



CALIBRATION CERTIFICATE

Hematology Analyzer "Cell Scan 60"

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, 94

Instrument Identification

Model :	Cell Scan 60	Date of Calibration :	28.04.2021	Calibration Passed : Y/N
Sr. No.	801214180492	Calibration Expiry :	27.04.2022	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			
Reagents are ok.	Yes			
Before Calibration instrument Passed Background test.	Yes			
Fresh Sample used.	Yes			
Gain of WBC and RBC Chamber within Range.	Yes			
Calibrator	Target Value	Control Range	Obtained Value	Remark
WBC	7.7	6.9 - 8.5	7.5	OK
RBC	4.6	4.42 - 4.78	4.7	OK
HGB	13.3	12.8 - 13.8	13.5	OK
MCV	80.0	76 -84	81.2	OK
PLT	255.0	215 - 295	258.0	OK
Calibration Results :			Yes	Remarks Yes



Technical Service Department :

Service Engineer : *DEVENDRA NAGAIR*

Designation : *Devesh*

Quality Manager

Name : Ganesh Brajapatt

Designation : Incharge (QC)

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

9214066046-49, 9414066046, 9414071400

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MediChem
(Biochemistry Analyzers)

CellScan
(Hematology Analyzers)

GD-Lyte
(Electrolyte Analyzers)

INCUB
(Electrolyte Analyzers)

All Medical Instruments
& Consumables

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

- 1.0 System Connections.
- 2.0 Reagent & Waste Connections.
- 3.0 Customizing the Analyzer Software.
- 4.0 System Booting, Initialization & Check.
- 5.0 Maintenance Procedures.
- 6.0 Customer Training - Operation & Maintenance

1.0 System Connection :

Serial No.	Name	Check	Remark
1.1	Main Unit	Op. Manual Page No. : 4	
1.2	Input Power Supply	Connected Page No. 4	
1.3	Printer Connection (If External Printer)	Op. Manual Page No. : 16	

2.0 Reagent & Waste Connections :

Serial No.	Name	Check	Remark
2.1	Diluent	Op. Manual Page No. : 8	
2.2	Lyse	Op. Manual Page No. : 8	
2.3	Rinse	Op. Manual Page No. : 8	
2.4	Waste Connection	Op. Manual Page No. : 8	

3.0 Customizing Analyzer Software :

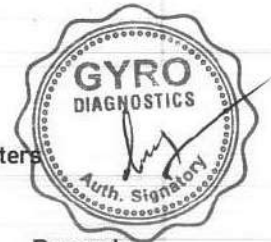
Serial No.	Parameters	Check	Remark
3.1	Date & Time	Op. Manual Page No. : 82	
3.2	Reagents	Op. Manual Page No. : 98	
3.3	Reference Ranges	Op. Manual Page No. : 47	
3.4	Reference Units	Op. Manual Page No. : 93	
3.5	Printing Format	Op. Manual Page No. : 49	
3.6	Creating New User	Op. Manual Page No. : 26	

4.0 System Booting, Initializing & Check :

Power On System and Check Instrument Initialization Successfully. Check Following Parameters

4.1. Temperatures & Gain

Serial No.	Parameters	Actual	Range	Remark
1	A-52/A, Shanti Path, Tikak Nagar, Jaipur-302004			
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4.1.1	Reagent Temp.	28	30 - 50
4.1.2	Room Temp.	28	30 - 45
4.1.3	RBC Gain	29	15 - 75
4.1.4	WBC Gain	35	15 - 85
4.1.5	PLT Gain	1	1 - 100
4.1.6	HGB	54	20 - 125

4.2. Normal Background Check

Serial No.	Parameter	Actual	Remark
4.2.1	WBC	0.00	< 0.3
4.2.2	RBC	0.00	< 0.03
4.2.3	HGB	0.00	< 0.1
4.2.4	MCV	0.00	< 0.1
4.2.5	PLT	0.00	< 10

5.0 Maintenance Procedures :

Serial No.	Parameters	Check	Remark
5.1	Using Maintenance Menu	Op. Manual Page No. : 103	
5.2	Replacing Priming Reagents	Op. Manual Page No. : 98	
5.3	Cleaning	Op. Manual Page No. : 105	
5.4	Maintenance	Op. Manual Page No. : 103	
5.5	Overall Maintenance	Op. Manual Page No. : 103	
5.6	Version Information	Op. Manual Page No. : 115	
5.7	Gain Window	Op. Manual Page No. : 99	
5.8	Touch Screen Calibration	Op. Manual Page No. : 109	
5.9	Servicing the Fluidics	Op. Manual Page No. : 106	
5.10	Voltage	Op. Manual Page No. : 114	

6.0 Customer Training - Operation & Maintenance.

Serial No.	Parameters	Check	Remark
6.1	Gain Voltage	Op. Manual Page No. : 99	
6.2	Error Messages & Recommendations	Op. Manual Page No. : 115	

Technical Service Department :

Name : **DEVENDRA NAGAR**
 Designation : Manager Service

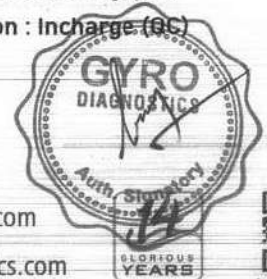
Sign : *Devendra*



Quality Manager

Name : Ganesh Prajapati
 Designation : Incharge (QC)

Sign :



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GLORIOUS YEARS

For Details Scan QR Code

PERFORMANCE QUALIFICATION (PQ)

CARRY OVER

Serial No.	Parameter	Actual	Range	Remark
1	WBC	0.34	0.50%	
2	RBC	0.26	0.50%	
3	HGB	0.42	1%	
4	MCV	0.42	1%	
5	PLT	0.31	1%	

REPRODUCIBILITY CHECK

Serial No.	Parameter	Actual	Range CV %	Remark
1	WBC	2.30%	3	
2	RBC	1.90%	2	
3	HGB	1.50%	2	
4	MCV	1.60%	2	
5	PLT	3.20%	4	

* 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 : **DEVENDRA NAGAR,**

Designation :

Sign :

Devendra

Quality Manager

Name : **Ganesh Prajapati**

Designation : **Incharge (QC)**

Sign :



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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 Cell Scan 60 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)	400mm	
3.2	Depth (mm)	300 mm	
3.3	Height (mm)	440 mm	
3.4	Weight (Kg)	22 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, Control, Calibrators Check :

Serial No.	Name	Check	Remark
5.1	Diluent	OK	
5.2	Lyse	OK	
5.3	Probe Cleaner	OK	
5.4	Conc. Cleaner	OK	
5.5	Control Normal	OK	
5.6	Control High	OK	
5.7	Calibrator	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 :

Designation :

Sign :

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