



Rapid Diagnostic Pvt. Ltd.

A5, D. N. Shree Nivas Apartments (First Floor)

16, Venu Reddy Street,
Guindy, Chennai - 600 032.

Phone : 044 - 43534413, 98426 34354, 98412 47081

Email: chennaioffice@rdgc.in



Calibration Certificate

Customer Name	Sri Samraj labs
Address	2 nd floor, No.217, Anna salai, Ramanadhapuram-623501.
Contact Person	Dr.Dinesh Subramaniam
Instrument	Fully Auto Biochemistry Analyzer
Model	Chem Ultra
Serial No.	AES2K1KH05179Y
Instrument Status	Outright
Calibration Done On	12.02.2022
Next Calibration Due On	11.02.2023

For Rapid Diagnostic Pvt. Ltd.

Deputy Manager -Service

A. Rajeswaran

RAPID DIAGNOSTIC PVT. LTD.
FLAT No.A5, D.N. SHREENIVAS APTS.
FLOOR No.16, VENU REDDY STREET,
GUINDY, CHENNAI-600 032.
PH:22333213, 22325610
FAX:43534413



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Chem Ultra - Fully Automated Chemistry Analyzer

**INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
PERFORMANCE QUALIFICATION**

(IQ/OQ/PQ)

(Sri Samraj labs)

**2nd Floor, No.217, Anna Salai,
Ramanadhapuram-623501.**

BY Rapid Diagnostic Pvt. Ltd



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ISO 9001: 2000
- CERTIFIED COMPANY -

CERTIFICATE OF INSTALLATION

Instrument Name : Chem Ultra
Serial Number : AES2K1KH05179Y
Customer Name : Sri Samraj Labs
Address : 2nd Floor, No.217, Anna Salai, Ramanadhapuram-623501.

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

Engineer

Signature : 
Name : A. Rajeswaran
Designation : Deputy Manager- Service
Company : **Rapid Diagnostic Pvt.Ltd.**

Quality Manager

Signature :
Name : Dr. Dinesh Subramaniam
Company : **Sri Samraj Labs**



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INSTALLATION REPORT

Customer Name : Sri Samraj Labs
Place : 2nd Floor, No.217, Anna Salai, Ramanadhapuram-623501.
Department : Laboratory
Contact Person : Dr.Dinesh Subramaniam
Instrument Name : Chem Ultra
Serial Number : AES2K1KH05179Y
Date of Installation : 12.02.2022

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 Rapid Diagnostic Pvt. Ltd.


A. Rajeswaran
Deputy Manager - Service

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FLAT No. A5, D.N. SHREENIVAS APTS.
ROOM No. 16, VENU REDDY STREET,
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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

Unpacked Chem Ultra instrument carefully and checked for any physical Damages.

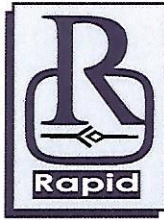
3. ACCESSORIES CHECK-

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 for the below mentioned dimensions

DIMENSIONS	
Parameter	Analyzer OV
Width	560 mm
Length	750 mm
Height	530 mm
Weight	80 kg



Rapid Diagnostic Pvt. Ltd.

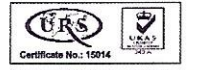
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Certificate No.: 15914
ISO 9001: 2000
- CERTIFIED COMPANY -

5. POWER REQUIREMENT –

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

6. REAGENTS, CALIBRATORS, CONTROL CHECK

QC NAME: Quality Control Level 1-Normal Control

Qc Name	Lot No	Expiry	Test	Target	Range	Result Obtained
ASPEN CONTROL	N3082 13-01R	05/2023	GLUCOSE	92.0	74-110	98
			UREA	36.1	29.5-42.7	35.9
			SGPT	40.0	31.0-49.0	37.0
			TOTAL BILIRUBIN	1.17	0.87-1.47	1.11

QC NAME : Quality Control Level 2-Abnormal Control

Qc Name	Lot No	Expiry	Test	Target	Range	Result Obtained
ASPEN CONTROL	P40821 4-02R	03/2023	GLUCOSE	233	195--271	221
			UREA	96.6	76.2-117	103
			SGPT	107	89-141	125
			TOTAL BILIRUBIN	3.38	2.62-4.14	3.79



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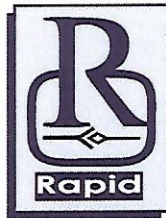
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PRE-INSTALLTION VERIFICATION REPORT :-

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



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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.

OQ 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	Computer connected	Operating Manual	Ok
2	LAN Cable connected	Operating Manual	Ok
3	DI Water Tube Connected	Operating Manual	Ok
4	Waste Tube Connected	Operating Manual	Ok
5	External Printer Insertion	Operating Manual	Ok



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2. REAGENT & WASTE CONNECTIONS -

Please refer to the User Manual and the Kit Literature supplied with the Reagent Kit:

3. CUSTOMIZING ANALYZER SOFTWARE –

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

4. SYSTEM BOOTING , INITIALIZATION & CHECK -

Power ON System and check for successful initialization of the instrument.

5.MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Operator Manual	Ok



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PERFORMANCE QUALIFICATION-

Parameter	Range	Results	Remarks
A/D Value for all filters	20000-60000	Around 46000	OK
Lamp Voltage	6V(+/-)0.2V	5.9V	OK
Cuvette Temp	37(+ &-)0.2 C	37.01	OK

PRECISION-FOR NORMAL CONTROL(for run of 5 times)

S/N	Parameter	Actual	Range	Remark
1	SGPT	1.5	5%	ok
2	GLUCOSE	1.7	5.0%	ok
3	TOTAL BILIRUBIN	2.7	5%	ok
4	UREA	2.0	5%	ok

PRECISION FOR ABNORMAL CONTROL(for run of 5 times)

S/N	PARAMETER	Actual	Range CV%	Remark
1	SGPT	2.8	5%	Ok
2	GLUCOSE	2.4	5%	Ok
3	TOTAL BILIRUBIN	1.2	5%	Ok
4	UREA	1.9	5%	Ok

For Rapid Diagnostic Pvt. Ltd.

A. Rajeswaran

Deputy Manager-Service

First Line

Second Line

QC(Name-Lot)	Test	Target Value	SD Value	QC Range	Result	Test Date	State
RANDOX	GLUC	108	8	92 ~ 124	112	19-06-2022	
RANDOX	UREA	43	3	37 ~ 49	43	19-06-2022	
RANDOX	CHO SR	159	11	138 ~ 180	163	19-06-2022	
RANDOX	TGL SR	93	7	78 ~ 107	101	19-06-2022	
RANDOX	HDL-D	60.20	4.45	51.30 ~ 69.10	63.30	19-06-2022	
RANDOX	SGOT	33	4	26 ~ 40	35	19-06-2022	
RANDOX	GGT	48	4	41 ~ 55	55	19-06-2022	
RANDOX	TBIL	1.71	0.18	1.35 ~ 2.07	1.75	19-06-2022	
RANDOX	DBIL	1.18	0.13	0.92 ~ 1.44	1.16	19-06-2022	
RANDOX	CREAT	1.46	0.15	1.16 ~ 1.76	1.18	19-06-2022	
RANDOX	SGPT	39	4	31 ~ 47	45	19-06-2022	
RANDOX	ALP	167	13	142 ~ 192	176	19-06-2022	
RANDOX	TP	5.85	0.59	4.67 ~ 7.03	5.42	19-06-2022	
RANDOX	ALB	4.23	0.32	3.59 ~ 4.87	4.18	19-06-2022	
RANDOX	CAL A3	8.7	0.4	7.9 ~ 9.6	9.3	19-06-2022	
RANDOX	UA	5.8	0.4	5.0 ~ 6.6	6.1	19-06-2022	
RANDOX	TBIL	1.71	0.18	1.35 ~ 2.07	1.68	19-06-2022	
RANDOX	DBIL	1.18	0.13	0.92 ~ 1.44	1.15	19-06-2022	