

**ROBONIK**[®]An ISO 9001 Certified Company
An ISO 13485 Certified CompanyHouse of
Diagnostic
Equipments
& Reagents**Calibration Certificate**

Calibrated For :- PRIMUS PATHOLOGY & DIAGNOSTICS LLP SH-14 to 16 & FL 1 Sheetal Darshan CHS, MTNL Road, Miraroad East Opp. Hotel Sahi, Sheetal Nagri, Thane-401107. Contact Person :Mrs.Sushman Contact No:93247 77585	Certificate No. : SB/INV/24-25/003
	Date of Calibration : 02/02/2024
	Calibration Due on : 01/02/2025
	Page No. : 1

Details Of Unit Under Calibration

Model Name : Prietest Touch Plus	Sr. No.: ATP0331219RBK
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Standard Used For Calibration

Parameters	Inst. Name & Sr. No.	Cert. No.	Calibrated by	Validity
Temperature Calibration	Digital Thermometer:(data scanner 4 CH.) 960413	RBK/TH/22-23/001	Robonik India Pvt.Ltd	31/03/24
	Calibration Cuvette ANA - A	ANA/22-23/001	Robonik india pvt.ltd	10/10/24

Observations**Temperature Calibration**

Parameters	Temperature to be checked.	Obtained Value	Range
Cuvette Temperature	37°C	37.1 °c	+/- 0.5 °c

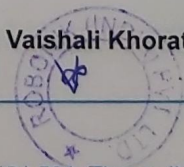
Optical Calibration

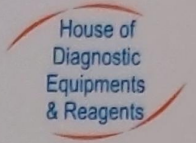
Wavelength	Film Type									
	ISP		IHP+ISP		ITP		2DP+1HP		3TP	
	Abs. Obtained	Range	Abs. Obtained	Range	Abs. Obtained	Range	Abs. Obtained	Range	Abs. Obtained	Range
340nm	0.588	0.623 0.569	0.920	-0.950 0.894	1.722	1.809 1.698	2.724	>2.500	NA	
405nm	0.324	0.341 0.312	0.510	0.523 0.479	1.009	1.039 0.969	1.557	1.630 1.492	3.080	>2.500
510nm	0.308	0.330 0.295	0.480	0.500 0.459	0.986	1.031 0.960	1.480	1.554 1.436	3.035	>2.500
545nm	0.284	0.308 0.269	0.429	0.500 0.400	0.908	0.945 0.882	1.372	1.425 1.324	2.789	>2.500
578nm	0.278	0.305 0.260	0.409	0.500 0.395	0.890	0.900 0.827	1.356	1.371 1.249	2.670	>2.500
630nm	0.331	0.350 0.304	0.478	0.505 0.460	1.070	1.091 1.025	1.584	1.650 1.501	3.227	>2.500

Semi Auto Analyser has been calibrated for above parameter and found to be within its acceptance criteria.

Calibrated By: Parnita Mhatre

Approved By: Vaishali Khorate

**ROBONIK (INDIA) PVT. LTD.**Plot No. 3 & 4, MIDC Industrial Area, Morivali, Near Ladi Naka, Ambarnath (W) - 421 501, Thane, INDIA
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Email : marketing@robonikindia.com, Website : www.robonik.in

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Calibration Certificate

Calibrated For : PRIMUS DIAGNOSTIC & DIAGNOSTICS LLP SH-14, PLOT NO. 1, Sheetal Darshan CHS, MTNL Road, Midroad East Opp. Hotel Sheetal Nagri, Thane- 401107. Contact Person: Sushman Contact No: 982017585	Certificate No. : Analyser-23-24 – RX –001
	Date of Calibration : 12/02/2024
	Calibration Due on : 11/02/2025
	Page No. : 02

DETAILS OF UNIT UNDER CALIBRATION

Model Name: Fully Automatic Random Access Biochemistry Analyser.	SR.NO. – AX002102CRBK
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STANDARD'S USED FOR CALIBRATION

Parameters	Inst. Name & Sr. No.	Cert. No.	Calibrated by	Validity
Temperature Calibration	TH/QC/AX/001	TH/QC/AX/001	Robonik india pvt.ltd.	31/03/2024
Reagent Volume Check	Digital Weighing Balance CA – 503 sr.no. - 2900323	RBK/DWB/AU/24 -25/002	Robonik india pvt.ltd.	10/06/2024
Sample Volume Check	Prietest Touch Sr.no.- SB0011023DMU{Sample is use as a Blue Solution (OD is 0.500 – 0.700)}	SB/24-25/001	Robonik india pvt.ltd.	06-06-2024
Reagent QC	Randox control	Randox 2 - Lot No. – 1543UN	Randox Laboratories Ltd	March.2025
		Randox 3 - Lot No. – 1211UE		March.2025

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
OBSERVATIONS


Parameters	Obtained				Criteria
Temperature Calibration	36.8 °c				36.7+/-0.7 °c
Reagent Volume Check	Cuvette no.	Empty cuvette weight	With 300ul water weight	Diff.	MAX. Reading & MIN. Reading Difference should be in between ± 3mg.
	1	2.248	2.547	0.299	
	2	2.201	2.501	0.300	
	3	2.219	2.519	0.300	
	4	2.168	2.467	0.299	
	5	2.200	2.499	0.299	
Sample Volume Check	Cuvette no.	Reading obtained on Prietest touch		Diff.	Dispense 3µl Blue Solution by Sample Needle in 300µl water and take reading on Prietest Touch. Criteria: Variation on Prietest touch should be <0.015.
	1	0.698		MAX= 0.698	
	2	0.696			
	3	0.693		MIN = 0.693	
	4	0.694			
	5	0.693		DIFF= 0.005	

Reagent QC

Test Name	Obtained Value(randox low)	RANDOX LOW CONTROL RANGE	
		MEAN	RANGE
GLUCOSE	110.9	107	91.2 – 123
CHOLESTEROL	152.5	155	135 – 175
SGOT	37.078	35	28 – 42
SGPT	37.3	36	29 – 43
UREA	41.6	43.7	37.1 – 50.3

Note: Aurora Biochemistry Analyser has been calibrated for above parameters and found to be within its acceptance criteria.

 Calibrated By: Parnita Mhatre 

 Approved By: Vanshali Khorate 
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Prietest TOUCH plus

Installation Qualification Protocol

& Calibration

Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
	Rev.Date	15 -01-19
Product: Biochemistry Analyser		

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Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
Product: Biochemistry Analyser	Rev.Date	15 -01-19

1. OBJECTIVE

The objective of this protocol is to provide an outline for the inspection of Prietest Touch Plus static characteristics to verify that :-

- ◀ Each installed instrument complies with the engineering designs and equipment specification & manufacturer recommendations.
- ◀ To ensure that appropriate interconnections are made for utilities / equipment and that the safety features are defined before the start up of Operational Qualification exercise.
- ◀ The system meets the EMC requirements & other regulatory requirements for *in vitro* medical devices.

2. SCOPE

The scope of this protocol is procedures for Installation of the subjected equipment within the following boundaries :-

- ◀ Identification & verification of the subjected instruments & its major components.
- ◀ Identification, Verification & Classification of all the process control instruments (stepper motors, optical sensors, indicators, controllers etc.)
- ◀ Identification & verification of all safety features, if any.
- ◀ Identification & Verification of all supporting utilities for proper connections.
- ◀ Identification & verification of all supporting documents.
- ◀ No unauthorized or unrecorded modifications have taken place.

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Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
	Rev.Date	15 -01-19
Product: Biochemistry Analyser		

3. INTRODUCTION

3.1. Description:

Prietest Touch Plus (Biochemistry analyser) is a programmable Biochemistry Analyzer with a userfriendly touch screen. It measures the optical densities of samples and it uses algorithm to calculate results, which are used for biochemical investigation. It is a photometer operating in the visible range. The instrument is an open photometer suitable for absorbance (optical density) measures as well as sample concentration determination. It has a user-friendly program and capacity of storing the programmed analytical methods and the QC results. It is intended for in vitro diagnostic use.

3.2. Special Features:

- Effective temperature regulation system with Peltier controlled cuvette /flow cell block. □ Dual reading mode
- Robust system with built in stabilizer.
- Latest technology with battery back up for 250 tests with QC, more than 2000 results.
- Robust in built 20 Column Thermal Printer with 384 stationary heads.
- Unique circuitry for long lamp life.
- Reliable peristaltic pump with maintenance free operations.
- Sophisticated software for kinetic graph with built in delta calculation for saturated (high) samples from graphic display without diluting and rerunning the samples.
- Monochromatic, Bichromatic Measurement □ Multi Standard Calibration □ Patients ID entry.
- Editing of saved tests.
- Human machine user interface: Touchpad, Keypad
- Built in Incubator
- Levey Jennings and standard deviation graphs.
- Optional interface for External Printer
- Patient report with PID & Name
- Access to Test by Touch of Key

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Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Product: Biochemistry Analyser	Doc. No. IQP/ATP
		Rev.Date 15 -01-19

4. ACCESSORIES PROVIDED WITH THE INSTRUMENT.



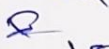

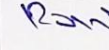

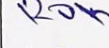
Sr. No.	Particulars	Quantity	Present		Checked by Sign & date	Remark
			YES	NO		
1.	Power Cord	01			Rohit 15-1-19	OK
2.	Thermal Paper Roll	02	YES		Rohit 15-1-19	OK
3.	Paper Roll Rod	01	YES		Rohit 15-1-19	OK
4.	Dust Cover	01	YES		Rohit 15-1-19	OK
5.	Tubing (02 Feet)	01	YES		Rohit 15-1-19	OK
6.	Stylus	03	YES		Rohit 15-1-19	OK
7.	Flowcell Cleaning Wire (1 Feet)	01	YES		Rohit 15-1-19	OK
8.	Waste Bottle	01	YES		Rohit 15-1-19	OK
9.	RS 232 Cable	01	YES		Rohit 15-1-19	OK
10.	Inlet Tubing	01	YES		Rohit 15-1-19	OK
11.	User Manual	01	YES		Rohit 15-1-19	OK

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Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
	Rev.Date	15 -01-19
Product: Biochemistry Analyser		

5. INSTALLATION CHECKS:

Sr. No.	Particulars	Checked by Sign & date	Remark
1	Avoid installation of instrument next to water fixtures, baths, sinks etc. exposed to excess heat, to direct sunshine or dusty area.	Rohit  15-1-19	OK
2	The instrument has to be placed on a level bench.	Rohit  15-1-19	OK
3	Do not place near centrifuges, dishwashers or heavy inductive loads.	Rohit  15-1-19	OK
4	Proper Earthing to be checked. L-E (approx. 230V) L-N (approx. 230V) N-E (approx. 0-7V)	Rohit  15-1-19	OK
5	Room temperature 10 to 35°C with a relative humidity below 85%.	Rohit  15-1-19	OK
6	Mains Voltage (90-270V)	Rohit  15-1-19	OK
7	Operational checks (as per user manual start up instructions)	Rohit  15-1-19	OK

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Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
Product: Biochemistry Analyser	Rev.Date	15-01-19

6. INSTALLATION VERIFICATION / REVIEW

Sr. No.	Particulars	Present		Checked by Sign & date	Remark
		YES	NO		
1	Verify that there is no observable physical Damage	YES	NO	Rohit 15-1-19	OK
2	Verify that Required electrical connections are tight	YES		Rohit 15-1-19	OK
3	Verify that equipment identification labels are properly visible.	YES		Rohit 15-1-19	OK
4	Equipment installed is in secure place and as per manufacturers recommendations	YES		Rohit 15-1-19	OK
5	Verify that the area is free from electromagnetic and Radio frequency interference.	YES		Rohit 15-1-19	OK
6	Verify that equipments preliminary checks are OK.	YES		Rohit 15-1-19	OK

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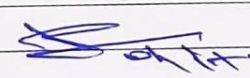
Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
	Rev.Date	15-01-19
Product: Biochemistry Analyser		

7. IDENTIFICATION AND VERIFICATION OF SUPPORTING UTILITIES.

Sr. No.	Particulars Specified		Observation Result	Checked by Sign & date	Remark
1	Mains Voltage	230V, 50Hz	230v, 50Hz	Rohit 15-1-19	OK ✓
2	Mains Current	0.5Amp.	0.5AMP	Rohit 15-1-19	OK ✓

Sr. No.	Observation	YES/NO	Checked by Sign & date	Remark
1	Properly Monitored	YES	Rohit 15-1-19	OK
2	Properly labeled and identified	YES	Rohit 15-1-19	OK

Reviewed By:

Name	Signature	Date
Rohit Upadh Yay		15-1-19.

Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
Product: Biochemistry Analyser	Rev.Date	15-01-19

8. IDENTIFICATION OF STANDARD OPERATING PROCEDURE

Sr. No.	observation	YES/NO
1	Operation , Cleaning and calibration procedure for Prietest Touch Plus	Yes.

Comments : Operation, Calibration
procedure and cleaning done.
for Prietest Touch Plus

Reviewed By:

Name	Signature	Date
494 Rohit Upadh	[Signature]	15-1-19.

Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
	Rev.Date	15 -01-19
Product: Biochemistry Analyser		

9. GENERAL

9.1. Documents

Sr. No.	Document Name	Document No	Sign & Date
1	Purchase Order/Invoice	AB065	[Signature] 15-1-19
2	System Specifications	AB065	[Signature] 15-1-19
3	Warranty Terms	2-year / -	[Signature] 15-1-19

9.2. Manuals :

Sr. No.	Document Name	Document No	Sign & Date
1	User manual	AB065	[Signature] 15-1-19

9.3. List :



Sr. No.	Document Name	Document No	Sign & Date
1	Packing List (accessories provided with instrument)	AB065	[Signature] 15-1-19

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Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
	Rev.Date	15-01-19
Product: Biochemistry Analyser		

9.4. Calibration or Test Certificate :

Sr. No.	Document Name	Document No	Sign & Date
1	Calibration certificate	AB065	 15-1-19
2	Customer Report	AB065	 15-1-19

9.5 Installation Certificate:

Sr. No.	Document Name	Document No	Sign & Date
1	Installation certificate	AB065	 15-1-19

Comments: Installation Certificate,
Calibration Certificate

Reviewed By:

Name	Signature	Date
Robin		15-1-19

Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
	Rev.Date	15-01-19
Product: Biochemistry Analyser		

10. DEFICIENCY AND CORRECTIVE ACTION REPORT

Description of deficiency observed & date :

15-1-19, Observed the Test Report in

Person responsible for corrective action and Date assigned :

Lab Technician corrective responsible
Person in

Corrective action taken and Date conducted :

OK

Reviewed By:

Name	Signature	Date
<u>Rohit</u>	<u>[Signature]</u>	<u>15-1-19</u>

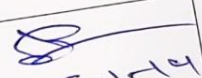
Installation Qualification Protocol	Model Name	Prietest TOUCH plus
	Doc. No.	IQP/ATP
	Rev.Date	15-01-19
Product: Biochemistry Analyser		

11. REPORT APPROVAL

Signatures in the block below indicate that all items in this Installation Qualification Protocol for Priestest Touch Plus, Sr. No: ATP0331219 have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

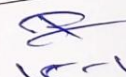
Report prepared by :

Compilation of the report is the responsibility of the executive member

Sr. No.	Name	Designation	Sign & Date
1	Rohit Upadhyay	Engineer	 15-1-19

Report checked by :

Checking of the report is the responsibility of task force leader

Sr. No.	Name	Designation	Sign & Date
1	Rohit Upadhyay	Engineer	 15-1-19

Prietest Touch Plus

Performance Qualification Protocol & Calibration

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PERFORMANCE QUALIFICATION PROTOCOL

Purpose: The purpose of the performance Qualification (PQ) is to confirm that the instrument is installed and performed as per requirement.

Performance Test Procedure:

Follow the proper test procedure of the instrument as given in the Operational Qualification Protocol.

Performance Test Report : OK

Acceptance: After checking all possible test/functions and minimum verification of SOPs shall be carried out to demonstrate that the Model Q1252 (Sr No ATP033019) is capable of achieving the desired results when operated as per the manufacturer instructions.

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Prepared by: Rohit Upadh 494	Checked by: Rohit Upadh 494	Verified by: Rohit Upadh 494
Date: 15-1-19	Date: 15-1-19	Date: 15-1-19

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Prietest TOUCH Plus

Operational Qualification Protocol & Calibration

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1. PRELIMINARY OPERATIONAL CHEKS of model Prietest Touch

1. Equipment/ System Start up :

Check the system has initialize as per the standard sequence of initializing and there is no any error message highlighting on display.

2. Functional checks :

To check and ensure the different functions such as switching devices, feedback system, indicators, display, printer, keyboard functions, etc. are operating as expected.

Sr. No.	Test Parameters	Acceptance Criteria	Result OK/NOK	Sign & Date
1	Display	Check all the characters are clearly visible on display. Adjust contrast knob for contrast adjustment.	OK	<i>[Signature]</i> 15-1-19
2	Touch Panel	Check touch panel with its appropriate functions.	OK	<i>[Signature]</i> 15-1-19
3	Keypad	Check all the keys by pressing them.	OK	<i>[Signature]</i> 15-1-19
4	Printer (External / Internal)	All the characters should be printed properly.	OK	<i>[Signature]</i> 15-1-19
5	Filter wheel Movement	There should not be any unusual sound or vibration.	OK	<i>[Signature]</i> 15-1-19
7	Pump aspiration	Use 'WASH' key and aspirate water. It should aspirate the water and throw out from waste outlet.	OK	<i>[Signature]</i> 15-1-19
8	Temperature	Check the cuvette temperature. It should be 37°C (+/- 0.5)	OK	<i>[Signature]</i> 15-1-19

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3. Lamp Amplitude Check

Select option Menu - Technical Diagnosis - Lamp Amplitude to check filter amplitude. System will ask to aspirate water. Aspirate clear distilled water and check the amplitude with flowcell using option "Stability Check".

Acceptance criteria: Above 3.000 to 9.300 for all filters

Filter	Observed Values
340 nm	5.467
405 nm	6.508
510 nm	7.489
546 nm	7.878
578 nm	7.965
630 nm	8.203
450 nm	-
700 nm	-

****Note: Refer USER Manual to check the test parameters.

Checked by:	Rohit Wadhvani
Sign & date:	<i>[Signature]</i> 15-1-19
Remark	OK / -

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