Calibration Certificate

This is to certify that the **Cobas E411** is a fully automated analyzer bearing the Serial Number **0936 -02** at Likhitha's Diagnostics and Speciality Lab, ZenRise, Madinaguda, Hyderabad – 500049, has been calibrated on **19.08.2021.**

The calibration includes:

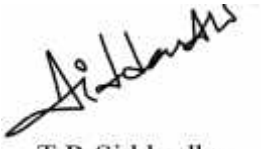
Adjustments: Checked and adjusted sample/Reagent Rotor, Incubator, Sample/Reagent probe, Bead Mixer and their respective home positions.

Incubation Disk:	Range: 36.8°C to 37.2°C Adjusted: 37°C
Detection Unit:	Target: 28.0°C Adjusted: 28.0°C
PC/CC:	Target: 28°C Adjusted: 28°C

Adding to this all the temperatures, PMT Voltage and volumes drawn by all pumps were checked and found they are OK.

Next calibration due on 18.08.2022

For Roche Diagnostics India Pvt Ltd.,



T R Siddardha,
Sr.Technical Service Specialist,
Hyderabad.

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cobas® e411 instrument

Qualification Service
Installation Qualification / Operation Qualification (v.1.0)

Roche

cobas® e411 instrument

General Information

Country:	INDIA
Customer Name:	LIKHITHA'S DIAGNOSTICS & SPECIALITY LAB
Customer Address:	Likhithas Diagnostics and Speciality Lab, ZenRise CRO, Plot No. 201, Mythrinagar, NH – 65, Madinaguda, Miyapur, Hyderabad - 500049.
Person Responsible for Quality Assurance:	Mr. Hanmant Jadhav

System Information

Cobas e411	Disk		
	S/N	IP Address	
cobas e411	0936 -02	182.18.38. 220	
cobas link:	SCL	NA	
Host provider:	NA		
User Software Version:	02 - 08.		

Installation Information

Installation Start Date:	16.08.2021		
First Installation:	YES		
Relocation:	From:	To:	

Roche Responsible Representative : Mr. Siddartha TR, Sr.Technical Service Engineer

Installation Qualification:

This document forms the basis of the Qualification Services Certificate. It certifies that the instrument is installed according to the manufacturer's specifications. The report presents and documents the test procedures, the documentation, reference and acceptance criteria used to verify that the system is installed according specifications. The report demonstrated that all installation qualification criteria have been met satisfactorily.

Notice: The following tests are to be carried out by trained Roche personnel only.

Purpose: The purpose of this test is to confirm that the instrument was delivered undamaged and installed correctly.

Test #	Test	Pass Fail	Signature Date
IQ.1.1	Operator's Manual available	Pass	
IQ 1.2	Environmental parameters met	Pass	
IQ 1.3	Instrument delivered undamaged and complete	Pass	
IQ 1.4	Transport locking successfully removed	Pass	
IQ 1.5	All connections correctly installed	Pass	
IQ 1.6	Instrument positioned according to Installation Manual	Pass	
IQ 1.7	Instrument boot process successfully	Pass	
IQ 1.8	Checksum according to specification	Pass	
IQ 1.9	Mechanical adjustments complete	Pass	
IQ 1.10	Auxiliary components positioned	Pass	
IQ 1.11	Instrument installation check	Pass	
IQ 1.12	Host communication settings checked	not applicable	

Test #	Test	Pass Fail	Signature Date
IQ.3	Installation Qualification for all cobas <e411>	yes	

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1	
NA	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #2	
NA	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

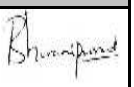
Deviation #3	
NA	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Operational Qualification:

This document is the basis of the Qualification Service Certificate. It certifies that the instrument is operating according to the manufacture's specifications. This report presents and documents the test procedures, documentation, references and acceptance criteria used to verify that the specified system is operating according the specifications. The report demonstrates that all operational qualification criteria have been met satisfactorily.

Notice: The following tests are to be carried out by trained Roche personnel only.

Purpose: The purpose of this test is to check that the modules are operating in accordance with the

Test #	Test	Pass Fail	Signature Date
OQ.1	Calibration successfully	Pass	
OQ.2	Quality Control successfully	Pass	
OQ.3	Accuracy check successfully	Pass	

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1	
NA	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #2	
NA	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Conclusion

All test results are acceptable.	yes
Any deviation or non-conformances observed have been recorded as a deviation and the relevant forms completed.	no
All acceptance criteria have been met. This equipment is deemed acceptable and the unit is approved for its intended use.	yes

Comments

All available parameter calibrations were passed. QC values were with in the range.

Completed by Roche Representative — Date 08 / 16/ 2021

Print Name Mr. Bhavani Prasad Varupula — Signature

Reviewed by Customer Contact — Date 08 / 16/ 2021

Print Name Mr. HANMANT JADHAV — Signature

Reviewed by Customer Quality Assurance — Date 08/16/2021

Print Name Mr. HANMANT JADHAV — Signature

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Qualification Service
Installation Qualification

Roche

Installation Qualification for cobas e411®

Description

IQ.3.1	Function check of e411 according to specifications	
	The e411 is installed according to the installation manual and using official tools	Pass
IQ.3.2	Mechanical adjustments complete	
	All mechanical adjustments for the different e411 mechanical parts are carried out	Pass
	Adjustment check during mechanical check function	Pass
	Sample LLD adjusted to spec.	Pass
IQ.3.3	Auxiliary components positioned	
	Sample probe, reagent probe, beads mixer paddle and measuring cell installed	yes
	Waste liner, CC/PC cups, CleanCell, ProCell positioned	yes
	System prime and system air purge for syringes and reagents	Pass
IQ 3.4	Instrument installation check	
	Incubator temperature 37°C ± 0.3°C	Pass
	No alarms during check	Pass
	System Volume Check (attached printout)	Pass
	PMT HV adjustment (attached printout)	Pass
	Assay Performance Check (AM+TSH, attached printout)	Pass
	Blank Cell calibration (attached printout)	Pass
	Mechanical adjustments parameter backed up	Pass

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1	
NA	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #2	
NA	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Deviation #3	
NA	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

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Qualification Service
Operation Qualification (v.1.0)

Roche

Operational Qualification:

Notice:

The steps described in OQ.1 have to be carried out after a new system installation and after any repair action which requires additional calibration.

If the service action does not affect the measurement performance, only apply steps OQ.2 and OQ.3 of the Operation Qualification.

Description

OQ 1	Calibration	
	Calibration of all Immuno parameters successful (attached printout)	yes
OQ.2	Quality Control	
	Specify the type of control used:	
	3rd Party control (Bio-Rad)	
	QC of Immuno parameters within acceptable range (attached printout)	yes
OQ.3	Accuracy check for Immunology Assays	
	Perform test with analytical reagents	

	Number of det.
Any non-infectious disease assay (e.g. TSH)	21

Sample solution: Applicable control material
Fill 21 Hitachi cups with control material and perform 21 determinations of each

Accuracy check for immunoassays was within acceptable range	Yes

Deviation Report: Any discrepancies found during the installation must be documented in the space below. Roche personnel will then investigate the deviation and decide upon the most appropriate action to be taken.

Deviation #1	
NA	
Investigation	
Action taken	
Deviation resolved satisfactorily?	specify

Attachments

1. Calibration Printout

2. QC Printout

3. Precision Data

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Qualification Service
Attachments

Roche

Likhitha's Diagnostics and Speciality Lab, ZenRise, Madinaguda, Hyderabad

Cobas E411 - Intrassay Precision Study

Date : 09.02.2022

Sample ID - Pooled Human Serum Sample

Analyte - Thyroid Stimulating Hormone

Replicate No.	Results
1	5.55
2	5.51
3	5.63
4	5.76
5	5.67
6	5.58
7	5.44
8	5.66
9	5.78
10	5.52
11	5.63
12	5.51
13	5.53
14	5.35
15	5.51
16	5.69
17	5.69
18	5.65
19	5.67
20	5.72
21	5.4
Mean	5.59
SD	0.11
%CV	**2.03**

Processed By : Lab Technician Mr. Sivashankar

Verified By : Quality Manager

02/09/2022

Roche Diagnostics Immunoanalyzer cobas e 411 S/N 16H021

Result Report Operator-ID: NELIMA 09/02/2022, 18:03

Sample/Control ID	Seq.	Pos.	Test	Dil	RPos	Result	Flag
000015142304	3523	0-21	TSH 0		3	5.55	H
000015142304	3522	0-20	TSH 0		3	5.59	H
000015142304	3521	0-19	TSH 0		3	5.63	H
000015142304	3520	0-18	TSH 0		3	5.76	H
000015142304	3519	0-17	TSH 0		3	5.67	H
000015142304	3518	0-16	TSH 0		3	5.58	H
000015142304	3517	0-15	TSH 0		3	5.44	H
000015142304	3516	0-14	TSH 0		3	5.66	H
000015142304	3515	0-13	TSH 0		3	5.78	H
000015142304	3514	0-12	TSH 0		3	5.52	H
000015142304	3513	0-11	TSH 0		3	5.63	H
000015142304	3512	0-10	TSH 0		3	5.51	H
000015142304	3511	0-9	TSH 0		3	5.53	H
000015142304	3510	0-8	TSH 0		3	5.35	H
000015142304	3509	0-7	TSH 0		3	5.51	H
000015142304	3508	0-6	TSH 0		3	5.69	H
000015142304	3507	0-5	TSH 0		3	5.69	H
000015142304	3506	0-4	TSH 0		3	5.65	H
000015142304	3505	0-3	TSH 0		3	5.67	H
000015142304	3504	0-2	TSH 0		3	5.72	H
000015142304	3503	0-1	TSH 0		3	5.40	H
000926896900	3502	0-4	T3 0 T4 1 TSH 0		1 2 3	1.09 6.43 2.45	
000926897000	3501	0-3	TSH 0		3	9.60	H
000910308103	3500	0-2	A-HCVII 0		14	0.050	
000014942704	3499	0-1	IGE 0		13	94.92	
000014942904	3498	0-20	TSH 0		3	1.72	
000910308503	3497	0-19	TSH 0		3	6.79	H

10/2/2022

04/04/2022 (Mon) 18:56

Calibration | QC | Utility

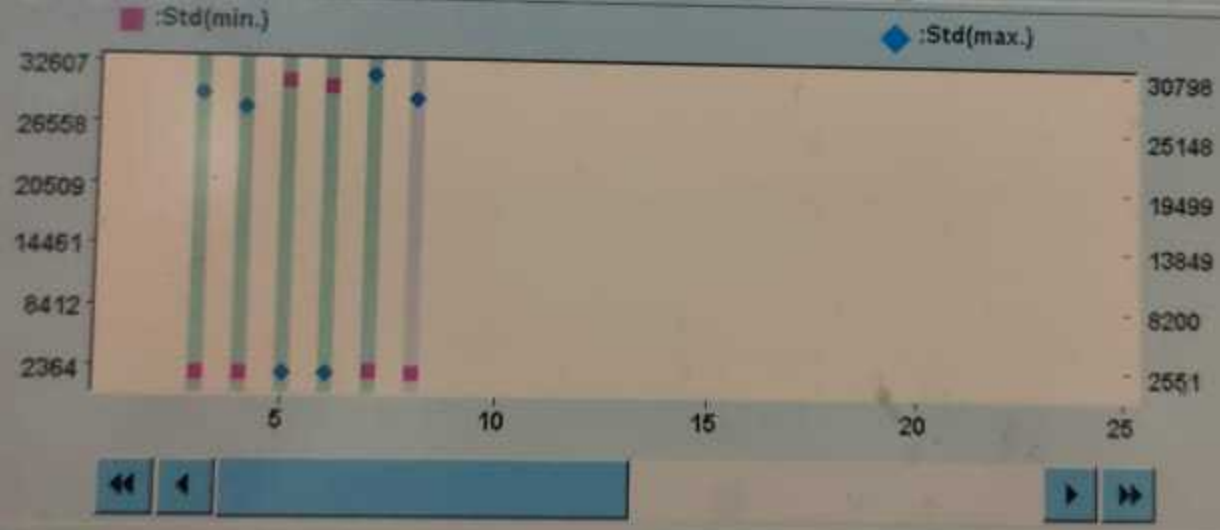
Stop | Logoff | S.Stop | Stat Mode | Alarm | Print | Start

Calibration Trace

Test: HIVCOMPT 0 | Scale Mode: Automatic | Period: 29/10/2021 - 08/03/2022

Calibrator	No.	Signal	Alarm	Date	Time
Std(Min.)	8	2391		08/03/2022	11:49
Std(Max.)	8	28298		08/03/2022	11:49

Reagent Lot No.	RP No.
00561758	009950



Scale | Comment | Close

bmserv 04/04/2022 (Mon) 18:56

Calibration | QC | Utility

Stop

Logoff

S.Stop

Stat Mode

Alarm

Print

Start

Calibration Result

Test	Calibration Type	Unit	Date Time	Calibrator Lot	Reagent Lot	RP No.
HIVCOMPT 0	Cutoff	COI	08/03/2022 11:49:43	00561758	00561758	032543

L-Calib. was generated!

	Level1	Level2
Signal1	2418	28014
Signal2	2365	28582
Dupl.	----	----
Sys.Err.	----	----
Slope	----	
Diff	----	
Cutoff	1402	
Border Area	0.900 - 1.00	

Close

bmserv 04/04/2022 (Mon) 18:55

Calibration QC Utility

Calibration Trace

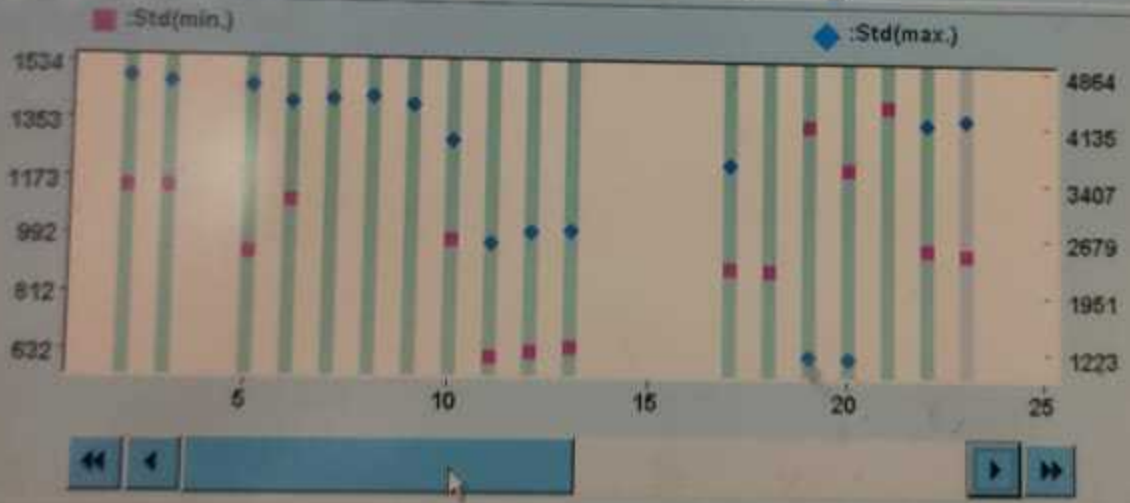
Test HBsAg II

Scale Mode Automatic

Period 06/01/2021 - 14/12/2021

Calibrator	No.	Signal	Alarm	Date	Time
Std(Min.)	23	964.5		14/12/2021	15:18
Std(Max.)	23	4315		14/12/2021	15:18

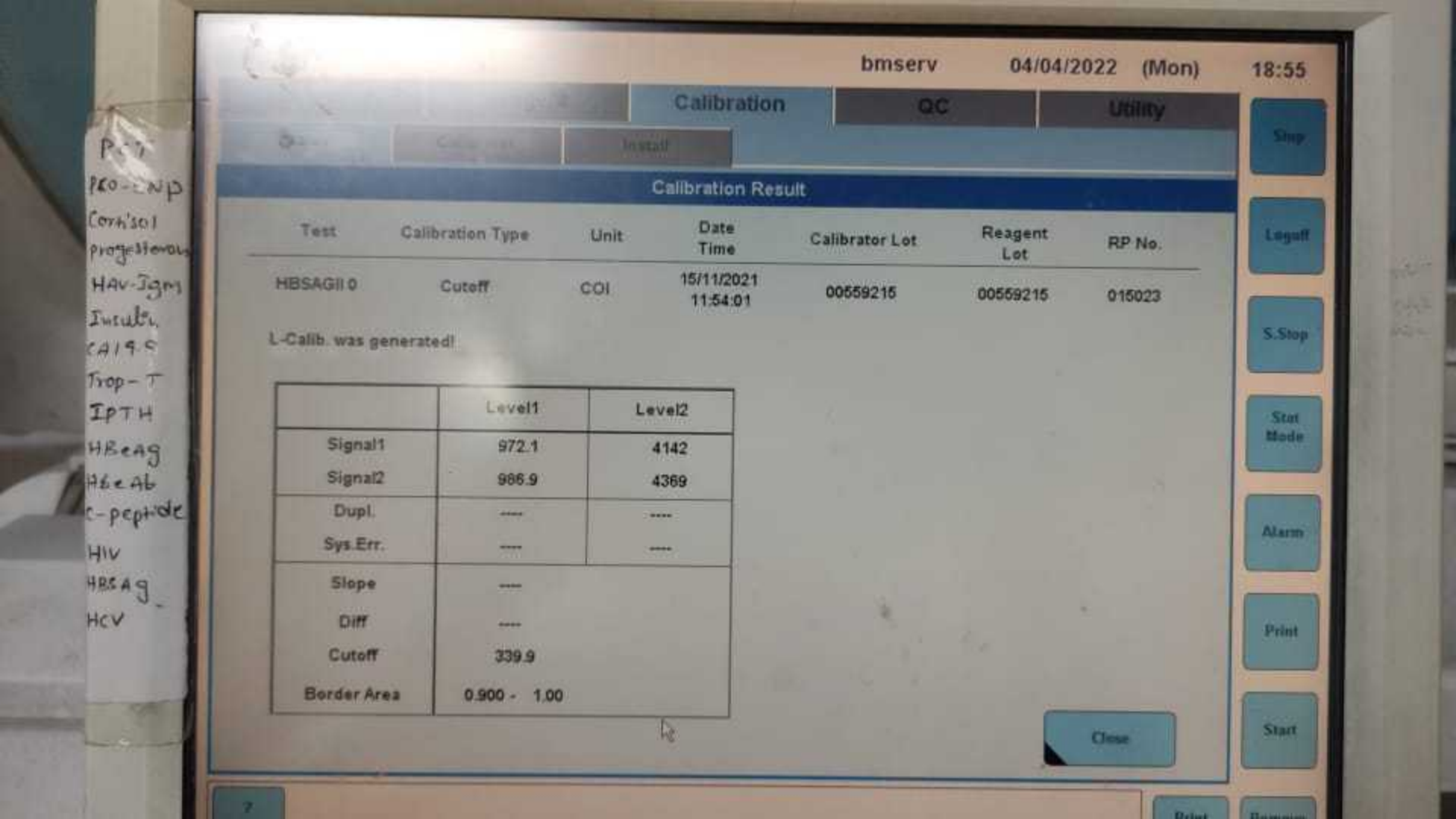
Reagent Lot No.	RP No.
00548342	025277



Scale Comment Close

Stop Logoff S.Stop Stat Mode Alarm Print Start

PRO-P
Cortisol
progesteron
HAV-IgM
Insulin
CA19-9
Trop-T
IPTH
HBeAg
HBeAb
C-peptide
HIV
HBsAg
CV


bmserv 04/04/2022 (Mon) 18:55
Calibration
QC
Utility
Install
Stop
Logoff
S.Stop
Stat Mode
Alarm
Print
Start
Calibration Result
Test
Calibration Type
Unit
Date Time
Calibrator Lot
Reagent Lot
RP No.
HBSAGII 0
Cutoff
COI
15/11/2021 11:54:01
00559215
00559215
015023
L-Calib. was generated!
Level1
Level2
Signal1 972.1 4142
Signal2 986.9 4369
Dupl. ---- ----
Sys.Err. ---- ----
Slope ----
Diff ----
Cutoff 339.9
Border Area 0.900 - 1.00
Close
PCT
PRO-BNP
Cort'sol
progesterone
HAV-IgM
Insulin
CA19-9
Trop-T
IPTH
HBeAg
HBeAb
C-peptide
HIV
HBSAg
HCV

bmserv 04/04/2022 (Mon) 18:54

Calibration | QC | Utility

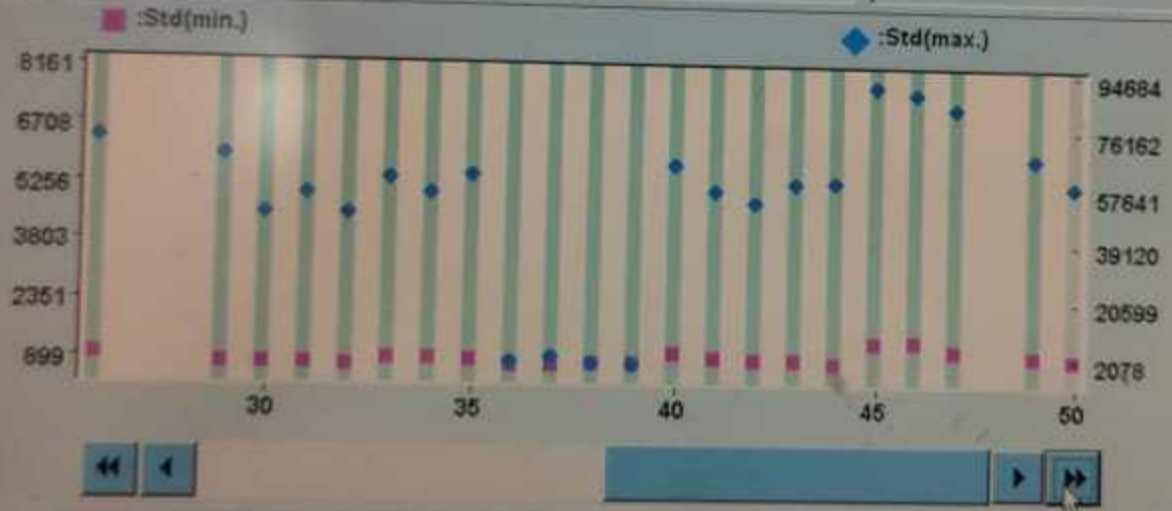
Stop | Logoff | S.Stop | Stat Mode | Alarm | Print | Start

Calibration Trace

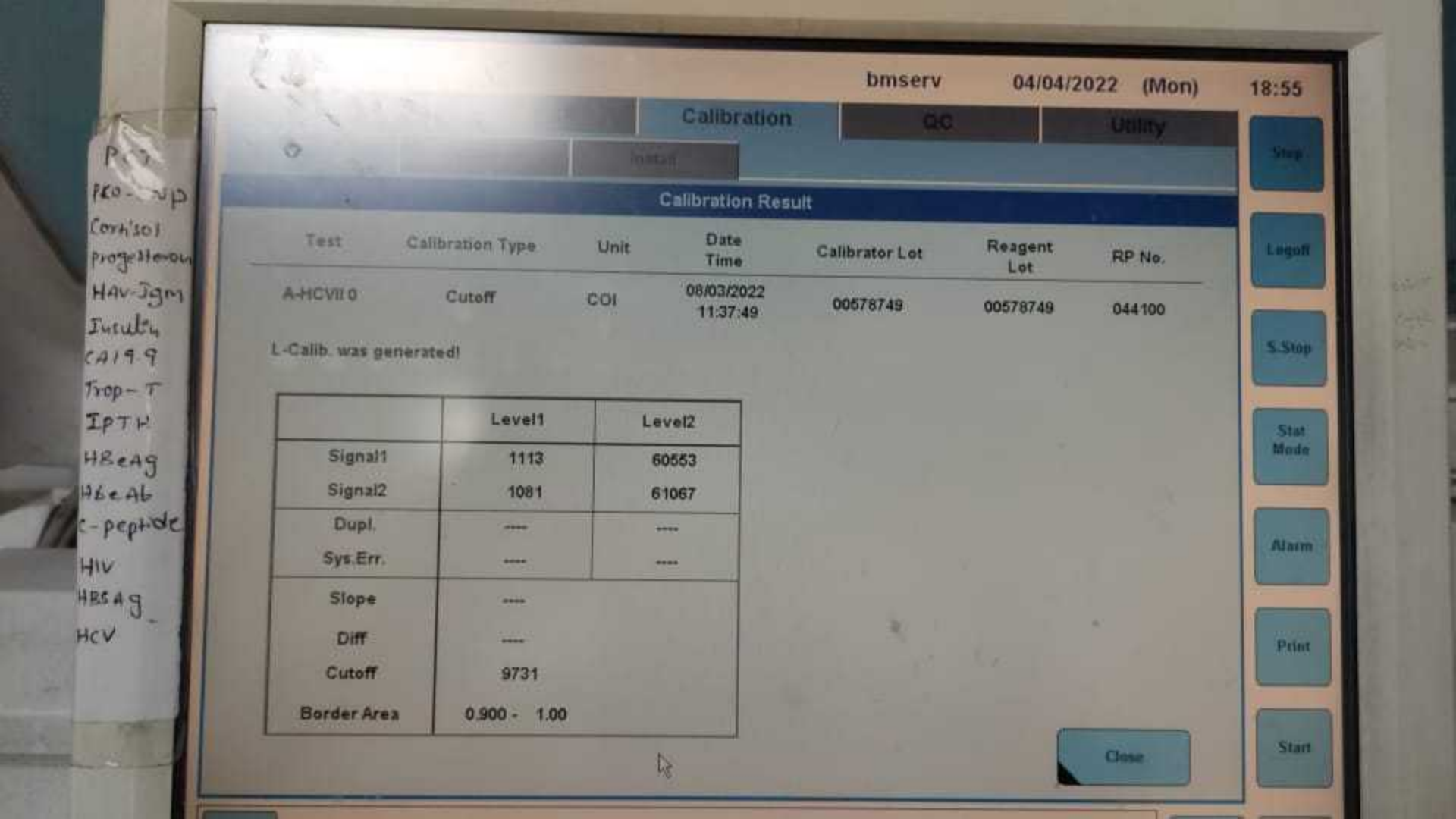
Test: A-HCVII 0 | Scale Mode: Automatic | Period: 31/03/2018 - 08/03/2022

Calibrator	No.	Signal	Alarm	Date	Time
Std(Min.)	50	1097		08/03/2022	11:37
Std(Max.)	50	60810		08/03/2022	11:37

Reagent Lot No.	RP No.
00578749	003030



Scale | Comment | Close


bmserv
04/04/2022 (Mon)
18:55
Calibration
QC
Utility
Calibration Result
Test
Calibration Type
Unit
Date Time
Calibrator Lot
Reagent Lot
RP No.
A-HCVII 0
Cutoff
COI
08/03/2022 11:37:49
00578749
00578749
044100
L-Calib. was generated!
Level1
Level2
Signal1
1113
60553
Signal2
1081
61067
Dupl.

Sys.Err.

Slope

Diff

Cutoff
9731
Border Area
0.900 - 1.00
Close
Stop
Logoff
S.Stop
Stat Mode
Alarm
Print
Start