

Installation Qualification

Fully Automatic Instrument Series

Company (Name & Add) : POCT Services
Lucknow, Uttar Pradesh

Customer (Name & Add) : District Women Hospital
Pilibhit, Lucknow, Uttar Pradesh

Contact Person : Ravi Upadhyay

Contact Person : Dr. Afzal Husain

Name of instrument : **Selectra PRO M**

Serial no. : 16-4152

Installation Date : 07-02-2017

Initial check

Parts missing?

(check against packing list)

Yes (please specify parts)

No

Part number

.....NO.....

.....NO.....

.....NO.....

Part description

.....NO.....

.....NO.....

.....NO.....

Installation

Perform the Following steps

Check Power Supply 230 V ($\pm 10V$)

Check Earth ... 3.9... V (<5.0 V)

Room Temperature25° C (15°C to 30° C)

Install Instrument on Flat & Dry Surface by leaving a space of 24" between instrument & back wall

Install (PC, Main unit, monitor, printer, keyboard & mouse)

Install Cooling Unit

Install Water & Waste Containers (add sufficient amount of System liquid in the water)

Install Cuvette Rotor(s)

Install Syringes (be aware the 1000 μ L is on the rear side).

Install the ISE unit (If Applicable)

Start up the PC, Analyzer, Cooling Unit and ISE Unit.

Set up the Analyzer Software.

Set the System Parameters.



Contd.....



Installation Qualification

Fully Automatic Instrument Series- Selectra ProM

- Run the function "Fill System".
- Install HCL 0.1N(on the reagent rotor(s)) and Needle Rinse solution(on the reagent & sample rotor)
- Run the function "Rotor Blank".
- Rotor blank should be acceptable ($SD \leq 0.020$ Abs)
- Check for any leakage in the syringes, tighten screws if required

Technical acceptance	
Date(dd-mm-yyyy).... 07/02/2017	
Service Engineer Name : Ravi Upadhyay	Customer Name :Dr Afzal Husain
Service Engineer Signature 	Customer Signature 

Operational Qualification

Fully Automatic Instrument Series

- Install dichromate solution on reagent rotor(s) & as sample on sample rotor. (Use service disk which has Pre-defined protocol installed for dichromate run)
- Run 20x "Check-S" as QC samples for Selectra PROM instruments and fill out the results in the table below.

Test	Target Value	Target CV[%]	Mean Result	CV[%]
Check- S	0.080(0.060-0.1000)	<1%	0.087	1.0

Remarks :

✓ Rotor Blank Acceptable. Instrument ready for chemical installation & calibration.

- Change reagent disk from Service to Standard
- Install the various reagents on reagent rotor
- Install ISE reagents on reagent rotor
- Run Reagent Blanks
- Run Calibrations

Technical acceptance

Date (dd-mm-yyyy) : 07/02/20

Service Engineer Name : *[Signature]*

Customer Name : *[Signature]*



POCT SERVICES

Complete Medical Solution

POCT SERVICES

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PERFORMANCE QUALIFICATION

Fully Automatic Instrument Series

- Run Reagent Blank
- Run Calibrations
- Run QC material for several clinical chemistry applications
(a few enzymes, a few substrate tests using customer's reagent)

Test	QC Range Level 1	Test Result	QC Range Level 2	Test Result
Glucose	94.1(80-108.2)	91	253.2(215.2-291.2)	238
Urea	40.4(34.3-46.5)	41	128.1(105.9-147.3)	125
Creatinine	1.06(0.89-1.27)	0.97	3.44(2.82-4.06)	2.92
Total Bilirubin	1.12(0.92-1.32)	1.10	4.34(3.56-5.12)	4.30
Direct Bilirubin	0.63(0.48-0.78)	0.54	2.57(1.95-3.19)	3.11
Albumin	4.97(4.08-5.86)	4.1	3.50(2.87-4.13)	2.93
ALP	159(130-188)	137	432(354-510)	390
SGOT	43.1(35.3-50.9)	44	139.7(114.6-164.9)	129
SGPT	50.9(41.7-60.1)	48	155.1(127.2-183)	133
Uric Acid	4.55(3.87-5.23)	4.5	11.43(9.72-13.14)	10.5

Remarks:

We hereby certify that Instrument standardization / calibrations have been carried out under the Warranty/ AMC. Verified by evaluating controls before processing patients Samples and obtained results are satisfactory. Instrument is ready for regular use.

Technical acceptance

Date (dd-mm-yyyy) : 07/02/2017

Service Engineer Name : *Paw*

Customer Name : *Star*

Service Engineer Signature..... Customer Signature.....

REGISTERED OFFICE :
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BIHAR :
Mati Villa, Janak Kishor Road,
Kadam Kuan, Patna-800003, Bihar, INDIA
E-mail : pocitpatna@pocitko.com

Control name: ELITROL 2
 Batch number:
 Expiry date:
 Measurement date: 07-02-2017 09:56:32 PM
 Sample type: Control
 Status: UNLOADED

Type: C
 Sample ID: ELITROL 1
 Patient name: C
 ELITROL 2

Test name	Value	Flags
GLUCOSE	238 mg/dl	
UREA	125 mg/dl	
CREATINE	2.92 mg/dl	
BIL-TOTAL	4.30 mg/dl	
BIL-DIRECT	3.11 mg/dl	
SGOT	129 U/l	
SGPT	133 U/l	
ALP	390 U/l	
ALBUMIN	2.93 g/dl	
URIC ACID	10.5 mg/dl	

Low

F1 Print
 F2 Blank/Calib Info
 F3 Result Handling
 Alt + F4/Shift + F4 Measure Again/Retrun
 F6 Quality Control
 F7 Result Details
 F8 Request Samples
 F9 Sample Handling
 F10 Main Menu

Control name: ELITROL 1
 Batch number:
 Expiry date:
 Measurement date: 07-02-2017 09:45:16 PM
 Sample type: Control
 Status: UNLOADED

Test name	Value	Flags
GLUCOSE	91 mg/dl	
UREA	41 mg/dl	
CREATINE	0.97 mg/dl	
BIL-TOTAL	1.10 mg/dl	
BIL-DIRECT	0.54 mg/dl	
SGOT	44 U/l	
SGPT	48 U/l	
ALP	137 U/l	
ALBUMIN	4.1 g/dl	
URIC ACID	4.5 mg/dl	

Ravi

Type	Sample ID	Patient name
C	ELITROL 1	
C	ELITROL 2	

F1 Print

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All + F4/Shift + F4 Measure Again/Repeat

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F10 Main Menu

CERTIFICATE OF CALIBRATION VERIFICATION

Customer Name : Pathology Lab, District Women Hospital, Pilibhit (U.P.)

Instrument Name : Selectra (Fully Automated Biochemistry Analyzer)

Model : Pro M

Serial Number : 16-4152

Calibration done on : 24-12-2021

Next Calibration due : 23-12-2022

Contact Person: Dr. Afzal Husain

This is to certify that during its scheduled PMS above mentioned instrument has been verified for instrument calibration. During instrument calibration Lamp check, filter check, Pipetter unit dispense check and potassium dichromate tests were performed and found complying for all the parameters as per the specifications provided by the manufacturer. After instrument mechanical calibration verification, individual tests were calibrated and controls were run for which results obtained were within the specified limits.



Calibration and PMS done by : Gajendra Pratap Singh
Service Engineer
POCT Services