



UNIQUE CALIBRATION & CONSULTANT SERVICES

AN ISO 9001:2015 CERTIFIED CALIBRATION LABORATORY



CALIBRATION CERTIFICATE

Format No.: UCCS-QF-7.8.1		Certificate No.: UCCSKP20230111-010			
Customer's Name & Address M/s. Kalra Pathology Laboratory Near Dabra Chowk, Delhi Road Hisar-125005		Page No.: 1 of 1	Calibration Performed: At Site		
		Date of Receipt: 11-01-2023			
		Service Request No.: UCCSKPSRN20230111-001			
		Certificate Issue Date: 16-01-2023			
		Date of Calibration: 14-01-2023			
Next Due Date (Suggested by Customer): 13-07-2023					
Equipment Description (UUC) & Identification					
Name of the Instrument: FULLY BIOCHEMISTRY ANALYZER		Make: N/A			
		Model: SX5200			
Range: As Per Instrument		Sr. No.: SY520190604			
Least Count: As Per Instrument		I.D. No.: KL/BME/F BIO/01/LAB			
Condition of Instrument: Ok		Location: LAB			
Master Equipment Used					
Sr. No.	Instrument Name	Range & I.D. No.	Calibration Agency	Calibration Certificate No.	Valid Up to
1	Compact Electrical Safety Analyser	As per Manual & UCCS/ES/01	Testncal Laboratory	TNC/JC/21-22/02/26	10-02-2023
2	DTI With PRT Sensor	-30 °C to 600 °C & UCCS/CAL/022	Bansal Calibration Services	BCS/N/22020003-002	01-02-2023
Environmental Conditions		Calibration Procedure	Calibration Reference Standard		
Temperature: 25 ± 5 °C, Humidity: 50 ± 10 %RH		UCCS 03 SOP MIS 40	-----		

CALIBRATION RESULTS

Visual Inspection: Ok
Result: The Calibration results are found satisfactory & instrument is fit for use

End of Certificate

Jata Shankar
Calibrated By
Jata Shankar

Calibration Engineer



Reviewed/Approved By
L.M. Mahato

Chief Executive Officer (CEO)

- Note: - 1. The calibration results reported in this certificate are valid at the time of and stated condition of measurement.
2. This report is not to be reproducing wholly or in part and cannot be used as evidence in the Court of Law and should not be used in any advertising media without our special permission in writing.
3. Total liability of our Organization is limited to the invoiced amount.
4. Calibration Certificate without signature are not valid.
5. All our certificates are metrological traceable.
6. The results relate only to the item calibrated.
7. UUC: Unit Under Calibration.
8. Expanded Uncertainty at 95 % confidence level with coverage factor K=2.

Working : W.Z.1390/Z-2, 1st Floor, Nangal Raya Extn., Pankha Road, New Delhi-110046

Regd. Office : R.Z.56A, Indra Park, Gali No.25, Palam Colony, New Delhi-110045
M.: 9958445875, 9313768426, 9999761885 E-Mail : uniquecalibrationservices@gmail.com

Preventive Maintenance Protocol SYS200



CUSTOMER DETAILS

Customer Name: Kelkar Pathology Lab
 Address: Kissan Haryana
 City: Haryana (Kissan) State: Haryana
 Pincode: 125001
 Contact Person: - Rishi Phone: - 987601700
 Installation Date: - 04/06/2019 Serial No.: - 54520190604
 Email: - kelkar.lab@gmail.com

CUSTOMER REQUIREMENTS

Prior Appointment	Gloves, Masks,	Tissue Paper, Gauze,	DI Water, Hypo 0.5%
2% Anti Bacterial	WD40, Grease, Oil	Hardware Tools	Blower

PRECAUTIONS

(Kindly fill the details as mentioned in description.)

Function	Description	Done Y/N	Engineer Remarks
Take Customer Feedback	Take Customer Feedback reg Machine Performance, Issues, Damage, etc.	Y	OK
Check Power Quality	Check Voltage, Earthing at UPS & Raw Power	Y	OK
Check Water TDS	TDS Should be less than 1ppm. Check Cleanliness of External Water Tank. Check for any Obstruction in Drain Tube	Y	OK
Check Results	Check Results of Patients, QC and Reaction Curve	Y	OK
Check Lamp	Check Lamp & Cuvette Values. Check Last Replacement Date	Y	OK
Check Performance	Run a Sample & Observe Machine Performance like Probe Movements, Alignments, Blockage, Washing Function etc. Then Store Reagents in Fridge.	Y	OK
Check Cooling	Check Reagent Tray Cooling & Incubation bath Temperature	Y	OK
Check for Damage	Inspect Machine Thoroughly for Any Damage.	Y	OK

PM-SYS01



PREVENTIVE MAINTENANCE PROCEDURE

Function	Description	Done Y/N	Engineer Remarks
Soak Cuvettes	Remove & Soak Cuvettes in 5% Alkaline Solution (50ml ALK in 1000ml DI Water)	Y	OK
Remove Covers	Remove Covers of Machine for Inspection & Cleaning Purpose	Y	OK
Clean Dust	Cover Reaction Tray, Loosen the Dust in all Parts using a Brush & Clean the Dust using a Blower.	Y	OK
Clean all Probes	Clean Sample Probe Tip, Wash Probes & Drier Tip with Alcohol soaked Gauze. Clean Mixer Probe with 2% Anti Bacterial. Use Syringe Tool with Hypo 0.5% for Cleaning Sample Probe in case of Block. Check Sample Probe Spring Action	Y	OK
Clean Wash Stations	Pour 5ml of 0.5% Hypo in Sample Probe Wash Station & Clean all Wash Stations with Hypo Soaked Ear Buds. Then Pour 50ml DI Water after 10 minutes to Rinse.	Y	OK
Clean Incubation Bath	Clean Incubation Bath Inner Surface with Alcohol Soaked Gauze without scratching the Lens.	Y	OK
Clean Filters	Clean DI Water Main Inlet Filter, Clean Incubation Bath Inlet & Drain Filters.	Y	OK
Clean Tubings	Remove & Clean All Tubings with Diluted Hypo 1:20. Clean De-Bubbler also same way. Rinse with DI Water thoroughly.	Y	OK
Clean Tray	Clean Reagent Tray Surface with 2% Anti Bacterial Solution. Put 5ml of 2% Anti Bacterial Solution in Reagent Tray Drain Hole.	Y	OK
Clean Syringe Sensor	Clean Dust in Syringe Sensor	Y	OK
Lubrication	Clean Probe Shafts with WD40 Soaked Tissue Paper & Then Apply Oil/Grease using Soft Tissue Paper	Y	OK
Install PM Kit, Tubings etc	Install PM Kit all spares and Tubings carefully	Y	OK
Rinse Cuvettes & Install	After Soaking for few Hrs, Rinse Cuvettes thoroughly with Running Tap Water & then with DI Water	Y	OK



POST PM VALIDATION

Function	Description	Done Y/N	Engineer Remarks
Check all Functions	Assemble Machine & Check all Functions	Y	OK
Check Light Check	Check Light Check Values. Repeat Light Check & Check Reoperation Value (17- 100)	Y	OK
Check Water Flow	Check Water Flow at all Wash Probes, Probe Wash Stations. Check Sample Probe Water Stream Flow. Check Cuvette is Dry after Washing Step.	Y	OK
Check Cuvette Blank	Carry out Cuvette Blank & Verify Values (17- 800)	Y	OK
Check Probe Alignment	Check Probe Alignment at all Positions & Do Probe Adjust if Required. Check Sample Probe is Straight.	Y	OK
Check Temperature	Check Reagent Tray Cooling again. Check Reaction Temperature 37° C	Y	OK
Check Precision & Control	Check Precision of GLU, CHOL, UREA, SGOT 5 times to assess machine performance. Check QC & Observe Samples.	Y	OK
Update Status to Customer	Update Machine Status to Customer & Take Service Report. Mention List of Spare Stock to be Kept at Customer Place.	Y	OK

Engineer's Remarks:

Customer's Feedback:

Pankaj
Engineer's Signature

Pradeep kumar
Customer's Signature/Stamp



TECHNICAL SERVICE REPORT



No.: CC-3/04683

To be filled as per TGR no. generated by CRM

Revision No - 02

<input checked="" type="checkbox"/> WARRANTY		<input type="checkbox"/> NON SERVICE CONTRACT		<input type="checkbox"/> SERVICE CONTRACT	
NAME OF LAB / HOSPITAL <u>Kailash Pathology Lab</u>		CONTACT PERSON: - <u>Kapil</u>		WORK CARRIED OUT AT <input type="checkbox"/> Site Service Centre	
ADDRESS - <u>Kissan Colony</u>		CONTACT NO.: <u>2870408700</u>		NATURE OF VISIT <input type="checkbox"/> Application <input type="checkbox"/> Emergency Call (Repairs) <input type="checkbox"/> Pack/Move/Reinstallation <input type="checkbox"/> Chargeable Service <input type="checkbox"/> Preventive Maintenance <input type="checkbox"/> Others	
EMAIL ID: - <u>kshg-lab@yaho.com</u>		CALL LOG		<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III	
PARTICULARS OF INSTRUMENT		Name: <u>S11200</u>		Start	
Serial No.: <u>S1120190604</u>		Date: <u>20/05/2013</u>		End: <u>20/05/13</u>	
		Time: <u>12:10 PM</u>		Time: <u>7:10 PM</u>	
PARTICULARS OF ACTION TAKEN		DI-Ionized water TDS: <u>1</u>			
Specify Your Diagnosis: - <u>Preventive maintenance. Clean instrument and change PM kit. Check reagent quantity is OK. Run control and sample match Result OK. Instrument working normal.</u>		Earthing: <u>2</u>			
		Online UPS Available <u>Y/N ()</u>			
		STATE ANY DAMAGES BEFORE SERVICE: <u>Preventive maintenance</u>			
		SPARE PARTS USED		SOURCE	
		/		/	
Condition after service: <input checked="" type="checkbox"/> Functioning normally		<input type="checkbox"/> Functioning but Requires action (See Remarks)			
(Please mark ✓) <input type="checkbox"/> Referred to Service Center (See Remarks)					
Customer Remark:		Remote Access Training Given - Yes () No () N/A ()			
Customer Feedback - Excellent (✓) Good () Poor ()		Engineer Remark:			
Approximate Service Charges:					
Service Engineer / Application Support Signature <u>[Signature]</u>		Date <u>20/05/2013</u>		Customer's Signature/Stamp <u>[Signature]</u>	

(Application support to which call center / center / result date)



INSTALLATION QUALIFICATION

The Installation for SYS 200 (Sl. No. SYS20190604) at M/s Kalra Pathology Laboratory, Near Dabra Chowk, Delhi Road Hissar – 125005

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.,

Asmat Sami



Asmat Sami

RSM (NORTH)

Date: 12/04/2023



PERFORMANCE QUALIFICATION

Carried out the following Checks for the Performance of the DiaSys SYS 200 (Sl. No. SYS20190604) at M/s Kalra Pathology Laboratory, Near Dabra Chowk, Delhi Road Hissar – 125005

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

Run the Trulab N & Trulab P control for Different Parameters.

Quality Checks 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.

Linearity Check: Carried out the linearity check for different parameters for which linearity was found to be satisfactory.

For DiaSys Diagnostics India Pvt. Ltd.,

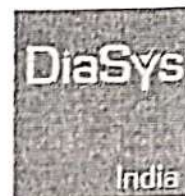




Asmat Sami

RSM (NORTH)

Date: 12/04/2023



OPERATIONAL QUALIFICATION

For Operational Qualifications carried out the following checks on the *SYS 200*
(Sl. No. SYS20190604)

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

RSM (NORTH)

Date: 12/04/2023





Calibration Certificate

Following voltages have been checked & adjusted on DiaSys SYS 200 (Sl. No. SYS20190604) at M/s Kalra Pathology Laboratory, Near Dabra Chowk, Delhi Road Hissar - 125005

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 11/04/2024.

For DiaSys Diagnostics India Pvt. Ltd.

Asmat Sami

Date: 12/04/2023

Regional Service Manager
www.DiaSys-Diagnostic.com
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Toll Free: 1800 120 1447

DiaSys Diagnostics India Private Limited

The Specialists for diagnostic system solutions
Point-of-care testing and automated Laboratory systems

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