

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

Corporate Office: 298-281, Transport Nagar,
Kanpur Road, Adjacent Transport Nagar
Metro Station, Lucknow-226012, UP, INDIA

Tel.: 0522-283023

E-mail: pocitko@rediffmail.com

www.pocitko.com



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 :
280/9, Kha, Blunt Square,
Lucknow-226004,
Uttar Pradesh, INDIA
E-mail: pocitko@rediffmail.com
Website : www.pocitko.com

DELHI NCR:
20A, Basement Floor,
Main Shivaji Marg, Najafgarh Road,
Near Moti Nagar Police Station,
New Delhi-110015, Delhi, INDIA
Tel.: 011-45577407
E-mail : pocitdelhi@pocitko.com

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:

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/Retest
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

F2 Blank/Calib Info

F3 Result Handling

All + F4/Shift + F4 Measure Again/Repeat

F6 Quality Control

F7 Result Details

F8 Request Samples

F9 Sample Handling

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

001:2008 CERTIFIED



POCT SERVICES
Complete Hospital Solution

Customer's Copy

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TECHNICAL SERVICE REPORT

CALL NO. 116-4153

07/02/2017

REPORT NO.: POCT/SD/ [] SERVICE NOTIFICATION NO.: []

CUSTOMER NAME: **Dist. Women Hospital**

ADDRESS: **Pathankot** STATE: [] PIN CODE: []

CITY: **Pathankot** CONTACT PERSON: **Mr. Umesh Chand** CONTACT NO.: []

DEPARTMENT: **Pathology**

INSTRUMENT STATUS: WARRANTY AMC/CMC/RENTAL/DEMO CHARGEABLE CALL

CONTRACT PERIOD: [] TO [] EXPIRED ON: [] WORKED CARRIED OUT AT: SITE OFFICE

SITE VOLTAGE: **230V** STABILISER/UPS: [] Y/N: []

INSTRUMENT NAME: **Selecta** MAKE: **Elitech** MODEL NAME: **PerDM** SR. NO.: []

CALL LOG DATE: [] CALL ATTEND DATE: [] CALL CLOSE DATE: [] TAT TIME: []

TIME: [] TIME: [] TIME: [] HR: []

- BREAKDOWN
- INSTALLATION
- PMS
- APPLICATION

PROBLEM REPORTED: **Installation completed**

ACTION TAKEN: **Blanking calibration control**

DETAIL OF TEST PERFORMED (ATTACH THE INSTRUMENT GENERATED RESULT PRINTOUT)

TEST DESCRIPTION	RESULT OBTAINED	REMARK
Blanking calibration control	OK	✓
	OK	✓
	OK	✓

ENGINEER'S REMARK:	PERSON TRAINED DURING INSTALLATION	
	NAME	SIGNATURE
Instrument is working well	Mr. Umesh Chand	[Signature]
	Mr. Ravindra Kumar	[Signature]

CUSTOMER'S REMARK: []

ENGINEER'S NAME: **Ravi Upadhyay** CUSTOMER'S NAME: **Dr. Ashok P. Singh**

SIGNATURE: **Quasheer Singh** SIGNATURE WITH STAMP: **[Signature]**

Dr. Ashok P. Singh
मुख्य चिकित्सा अधीक्षक
जिला महिला चिकित्सालय, 4
पीलीभीत
Pathankot Imp. [Signature]

4/02/17

PLEASE ENSURE FILLING AND SENDING OF INSTALLATION REPORT ALONG WITH THIS REPORT AT THE TIME OF INSTALLATION.

POCT SERVICES PRIVATE LIMITED
CORP. OFF. - 101A- 102B FIRST FLOOR DIAMOND TOWER, CANTT ROAD, UDAI GANJ, LUCKNOW(U.P.) PIN - 226001, INDIA
Subject to Lucknow Jurisdiction

TELIFAX + 91-522-4009779 TOLL FREE No. 18001201141 WEB : www.poctservices.com

Selectra from calibration Raw data (Level 1)

Active | DUAL MODE | Req./tray buffer: 0/35 | Standard | 02:28:20 PM | 24-Dec-2021 HOST | Cooling unit ERROR | Archived Results

Control name: ELITROL 1
 Batch number:
 Expiry date:
 Measurement date: 24-Dec-2021 09:45:16 AM
 Sample type: Control
 Status: UNLOADED

Test name	Value	Flags
GLUCOSE	91 mg/dl	
UREA	41 mg/dl	
CREATINE	0.67 mg/dl	
BIL-TOTAL	2.03 mg/dl	
BIL-DIRECT	1.17 mg/dl	
SGOT	44 U/l	
SGPT	40 U/l	
ALP	137 U/l	
ALBUMIN	3.1 g/dl	
URIC ACID	5.5 mg/dl	
CHOLESTROL	101 mg/dl	
TRIGLYCERIDE	102 mg/dl	
HDL	25 mg/dl	
AMYLASE	81 U/l	
CALCIUM	9.0 mg/dl	
TP	4.4 g/dl	

Type	Sample ID	Patient name
C	ELITROL 1	
C	ELITROL 2	

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

Selectra Pro m Calibration Raw data (level 2)

Active | DUAL MODE | Req./tray buffer:0/35 | Standard | 02:28:35 PM | 24-Dec-2021 | HOST | Cooling unit ERROR | Archived Results

Control name: ELITROL 2
 Batch number:
 Expiry date:
 Measurement date: 24-Dec-2021 09:45:12 AM
 Sample type: Control
 Status: UNLOADED

Type	Sample ID	Patient name
C	ELITROL 1	
G	ELITROL 2	

Test name	Value	Flags
GLUCOSE	238 mg/dl	
UREA	125 mg/dl	
CREATINE	2.52 mg/dl	
BIL-TOTAL	6.30 mg/dl	
BIL-DIRECT	3.21 mg/dl	
SGOT	129 U/l	
SGPT	123 U/l	
ALP	309 U/l	
ALBUMIN	4.9 g/dl	
URIC ACID	10.5 mg/dl	
CHOLESTROL	173 mg/dl	
TRIGLYCERIDE	204 mg/dl	
HDL	37 mg/dl	
AMYLASE	287 U/l	
TP	7.6 g/dl	

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