



## CALIBRATION CERTIFICATE

### Biochemistry Analyzer "Medichem Plus"

Name :	Maheshwaram Hospital & Research Pvt. Ltd.		
Address :	C/o Post Box No. 20,		
Place	DEOLI (TONK) 304804		
Contact Person:	Dr. Mahesh Jindal	Contact No. :	01434 230059, 232585, 941

#### Instrument Identification

Model :	Medichem Plus	Date of Calibration :	1.02.2022	Calibration Passed : Y/N
Sr. No.	ES1001401P68	Calibration Expiry :	31.01.2023	Yes

#### Inspection List (Relevant Information should be fill in)

	Yes / No
The Voltage of Instrument should be 220 V ± 10%.	Yes
Ground Voltage should be less than 10 Volts.	Yes
No Interference found Near Instrument.	Yes
A/D Value with in Range.	Yes
Optical Calibration Passed.	Yes
Aspiration System is OK.	Yes
Fresh Sample used.	Yes

Calibrator	Target Value	Control Range	Obtained Value	Remark
Glucose	113.0	96.4 - 130	111.7	OK
Bilirubin Total	2.0	1.57 - 2.39	1.94	OK
Urea UV	41.8	35.5 - 48.1	40.9	OK
SGOT	36.0	29.0 - 43.0	37.1	OK
SGPT	38.0	30.0 - 48.0	37.2	Ok
Calibration Results :			Yes	Remarks Yes

Technical Service Department :

Service Engineer :

Designation :

DEVENDRA NAGAR



Quality Manager

Name :

Ganesh Prajapati

Designation :

Incharge (QC)



Sign :

A-52/A, Shanti Path, Tilak Nagar, Jaipur-302004

9214066046-49, 9414066046, 9414071400

Sign :

gyrojaipur@gmail.com

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(Biochemistry Analyzers)

CellScan  
(Hematology Analyzers)

GD-Lyte  
(Electrolyte Analyzers)

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(Electrolyte Analyzers)

All Medical Instruments  
& Consumables

## Installation Qualification (IQ) IQ PROTOCOL

- 1 System Unpacking & System Checking
- 2 All Accessories as per Check List Verification.
- 3 Space Requirement.
- 4 Power Requirement.
- 5 Reagent, Control, Calibrators Verification.

### 1 System Unpacking & System Checking.

Unpack Medichem Plus Instrument Carefully and check for any physical Damages

### 2 Accessories Check :

Check all Accessories as per Check List.

### 3 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 and Pneumatic Unit and Waste Containers.

Serial No.	Parameters	Analyzer OV	Additional Item (If Supplied)
3.1	Width (mm)	300mm	
3.2	Depth (mm)	450 mm	
3.3	Height (mm)	205 mm	
3.4	Weight (Kg)	7.5 Kg.	

### 4 Power Requirement :

Serial No.	Requirement	Acceptable Range	Observed Range	Remarks
4.1	Input Range	220 +/- 10 V	230 Volts	
4.2	Line Frequency	50 Hz	50 Hz	
4.3	Humidity	<85 %	<85 %	
4.4	Ambient Temp.	15 C - 30 C	26 C	

### 5 Reagents Kits , Control, Calibrators & Instrument Check :

Serial No.	Name	Check	Remark
5.1	Reagent Kit Expiry	OK	
5.2	Reagent Kit Storage Temp (2-8 Degree)	OK	
5.3	Prewarm of Reagent	OK	
5.4	Incubator Temp. 37 Degree.	OK	
5.5	Optical Calibration	OK	
5.6	Peristaltic Calibration	OK	
5.7	Calibrator & Control	OK	

### 6 Pre Installation Verification Report :

Serial No.	Parameter	Check	Remark
6.1	Unpacking Instrument	OK	
6.2	System Checking for Damages	OK	
6.3	Accessories Check	OK	
6.4	Space Check	OK	
6.5	Power Check	OK	
6.6	Reagents Check	OK	

Technical Service Department :

Name : *Devendra Nagar*

Designation : Manager Service

Sign :

*Devendra*

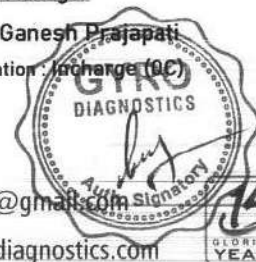


Quality Manager

Name : *Ganesh Prajapati*

Designation : Incharge (QC)

Sign :



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## PERFORMANCE QUALIFICATION (PQ)

### CARRY OVER

Serial No.	Parameter	Actual	Range	Remark
1	GLUCOSE	0.72%	1%	
2	Bilirubin Total	0.51%	1%	
3	Urea UV	0.37%	1%	
4	SGOT	0.54%	1%	
5	SGPT	0.81%	1%	

### REPRODUCIBILITY CHECK

Serial No.	Parameter	Value 1	Value 2	Value 3
1	GLUCOSE	111.70	112.5	112.9
2	Bilirubin Total	1.94	1.93	1.94
3	Urea UV	40.90	39.4	41.3
4	SGOT	37.10	36.9	37.6
5	SGPT	36.90	37.2	37.8

\* Checked and found all the control parameters to be within the acceptable CV limits and in range. Checked and found all controls to be within the acceptable SD

## GYRO DIAGNOSTICS

AN CE, ISO 9001:2008, ISO 10002:2014 & ISO 13485:2016

### Technical Service Department :

Name : **DEVENDRANAGAR**

Designation : **Service Eng.**

Sign :



### Quality Manager

Name : **Ganesh Prajapati**

Designation : **Incharge (QC)**

Sign :



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## OPERATIONAL QUALIFICATION (OQ)

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.

### OQ PROTOCOL

- 2.0 System Description
- 3.0 Software
- 4.0 Service & Maintenance
- 5.0 Trouble Shooting

#### 2.0 System Description

Serial No.	Name	Operation Manual Page No.	Remark
2.3.1	Main Screen	7	
2.4	Input Panel Functions	10	
2.5	External USB Mouse & Keyboard	11	
1.3	External USB Printer	12	

#### 3.0 Software

Serial No.	Name	Operation Manual Page No.	Remark
3.1	Test	13 - 22	
3.2	View Results	23 - 30	
3.3	Test Setup	31	
3.4	QC Setup	34 - 36	
3.5	System Setup	37 - 40	
3.6	Maintenance	41 - 44	

#### 4.0 Service & Maintenance

Serial No.	Parameters	Operation Manual Page No.	Remark
4.1	Wash Flowcell	47	
4.2	Printer Paper Installation	48	
4.3	Touch Screen Calibration	49	
4.4	Pump Hose Replacement	50	

#### 5.0 Trouble Shooting

#### 6.0 Appendix

Serial No.	Parameters	Operation Manual Page No.	Remark
Appendix 1	Technical Specification	53	
Appendix 2	Calculation Methods	54	

Technical Service Department :

Name : **DEVENDRA NAGAR**

Designation : Manager Service

Sign :

*Deve*

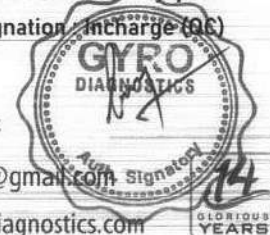


Quality Manager

Name : Ganesh Prajapati

Designation : Incharge (QC)

Sign :



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MAHESH DIAGNOSTIC CENTRE  
P.O. BOX 20, DEOLI

Sample ID: 3319  
Test Name: GLUCOSE  
Abs.: 0.3396  
Result: 98.32  
Unit: mg/dl  
Ref. Low: 60.00  
Ref. High: 110.00  
Test Date: 2000-01-01 02:45:46



Min Abs.: 0.3361  
Max Abs.: 0.3399

MAHESH DIAGNOSTIC CENTRE  
P.O. BOX 20, DEOLI

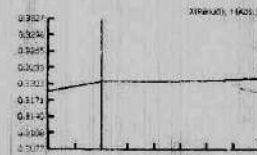
Sample ID: 0652  
Test Name: CHOLEST  
Abs.: 0.5630  
Result: 248.66  
Unit: mg/dl  
Ref. Low: 150.00  
Ref. High: 250.00  
Test Date: 2000-01-01 02:48:28



Min Abs.: 0.6118  
Max Abs.: 0.6142

MAHESH DIAGNOSTIC CENTRE  
P.O. BOX 20, DEOLI

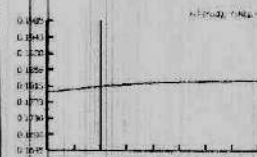
Sample ID: 0266  
Test Name: TRIGLY  
Abs.: 0.3209  
Result: 172.87 ↑  
Unit: mg/dl  
Ref. Low: 60.00  
Ref. High: 170.00  
Test Date: 2000-01-01 02:50:42



Min Abs.: 0.3188  
Max Abs.: 0.3212

MAHESH DIAGNOSTIC CENTRE  
P.O. BOX 20, DEOLI

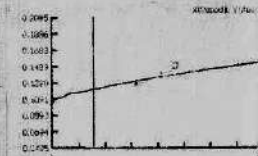
Sample ID: 0771  
Test Name: UREAER  
Abs.: 0.1827  
Result: 26.02  
Unit: mg/dl  
Ref. Low: 15.00  
Ref. High: 45.00  
Test Date: 2000-01-01 02:53:15



Min Abs.: 0.1797  
Max Abs.: 0.1830

MAHESH DIAGNOSTIC CENTRE  
P.O. BOX 20, DEOLI

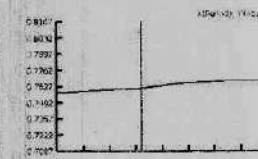
Sample ID: 0744  
Test Name: CREAT  
Abs.: 0.0317  
Result: 2.57 ↑  
Unit: mg/dl  
Ref. Low: 0.50  
Ref. High: 1.50  
Test Date: 2000-01-01 03:01:43



Min Abs.: 0.1052  
Max Abs.: 0.1528

MAHESH DIAGNOSTIC CENTRE  
P.O. BOX 20, DEOLI

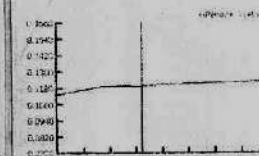
Sample ID: 0026  
Test Name: ALB  
Abs.: 0.7667  
Result: 3.27 ↓  
Unit: gm  
Ref. Low: 3.50  
Ref. High: 5.00  
Test Date: 2000-01-01 03:09:45



Min Abs.: 0.7572  
Max Abs.: 0.7679

MAHESH DIAGNOSTIC CENTRE  
P.O. BOX 20, DEOLI

Sample ID: 0211  
Test Name: TBIL  
Abs.: 0.1218  
Result: 2.46 ↑  
Unit: mg/dl  
Ref. Low: 0.00  
Ref. High: 1.10  
Test Date: 2000-01-01 03:11:55



Min Abs.: 0.1132  
Max Abs.: 0.1227

MAHESH DIAGNOSTIC CENTRE  
P.O. BOX 20, DEOLI

Sample ID: 0054  
Test Name: URACID  
Abs.: 0.2395  
Result: 6.2  
Unit: mg/dl  
Ref. Low: 2.4  
Ref. High: 7.0  
Test Date: 2000-01-01 03:20:50



Min Abs.: 0.2373  
Max Abs.: 0.2396

20/3/22

MAHESH DIAGNOSTIC CENTRE  
P.O. BOX 20, DEOLI

Sample ID: 0024  
Test Name: TP  
Abs.: 0.3652  
Result: 8.57 ↑  
Unit: mg/dl  
Ref. Low: 0.30  
Ref. High: 3.40  
Test Date: 2000-01-01 03:22:14



Min Abs.: 0.3592  
Max Abs.: 0.3654