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

;-	Inspection Item		1 ዕ ፡ ዕ 3 · 2 ፡ 2 ነ ₁ Due Date:- 1 ዕ Criterion of QC test		Result	Conclusion
		CRITERIA OF QC TEST				
		a) Analytical method may analyse 40 pos at the same time.			ок	
		b) Programming item			ОК	
		- 17 T	nspect of emergency sample.		ОК	
		d) Calibration linearity/	non-linearity multi-neigh seliber	****	64,0400	
		d) Calibration linearity/non-linearity multi point calibration. e) QC at may operate most of QC at same item. g)Storage			OK	-
	Cathara ta				OK	1
ľ	Software functions	F-8			ОК	PASS
		in) Printer multiple repo	ort formats available, user can s	elf edit report formats.	ОК	
		i) STAT			OK	
		j) Sample rerun/reched			ОК	
		k) Sample /reagent pro	be liquid check.		ок	
		I) Mixing function.			ок	
		m)Results storage,que	ry,quality control chart,the who	e process ·	ок	
		n) Crash gard function		- E	ок	
2	Dark Abs	Absorbance >= 3.400			5.8	ок
3	Linearity range of	The maximum absorba	ance should be not less than 3.7	00A within the	340nm: 5.1	OK
	absorbance.	relative range of ± 5%			505nm: 4.8	OK
4	Accuracy of	Less than ± 0.040A at 1.00A		0.012	ок	
4	absorbance	Less than ± 0.060A at 1500A			0.027	ОК
	Accuse ou of	Less than ± 0.020A wi	than ± 0.020A within 0.500A		0.048	ОК
5	Accuracy of absorbance	Absorbance change sl	nould be less than 0.005A/min		340nm: 0.003A	ОК
	Reproducibility of				505nm: 0.002A	ОК
6	absorbance	cofficient of variation of	v ≦ 3%		2.73%	ок
7	Temperature of	Accuracy less than the	an ± 0.1° C			
′	reaction cuvette 37	Fluctuate of temperatu	re less than ± 0.1°C		37'C	ок
8	Teperature of				0.005°C	ОК
	reagent storage		ndition, reagent storage should I	e 2-8°C	6.0'C	ок
9	Carryover	Sample carryover less	s than 0.05%		DAGO	OIC
	A	Items	Concentration	CV	PASS	
10	Accuracy of parameter	UREA GLUC	76.3-109.9	≦ 3%	1.30%	OV
	parameter	SGOT	81.0-116.6 55-87	≦ 3%	1.20%	OK OK
				≦ 3%	2.70%	OK
		a) whole appearance corrosion and surface	of the surface should not have o	bvious mechanical abrasion		- OK
11	Apperance	Transmit and buildoc	coating spaining.	,		
		b) All connections are stable and fixed well. c) Moving parts running smooth and keypad works well		PASS		
						1
12	Protect ground	The impedance betwe	en ground outlet from power sur	ply net and ground		
	connect	The impedance between ground outlet from power supply net and ground protected touchable metal should not more than 0.1 Ω		PASS		
12	Power grid, power	Basic insulation:50Hz	the sine 230V alternating voltage	1.00		
13	supply, circuit	brakdown or occur ele	ctric arcing.	e test, should not apper	PAGG	
	-				PASS	1

Inspection/Calibration date: 11.03.2024

Check: Swarup & Losh

re-check: S

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		⊵Yes
		of measuring absorbance of contents in		□No
		microcuvettes.		
2	Typical working volume For cuvettes	300 micro ltr		Yes
3	Filter range	340 to 700 nm		yes
4	Communication	USB- Interface		
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
76 T	10 to 30 degrees	YES: ☑ NO: ☐
Maximum Kelative	30% to 80 %	YES: ☑ NO: □
Humidity Supply Voltage & Frequency	220-230V, 50 Hz ac	YES: ⊞ NO: □

3. Instrument Delivery and Documentation:

Unpack the Instrument carefully. A	Are any items missing agains	t the Packing List?				
YES: □		NO: 🖳				
If yes, state the missing Items:						
Is there any damage to the Instrument or Accessories?						
YES: □ If yes: Description of Damage:		NO: ☑				
Manufacturing informed:	YES: □	NO: □				
Is all Standard Documentation Inc	cluded?					
Operating Manual:	Present: ☑	Missing: \square				
Warranty Card:	Present: 🖳	Missing: \square				
Is all additional documentation I	ncluded:					
	Present: ☑	Missing: \square				
Installation Qualification:						
Operational Qualification:						
Performance Qualification:						

3. Instrument Delivery and Documentation:

Unpack the Instrument carefully.	Are any items missing ag	gainst the Packing List?		
YES: □		NO: 🖳		
If yes, state the missing Items:				
Is there any damage to the Instru	ment or Accessories?			
YES: □ If yes: Description of Damage:		NO: 🖳		
Corrective Action:				
Manufacturing informed:		NO: □		
Is all Standard Documentation Included?				
Operating Manual:	Present: 🖳	Missing: □		
Warranty Card:	Present: 🖳	Missing: \Box		
Is all additional documentation Ir	ncluded:			
	Present: ☑	Missing: \square		
Installation Qualification:				
Operational Qualification:				
Performance Qualification:				

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 YES: ☑ NO: ☐ Easily accessible
Beware of moving parts during working YES: № NO: □
Do not use Heat material that could cause fire or other YES: $lacktriangle$ NO: $lacktriangle$ Hazards
Read Operator Manual before use YES: ☑ NO: ☐

5. Assembly and Installation:

Assembled and installed By: Swanup Ghasuser:	Specialized Engineer: Yes	N/A
Installation Procedure:		
Unpack and retain Packaging -		
Verifying the site before connecting to power supply- Checking the instrument before performing the Test-		
Checking the materials		

o. <u>Summary Report :</u>			
Instrument Name: Co	ralyzer Smart		
Sr. No.: AES2K2KH09	087Y		
Manufacturer: Tulip D	Diagnostics (P) Ltd.		
Assessment of compl	ete Installation Quali	fication:	
No Devia	ations: 🖳 Deviati	ons:	
Deviation	Impact on	Operation	Justification for
Della			Acceptance
this Instrumen instrument ha now be releas	nt is installed successing is passed the Installated ed for use.	fully as per the set	
IQ Completed By:	Swarup Giho8h	Date: 10:03:202	3 stanopation.
Deviations Approved By:		Date:	
IQ Approved By:	Tow Day	Date: 15.63.212	3

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	달		10.03.2023	Swarup orhogh
UPS Supply	¥			

2. Pre-Run Checks:

Biochemistry Analyzer (Coralyzer Smart)

		N/A
Pre run check	OK	
Printer connection	<u> </u>	
No of cuvettes in reaction	₩	<u> </u>
tray		
Hardware setting	—————————————————————————————————————	П
Reaction cuvette Temp	<u> </u>	
Filter ADC		

3. Functional Tests: Coralyzer Smart:

Functional Test			r-::
Instrument	Acceptance Criteria Instrument initializes after	Pass	Fail
power ON	clicking on Device Reset & shows		
	in the screen below:		
	Ten finance Services	yes	
Reaction Tray	Movement	Image: Control of the	
Reagent/Mixer Arm	Movement	☐ ☐ ☐ ·	
Reagent/	Movement	团	
Sample tray			
Wash Arm	Movement		
Water/Waste	Suction / Noise level		
Pump			

4.Training:

Trained Operators	Read Operator Manual	Read SOP	Practical Training	Authorizing Signature
	,			Seyran
Solman Man Sal	~			Seynan Mandal.

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)

io-chemestry An	alyzer (Coralyzer Smart)			Fail
	Acceptance Criteria	Pass		ran
unctional Test	Login the software and shows the			1
CONTRACTOR DESCRIPTION	Logili the solena.			
ower ON	main menu as seen below:			\
	THE Seagest Contents Of Marketing System States Service Arrange Seages Review Templates Service Arrange Seages Review Templates Service Arrange Seages Review Seages Re	yes		
	. / Desitioning		당	
Reaction Tray	Movement / Positioning		団	
Reagent /	Movement /Positioning			П
Sample tray			区	<u>L</u>
Wash Arm	Movement		团	
Reagent /Mixer	Movement			
Arm			团	Ц
Test	EP / KIN and FXT , minimum			
Repeatability.	repeats of 5 each			

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 Don
Routine Maintenance	5/23	~	
1st Routine visit.	100	~	
2nd Routine visit	9/23		
. Doubine visit	1/2024		
229 Booting Algert	2 221		

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	区		10.03.2023	Being Charles
UPS Supply	Image: Control of the			Solicolo

4) Summary Report:

Instrument Name: Coralyzer Smart.

Sr. No : **AES2K2KH09087Y**

Manufacturer: Tulip Diagnostics (P) Ltd.

Assessment of complete Performance Qualification:

No Deviations:	Y	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:	Swanup Ghosh	Date: 10.03.2013	Stand Chest
Deviations Approved By:		Date:	Coeid g
PQ Approved By:	Joy Das	Date: 18.03.2023	

	Acceptance
Successful completion of the preceding	
Inctain Completion of H	
""strument is operation the preceding	

Instrument is operating satisfactorily following and checks:

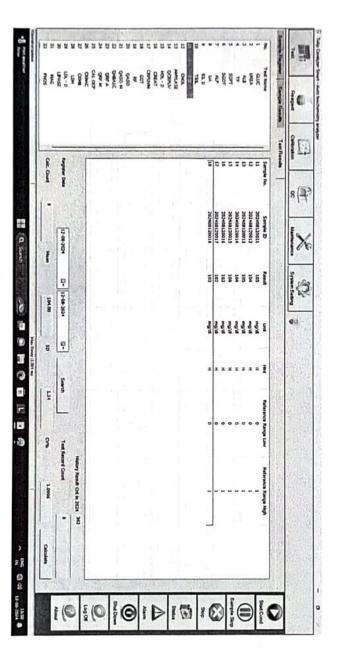
released to passed the preceding activities and checks:

TULIP DIAGNOSTICS (P) LTD.

a revvity company

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Flat No 9A, 9th Floor, JA, Auckland Place.
Kolkata . 700 0 7, INDIA
Tel. (003) 22837919
E-mait hulip kolkata@tulipgroup.com





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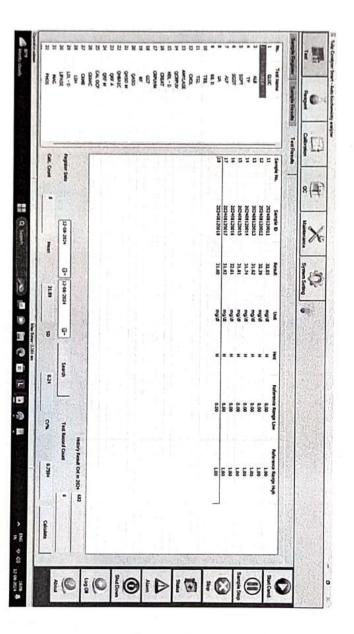


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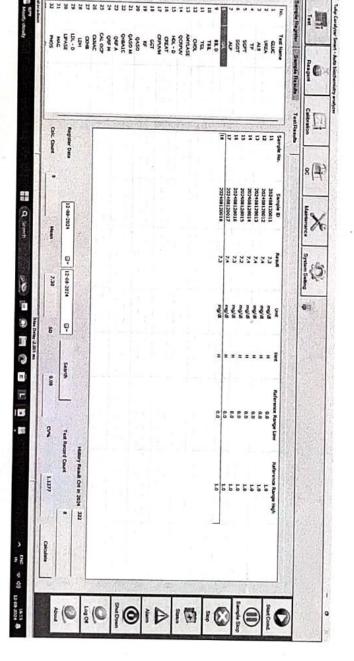
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