

Calibration Certificate

Following voltages have been checked & adjusted on (Sl. No. SYS20180402) at Pathkind Lab, opp Manchanda Petrol Pump, Sai Hotel, Main civil line, Bijnor - 246701 (UP)

Calibration Report:

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

S.No.	Module	Observed Value	Acceptable Range
1	Power supply board o/p	+24.1 VDC	+24.0 +/- 0.5 VDC
		+05.0 VDC	+05.0 +/- 0.2 VDC
2	Lamp voltage	+12.1 VDC	12.0 +/- 0.5 VDC

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

S.No.	Module	Observed Value	Acceptable Range
1	Reaction Disk Temp	37.0 C	37.0 C +/- 0.3 C

Photometer Adjustment Values are within range as recommended:

S.No.	Module	Observed Value	Acceptable Range
1	ADC Count for all Wavelengths	10,240 to 10,300	8000 to 18,000

- All other mechanisms have been checked through field service program & Software, found OK.
- Performed calibration for End Point, Kinetic & Fixed Time Kinetic. Run control & sample. Results were satisfactory.
- Next Calibration will be performed on 28/09/2022.

For DiaSys Diagnostics India Pvt. Ltd.

Asmat Sami

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Date: 29/09/2021

Regional Service Manager

www.DiaSys-Diagnostic.com

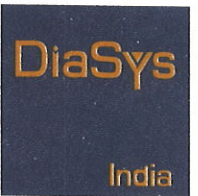
Contact: 022 3371 4323

Toll Free: 1800 120 1447

Daily QC Report

Qc Test	Lot No.	QC Name	Target Mean	Target SD	Result	Unit	Status
ALB	28657	TRULAB N	3.57	0.274	3.75	g/dL	Normal
ALP	28657	TRULAB N	76	6.33	86.3	U/L	> +1SD
ALT	28657	TRULAB N	50.7	3.89	49	U/L	Normal
AST	28657	TRULAB N	39.9	3.06	35.7	U/L	< -1SD
Ca	28657	TRULAB N	8.65	0.317	8.68	mg/dL	Normal
cre erba	28657	TRULAB N	1.33	0.1	1.25	mg/dL	Normal
CRP	30682	CRP	59.3	5.9	64.6	mg/L	Normal
DBIL	28657	TRULAB N	0.721	0.062	0.71	mg/dL	Normal
GLUCOSE	28657	TRULAB N	85.6	4.56	82.5	mg/dL	Normal
HDL-C	28657	TRULAB N	45	2.1	44.1	mg/dL	Normal
TBIL	28657	TRULAB N	1.48	0.128	1.57	mg/dL	Normal
TG	28657	TRULAB N	87	5.22	86.8	mg/dL	Normal
TP	28657	TRULAB N	5.51	0.202	5.6	g/L	Normal
UA	28657	TRULAB N	5.07	0.236	4.61	mg/dL	< -1SD
UREA	28657	TRULAB N	36.2	2.65	37.7	mg/dL	Normal





INSTALLATION QUALIFICATION

The Installation for SYS200 Biochemistry Analyzer Instrument(S/N- SYS20180402) has been successfully Installed and Commissioned at PATHKIND LAB,Opp. Manchanda Petrol Pump,Sai Hotel,Main Civil Line,Bijnor-246701 U.P

Checked all the Mechanisms through the Software like Robotic Arm (Sample/Reagent Arm), Reagent Tray & Sample Tray Movement for different position.

Robotic Arm: Carried out the Adjustment for Robotic Arm for Wash station for Sample, Reagent, Cuvettes positions.

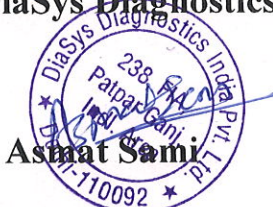
Lamp: The Photometer all channels are within range for all wavelengths.

Checked the system performance for different Parameters like End Point, Kinetic & Fixed-Time Kinetic.

Calibration & Control for all the Assays was satisfactory.

Carried out the Precision Check for above parameters which was also good.

For DiaSys Diagnostics India Pvt. Ltd.,



Area Service Manager (Delhi & NCR)

Date: 02/10/2018

OPERATIONAL QUALIFICATION

For Operational Qualifications carried out the following checks on the SYS200 (S/N- SYS20180402) in Pathkind Lab Opp. Manchanda Petrol Pump, Sai Hotel, Main Civil Line, Bijnor-246701 U.P

Checked the overall System Mechanism found the Robotic Arm (Sample/ Reagent Arm), Vertical and Horizontal Movement In/Out) Performance is ok.

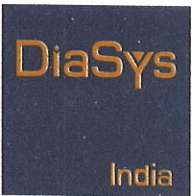
Software Checks: Carried out the check for Calibration, Control, Assay, Results, Data & the performance is ok.

Checked all the Operational Qualifications & found the functioning is Satisfactory.

For DiaSys Diagnostics India Pvt. Ltd.,


Asmat Sami
Area Service Manager (Delhi & NCR)

Date: 02/010/2018



PERFORMANCE QUALIFICATION

Carried out the following Checks for the Performance of the System SYS200 (S/N-SYS20180402) in Pathkind Lab Opp. Manchanda Petrol Pump,Sai Hotel,Main Civil Line,Bijnor-246701 U.P

Run the Calibration for End Point, Kinetic & Fixed-Time Kinetic Calibration was Successful.

Run the DIASYS CONTROL L1 & L2 control for Different Parameters.

QualityChecks for which the performance is OK & the Results are Satisfactory, within the Specified range.

Precision Checks: Carried out the Precision checks for different Parameters for which Precision was found to be satisfactory.

For Diasys Diagnostics India Pvt. Ltd.



Area Service Manager (Delhi & NCR)

Date: 02/10/2018