

Tulip Diagnostics (P) Ltd.

**Installation Qualification
For
Biochemistry Analyzer
(Coralyzer Smart)**


Contents

- 1) Instrument Identification
- 2) Environment Condition
- 3) Instrument Delivery and Documentation
- 4) Instrument Safety
- 5) Assembly and Installation
- 6) Summary Report

1) Instrument Identification :

□

Biochemistry Analyzer -Coralzer Smart.

Sr. No.	Specification	As per design qualification	Specification received	Match (Yes/No)
1	General Feature	Random access chemistry, Multichannel photometer capable of measuring absorbance of contents in microcuvettes. 		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2	Typical working volume For cuvettes	300 micro ltr		Yes
3	Filter range	340 to 700 nm		Yes
4	Communication port	USB- Interface		Yes
5	Printer	External Printer		Yes
6	Power requirement	500 VA+ PC		Yes
7	Grounding	< 5 volt ac		Yes
8	Throughput	200 test/hr		Yes

Comments:

2.Environment Condition:

Has the Instrument been adequately acclimatized since transport or storage?

YES:

NO:

Operating Parameters	Specified Range	Conditions Met
Ambient Temperature	10 to 30 degrees	YES: <input checked="" type="checkbox"/> NO: <input type="checkbox"/>
Maximum Relative Humidity	30% to 80 %	YES: <input checked="" type="checkbox"/> NO: <input type="checkbox"/>
Supply Voltage & Frequency	220-230V, 50 Hz ac	YES: <input checked="" type="checkbox"/> NO: <input type="checkbox"/>

Comments:

3. Instrument Delivery and Documentation :

Unpack the Instrument carefully. Are any items missing against the Packing List?

YES:

NO:

If yes, state the missing Items: _____

Is there any damage to the Instrument or Accessories?

YES:

NO:

If yes: Description of Damage: _____

Corrective Action: _____

Manufacturing informed: YES:

NO:

Is all Standard Documentation Included?

Operating Manual:

Present:

Missing:

Warranty Card:

Present:

Missing:

Is all additional documentation Included:

Present:

Missing:

Installation Qualification:

Operational Qualification:

Performance Qualification:

Comments:

3. Instrument Delivery and Documentation :

Unpack the Instrument carefully. Are any items missing against the Packing List?

YES:

NO:

If yes, state the missing Items: _____

Is there any damage to the Instrument or Accessories?

YES:

NO:

If yes: Description of Damage: _____

Corrective Action: _____

Manufacturing informed: YES:

NO:

Is all Standard Documentation Included?

Operating Manual:

Present:

Missing:

Warranty Card:

Present:

Missing:

Is all additional documentation Included:

Present:

Missing:

Installation Qualification:

Operational Qualification:

Performance Qualification:

Comments:

5. Assembly and Installation :

Assembled and installed By: <i>Swarup Ghosh</i> User:	Specialized Engineer:	
	Yes	N/A
Installation Procedure :	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Unpack and retain Packaging -	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Verifying the site before connecting to power supply-	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Checking the instrument before performing the Test-	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Comments:

6. Summary Report :

Instrument Name: **Coralyzer Smart**

Sr. No.: **AES2K2KH09087Y**


Manufacturer: Tulip Diagnostics (P) Ltd.

Assessment of complete Installation Qualification:

No Deviations: Deviations:

Deviation	Impact on Operation	Justification for Acceptance

Successful completion of the preceding activities and checks indicates that this Instrument is installed successfully as per the set protocol. The instrument has passed the Installation Qualification procedure and may now be released for use.

IQ Completed By:	Swarup Ghosh	Date: 10.03.2023	
Deviations Approved By:		Date:	
IQ Approved By:	Joy Das	Date: 10.03.2023	

Comments:

Operation Qualification
For
Biochemistry Analyzer
(Coralyzer Smart)

Contents

- 1) Safety Tests
- 2) Pre-Run Checks
- 3) Functional Tests
- 4) Training
- 5) Summary Report

1. Safety Tests :

This instrument confirms to the following standards and is supplied fully tested by the Manufacturer.

- Electrical equipment for measurement, control and laboratory use.
- Instrument requirement for laboratory for Blood testing.

The following electrical safety tests should be carried out by a competent person after Installation.

Safety Tests	Pass	Fail	Date	Signed
Earthing	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10.03.2023	Swarup Ghosh
UPS Supply	<input checked="" type="checkbox"/>	<input type="checkbox"/>		

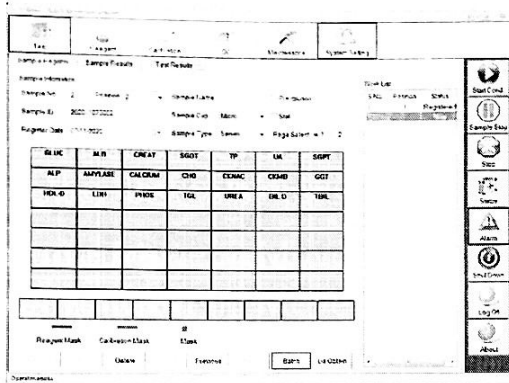
Comments:

2. Pre-Run Checks :**Biochemistry Analyzer (Coralyzer Smart)**

Pre run check	OK	N/A
Printer connection	<input checked="" type="checkbox"/>	<input type="checkbox"/>
No of cuvettes in reaction tray	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Hardware setting	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Reaction cuvette Temp	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Filter ADC	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Comments:

3. Functional Tests : Coralyzer Smart :

Functional Test	Acceptance Criteria	Pass	Fail
Instrument power ON	Instrument initializes after clicking on Device Reset & shows in the screen below: 	yes	
Reaction Tray	Movement	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Reagent/Mixer Arm	Movement	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Reagent/ Sample tray	Movement	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Wash Arm	Movement	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Water/Waste Pump	Suction / Noise level	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Comments:

4.Training:

Trained Operators	Read Operator Manual	Read SOP	Practical Training	Authorizing Signature
<i>Suman Mandal</i>	✓	✓	✓	<i>Suman Mandal.</i>

Comments:

Tulip Diagnostics (P) Ltd.

Comments :

**Performance Qualification
For
(Coralyzer Smart)**

Contents

- 1) Performance Check
- 2) Routine Maintenance
- 3) Safety Tests
- 4) Summary Report

2) Routine Maintenance :

This instrument has been designed for Blood Testing. If any fault occurs, it is advised to contact Tulip Diagnostics Service Engineer.

The frequency with which routine maintenance tasks are being completed should be recorded below.

Routine Maintenance	Date	Done	Not Done
1st Routine visit.	5/23	✓	
2nd Routine visit	9/23	✓	
3rd Routine visit	1/2024	✓	

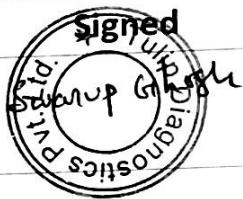
Comments:

3) Safety Tests :

This instrument confirms to the following standards and is supplied fully tested by the Manufacturer.

- Electrical equipment for measurement, control and laboratory use.
- Instrument requirement for laboratory for Blood testing.

The following electrical safety tests should be carried out by a competent person after Installation.

Safety Tests	Pass	Fail	Date	Signed
Earthing	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10.03.2023	
UPS Supply	<input checked="" type="checkbox"/>	<input type="checkbox"/>		

Comments:

4) Summary Report :

Instrument Name: Coralyzer Smart.

Sr. No : AES2K2KH09087Y

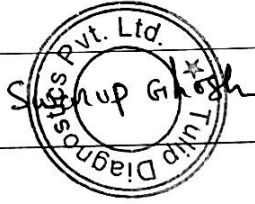
Manufacturer: Tulip Diagnostics (P) Ltd.

Assessment of complete Performance Qualification:

No Deviations: Deviations:

Deviation	Impact on Operation	Justification for Acceptance

Successful completion of the preceding activities and checks indicates that this Instrument is operating satisfactorily following delivery and installation. The instrument has passed the Operational Qualification procedure and may now be released for use.

PQ Completed By:	Swarup Ghosh	Date: 10.03.2023	
Deviations Approved By:		Date:	
PQ Approved By:	Joy Das	Date: 10.03.2023	

Comments:

Acceptance

Successful completion of the preceding activities and checks
Instrument is operating satisfactorily following
instrument has passed the
release

T TULIP DIAGNOSTICS (P) LTD.

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Tulip Diagnostic Server - Admin Webpage

Test Results

Sl. No.	Test Name	Sample ID	Result	Unit	Ref	Reference Range Low	Reference Range High
11	HB	202048120011	152	g/dl	H	0	1
12	HCT	202048120011	45	%	H	0	1
13	WBC	202048120013	105	mm ³	H	0	1
14	RBC	202048120014	348	mm ³	H	0	1
15	PLT	202048120015	183	mm ³	H	0	1
16	MPV	202048120016	183	fL	H	0	1
17	PCT	202048120017	183	%	H	0	1
18	RDW	202048120018	183	%	H	0	1

Engineer Date: 12-08-2024
 Calc. Date: 12-08-2024
 Time: 10:40:00
 ID: ED
 Search: L14
 Test Record Count: 9
 History Panel: On in 2024 302
 CV%: 1.50%

Buttons: Stop Cond, Sample Stop, Stop, Alarm, Shut Down, Log Off, Abort



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T TULIP DIAGNOSTICS (P) LTD.

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CIN U65192CA1999PT0005111

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Tulip Carefree Smart - Auto biochemistry analyzer

Test Request Calibration QC Maintenance System Setting

Sample Register Test Results

No.	Test Name	Sample No.	Sample ID	Result	Unit	Unit	Reference Range Low	Reference Range High
1	CLIC	11	202408120011	7.2	mg/dl	H	0.0	1.0
2	ALB	12	202408120012	7.4	mg/dl	H	0.0	1.0
3	ALP	13	202408120013	7.4	mg/dl	H	0.0	1.0
4	SCF	14	202408120014	7.2	mg/dl	H	0.0	1.0
5	SCOT	15	202408120015	7.2	mg/dl	H	0.0	1.0
6	ALP	16	202408120016	7.2	mg/dl	H	0.0	1.0
7	ALP	17	202408120017	7.2	mg/dl	H	0.0	1.0
8	ALP	18	202408120018	7.2	mg/dl	H	0.0	1.0
9	B.D							
10	TEL							
11	TEL							
12	ORL							
13	ADP							
14	OCN							
15	HG - 0							
16	CREAT							
17	CRP							
18	CRP							
19	IF							
20	IF							
21	IF							
22	IF							
23	IF							
24	IF							
25	IF							
26	IF							
27	IF							
28	IF							
29	IF							
30	IF							
31	IF							
32	IF							

Register Date: 12-08-2024
 Clik Count: 3
 Mean: 7.28
 SD: 0.0
 Search: 0.08
 Test Record Count: 8
 History Result Cnt in 2024: 222
 CV%: 1.177
 Clikable

15:13
 12-08-2024



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