



Chennai Office:

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CALIBRATION CERTIFICATE

Instrument : 3000 Evolution

Serial No: 38881

ELECTRONIC CONTROL

PASSED

FAILED

SAMPLE CONTROL

Cuvette Kinetic Test

PASSED

FAILED

Flow-cell Kinetic Test

PASSED

FAILED

Cuvette EP Test

PASSED

FAILED

Flow-cell EP Test

PASSED

FAILED

Cuvette-Fixed Time Test

PASSED

FAILED

Flow-Fixes Time Test

PASSED

FAILED

SOLUTION CONTROL

Flow Cell Checking

PASSED

FAILED

Cuvette Linearity 340 nm

PASSED

FAILED

Flow Cell Linearity 340nm

PASSED

FAILED

Cuvette MSD 340 nm

PASSED

FAILED

Flow Cell MSD 340

PASSED

FAILED

Incubator Temperature: 37°C

PASSED

FAILED

Instrument has

PASSED

FAILED

the QC calibration protocol and it is ready for use.

Tested by: RAMESH S

Date: 23 / 09 / 2021

Calibration Due Date: 22 / 09 / 2022

Note: Necessary QC report / control value sheet to be attached.

S. P.
23/09/21

24/09/2021 - 10:31
3000 Evolution

[7]:65535,65535
[6]:35482,34406
[5]:28035,27991
[4]:22386,22589
[3]:17155,17401
[2]:12068,12285
[1]: 1992, 1992
[0]: 0, 0

SLV : 1.07
SWR : 1.27
MSG : 1.06
HDWR: 1
EEP : 3KEV_1.16

q = 0.879509
m = 0.049505
CODelay: 003
Int OK : 012
IntChk : 002
Amax : 00450
OnCond : 03750
Timeout: 60000
NMet: 120
NLet: 04
MotV: 0200 ms
MotL: 1000 ms
Lamp: off=060 s
Lamp: on =090 s

Ta : 37.4 Fan: 30 C
Tw : 37.0 C
PMP : 9894
CAL : 10376

Filter #8: 209
Filter #7: 17170
Filter #6: 7942
Filter #5: 11694
Filter #4: 6944
Filter #3: 13289
Filter #2: 9021
Filter #1: 7074

EEP : 3KEV_1.16 HDWR: 1

EVOLUTION 3000

CALIBRATION REPORT OF TEST PARAMETERS

DATE	PARAMETER	STANDARD CONCENTRATION mg/dl	FACTOR
24/09/2021	Glucose	95	276
24/09/2021	Urea	48.8	153.6
24/09/2021	Creatinine	2.1	32.4
24/09/2021	Total Protein	5.7	17.9
24/09/2021	Albumin	3.5	7.5
24/09/2021	Uric acid	6.1	30.9
24/09/2021	Cholesterol	189	486
24/09/2021	Triglyceride	201	610

24/09/2021


24/09/2021

Dr.S.BOOPESH DCP.,

LAB DIRECTOR

MUKILANS LAB
No. 167/56, 1st Main Road,
Bannu Nagar, Ambattur,
Chennai-600 053.

**Installation Qualification
For
Semi Auto Biochemistry Analyzer
(3000 Evolution)**

Contents

Instrument Identification

Environment Condition

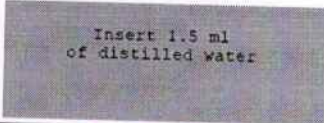
Instrument Delivery and Documentation

Instrument Safety

Assembly and Installation

Summary Report

Instrument Identification**Biochemistry Analyzer (3000 Evolution)**

Sr. No.	Specification	As per design qualification	Specification received	Match (Yes/No)
1	General Feature	Semi auto chemistry analyzer, single channel photometer capable of measuring absorbance of contents in micro-cuvette & flowcell. 	Yes	Yes
2	Typical working volume For cuvettes & flow cell.	500 micro ltr	Yes	Yes
3	Filter range	340 to 630 nm	Yes	Yes
4	Communication port	Serial port for interface		Yes
5	Printer	Inbuilt Thermal Printer.	Yes	Yes
6	Power requirement	220-230V, 50 Hz ac, 150 VA	Yes	Yes
7	Grounding	< 5 volt ac	Yes	Yes

Comments: The features of this equipment and the above specifications are Good.

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:✓ NO:
Maximum Relative Humidity	30% to 80 %	YES:✓ NO:
Supply Voltage & Frequency	220-230V, 50 Hz ac	YES:✓ NO:

Comments: The environmental conditions of the equipment is Good

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: All the documentations of the equipment is available.

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. Ensure correct power supply and all power switches easily accessible.	YES: ✓ YES: ✓	NO: NO:
Do not use Heat material that could cause fire or other Hazards.	YES: ✓	NO:
Read Operator Manual before use.	YES: ✓	NO:

Comments: The safety measures for this equipment is well maintained.

Assembly and Installation

Assembled and installed By:	User:	Specialized Engineer:	
Installation Procedure:		OK	N/A
Unpack and retain Packaging		OK	
Verifying the site before connecting to UPS power supply		OK	
Checking the instrument before performing the Test		OK	

Comments: The assembly & installation have been done by the Specialized Engineer.

Summary Report

Instrument Name: 3000 Evolution.

Sr. No: 38881

Manufacturer: Tulip Diagnostics (P) Ltd.

Assessment of complete Installation Qualification:

No Deviations:Nil

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:	Ramesh	Date:	23/09/2021
Deviations Approved By:	-	Date:	-
IQ Approved By:	Ramesh	Date:	23/09/2021

Comments: Overall the equipment installation is Good.

S. P.
23/09/21

Operation Qualification
For
Semi Auto Biochemistry Analyzer
(3000 Evolution)

Contents

Safety Tests

Pre-Run Checks

Functional Tests

Training

Summary Report

Safety Tests

This instrument confirms to the following standards and is supplied fully tested by the Manufacturer.

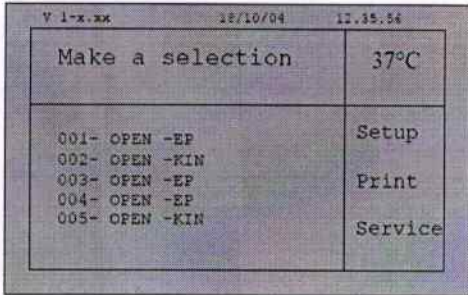
Electrical equipment for measurement, control and laboratory use.
Instrument requirement for laboratory for Blood testing.

The following electrical safety tests should be carried out by a competent person after Installation.

Safety Tests	Pass	Fail	Date	Signed
Earthing	✓		23/09/2021	S.P.
UPS Supply	✓		23/09/2021	

Comments: The Earthing and UPS supply for this instrument is Good

Functional Tests**Semi auto analyzer (3000 Evolution)**

Functional Test	Acceptance Criteria	Pass	Fail
Instrument power ON	<p>Instrument initializes and prompts for 1.5 ml distilled water.</p> <p>Temp window stops blinking as incubation temp is attained. & shows in the screen below.</p>  <p>Printer self test.(By pressing paper feed key & power ON the instrument)</p>	✓	
Self Test	Filter wheel movement.	✓	

Comments: The equipments functional test are Good

Training

Trained Operators	Read Operator Manual	Read SOP	Practical Training	Authorizing Signature
Dr.Boopesh	✓	✓	✓	
Mrs.Hemalatha	✓	✓	✓	
Ms.Priyanka	✓	✓	✓	

Comments: All the above staffs are trained well with this equipment

Summary Report

Instrument Name: 3000 Evolution.

Sr. No.:38881

Manufacturer:Tulip Diagnostics (P) Ltd.

Assessment of complete Operational Qualification:

No Deviations: Nil

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.

OQ Completed By:	Ramesh	Date:	23/09/2021
Deviations Approved By:	-	Date:	-
OQ Approved By:	Ramesh	Date:	23/09/2021

Comments: All the operations in the equipment is Good

S.P.
23/09/21

**Performance Qualification
For
(3000 Evolution)**

Ltd.

Contents

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

1) Performance Check

Bio-chemistry Analyzer (Coralizer Mini)

Functional Test	Acceptance Criteria	Pass	Fail																					
Instrument power ON	<div data-bbox="395 600 911 786" style="border: 1px solid black; padding: 5px; text-align: center;"> Insert 1.5 ml of distilled water </div> <p data-bbox="384 831 895 887">Once self Test is passed, shows the main menu as seen below:</p> <div data-bbox="395 898 911 1223" style="border: 1px solid black; padding: 5px;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="font-size: small;">V 1-x.xx</td> <td style="font-size: small;">18/10/09</td> <td style="font-size: small;">12.35.56</td> </tr> <tr> <td style="text-align: center;">Make a selection</td> <td style="text-align: center;">37°C</td> <td></td> </tr> <tr> <td>001- OPEN -EP</td> <td>Setup</td> <td></td> </tr> <tr> <td>002- OPEN -KIN</td> <td>Print</td> <td></td> </tr> <tr> <td>003- OPEN -EP</td> <td>Service</td> <td></td> </tr> <tr> <td>004- OPEN -EP</td> <td></td> <td></td> </tr> <tr> <td>005- OPEN -KIN</td> <td></td> <td></td> </tr> </table> </div>	V 1-x.xx	18/10/09	12.35.56	Make a selection	37°C		001- OPEN -EP	Setup		002- OPEN -KIN	Print		003- OPEN -EP	Service		004- OPEN -EP			005- OPEN -KIN			Pass	
V 1-x.xx	18/10/09	12.35.56																						
Make a selection	37°C																							
001- OPEN -EP	Setup																							
002- OPEN -KIN	Print																							
003- OPEN -EP	Service																							
004- OPEN -EP																								
005- OPEN -KIN																								
Incubation Temperature	37°C ± 0.5	Pass																						

Comments: The performance of this instrument is Good.

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
Glucose	23/09/2021	Done	
creatinine	23/09/2021	Done	
Urea	23/09/2021	Done	
Uric Acid	23/09/2021	Done	
Cholesterol	23/09/2021	Done	
Triglycerides	23/09/2021	Done	
Total billirubin	23/09/2021	Done	
Albumin	23/09/2021	Done	

Comments: The frequency of the routine maintenance is Good


Ltd.

Tulip Diagnostics (P)

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	✓		23/09/2021	
UPS Supply	✓		23/09/2021	

Ltd.

Tulip Diagnostics (P)

4) Summary Report

Instrument Name: 3000 Evolution.

Sr. No.:38881

Manufacturer: Tulip Diagnostics (P) Ltd.

Assessment of complete Performance Qualification is Good

No Deviations: nil


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:	RAMESH	Date:	23/09/2021
Deviations Approved By:		Date:	
PQ Approved By:	RAMESH	Date:	23/09/2021

Comments: Overall the performance the equipment is Good

 23/09/21

Pre-Run Checks**Biochemistry Analyzer (3000 Evolution)**

Pre run check	OK	N/A
Printer connection	✓	
Flowcell / cuvettes placement in reading chamber	✓	
Quick Diagnostics	✓	
Reaction cuvette Temp	✓	
Filter ADC (Gains)	✓	

Comments: All the above categories are Good