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# TULIP DIAGNOSTICS (P) LTD.

a PerkinElmer company

CIN: U85195GA1988PTC005717

To  
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103/49, South Fort street,  
Vriddhachalam 606001

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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: Coralzyer Smart, S/N: AES2KOKH12171F																
Meter used for calibration: Multimeter, Cal Date:- 08.09.21, Cal Due Date: 07.03.2022																
:-	Inspection Item	Criterion of QC test	Result	Conclusion												
1	Software functions	<b>CRITERIA OF QC TEST</b> a) Analytical method may analyse 40 pos at the same time. b) Programming item c) Automatic priority inspect of emergency sample. d) Calibration linearity/non-linearity multi point calibration. e) QC at may operate most of QC at same item. g)Storage h) Printer multiple report formats available, user can self edit report formats. i) STAT j) Sample dilute/recheck. k) Sample /reagent probe liquid check. l) Mixing function. m)Results storage,query,quality control chart,the whole process n) Crash gard function.	OK OK OK OK OK OK OK OK OK OK OK OK	PASS												
2	Dark Abs	Absorbance $\geq 3.400$ A	5.8	OK												
3	Linearity range of absorbance.	The maximum absorbance should be not less than 3.800A within the relative range of $\pm 5\%$	340nm: 5.1 505nm: 4.8	OK OK												
4	Accuracy of absorbance	Less than $\pm 0.040$ A at 1.00A Less than $\pm 0.060$ A at 1500A Less than $\pm 0.020$ A within 0.500A	0.012 0.027 0.048	OK OK OK												
5	Accuracy of absorbance	Absorbance change should be less than 0.005A/min	340nm: 0.003A 505nm: 0.002A	OK OK												
6	Reproducibility of absorbance	coefficient of variation $cv \leq 3\%$	2.73%	OK												
7	Temperature of reaction cuvette 37	accuracy less than than $\pm 0.1^\circ$ C Fluctuate of temperature less than $\pm 0.1^\circ$ C	37°C 0.005°C	OK OK												
8	Teperature of reagent storage	Under normal work condition, reagent storage should be 2-8°C	6.0°C	OK												
9	Carryover	0.05% Sample carryover less than 0.05%	PASS													
10	Accuracy of parameter	<table border="1"> <thead> <tr> <th>Items</th> <th>Concentration</th> <th>CV</th> </tr> </thead> <tbody> <tr> <td>UREA</td> <td>106</td> <td>3%</td> </tr> <tr> <td>GLUC</td> <td>237</td> <td>3%</td> </tr> <tr> <td>SGOT</td> <td>38</td> <td>3%</td> </tr> </tbody> </table>	Items	Concentration	CV	UREA	106	3%	GLUC	237	3%	SGOT	38	3%	1.30% 1.20% 2.70%	OK OK OK
Items	Concentration	CV														
UREA	106	3%														
GLUC	237	3%														
SGOT	38	3%														
11	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 well. c) Moving parts running smooth and keypad works well	PASS													
12	Protect ground connect	The impedance between ground outlet from power supply net and ground protected touchable metal should not more than 0.1 $\Omega$	PASS													
13	Power grid, power supply, circuit	Basic insulation:50Hz the sine 230V alternating voltage test, continue 2s. should not apper brakdown or occur electric arcing	PASS													
Inspection/Calibration date: 08.09.21      Check: Ramesh S      re-check:Ramesh 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 -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:

<b>Operating Parameters</b>	<b>Specified Range</b>	<b>Conditions Met</b>
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"/>

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**Comments:**



5) Assembly and Installation

Assembled and installed By:	User:	Specialized Engineer: YES	
Installation Procedure :		Yes	N/A
		<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.

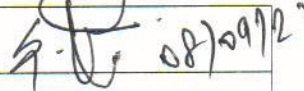
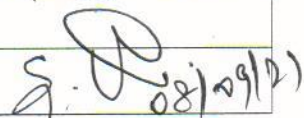
Manufacturer: Tulip Diagnostics (P) Ltd.

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	 08/09/21
Deviations Approved By:		Date:	
IQ Approved By:	RAMESH S	Date: 08.09.21	 08/09/21

Comments:

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

**Contents**

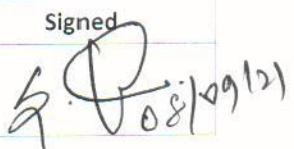
- 1) Safety Tests
- 2) Pre-Run Checks
- 3) Functional Tests
- 4) Training
- 5) Summary Report

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"/>		

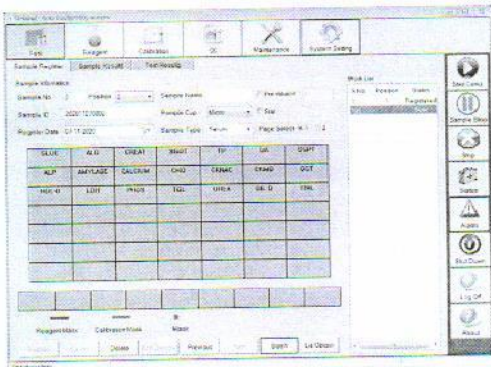
Comments:

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"/>

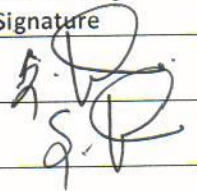
Comments:

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:

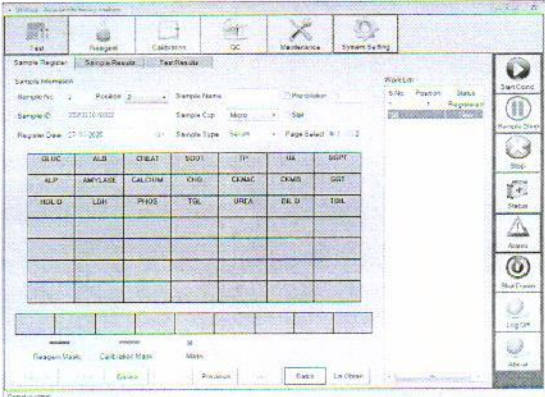
**Performance Qualification  
For  
( Coralyzer Smart )**

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.

<b>Routine Maintenance</b>	<b>Date</b>	<b>Done</b>	<b>Not Done</b>
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