

**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 -Coralizer 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: YES

Operational Qualification: YES

Performance Qualification: YES

Comments:

4) Instrument Safety**Manufacturer Safety Recommendations:**

Allow enough space for the Instrument	YES: <input checked="" type="checkbox"/>	NO: <input type="checkbox"/>
Position on level, non-combustible surface Indoors	YES: <input checked="" type="checkbox"/>	NO: <input type="checkbox"/>
Area free from aggressive/ explosive chemical mixtures	YES: <input checked="" type="checkbox"/>	NO: <input type="checkbox"/>
Ensure correct power supply and all power switches Easily accessible	YES: <input checked="" type="checkbox"/>	NO: <input type="checkbox"/>
Beware of moving parts during working	YES: <input checked="" type="checkbox"/>	NO: <input type="checkbox"/>
Do not use Heat material that could cause fire or other Hazards	YES: <input checked="" type="checkbox"/>	NO: <input type="checkbox"/>
Read Operator Manual before use	YES: <input checked="" type="checkbox"/>	NO: <input type="checkbox"/>

Comments:

5) Assembly and Installation

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

Comments:

6) Summary Report

Instrument Name: Coralyzer Smart

Sr. No.:AES2K0KH12171F.

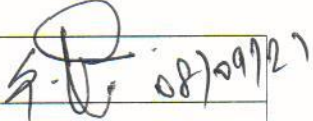
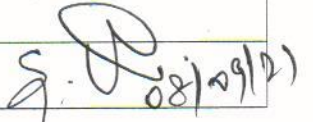
Manufacturer: Tulip Diagnostics (P) Ltd.

Assessment of complete Installation Qualification:

No Deviations: Deviations:

Deviation	Impact on Operation	Justification for Acceptance
NIL		

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:	RAMESH S	Date: 08.09.21	
Deviations Approved By:		Date:	
IQ Approved By:	RAMESH S	Date: 08.09.21	

Comments:

Operation Qualification
For
Biochemistry Analyzer
(Coralyzer Smart)

Contents

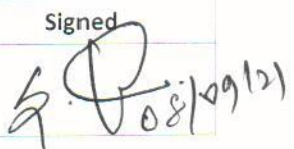
- 1) Safety Tests
- 2) Pre-Run Checks
- 3) Functional Tests
- 4) Training
- 5) Summary Report

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"/>	08.09.21	
UPS Supply	<input checked="" type="checkbox"/>	<input type="checkbox"/>		

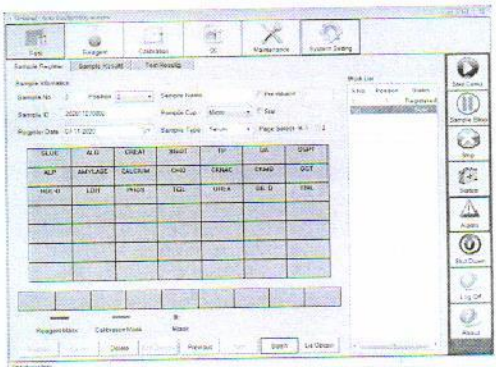
Comments:

2) Pre-Run ChecksBiochemistry 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"/>

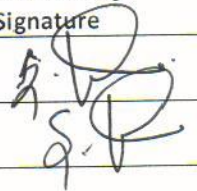
Comments:

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: 	PASS	
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
G.RAJA	YES	YES	YES	
AMBIKA	YES	YES	YES	

Comments:

5) **Summary Report**

Instrument Name: Coralyzer Smart.

Sr. No.:AES2K0KH12171F

Manufacturer: Tulip Diagnostics (P) Ltd.

Assessment of complete Operational Qualification:

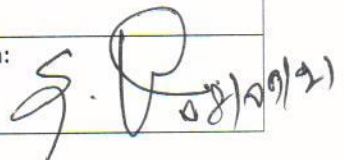
No Deviations:

Deviations:

Deviation	Impact on Operation	Justification for Acceptance
NIL		

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.

OQ Completed By:	RAMESH S	Date: 08.09.21	Sign: 
Deviations Approved By:		Date:	Sign:
OQ Approved By:	RAMESH S	Date: 08.09.21	Sign: 

Comments:

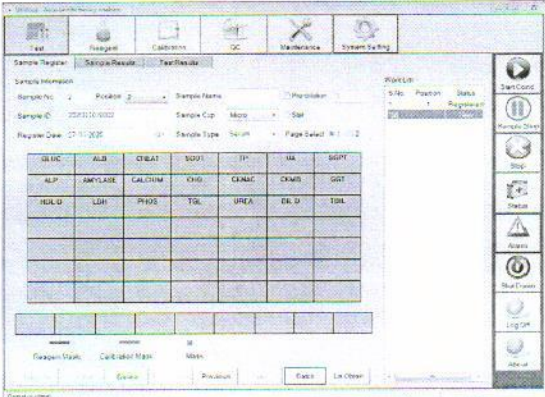
**Performance Qualification
For
(Coralyzer Smart)**

Contents

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

1) Performance Check

Bio-chemistry Analyzer (Coralyzer Smart)

Functional Test	Acceptance Criteria	Pass	Fail
Instrument power ON	Login the software and shows the main menu as seen below: 	PASS	
Reaction Tray	Movement / Positioning	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Reagent / Sample tray	Movement /Positioning	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Wash Arm	Movement	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Reagent /Mixer Arm	Movement	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Test Repeatability.	EP / KIN and FXT , minimum repeats of 5 each	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Comments:

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
GENERAL ROUTINE SERVICE	08.09.21	DONE	

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"/>	08.09.21	S. P. 08.09.21
UPS Supply	<input checked="" type="checkbox"/>	<input type="checkbox"/>		

Comments:

4) Summary Report

Instrument Name: Coralyzer Smart.

Sr. No.:AES2K0KH12171F

Manufacturer: Tulip Diagnostics (P) Ltd.

Assessment of complete Performance Qualification:

No Deviations:

Deviations:

Deviation	Impact on Operation	Justification for Acceptance
NIL		

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:	RAMESH S	Date:	08.09.21
Deviations Approved By:		Date:	
PQ Approved By:	RAMESH S	Date:	08.09.21

Comments:

[Handwritten Signature]
08/09/21