RANDOX

CERTIFICATE OF INSTALLATION

INSTRUMENT NAME: **Rx Daytona+**

SERIAL NUMBER: 7241-0189

CUSTOMER NAME: Arpan Diagnostic Centre

ADDRESS: 150 ft Ring Road , Indira Circle , Nr Raj Bank , Rajkot : 360005.

The undersigned performer certifies that the **Installation Qualification** protocol has been successfully completed for the instrument stated above.

ENGINEER

Signature 

Name: Jinesh Vadera
Designation: Customer Support Engineer
Company: Randox Laboratories India Pvt. Limited

LABORATORY INCHARGE:-

Signature

Name:

Designation:

Company

Randox Laboratories (India) Private Limited
Regd Office : Plot No.191 - 195 & 246 - 250, KIADB Industrial Area,
Bommasandra-Jigani Link Road, Bengaluru, India - 560 105
T +91 80 2802 5000 Fax: +91 80 2802 5012
www.randox.com CIN : U24230KA2004PTC070372

INSTALLATION REPORT

INSTRUMENT:	**Rx Daytona+**
INSTRUMENT SERIAL NUMBER :	7241-0189
TELEPHONE:	9825082454/ 9428344158
INSTALLATION DATE:	16th December 2020

INSATALLATION COMPLETION STATEMENT

1.	INSTALLATION PROCEDURE	**Done**	**OK**
2.	INSTALLATION CHECK	**Done**	**OK**
3.	PERFORMANCE CHECK	**Done**	**OK**

FOR RANDOX LABORATORIES INDIA PVT. LTD.

The **Rx Daytona+** bearing Serial Number – **7241-0189**
has been successfully installed at **Arpan Diagnostic Centre.**

Accepted

Date: 16th December 2020

Name: Jinesh Vadera

Designation: Customer Support Engineer

Name of the customer	Make
Arpan Diagnostic Centre	**Randox**

Product Name	Serial Number
Rx Daytona+	**7241-0189**

This is to certify that this machine has been inspected and calibrated and details given below.

Sr. No	Test Parameters	Measured / Calibrated	Remarks
1.	Input Voltage	230 V AC	O.K
2.	Power Consumption	900 watts	O.K
3.	Input frequency	50 Hz	O.K
4.	Operating Temperature	15 – 30 Deg Celsius	O.K

Name of Engineer
Jinesh Vadera

Signature


Training Report

Customer : Arpan Diagnostic Centre	**Product Description** : Rx Daytona+ **Instrument Serial #** : 7241-0189 **Installed on :** 16th December 2020	**Date** : 16th December 2020 **Training Period** : 21st to 23rd December 2020

Instrument : Rx Daytona+	**Action taken** : Rx Daytona+ installed properly with all accessories and validation of instrument done.
Training provided by : Jinesh Vadera Training provided to : 1. Riddhi Pipaliya. 2. Shital Dobariya.	**Check list** : 1. Explained all major hardware components and their functions 2. Explained in detail the different software aspects and their use 3. Consumable usage and replacement 4. interpretation of calibration and Control results and calibration frequencies 5. Daily, Weekly & Monthly procedures **Follow up** : Adequate follow up done **Chemistries standardized with good QC Results :** Glucose, ALT,AST,UREA,Creatinine,Glucose, ALP, Total Protein, TBIL,DBIL, ALB, TG,UA,DHDL,CRP.
Customer Signature	**Trainee Signature :** 

Rx Daytona+

INSTALLATION QUALIFICATION

FOR

Arpan Diagnostic Centre

RANDOX LABORATORIES INDIA PVT. LTD.

INSTALLATION QUALIFICATION

Instructions:

1. This document is to be completed at the time the system is unpacked and set up for operation

2. An authorized Randox representative will check out each module and verify the alignment as outlined in service manual

3. All deviations from normal specification to include any problems with installation will be noted in the comments section

4.

INSTALLATION QUALIFICATION

This Installation Qualification Protocol will be performed on the instrumentation located at Arpan Diagnostic Centre. .
This protocol will define the documentation that will be used to evaluate the instrument documented in accordance with the manufacturer's specifications and intended use.
Successful completion of this protocol will verify that the instrumentation identified has been installed in accordance with intended usage.

Installation checks will be performed to verify that the instrumentation has been installed with proper connections and utilities.

Trained knowledgeable personnel will perform qualification studies as mentioned in Randox Service Manual.

Any exceptional conditions encountered during the Qualification studies will be identified for review.
Exceptional conditions will be investigated and appropriate course of action will be determined.

INSTALLATION QUALIFICATION

System Certification

Study data has been determined that the system described in this document either meets all criterial outlines in this Installation Qualification, or exceptional conditions have been identified and documentation included.
Exceptional conditions, if any have been addressed.
The system is ready for specified usage.

Protocol performed by: Randox Laboratories Representative

Name: Jinesh Vadera

Title: Customer Support Engineer

Company: Randox Laboratories India (P) Limited

Customer authorization:

Name:

Title:

Jinesh Vadera
Engineer Name & Signature
Date : 18-01-2021

Customer Signature
Date :

Rx Daytona+

Clinical Chemistry Analyzer

Installation Qualification

Reference: Service Manual

1. Unpacking the Analytical Unit
2. Checking inventory
3. Placing the Analytical Unit
4. Detaching Analytical init protection plates
5. Checking & adjusting the surface level where Analytical unit is placed using level sensors
6. Connecting the peripherals to the Analytical unit like Waste containers, tubing's
7. Filling the System Water and Wash Solutions in the containers
8. Installing & interfacing the interface cable & PC to the Analytical Unit
9. Connecting the printer
10. Seating the circuit boards and checking connections
11. Performing Final Visual Inspection
12. Applying power to the Analytical Unit
13. Installing the software

Rx Daytona+

OPERATIONAL QUALIFICATION

FOR

Arpan Diagnostic Centre

RANDOX LABORATORIES INDIA (P) LIMITED

Rx Daytona+

Clinical Chemistry Analyzer

OPERATIONAL QUALIFICATION

Reference: Operator and Service manual

1. Verifying configuration and alignment
2. Priming and filling the system
3. Daily maintenance procedure
4. Weekly maintenance procedure
5. Performing System Check Procedure
6. Customer Training – Operation and Maintenance

SYSTEM CHECK PROCEDURE

SYSTEM CHECK	ACCEPTABLE RESULTS	OBTAINED RESULTS
Cuvette check	< 0.5 Abs for all cuvettes	0.18 – 0.29 for all cuvettes
Photometer check	< 0.5 Abs at all filters	0.25 – 0.29 at all filters
Incubator temperature check	37 Deg Centigrade with max 0.3 Deg variation	Within acceptable range
Reagent compartment cooling check	8 to 15 deg Centigrade	Within acceptable range
Sensor status check	Status On / Off	Ok for all sensors

The results obtained are as per specifications

Engineer signature

Customer signature

Rx Daytona+

PERFORMANCE QUALIFICATION

FOR

Arpan Diagnostic Centre

RANDOX LABORATORIES INDIA (P) LIMITED

Rx Daytona+

Clinical Chemistry Analyzer

PERFORMANCE QUALIFICATION

1. Calibrating Assays and running Controls

Chemistries: ALT,CREATININE,UREA,GLUCOSE,AST, ALB,TBIL,DBIL,ALP,TP , UA, DHDL, TG,CRP.

Calibrator CAL-2 (1320UN) , CAL-3 (1086UE)
Calibrator
Q. C. L-2 (1390UN)
Q. C. L-3 (1102UE)

Controls and Calibrators: CAL2 (1320UN) , CAL3 (1086UE) , L2 QC (1390UN) , L3 QC (1102UE)

The chemistry parameters were standardized & controls run for them.
The SD and CV are within acceptable range

Training Schedule

(Conduct of Training)

During the course of training the following training requirements have been covered

1. System hardware & Software review

2. System configuration and supply management

3. Sample processing & Test results

4. Calibration & Review

5. Quality Controls

6. Maintenance : Daily & Weekly

7. Diagnostics & Trouble shooting

PERFORMANCE QUALIFICATION

System Certification

Study data has been determined that the system described in this document either meets all criterial outlines in this Installation Qualification, or exceptional conditions have been identified and documentation included.
Exceptional conditions, if any have been addressed.
The system is ready for specified usage.

Protocol performed by: Randox Laboratories Representative

Name: Jinesh Vadera
Title: Customer Support Engineer

Company: Randox Laboratories India (P) Limited

Customer authorization:

Name:

Title:

Jinesh Vadera
Engineer Name & Signature
Date : 18-01-2021

Customer Signature
Date

RANDOX

Calibration Certificate – Rx Daytona+

Instrument	**Rx Daytona+ Clinical Chemistry Analyser**
Serial No	7201-0189
Account Name	Arpan Diagnostic Centre, Rajkot
Installation Date	16/12/2020
Calibration Date	16/07/2021
Next Calibration Due	16/01/2022

This is to certify that this analyser has been inspected and calibrated for following parameters:

Test Parameter	**Target Value**	**Obtained Value**
Input Voltage	230 -240 V AC	231 V AC
Cuvette Check	< 0.50 Abs for all cuvettes	< 0.18 Abs for all cuvettes
Photometer Gain Check	< 127 for all wavelengths	Between 1 to 104 for all wavelengths.
Gain Voltage for all wavelengths	> 8.5 V DC	Between 8.6 to 9.13 V DC
Absorbance for all wavelengths	50 - 150 Abs	65 - 105 Abs
Check Lamp voltage	< 8.3 V DC	8.3 V DC
Incubator Temperature	37º C ± 0.3 max	37.0º C
Reagent Tray Temperature	8- 15 º C	7.84º C
12V Lamp Supply	12 ± 0.3 volts	12.06 volts
5V Supply	5 ± 0.3 volts	5.04 volts
24V Supply	24 ± 0.3 volts	24.05 volts

The results obtained are as per specifications & tolerance ranges. The above calibration was done with an M/s. Mastech Digital Multimeter. (Model no. MAS830L). (Calibration certificate is enclosed herewith).

Thank You

Shyam Kale

Customer Support Engineer, Mumbai.

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RANDOX

Calibration Certificate – Rx Daytona+

Instrument	**Rx Daytona+ Clinical Chemistry Analyser**
Serial No	7201-0189
Account Name	Arpan Diagnostic Centre, Rajkot
Installation Date	16/12/2020
Calibration Date	02/02/2022
Next Calibration Due	02/08/2022

This is to certify that this analyser has been inspected and calibrated for following parameters:

Test Parameter	**Target Value**	**Obtained Value**
Input Voltage	230 -240 V AC	231 V AC
Cuvette Check	< 0.50 Abs for all cuvettes	< 0.18 Abs for all cuvettes
Photometer Gain Check	< 127 for all wavelengths	Between 1 to 104 for all wavelengths.
Gain Voltage for all wavelengths	> 8.5 V DC	Between 8.6 to 9.13 V DC
Absorbance for all wavelengths	50 - 150 Abs	65 - 105 Abs
Check Lamp voltage	< 8.3 V DC	8.3 V DC
Incubator Temperature	37º C ± 0.3 max	37.0º C
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Thank You

Shyam Kale

Customer Support Engineer, Mumbai.

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