52,000 +/-40	48,000 to 55,000

Pipetting Syringes are Ok volume dispensed measured on Digital Weighing Machine:

S.No.	Module	Observed Value	Acceptable Range
1	Reagent/Sample Syringe	500 uL	500 +/-1uL

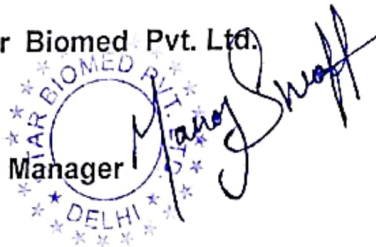
Washing Dispense are Ok volume dispensed measured on Digital Weighing Machine

S.No.	Module	Observed Value	Acceptable Range
1	Interior Washing	3.01 mL	3.00 +/- 500uL
2	Exterior Washing	3.01 mL	3.00 +/- 500uL

- All other mechanisms have been checked through software and found OK.
- Performed calibration for End Point, Kinetic & Fixed Time Kinetic.Run control & sample, Results were satisfactory.
- Next Calibration will be performed on 24-07-2022

For Star Biomed Pvt. Ltd.

Service Manager



Date: 25-07-2021

Patient:
 Patient ID: 04
 Date of Birth:
 Age:
 Gender:
 Physician:
 Department:

Sample ID: 3
 Sample Type: Serum
 Bar Code: 010
 Collection Date: 2021/09/15
 Collection Time:
 Department:
 Comment:

Chemistry	Result	Unit	Flag	Ref Range
GLU	136.3	mg/dl		
GLU	137.4	mg/dl		
GLU	137.6	mg/dl		
GLU	137.8	mg/dl		
GLU	139.4	mg/dl		
GLU	139.3	mg/dl		
GLU	137.7	mg/dl		
GLU	136.9	mg/dl		
GLU	137.3	mg/dl		
GLU	137.4	mg/dl		
GLU	138.7	mg/dl		
GLU	137.3	mg/dl		
GLU	138.9	mg/dl		
GLU	137.7	mg/dl		
GLU	138.7	mg/dl		
GLU	138.1	mg/dl		
GLU	139.1	mg/dl		
GLU	138.1	mg/dl		
GLU	138.1	mg/dl		
GLU	138.0	mg/dl		
UREA	50.2	mg/dl		
UREA	49.9	mg/dl		
UREA	50.0	mg/dl		
UREA	50.1	mg/dl		
UREA	49.9	mg/dl		
UREA	50.0	mg/dl		
UREA	50.6	mg/dl		
UREA	50.7	mg/dl		
UREA	50.1	mg/dl		
UREA	50.9	mg/dl		
UREA	50.2	mg/dl		
UREA	49.6	mg/dl		

Ordering Date/Time: 2021/09/15 Test Date/Time: 2021/09/15 Print Date/Time: 2021/09/15 06:37:42 PT
 Operator: Reviewer:

The result are for this sample onl

Patient:
 Patient ID: pq
 Date of Birth:
 Age:
 Gender:
 Physician:
 Diagnosis:

Sample ID: 3
 Sample Type: Serum
 Bar Code: 010
 Collection Date: 2021/09/15
 Collection Time:
 Department:
 Comment:

Chemistry	Result	Unit	Flag	Ref Range
UREA	49.7	mg/dL		
UREA	50.2	mg/dL		
UREA	49.9	mg/dL		
UREA	50.8	mg/dL		
UREA	50.8	mg/dL		
UREA	50.0	mg/dL		
UREA	50.4	mg/dL		
UREA	50.5	mg/dL		
SGPT	65.5	U/L		
SGPT	65.5	U/L		
SGPT	65.5	U/L		
SGPT	65.4	U/L		
SGPT	65.4	U/L		
SGPT	65.2	U/L		
SGPT	65.5	U/L		
SGPT	65.3	U/L		
SGPT	65.4	U/L		
SGPT	65.1	U/L		
SGPT	67.1	U/L		
SGPT	65.3	U/L		
SGPT	64.9	U/L		
SGPT	65.0	U/L		
SGPT	65.5	U/L		
SGPT	65.3	U/L		
SGPT	64.9	U/L		
SGPT	65.6	U/L		
SGPT	65.4	U/L		
SGPT	65.6	U/L		
SGOT	30.6	IU/L		
SGOT	29.7	IU/L		
SGOT	30.3	IU/L		
SGOT	29.8	IU/L		

Ordering Date/Time: 2021/09/15

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Reviewer:

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Sample ID: 3
 Sample Type: Serum
 Bar Code: 010
 Collection Date: 2021/09/15
 Collection Time:
 Department:
 Comment:

Chemistry	Result	Unit	Flag	Ref Range
SGOT	29.7	IU/L		
SGOT	29.9	IU/L		
SGOT	29.6	IU/L		
SGOT	29.5	IU/L		
SGOT	30.0	IU/L		
SGOT	30.0	IU/L		
SGOT	29.1	IU/L		
SGOT	29.6	IU/L		
SGOT	29.3	IU/L		
SGOT	29.4	IU/L		
SGOT	29.6	IU/L		
SGOT	29.7	IU/L		
SGOT	28.8	IU/L		
SGOT	29.2	IU/L		
SGOT	29.2	IU/L		
SGOT	29.1	IU/L		
CHO	214.6	mg/dL		
CHO	216.5	mg/dL		
CHO	216.7	mg/dL		
CHO	217.5	mg/dL		
CHO	215.1	mg/dL		
CHO	215.3	mg/dL		
CHO	214.5	mg/dL		
CHO	215.4	mg/dL		
CHO	215.2	mg/dL		
CHO	215.3	mg/dL		
CHO	213.6	mg/dL		
CHO	215.3	mg/dL		
CHO	215.1	mg/dL		
CHO	217.6	mg/dL		
CHO	214.8	mg/dL		
CHO	214.7	mg/dL		

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 Sample Type: Serum
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Chemistry	Result	Unit	Flag	Ref Range
CHO	215.9	mg/dL		
CHO	217.1	mg/dL		
CHO	217.5	mg/dL		
CHO	217.0	mg/dL		
HDL	39.91	mg/dL		
HDL	39.14	mg/dL		
HDL	39.72	mg/dL		
HDL	37.98	mg/dL		
HDL	39.01	mg/dL		
HDL	39.34	mg/dL		
HDL	39.01	mg/dL		
HDL	38.66	mg/dL		
HDL	38.72	mg/dL		
HDL	39.26	mg/dL		
HDL	39.27	mg/dL		
HDL	38.56	mg/dL		
HDL	38.75	mg/dL		
HDL	38.63	mg/dL		
HDL	39.05	mg/dL		
HDL	39.40	mg/dL		
HDL	39.56	mg/dL		
HDL	38.74	mg/dL		
HDL	38.57	mg/dL		
HDL	38.74	mg/dL		
TG	226.82	mg/dL		
TG	228.38	mg/dL		
TG	229.80	mg/dL		
TG	229.93	mg/dL		
TG	227.35	mg/dL		
TG	229.02	mg/dL		
TG	228.31	mg/dL		
TG	224.27	mg/dL		

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Chemistry	Result	Unit	Flag	Ref Range
TG	226.13	mg/dL		
TG	225.38	mg/dL		
TG	225.70	mg/dL		
TG	224.01	mg/dL		
TG	224.28	mg/dL		
TG	222.92	mg/dL		
TG	224.15	mg/dL		
TG	224.33	mg/dL		
TG	225.53	mg/dL		
TG	223.30	mg/dL		
TG	224.57	mg/dL		
TG	223.28	mg/dL		
Ca +	3.8	mg/dL		
Ca +	3.5	mg/dL		
Ca +	3.7	mg/dL		
Ca +	3.7	mg/dL		
Ca +	3.7	mg/dL		
Ca +	4.1	mg/dL		
Ca +	3.9	mg/dL		
Ca +	3.8	mg/dL		
Ca +	3.6	mg/dL		
Ca +	3.7	mg/dL		
Ca +	3.8	mg/dL		
Ca +	3.7	mg/dL		
Ca +	4.1	mg/dL		
Ca +	3.9	mg/dL		
Ca +	5.5	mg/dL		
Ca +	6.3	mg/dL		
Ca +	6.4	mg/dL		
Ca +	6.8	mg/dL		
Ca +	6.9	mg/dL		
Ca +	6.8	mg/dL		

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Sample ID: 3
 Sample Type: Serum
 Bar Code: 010
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 Collection Time:
 Department:
 Comment:

Chemistry	Result	Unit	Flag	Ref Range
T.P	9.02	g/dL		
T.P	9.11	g/dL		
T.P	8.99	g/dL		
T.P	8.97	g/dL		
T.P	8.84	g/dL		
T.P	8.91	g/dL		
T.P	9.00	g/dL		
T.P	8.90	g/dL		
T.P	8.92	g/dL		
T.P	8.92	g/dL		
T.P	8.87	g/dL		
T.P	8.98	g/dL		
T.P	9.05	g/dL		
T.P	9.05	g/dL		
T.P	8.81	g/dL		
T.P	9.08	g/dL		
T.P	9.03	g/dL		
T.P	9.02	g/dL		
T.P	9.02	g/dL		
T.P	8.94	g/dL		
ALB	4.25	g/dL		
ALB	4.28	g/dL		
ALB	4.30	g/dL		
ALB	4.26	g/dL		
ALB	4.30	g/dL		
ALB	4.32	g/dL		
ALB	4.39	g/dL		
ALB	4.57	g/dL		
ALB	4.36	g/dL		
ALB	4.53	g/dL		
ALB	4.77	g/dL		
ALB	4.34	g/dL		

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 Physician:
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 Comment:

Chemistry	Result	Unit	Flag	Ref Range
ALB	4.49	g/dL		
ALB	4.37	g/dL		
ALB	4.39	g/dL		
ALB	4.31	g/dL		
ALB	4.24	g/dL		
ALB	6.73	g/dL		
ALB	4.22	g/dL		
ALB	4.28	g/dL		
BILI T ERB	0.78	mg/dL		
BILI T ERB	0.89	mg/dL		
BILI T ERB	0.80	mg/dL		
BILI T ERB	0.83	mg/dL		
BILI T ERB	0.62	mg/dL		
BILI T ERB	0.87	mg/dL		
BILI T ERB	0.84	mg/dL		
BILI T ERB	0.13	mg/dL		
BILI T ERB	0.88	mg/dL		
BILI T ERB	0.86	mg/dL		
BILI T ERB	0.02	mg/dL		
BILI T ERB	0.95	mg/dL		
BILI T ERB	0.88	mg/dL		
BILI T ERB	0.89	mg/dL		
BILI T ERB	0.84	mg/dL		
BILI T ERB	0.91	mg/dL		
BILI T ERB	0.91	mg/dL		
BILI T ERB	0.93	mg/dL		
BILI T ERB	0.92	mg/dL		
BILI T ERB	0.92	mg/dL		
BILI D ERB	0.36	mg/dL		
BILI D ERB	0.35	mg/dL		
BILI D ERB	0.35	mg/dL		
BILI D ERB	0.35	mg/dL		

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Sample ID: 3
 Sample Type: Serum
 Bar Code: 010
 Collection Date: 2021/09/15
 Collection Time:
 Department:
 Comment:

Chemistry	Result	Unit	Flag	Ref Range
BILI D ERB	0.37	mg/dL		
BILI D ERB	0.36	mg/dL		
BILI D ERB	0.36	mg/dL		
BILI D ERB	0.36	mg/dL		
BILI D ERB	0.36	mg/dL		
BILI D ERB	0.37	mg/dL		
BILI D ERB	0.35	mg/dL		
BILI D ERB	0.37	mg/dL		
BILI D ERB	0.36	mg/dL		
BILI D ERB	0.11	mg/dL		
BILI D ERB	0.38	mg/dL		
BILI D ERB	0.38	mg/dL		
BILI D ERB	0.38	mg/dL		
BILI D ERB	0.39	mg/dL		
BILI D ERB	0.37	mg/dL		
BILI D ERB	0.38	mg/dL		
ALP	199.4	U/L		
ALP	199.7	U/L		
ALP	198.4	U/L		
ALP	199.7	U/L		
ALP	194.8	U/L		
ALP	194.5	U/L		
ALP	187.0	U/L		
ALP	193.1	U/L		
ALP	124.4	U/L		
ALP	166.5	U/L		
ALP	17.0	U/L		
ALP	9.7	U/L		
ALP	44.0	U/L		
ALP	31.6	U/L		
ALP	32.2	U/L		
ALP	28.3	U/L		

Ordering Date/Time: 2021/09/15 Test Date/Time: 2021/09/15 Print Date/Time: 2021/09/15 06:37:42 PM

Operator: Reviewer:

The result are for this sample onl

Patient:
Patient ID: pq
Date of Birth:
Age:
Gender:
Physician:
Diagnosis:

Sample ID: 3
Sample Type: Serum
Bar Code: 010
Collection Date: 2021/09/15
Collection Time:
Department:
Comment:

Chemistry	Result	Unit	Flag	Ref Range
CRET AVT	1.57	mg/dL		
CRET AVT	1.62	mg/dL		
CRET AVT	1.53	mg/dL		
CRET AVT	1.64	mg/dL		
CRET AVT	1.95	mg/dL		
CRET AVT	0.01	mg/dL		
CRET AVT	1.63	mg/dL		
CRET AVT	1.65	mg/dL		
CRET AVT	0.96	mg/dL		
CRET AVT	0.01	mg/dL		
CRET AVT	1.63	mg/dL		
CRET AVT	1.48	mg/dL		

Ordering Date/Time: 2021/09/15

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Operator:

Reviewer:

The result are for this sample onl

AUTO CHEMISTRY ANALYZER

Mindray BS-240

**INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
PERFORMANCE QUALIFICATION
(IQ/OQ/PQ)**

**Dr Dham's Diagnostic Centre
2856/23 Regar pura Arya Samaj Road
Karol Bagh New Delhi 110005**

BY:

Star Bio Med Pvt. Ltd

Date:14/06/2018



CERTIFICATE OF INSTALLATION

INSTRUMENT NAME : MINDRAY BS240 AUTO CHEMISTRY ANALYZER

SERIAL NUMBER : YX- 64000027

CUSTOMER NAME : Dr Dham's Diagnostic Centre

ADDRESS : 3856/23 Regar pura Arya Samaj Road
Karol Bagh New Delhi 110005

The undersigned performers certify that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

Engineer

Signature :



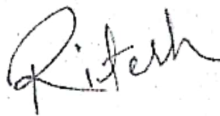
Name : Shivam Gupta

Designation : Service Engineer

Company : Star Biomed Pvt. Ltd.,

Quality Manager

Signature :



Name : Ritesh Mishra

Designation : Quality Manager

Company : Star Biomed Pvt. Ltd.,

Date: 14/06/2018

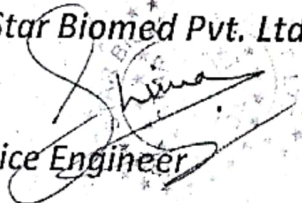


INSTALLATION REPORT

Customer Name : Dr Dham's Diagnostic Centre
3856/23 Regar Pura Arya Samaj Road
Karol Bagh New Delhi 110005
Place : Delhi
Department : Laboratory
Contact Person : Dr JASPREET KAUR
Instrument Name : Mindray BS-240
Serial Number : YX- 64000027
Date of Installation : 14/06/2018

The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are 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 satisfactorily.

For Star Biomed Pvt. Ltd


Service Engineer



INSTALLATION QUALIFICATION/IQ PROTOCOL

1. *System Unpacking*
2. *System Checking For any Damages*
3. *All accessories as per check List verification*
4. *Space Requirement*
5. *Power Requirement*
6. *Reagents, Control, Calibrators verification.*

1. SYSTEM UNPACKING & 2. SYSTEM CHECKING

Unpack D5 instrument carefully and check for any physical Damages.

3. ACCESSORIES CHECK-

Check all accessories as per check List

4. SPACE REQUIREMENT –

- Checked site for proper space allocation. At least 100 CM on each side and enough room on below the countertop to accommodate the reagents & pneumatic unit and waste containers.

DIMENTIONS		
PARAMETER	Analyzer OV	Pneumatic Unit
Width mm	690	650
Depth mm	570	520
Height mm	595	520
Weight Kg	100	75

5. POWER REQUIREMENT -

<i>Requirement</i>	<i>Acceptable Range</i>	<i>Observed Ranged</i>
Input Voltage	220 +/- 10 V	225 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C - 30 C	23

7. Reagents , Calibrators Check-

Auto Cal Lot. No H015 Exp.-30/06/2018

REAGENT CALIBRATION CHECK		
NAME	Auto Cal value	Remark
Glucose Human	218	OK
ALP Human	465	OK
TP Human	7.36	OK
CHO Human	265	OK
TG Human	252	OK
UREA Human	46.5	OK
CRE MINDRAY	4.70	OK
UA Human	10.5	OK
ALB Human	5.48	OK
SGOT Human	130	OK
SGPT Human	134	OK
CALCIUM MINDRAY	13.0	OK
T BILL Human	4.0	OK
D BILL Human	3.0	OK

PRE-INSTALLTION VERIFICATION REPORT :-

PRE-INSTALLATION VERIFICATION REPORT		
S/N	PARAMETER	REMARK
1	Unpacking Instrument	OK
2	System Checking for damages	OK
3	Accessories check	OK
4	SPACE CHECK	OK
5	Power Check	OK
6	Reagents Check	OK

OPERATIONAL QUALIFICATION

The Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OO PROTOCOL

1. System Connections
2. Reagent & Waste Connections
3. Customizing the Analyzer Software
4. System Booting , Initialization & Check
5. Maintenance procedures.
6. Customer Training – Operation & Maintenance.

1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N	NAME	Check	Remark
1	Pneumatic Unit	Yes	OK
2	Input Power supply	Yes	OK
4	Printer Connection	Yes	OK

2. REAGENT & WASTE CONNECTIONS -

REAGENT CONNECTION CHECK		
NAME	CHECK	Remark
Glucose Human	YES	Ok
ALP Human	YES	Ok
TP Human	YES	Ok
TCHO Human	YES	Ok
TG Human	YES	Ok
UREA Human	YES	Ok
CRE MINDRAY	YES	Ok
UA Human	YES	Ok
ALB Human	YES	Ok
SGOT Human	YES	Ok
SGPT Human	YES	Ok
CALCIUM MINDRAY	YES	Ok
T BILL Human	YES	Ok
D BILL Human	YES	Ok

Date.-14/06/2018

3. CUSTOMIZING ANALYZER SOFTWARE –

CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Remark
1	Date & Time	Operating Manual 5.2.1	OK
2	Reagents	Operating Manual 5.2.1	OK
3	Reference Ranges	Operating Manual 5.3.1	OK
4	Reference Units	Operating Manual 5.3.1	OK
5	Printing format	Operating Manual 5.3.1	OK
6	Creating New User	Operating Manual 5.3.2	OK

4. SYSTEM BOOTING, INITIALIZATION & Check -

Power ON System and check instrument Initialization successfully.
Check following Parameters.

TEMPERATURES & PRESSURES				
S/N	Parameters	Actual °C	Range °C	Remark
1	Preheat Bath	40	30 to 50	Ok
2	Reaction Bath	36.9	30 to 45	Ok
3	Ambience	25.4	15 to 35	Ok
4	Laser Diode	35.9	15 to 45	Ok

MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Yes	Ok
2	Replacing Priming Reagents	Yes	Ok
3	Cleaning	Yes	Ok
4	Maintenance	Yes	Ok
5	Overall Maintenance	Yes	Ok
6	Version Information	Yes	Ok
7	Temperature & Pressure	Yes	Ok
8	Touch Screen Calibration	Yes	Ok
9	Cleaning SRV Manually	Yes	Ok
		Yes	Ok

Date: 15/06/2018

ADJUSTMENT			
S/N	Parameters	Check	Remark
1	Vacuum & Pressure	Yes	Ok
2	Error Messages & Recommendations	Yes	Ok

PERFORMANCE QUALIFICATION-

Serodos Control Level 1 (Lot. No.0003 Exp. 30/09/2018)			
TEST	Mean conc.	SD (Calc)	
Glucose Human	88.3	13.9	
ALP Human	238	55.5	
TP MINDRAY	6.37	0.53	
UREA Human	33.1	7.3	
CRE MINDRAY	2.50	0.202	
ALB Human	3.80	0.67	
SGOT Human	35.5	6.1	
SGPT Human	32.8	7.5	
CALCIUM MINDRAY	9.49	0.706	
PHOS HUMAN	3.77	0.68	
Serodos control Level-Plus (Lot. No.0003 Exp. 30/06/18)			
TEST	Mean conc.	SD (Calc)	
Glucose Human	223	36.0	
ALP Human	475	119.0	
TP Human	6.52	0.71	
CHO Human	264	37.0	
TG Human	186	33.5	
UREA Human	46.2	10.05	
CRE MINDRAY	5.59	0.506	
UA Human	10.9	1.52	
ALB Human	4.47	1.03	
SGOT Human	135	30.5	
SGPT Human	13.5	31.0	
CALCIUM MINDRAY	12.15	0.81	
PHOS Human	8.45	1.52	

For Star Biomed Pvt. Ltd

Shivan
Service Engineer
Date: 15/06/2018