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a PerkinElmer company

CRV U85195BA1988PT0005717

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### Coralyzer Series Fully Automatic Biochemistry Analyzer, Inspection/calibration Report

Test QC refer to: <<Coralyzer Series Fully Automatic Analyser>> Registered Standard Model: Cralyzer Smart, S/N: AES2KOKH12171F

2	Inspection Item		Criterion of QC test		Result	Conclusion
		CRITERIA OF QC TEST			-	
		a) Analytical method may analyse 40 pos at the same time.			ОК	
					OK	
		b) Programming item				
		Automatic priority inspect of emergency sample.     d) Calibration linearity/non-linearity multi point calibration.			OK	
					OK	
		e) QC at may operate r	nost of QC at same item.		OK	PASS
	Software functions	g Storage			OK	
	DOMMARC MINOUTS	h) Printer multiple repo	ort formats available, user can se	If edit report formats.	OK	10000
		i) STAT			OK	
		i) Sample dilute/reches	4		OK	
		k) Sample /reagent pro			ОК	
		The state of the s	toe aquita craeca.		OK	
		I) Mixing function.			2000000	
			ry, quality control chart, the whole	e process	OK	
		n) Crash gard function	f		OK	
5	Dark Aba	Absorbance >= 3,400 /	4		5.8	OK
	Linearity range of	The maximum absorba	ince should be not less than 3.80	DOA within the	340nm: 5.1	OK
	absorbance.	relative range of ± 5%			505nm: 4.8	OK
	I Charles a	Less than ± 0.040A at 1.00A				OK
	Accuracy of absorbance	Less than ± 0.060A at 1500A			0.027	OK
		Less than ± 0.020A within 0.500A			0.048	OK
	Accuracy of	Absorberge absorbed	and he has shown a confidence		340nm: 0.003A	OK
	absorbance	Absorbance change st	rould be less than 0.005A/min		505nm: 0.002A	OK
	Reproducibility of absorbance	cofficient of variation of	v ≦ 3%		2.73%	OK
	Temperature of	accuracy less than the	n ± 0.1° C		37°C	OK
	reaction cuvette 37	Fluctuate of temperatu	re less than ± 0.1°C		0.005°C	OK
	Teperature of reagent storage		ndition, reagent storage should b	e 2-8°C	6.0°C	OK
	Carryover	0.05% Sample carryov	er less than 0.05%		PASS	
_	Carryover	Items	Concentration	CV		
	Accuracy of	UREA	106	≤ 3%	1.30%	OK
0	paramoter	GLUD	237	≦ 3%	1.20%	CK
		SGOT	38	≤ 3%	2.70%	OK
1	Apperance	a) Whole appearance of the surface should not have obvious mechanical abrasion, corrosion and surface coating spalling.     b) All connections are stable and fixed wall.     c) Moving perts running smooth and keypad works well.			PASS	
2	Protect ground connect	The impedance between ground outlet from power supply net and ground protected touchable metal should not more than 0.1 \( \Data \)			PASS	
3	Power grid, power supply, circuit		he sine 230V alternating voltage rakdown or occur electric arcing	test, continue	PASS	

Inspection/Calibration date: 08.09.21

Check: Ramesh S

re-check Ramesh S

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## 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 -Coralyzer 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.		<b></b> ✓Yes □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

### 2) Environment Condition

Has the Instrument been adequately acclimatized since transport or storage?

YES: ☐ NO: ☐

<b>Operating Parameters</b>	Specified Range	Conditions Met
Ambient Temperature	10 to 30 degrees	YES: ☑ NO: □
Maximum Relative Humidity	30% to 80 %	YES: ☑ NO: □
Supply Voltage & Frequency	220-230V, 50 Hz ac	YES: ☑ NO: □

### 3) <u>Instrument Delivery and Documentation</u>

Inpack the Instrument carefully.	Are any items missing	g against the Packing List?
		NO: ☑
YES: □		
yes, state the missing Items:		
there any damage to the Instru	ument or Accessories?	
YES:		NO: ☑
yes: Description of Damage:		
Corrective Action:		
Manufacturing informed:	YES:	NO: □
all Standard Documentation Ir	ncluded?	
perating Manual:	Present: ☑	Missing:
Varranty Card:	Present: ☑	Missing: □
all additional documentation	Included:	
	Present: ☑	Missing: 🗆
nstallation Qualification: YES		
Operational Qualification: YES		
40.		
Performance Qualification: YES		

Tulip Diagnostics (P) Ltd	Tulip	Diagnostics	(P)	Ltd
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### 4) Instrument Safety

### Manufacturer Safety Recommendations:

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

### 5) Assembly and Installation

Assembled and installed By:	User:		Specialized Engineer: YES	
Installation Procedure :		Yes ☑	N/A	
Unpack and retain Packaging -				
Verifying the site before connecting to power	r supply-			
Checking the instrument before performing t	he Test-			

### 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		3

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	6/100/2
Deviations Approved By:		Date:	
IQ Approved By:	RAMESH S	Date: 08.09.21	S. Diginglo

# 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			08.09.21	1 ( )-10
UPS Supply				2. Vo81

### 2) Pre-Run Checks

### Biochemistry Analyzer (Coralyzer Smart)

Pre run check	OK	N/A
	$\square$	
Printer connection	<u> </u>	
No of cuvettes in reaction tray		
Hardware setting	<b>V</b>	
Reaction cuvette Temp	M	
Filter ADC		

### 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	$\square$	
Reagent/Mixer Arm	Movement	$\square$	
Reagent/ Sample tray	Movement	$\square$	
Wash Arm	Movement	$\square$	
Water/Waste Pump	Suction / Noise level	✓	

### 4) Training

Trained Operators	Read Operator Manual	Read SOP	Practical Training	Authorizing Signature
G.RAJA	YES	YES	YES	2
AMBIKA	YES	YES	YES	Sit

5)	Summary	Report

Instrument	Name: Cora	lyzer Smart.
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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.

Tulip Diagnostics (P) Ltd.

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:

### Performance Qualification For ( Coralyzer Smart )

### Contents

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

### 1) Performance Check

### Bio-chemestry Analyzer ( Coralyzer Smart )

Functional Test	Acceptance Criteria	Pass	Fail
Instrument power ON	Login the software and shows the main menu as seen below:  **GROUND SECRETARY SECRETAR	PASS	
Reaction Tray	Movement / Positioning	✓	
Reagent / Sample tray	Movement /Positioning	✓	
Wash Arm	Movement		
Reagent /Mixer Arm	Movement		
Test Repeatability.	EP / KIN and FXT , minimum repeats of 5 each	$\square$	

### 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	

### 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			08.09.21	(1) 92
UPS Supply	$\square$			2:158.01

### 4) Summary Report

nstrument Name: Coralyzer Smart	6	
r. No.:AES2K0KH12171F		
Manufacturer: Tulip Diagnostics (P	Ltd.	
Assessment of complete Performan	nce Qualification:	
lo Deviations:	Deviations:	
Deviation	Impact on Operation	Justification for Acceptance
IL		
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.

RAMESH S	Date:	08.09.21
	Date:	
RAMESH S	Date:	08.09.21
		Date:

Comments:

5. 508/09/27