

Coralyzer Series Fully Automatic Biochemistry Analyzer, Inspection/calibration Report

Test QC refer to: <<Coralyzer Series Fully Automatic Analyser>> Registered Standard Model: Coralyzer Smart, S/N: AES2K2KH09087Y

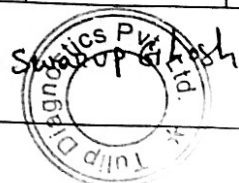
Meter used for calibration: Multimeter Cal Date:- 10.03.2024 Due Date:- 10.03.2025

S. No.	Inspection Item	Criterion of QC test	Result	Conclusion
1	Software functions	CRITERIA OF QC TEST		
		a) Analytical method may analyse 40 pos at the same time.	OK	PASS
		b) Programming item	OK	
		c) Automatic priority inspect of emergency sample.	OK	
		d) Calibration linearity/non-linearity multi point calibration.	OK	
		e) QC at may operate most of QC at same item.	OK	
		g) Storage	OK	
		h) Printer multiple report formats available, user can self edit report formats.	OK	
		i) STAT	OK	
		j) Sample rerun/recheck.	OK	
		k) Sample /reagent probe liquid check.	OK	
		l) Mixing function.	OK	
		m) Results storage, query, quality control chart, the whole process	OK	
		n) Crash gard function.	OK	
2	Dark Abs	Absorbance $\geq 3.400 A$	5.8	
3	Linearity range of absorbance.	The maximum absorbance should be not less than 3.700A within the relative range of $\pm 5\%$	340nm: 5.1	OK
			505nm: 4.8	OK
4	Accuracy of absorbance	Less than $\pm 0.040A$ at 1.00A	0.012	OK
		Less than $\pm 0.060A$ at 1500A	0.027	OK
		Less than $\pm 0.020A$ within 0.500A	0.048	OK
5	Accuracy of absorbance	Absorbance change should be less than 0.005A/min	340nm: 0.003A	OK
			505nm: 0.002A	OK
6	Reproducibility of absorbance	cofficient of variation $cv \leq 3\%$	2.73%	OK
7	Temperature of reaction cuvette 37	Accuracy less than than $\pm 0.1^\circ C$	37°C	OK
		Fluctuate of temperature less than $\pm 0.1^\circ C$	0.005°C	OK
8	Teperature of reagent storage	Under normal work condition, reagent storage should be 2-8°C	6.0°C	OK
9	Carryover	Sample carryover less than 0.05%	PASS	
10	Accuracy of parameter	Items	Concentration	CV
		UREA	76.3-109.9	$\leq 3\%$
		GLUC	81.0-116.6	$\leq 3\%$
		SGOT	55-87	$\leq 3\%$
			2.70%	OK
11	Apperance	a) Whole appearance of the surface should not have obvious mechanical abrasion, corrosion and surface coating spalling.	PASS	
		b) All connections are stable and fixed well.		
		c) Moving parts running smooth and keypad works well		
12	Protect ground connect	The impedance between ground outlet from power supply net and ground protected touchable metal should not more than 0.1 Ω	PASS	
13	Power grid, power supply, circuit	Basic insulation: 50Hz the sine 230V alternating voltage test. should not apper brakdown or occur electric arcing.	PASS	

Inspection/Calibration date: 10.03.2024

Check: Swarup Ghosh

re-check:



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 -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:

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"/>		

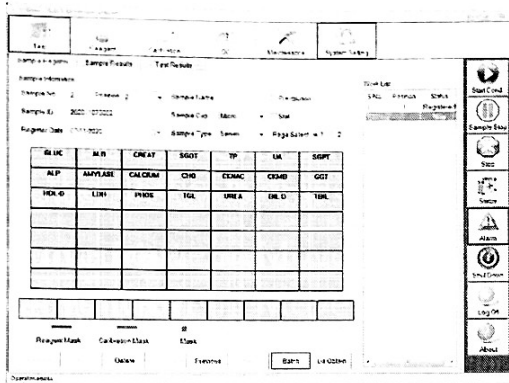
Comments:

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 Mandat</i>	✓	✓	✓	<i>Suman Mandat.</i>

Comments:

Comments :

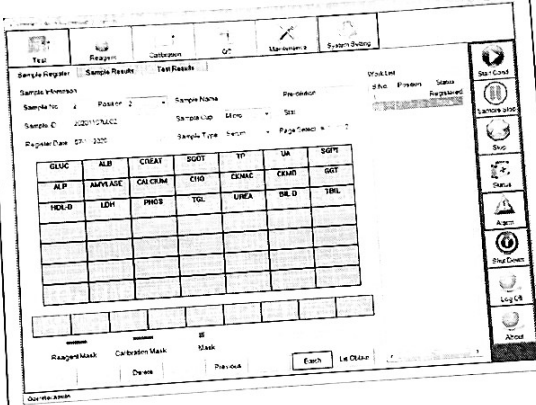
**Performance Qualification
For
(Coralyzer Smart)**

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: 	Yes	
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
1st Routine visit.	5/23	✓	
2nd Routine visit	9/23	✓	
3rd Routine visit	1/2024	✓	

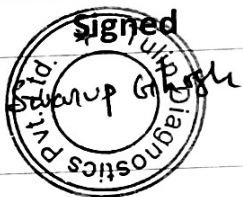
Comments:

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

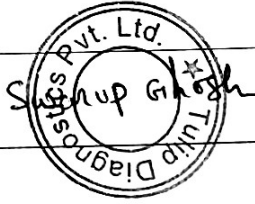
Manufacturer: Tulip Diagnostics (P) Ltd.

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