



Rapid Diagnostic Pvt. Ltd.

B.O.: F-2, Aakar Apartments, No 29, V.S.Raju Road, Kumarapark (W), Bengaluru- 560020
Tel: 080-40976930 Fax: 080-23344274, e-mail: zakir@rdgc.in, rapidblroffice@gmail.com



ISO 9001:2008
CERTIFIED COMPANY

Chem Ultra Fully Automated Chemistry Analyzer

INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
PERFORMANCE QUALIFICATION
(IQ/OQ/PQ)

(FOR: Sri Spectra Diagnostics, Yelenahalli,
Bangalore)

BY Rapid Diagnostic Pvt. Ltd





Rapid Diagnostic Pvt. Ltd.

B.O.: F-2, Aakar Apartments, No 29, V.S.Raju Road, Kumarapark (W), Bengaluru- 560020

Tel: 080-40976930 Fax: 080-23344274, e-mail: zakir@rdgc.in, rapidbrooffice@gmail.com



ISO 9001:2008
CERTIFIED COMPANY

CERTIFICATE OF INSTALLATION

INSTRUMENT NAME : Chem Ultra

SERIAL NUMBER : AES2K1KH03201Y

CUSTOMER NAME : Sri Spectra Diagnostics,

ADDRESS : Sri Ganapathi Complex,
2nd Main,
Akshayanagara

50ft Road, Near DLF,
Yelenahalli, Begur Post,
Bangalore-560068

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



Rapid Diagnostic Pvt. Ltd.

B.O.: F-2, Aakar Apartments, No 29, V.S.Raju Road, Kumarapark (W), Bengaluru- 560020
Tel: 080-40976930 Fax: 080-23344274, e-mail: zakir@rdgc.in, rapidblroffice@gmail.com



ISO 9001:2008
CERTIFIED COMPANY

Engineer

Signature :

Vishnu Shaji

Name :

Mr. Vishnu Shaji

Designation :

Service Engineer

Company :

Rapid Diagnostics Pvt. Ltd.

Quality Manager

Signature :

:

Name :

Mr. Raveesh B

Designation :

Application specialist

Company :

Rapid Diagnostics Pvt. Ltd.



Rapid Diagnostic Pvt. Ltd.

B.O.: F-2, Aakar Apartments, No 29, V.S.Raju Road, Kumarapark (W), Bengaluru- 560020
Tel: 080-40976930 Fax: 080-23344274, e-mail: zakir@rdgc.in, rapidblroffice@gmail.com



ISO 9001:2008
CERTIFIED COMPANY

INSTALLATION REPORT

Customer Name : Sri Spectra Diagnostics,
Place : Bangalore, Karnataka
Department : Laboratory
Contact Person : Mrs. Shalini M.B / Mr. Balaji
Instrument Name : Chem Ultra
Serial Number : AES2K1KH03201Y
Date of Installation : 14.06.2021

Warranty Expiry : 13.06.2022

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 Diagnostics Pvt. Ltd

Vishnu shaji
Service Engineer





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 -

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

Checked site for proper space allocation. At least 100 CM on each side and enough room for the below mentioned dimensions

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
SERA CONTROL N	N104211-01R	05-2023	GLUCOSE	92.00	83.00-101.00	84.46
			CHOLESTEROL	143	127.80-158.20	133.33
			TRIGLYCERIDS	124	103.00-145.00	112.51
			UREA	36.10	29.50-42.70	34.38
			CREATININE	1.25	0.95-1.55	1.24
			SGOT	39.00	30.00-48.00	36.67
			SGPT	40.00	31.00-49.00	39.01
			ALKALINE PHOSPHATASE	89.00	74.00-104.00	87.75
			TOTAL BILIRUBIN	1.17	0.87-1.47	1.16
			DIRECT BILIRUBIN	0.53	0.33-0.73	0.52
			TOTAL PROTEIN	5.43	4.65-6.21	5.26



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

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

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

PERFORMANCE QUALIFICATION-

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



Rapid Diagnostic Pvt. Ltd.

B.O.: F-2, Aakar Apartments, No 29, V.S.Raju Road, Kumarapark (W), Bengaluru- 560020
Tel: 080-40976930 Fax: 080-23344274, e-mail: zakir@rdgc.in, rapidblroffice@gmail.com



ISO 9001:2008
CERTIFIED COMPANY

PRECISION-FOR NORMAL CONTROL(for run of 5 times)				
S/N	PARAMETER	Actual	Range	Remark
1	SGOT	0.98	< 5%	In Range
2	CREATININE	1.85	< 5%	In Range
3	URIC ACID	2.76	< 5%	In Range
4	DIRECT BILIRUBIN	1.04	< 5%	In Range
5	GLUCOSE	1.12	< 5%	In Range

PRECISION FOR ABNORMAL CONTROL(for run of 5 times)				
S/N	PARAMETER	Actual	Range CV%	Remark
1	SGOT	0.41	< 5%	In Range
2	CREATININE	1.31	< 5%	In Range
3	URIC ACID	0.74	< 5%	In Range
4	DIRECT BILIRUBIN	0.83	< 5%	In Range
5	GLUCOSE	0.52	< 5%	In Range

First Line

Second Line

July - 2021

QC(Name-Lot)	Test	Target Value	SD Value	Sum. Count	Sum Mean	Sum. SD	Sum. CV(%)
CONTROL	UREA	36.10	3.30	11	36.62	5.47	14.93
CONTROL	TG	193.00	15.00	7	191.42	12.15	6.35
CONTROL	DBIL	1.32	0.33	6	1.05	0.25	23.73
CONTROL	SGPT	115.00	13.00	6	115.87	10.82	9.34
CONTROL	SGPT	40.00	4.50	9	39.03	3.59	9.21
CONTROL	CREAT	1.25	0.15	14	1.76	2.23	126.53
CONTROL	TP	7.39	0.19	7	7.37	0.53	7.22
CONTROL	CHOL	183.00	15.00	6	189.04	12.07	6.38
CONTROL	SGOT	39.00	4.50	10	41.43	3.84	9.26
CONTROL	ALKP	290.00	20.00	9	351.92	70.32	19.98
CONTROL	GLU	233.00	19.00	6	249.57	17.61	7.06
CONTROL	ALB	3.59	0.43	8	4.37	2.15	49.24
CONTROL	CREAT	3.69	0.38	7	3.21	1.56	48.60
CONTROL	TP	5.43	0.39	7	5.45	0.19	3.52
CONTROL	GLU	92.00	9.00	10	93.12	4.12	4.42
CONTROL	UA	8.47	0.90	7	9.07	0.51	5.60
CONTROL	LDHL	162.00	16.00	5	163.44	1.90	1.16
CONTROL	UA	4.68	0.38	12	5.17	1.60	30.92
CONTROL	SGOT	170.00	14.00	8	163.18	28.91	17.72
CONTROL	ALKP	89.00	7.50	7	112.85	69.70	61.76
CONTROL	LDHL	279.00	27.00	4	282.69	25.58	9.05
CONTROL	ALB	4.70	0.44	5	6.46	3.19	49.39
CONTROL	UREA	96.60	10.20	7	95.94	6.07	6.33
CONTROL	T BIL	3.38	0.38	6	2.92	0.55	18.95
CONTROL	TG	124.00	10.50	10	115.87	4.03	3.47
CONTROL	CHOL	143.00	7.60	10	148.30	4.41	2.97
CONTROL	DBIL	0.53	0.10	8	0.49	0.07	14.95
CONTROL	T BIL	1.17	0.15	8	1.15	0.12	10.30

31/ July 2021

[Signature]

First Line

Second Line

August - 2021

QC(Name-Lot)	Test	Target Value	SD Value	Sum. Count	Sum. Mean	Sum. SD	Sum. CV(%)
CONTROL	UREA	36.10	3.30	13	33.46	2.59	7.75
CONTROL	TG	193.00	15.00	12	182.14	7.02	3.85
CONTROL	DBIL	1.32	0.33	10	1.15	0.11	9.23
CONTROL	SGPT	115.00	13.00	12	103.58	6.16	5.95
CONTROL	CREAT	1.25	0.15	9	1.12	0.10	8.61
CONTROL	SGPT	40.00	4.50	13	39.11	3.41	8.71
CONTROL	TP	7.39	0.19	6	7.36	0.05	0.74
CONTROL	CHOL	183.00	15.00	12	183.53	3.12	1.70
CONTROL	SGOT	39.00	4.50	13	41.43	2.61	6.29
CONTROL	ALKP	290.00	20.00	5	290.02	21.41	7.38
CONTROL	GLU	233.00	19.00	12	238.85	5.44	2.28
CONTROL	ALB	3.59	0.43	10	3.52	0.05	1.35
CONTROL	CREAT	3.69	0.38	8	3.37	0.29	8.48
CONTROL	TP	5.43	0.39	9	5.49	0.10	1.88
CONTROL	GLU	92.00	9.00	13	92.03	1.96	2.13
CONTROL	UA	8.47	0.90	13	8.01	0.36	4.55
CONTROL	LDHL	162.00	16.00	3	142.05	4.47	3.15
CONTROL	UA	4.68	0.38	12	4.55	0.44	9.69
CONTROL	SGOT	170.00	14.00	12	174.16	10.93	6.27
CONTROL	ALKP	89.00	7.50	7	82.62	9.04	10.94
CONTROL	ALB	4.70	0.44	7	4.34	0.33	7.62
CONTROL	UREA	96.60	10.20	12	91.26	7.65	8.38
CONTROL	T BIL	3.38	0.38	12	3.32	0.37	11.01
CONTROL	TG	124.00	10.50	12	113.09	7.69	6.80
CONTROL	CHOL	143.00	7.60	13	143.68	3.70	2.58
CONTROL	DBIL	0.53	0.10	11	0.53	0.02	4.52
CONTROL	T BIL	1.17	0.15	12	1.21	0.07	5.85

[Signature]
21/08/21

First Line

Second Line

SEN PETER - 2021

QC(Name-Lot)	Test	Target Value	SD Value	Sum. Count	Sum. Mean	Sum. SD	Sum. CV(%)
CON--N--N104211-01R	UREA	36.10	3.30	19	34.79	1.72	4.93
CON-P+-P204212-02R	TG	193.00	15.00	18	174.49	4.48	2.57
CON-P+-P204212-02R	DBIL	1.32	0.33	15	1.09	0.29	26.96
CON-P+-P204212-02R	SGPT	115.00	13.00	18	95.81	23.41	24.43
CON--N--N104211-01R	CREAT	1.25	0.15	14	1.20	0.07	5.95
CON--N--N104211-01R	SGPT	40.00	4.50	17	38.11	2.15	5.64
CON-P+-P204212-02R	TP	7.39	0.19	16	6.34	2.40	37.90
CON-P+-P204212-02R	CHOL	183.00	15.00	19	177.64	2.85	1.60
CON--N--N104211-01R	SGOT	39.00	4.50	18	38.97	2.47	6.34
CON-P+-P204212-02R	ALKP	290.00	20.00	18	281.45	71.00	25.23
CON-P+-P204212-02R	GLU	233.00	19.00	18	228.43	3.10	1.36
CON--N--N104211-01R	ALB	3.59	0.43	12	3.42	0.02	0.68
CON-P+-P204212-02R	CREAT	3.69	0.38	17	3.39	0.18	5.23
CON--N--N104211-01R	TP	5.43	0.39	10	5.35	0.15	2.87
CON--N--N104211-01R	GLU	92.00	9.00	18	84.67	1.49	1.76
CON-P+-P204212-02R	UA	8.47	0.90	20	9.34	0.70	7.51
CON--N--N104211-01R	UA	4.68	0.38	3	5.05	0.53	10.56
CON-P+-P204212-02R	SGOT	170.00	14.00	19	164.69	7.86	4.77
CON--N--N104211-01R	ALKP	89.00	7.50	14	89.68	5.58	6.22
CON-P+-P204212-02R	LDHL	279.00	27.00	5	1.85	2.28	122.90
CON-P+-P204212-02R	ALB	4.70	0.44	15	3.78	1.48	39.24
CON-P+-P204212-02R	UREA	96.60	10.20	20	91.63	3.25	3.54
CON-P+-P204212-02R	T BIL	3.38	0.38	18	3.23	0.80	24.87
CON--N--N104211-01R	TG	124.00	10.50	17	110.53	4.64	4.20
CON--N--N104211-01R	CHOL	143.00	7.60	18	135.60	3.57	2.63
CON--N--N104211-01R	DBIL	0.53	0.10	16	0.52	0.01	2.41
CON--N--N104211-01R	T BIL	1.17	0.15	17	1.13	0.05	4.84

[Signature]
20/09/21

First Line

Second Line

OCTOBER-2021

QC(Name-Lot)	Test	Target Value	SD Value	Sum. Count	Sum. Mean	Sum. SD	Sum. CV(%)
CON--N---N104211-01R	UREA	36.10	3.30	16	33.77	2.51	7.45
CON-P+--P204212-02R	TG	193.00	15.00	13	179.47	6.01	3.35
CON-P+--P204212-02R	DBIL	1.32	0.33	16	1.29	0.25	19.57
CON-P+--P204212-02R	SGPT	115.00	13.00	14	97.72	4.18	4.28
CON--N---N104211-01R	SGPT	40.00	4.50	9	35.30	2.84	8.03
CON--N---N104211-01R	CREAT	1.25	0.15	5	1.12	0.06	5.11
CON-P+--P204212-02R	TP	7.39	0.19	11	6.13	2.90	47.22
CON-P+--P204212-02R	CHOL	183.00	15.00	16	183.51	3.46	1.88
CON--N---N104211-01R	SGOT	39.00	4.50	15	40.56	1.28	3.15
CON-P+--P204212-02R	ALKP	290.00	20.00	10	291.66	17.44	5.98
CON-P+--P204212-02R	GLU	233.00	19.00	16	236.40	4.85	2.05
CON--N---N104211-01R	ALB	3.59	0.43	8	3.59	0.04	1.14
CON-P+--P204212-02R	CREAT	3.69	0.38	11	3.39	0.44	13.12
CON--N---N104211-01R	TP	5.43	0.39	7	5.62	0.13	2.30
CON--N---N104211-01R	GLU	92.00	9.00	15	87.89	2.75	3.12
CON-P+--P204212-02R	CAL	12.40	0.70	1	0.00	0.00	0.00
CON-P+--P204212-02R	UA	8.47	0.90	18	9.72	0.22	2.24
CON--N---N104211-01R	UA	4.68	0.38	1	5.40	0.00	0.00
CON-P+--P204212-02R	SGOT	170.00	14.00	16	178.49	3.92	2.20
CON--N---N104211-01R	ALKP	89.00	7.50	9	90.63	9.23	10.19
CON-P+--P204212-02R	ALB	4.70	0.44	13	4.27	1.24	28.90
CON-P+--P204212-02R	UREA	96.60	10.20	16	93.71	3.56	3.79
CON-P+--P204212-02R	T BIL	3.38	0.38	13	3.44	0.41	11.96
CON--N---N104211-01R	TG	124.00	10.50	13	113.24	3.48	3.07
CON--N---N104211-01R	CHOL	143.00	7.60	15	141.89	4.38	3.09
CON--N---N104211-01R	DBIL	0.53	0.10	11	0.53	0.04	7.00
CON--N---N104211-01R	T BIL	1.17	0.15	15	1.13	0.11	10.18



31/10/2021