

CERTIFICATE OF INSTALLATION

INSTRUMENT NAME: Rx Suzuka
SERIAL NUMBER: S1200800CS0026MA
CUSTOMER NAME: PGIMS, Rohtak
ADDRESS: Dept. Of Bio-Chemistry, Rohtak
Haryana - 124001

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

ENGINEER

Signature *Raju Vikal Yadav*

Name: RAJU VIKAL YADAV

Designation: CUSTOMER SUPPORT ENGINEER

Company: RANDOX LABORATORIES (I) PVT. LTD.

LABORATORY INCHARGE:-

Signature *Dr. Chaitanya Dolewal*

Name: Dr. Chaitanya Dolewal

Designation: Asstt. Prof.

Company: PGIMS, Rohtak

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 SUZUKA

INSTRUMENT SERIAL NUMBER : S1100800CS0068MA

TELEPHONE 9416974157

INSTALLATION DATE 01/10/2013

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 SUZUKA bearing Serial Number
S1200800CS0026MA

has been successfully installed at PGIMS,
ROHTAK

Date: 01/10/2013

Name: Raju Vikal Yadav

Designation: Customer Support Engineer

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Name of the customer	Make
PGIMS, ROHTAK	Randox

Product Name	Serial Number
RX SUZUKA	S1200800CS0026MA

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	6000 VA	O.K
3.	Input frequency	50 Hz	O.K
4.	Operating Temperature	15 – 30 Deg Celsius	O.K

Name of Engineer

RAJU VIKAL YADAV

Signature



Raju Vikal Yadav

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Training Report

Customer : PGIMS ,ROHTAK	Product Description : RX SUZUKA Instrument Serial # : S1200800CS0026MA Installed on : 01/10/2013	Date : 28/09/2013 – 01/10/2013 Training Period : 3 days
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Instrument : RX SUZUKA Training provided to : Mr. Som Mr. harish chawla Mr. Jitendra Training provided by : Raju Vikal Yadav	Action taken : <ol style="list-style-type: none"> 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 :
Customer Signature 	Trainee Signature : 

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RX SUZUKA

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

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SYSTEM CHECK PROCEDURE

SYSTEM CHECK	ACCEPTABLE RESULTS	OBTAINED RESULTS
Cuvette check	Bet. (0.8 – 1.8) Abs for 1 st cuvette. & +/- 800 for all cuvette	Within acceptable range
Photometer check	Bet. (0.8 – 1.8) Abs at all filters	Within acceptable range
Incubator temperature check	37 Deg Centigrade with max 0.5 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

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Management

RX Suzuka

**PERFORMANCE QUALIFICATION
FOR
RX SUZUKA**

RANDOX LABORATORIES INDIA (P) LIMITED

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Management

Rx SUZUKA

Clinical Chemistry Analyzer

PERFORMANCE QUALIFICATION

1. Calibrating Assays and running Controls

Chemistry Parameters:

1. Glucose
2. Cholestrol
3. AST
4. ALT
5. ALP
6. ALB
7. Creatinine
8. T.Bil
9. Urea
10. TG
11. Uric Acid

Controls and Calibrators:

The following chemistry parameters were standardized & controls run for them.

The SD and CV are within acceptable range

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PERFORMANCE QUALIFICATION

System Certification

Study data has been determined that the system described in this document either meets all critical 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: Raju Vikal Yadav

Title: Customer support Engineer

Company: Randox Laboratories India (P) Limited

Customer authorization:

Name:

Title:

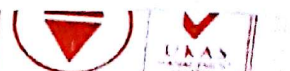
Engineer Name & Signature RAJU VIKAL YADAV

Date 01/10/2013 Raju Vikal Yadav

✓
Customer Signature

Date

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AUGUST 2017

Monthly QC Report

Test Item: ALB

QC Name: QC2

Target Mean: 4.21

Target SD: 0.33

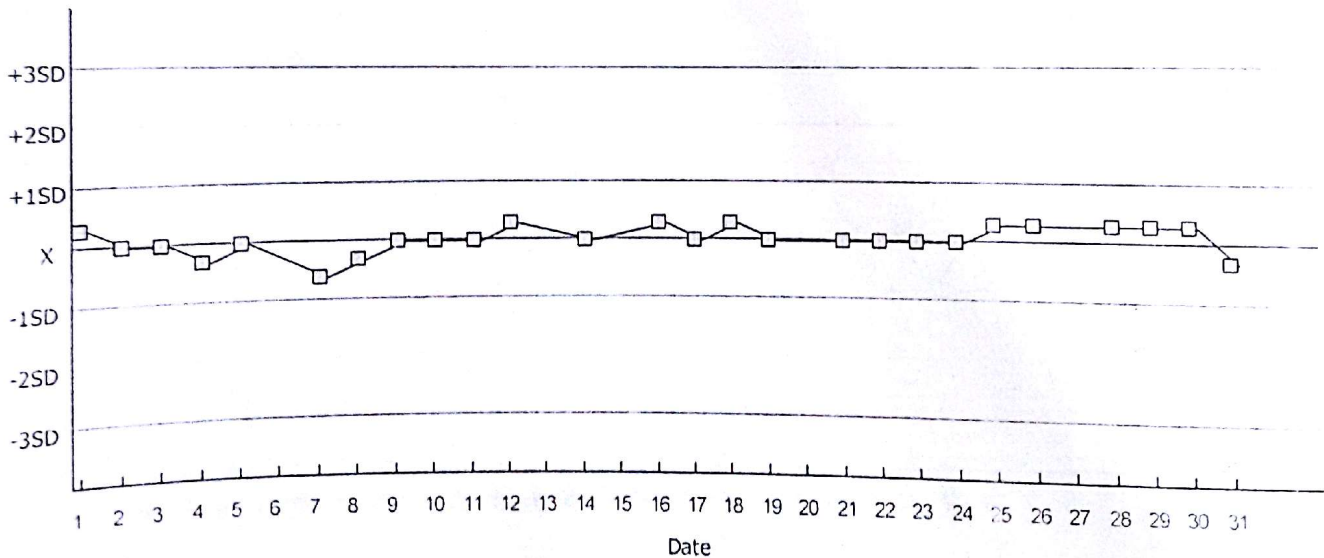
QC Lot No.(1108UN)

Actual X: 4.22

Actual SD: 0.08

CV(%): 1.86

Date	Result	Date	Result	Date	Result
8/1/2017	4.3	8/2/2017	4.2	8/3/2017	4.2
8/4/2017	4.1	8/5/2017	4.2	8/7/2017	4
8/8/2017	4.1	8/9/2017	4.2	8/10/2017	4.2
8/11/2017	4.2	8/12/2017	4.3	8/14/2017	4.2
8/16/2017	4.3	8/17/2017	4.2	8/18/2017	4.3
8/19/2017	4.2	8/21/2017	4.2	8/22/2017	4.2
8/23/2017	4.2	8/24/2017	4.2	8/25/2017	4.3
8/26/2017	4.3	8/28/2017	4.3	8/29/2017	4.3
8/30/2017	4.3	8/31/2017	4.1		



Ritika

Operator: 001

Report Date: 9/1/2017 9:22:52 AM



**National Accreditation Board for
Testing and Calibration Laboratories**

(A Constituent Board of Quality Council of India)



CERTIFICATE OF ACCREDITATION

**CLINICAL BIOCHEMISTRY LABORATORY,
PGIMS**

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

Pt BDS PGIMS, Rohtak, Haryana

in the field of

MEDICAL TESTING

Certificate Number MC-2448

Issue Date 15/11/2017

Valid Until 14/11/2019

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Signed for and on behalf of NABL

Dr. Vandana Jain
Program Director



89076977300010000119

Anil Relia
Chief Executive Officer

Radox Engineering Site Vis

Report No. : **4743**

Customer Name PGIMS
 Address Kohat, Haryana
 Purchase Order No. -
 Query Ref. No. -
 Operator / Technician Mr. Harish J.
 Contract ☐ CMC ☐ AMC ☐ RRC

Date 10/10/2017
 System Serial No. 68MA
 Software version -
 Parameter version No. -
 Travel Time to Site (Hrs) 3 hrs
 Time on site (Hrs) 6 hrs

For the section below, complete with reference to section 803 of CFR title 21 and meddev2.121

Does this incident represent a serious health threat to the user
 Has the event led or might have led to death or injury of the user person
 Yes ☐ No ☒
 Yes ☐ No ☒

Reason For Visit
 PM Visit ☒ Technical Visit ☐ System Breakdown ☐
 Others : Preventive Maintenance

Action Taken
 (x) changed new cuvettes
 (x) cleaned incubation bath, filter of incubation bath and photometric lens of incubation bath
 (x) cleaned all the probes from inside & outside, cleaned troughs mixer paddles, RUV & sample containers & tray.
 (x) changed the inlet water filter & exhaust filter

Reason for Breakdown if applicable: N/A
 Travel / Labour Chargeable Yes ☐ No ☒

Precision Test Performed? (if applicable) Yes ☐ No ☐
 Test _____ Mean _____ % CV _____ Test _____ Mean _____ % CV _____
 Precision Test Passed? Yes ☐ No ☐ (If no give details)

Part Number	Description	Qty	Serial / Lot no installed	Chargeable
	<u>Cuvettes</u>	<u>1 set</u>		

The instrument has been maintained and tested to the manufacturer specification
 It is the responsibility of customer to ensure that the instrument is fit for purpose
 Engineer Name RADU VIRAL YADAV
 Signature [Signature]
 Date Work Commence 10/10/2017
 Customer Name [Signature]
 Signature [Signature]
 Date Work Completed [Signature]

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 REVISION (0)
 19 Aug 2015