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To Whom It May Concern

For ISO 15189:2012 and ISO 15189:2014 accredited Laboratories — requirements regarding "Calibration & Verification Procedures" [1]

All In vitro Diagnostics Products which are manufactured and distributed by Roche Diagnostics GmbH and for which a Free-Sales-Certificate is issued, are CE-marked.

The In-Vitro-Diagnostics Directive of the European Union [2A.] which is currently switching to IVD Regulation 2017/746/EU (final timeline: May 26, 2022) [2B.] requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the mentioned directive or regulation. This means that all processes in development and manufacturing of Roche Diagnostics GmbH products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 13485:2016 [3] and 21 CFR Part 820 [4].
The mentioned regulations and standards require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated. This status has to be assured by scheduled maintenance and by regular qualification resp. validation reviews and updates.

All physical quantities, calibrators and controls used in Roche Diagnostic systems are fully traceable to certified standards or reference materials. The performance of all In-vitro diagnostics systems of Roche Diagnostics GmbH at the customer site is assured if regular Quality Control measurements, cleaning and maintenance procedures as described in the instructions for use or service documentation are performed. By having controlled internal procedures and by running the tasks required in the respective user documentation, all In-vitro diagnostics systems of Roche Diagnostics GmbH will be performed as specified during their defined lifetime.

Additional calibration or verification procedures are NOT required by the user in order to assure the specified performance of every system of Roche Diagnostics GmbH. Only if a user deviates from these manufacturer's recommendations, the user have to establish site-specific calibration and verification procedures as part of his accreditation process.

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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[1] ISO 15189:2012/ ISO 15189:2014 Medical laboratories — Requirements for quality and competence

[2] A. Directive 98/79/EC of the European Parliament and of the Council of the 27 October 1998 on vitro diagnostics medical devices;
B. IVD Regulation 2017/746/EU of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

[3] EN ISO 13485:2016 Medical devices — Quality management systems-Requirements for regulatory purposes

[4] CFR Part 820, Quality System regulations 21 Regulations on medical devices

Mannheim, 10. August 2021

Sincerely,

Roche Diagnostics GmbH

i.V./*on behalf of the company*

DocuSigned by:
ECA5294AC4E94AF...

Andrea Weber
Manager Global Regulatory Affairs
Centralised and Point of Care Solutions

ppa/*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

Roche Professional Services *(ISO 9001:2015 certified)*

Customer Support Center No: 1800-123-7599 /Toll No: +91-44-30413900

Case No.	CAS-0013934445	Instrument Model	cobas 6000 core unit 150
Order No.	ORD-0017985909	Instrument Serial No.	1288-04
Contract Type	IN-COMPREHENSIVE	Finance Status	RENT
Lab/Inst./hosp.Name		Bioline Laboratory	
Customer No.		0052611292	
Contact Name :		Jasheera Rahman	
Contact Number :		+919961878447	
Address :		21/829, CKS Building,	
City :		Kozhikode	

Call Received Date/Time:	12.08.2021 16:30	Call Attended Date/Time:	22.10.2021 07:00

Job Type	PM Visit
Job Description	
Action Summary	Cause:Preventive maintenance cobas 6000 core unit Workdone:PM has been performed as per the checklist Verification:Rebooted the instrument.Performed mechanism check Customer Satisfaction Rating (1-5):5

Spare Part Replaced					
Part No	Parts Description	Batch No	Batch Expiry Date	Qty	Invoice Type

Time Report	
Effective Visit Date : 22.10.2021	Complete Date : 22.10.2021

Date	Type	Time
2021.10.22	Travel Time--Standard	0.5
2021.10.22	Working Time--Standard	2
	Total:	2.5

Customer's Signature Name : Mrs. Jasheera Rahman	Service Engineer/Application Specialist Name : Thomas Antony
	
Date: 22.10.2021	Date: 22.10.2021

Disclaimer
1. This Service report has been signed by the authorized representative of your organization. 2. Discrepancies if any must be intimated within a period of seven (7) days of the receipt of the email, in the absence of which the report will be final and conclusive. 3. This report shall be governed by the laws of India and the courts at Mumbai shall have the exclusive jurisdiction to deal with the disputes arising hereunder.

Roche Professional Services *(ISO 9001:2015 certified)*

Customer Support Center No: 1800-123-7599 /Toll No: +91-44-30413900

Case No.	CAS-0013934443	Instrument Model	cobas 6000 c 501 module
Order No.	ORD-0017985906	Instrument Serial No.	1294-14
Contract Type	IN-COMPREHENSIVE	Finance Status	RENT
Lab/Inst./hosp.Name		Bioline Laboratory	
Customer No.		0052611292	
Contact Name :		Jasheera Rahman	
Contact Number :		+919961878447	
Address :		21/829, CKS Building,	
City :		Kozhikode	

Call Received Date/Time:	12.08.2021 16:30	Call Attended Date/Time:	22.10.2021 09:00

Job Type	PM Visit
Job Description	
Action Summary	Cause:Preventive maintenance cobas c501 Workdone:PM has been performed as per the checklist Verification:Run Qc and samples Customer Satisfaction Rating (1-5):5

Spare Part Replaced

Part No	Parts Description	Batch No	Batch Expiry Date	Qty	Invoice Type
07783175001(1)	KIT MAINTENANCE 4 501/502(1)			1	Free of charge
05521521001(1)	KIT MAINTENANCE 1 501/502(1)			1	Free of charge

(1): Customer owned

Time Report

Effective Visit Date : 22.10.2021	Complete Date : 22.10.2021

Date	Type	Time
2021.10.22	Travel Time--Standard	0.5
2021.10.22	Working Time--Standard	4
	Total:	4.5

Customer's Signature Name : Mrs.Jasheera Rahman	Service Engineer/Application Specialist Name : Thomas Antony
	
Date: 22.10.2021	Date: 22.10.2021

Disclaimer
1. This Service report has been signed by the authorized representative of your organization. 2. Discrepancies if any must be intimated within a period of seven (7) days of the receipt of the email, in the absence of which the report will be final and conclusive. 3. This report shall be governed by the laws of India and the courts at Mumbai shall have the exclusive jurisdiction to deal with the disputes arising hereunder.

Data Monitor 23/03/22 15:39

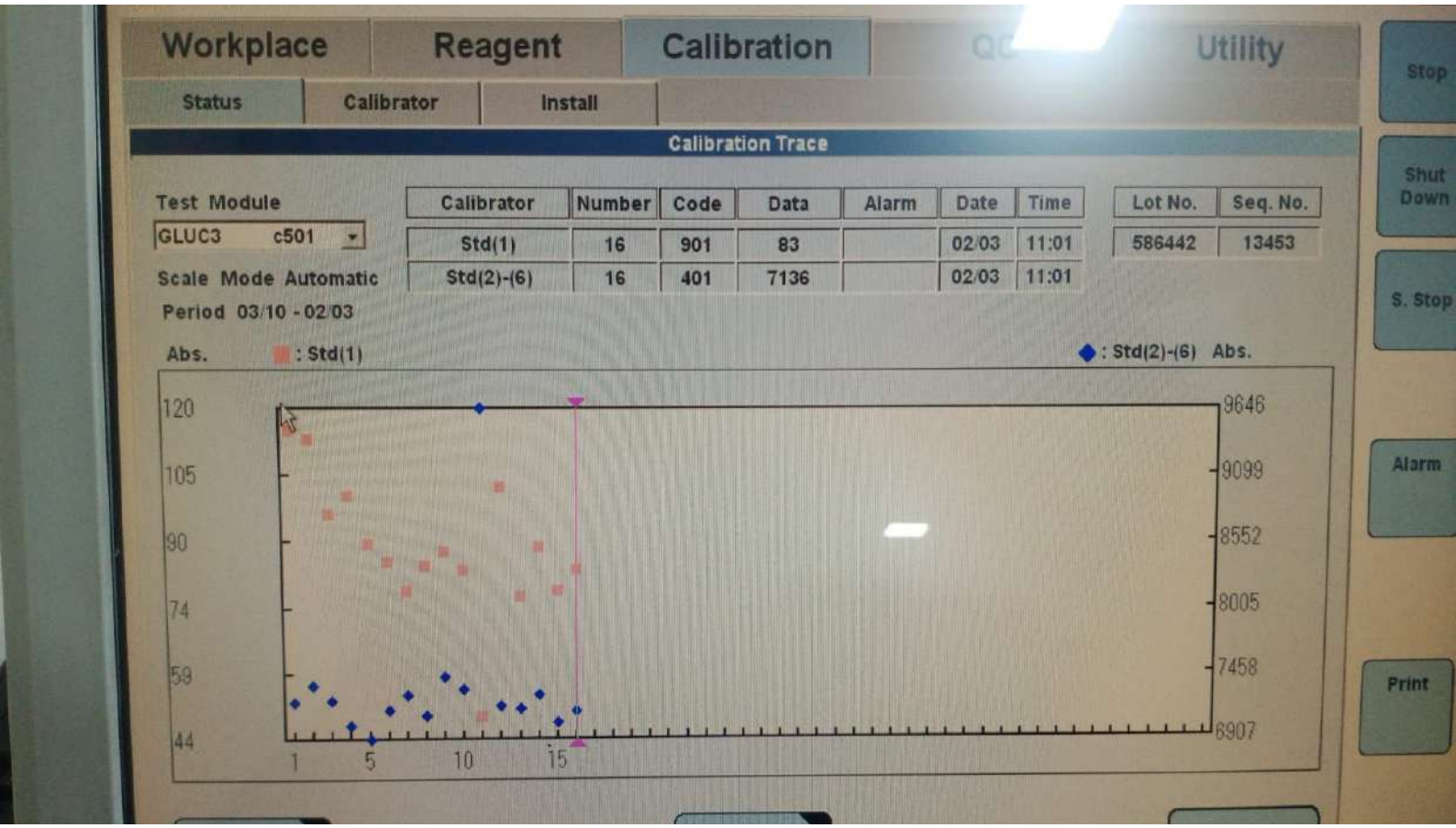
C061106 0001-2 LOT 26492 26492

22/10/21 14:04:21 bmserv	GLUC3(C) 263.1	ALB2(C) 2.61	ASTL(C) 187.8	BILD2(C) 1.76	BILT3(C) 3.82
	UA2(C) 9.1	CHO2I(C) 105.7	HDLC4(C) 14.7	TRIGL(C) 92.2	TP2(C) 3.9
	U-BUN(C) 45.6	ALTL(C) 102.2	ALP2L(C) 365	UREAL(C) 98.1	PHOS2(C) 7.2
	CA2(C) 11.8	GGTI2(C) 159	LIP(C) 77	AMYL2(C) 353	LDLC3(C) 62.7
	IRON2(C) 69.82	UIBCI(C) 102.9	CK2(C) 424	MG-2(C) 4.50	LDHI2(C) 401

Data Monitor 23/03/22 15:42

C060106 0001-1 LOT 26491 26491

22/10/21 14:04:21 bmserv	GLUC3(C) 78.5	ALB2(C) 4.09	ASTL(C) 37.5	BILD2(C) 0.40	BILT3(C) 0.84
	UA2(C) 4.5	CHO2I(C) 257.3	HDLC4(C) 52.4	TRIGL(C) 188.9	TP2(C) 6.1
	U-BUN(C) 15.2	ALTL(C) 27.4	ALP2L(C) 95	UREAL(C) 32.9	PHOS2(C) 3.5
	CA2(C) 9.2	GGTI2(C) 66	LIP(C) 47	AMYL2(C) 78	LDLC3(C) 129.2
	IRON2(C) 252.81	UIBCI(C) 48.2	CK2(C) 131	MG-2(C) 1.97	LDHI2(C) 168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Utility
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Install
Shut Down
Calibration Trace
S. Stop
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GLUC3 c501
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Period 03/10 - 02/03
Calibrator | Number | Code | Data | Alarm | Date | Time | Lot No. | Seq. No.
Std(1) | 16 | 901 | 83 | | 02/03 | 11:01 | 586442 | 13453
Std(2)-(6) | 16 | 401 | 7136 | | 02/03 | 11:01
Alarm
Abs.
: Std(1)
: Std(2)-(6) Abs.
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74
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15
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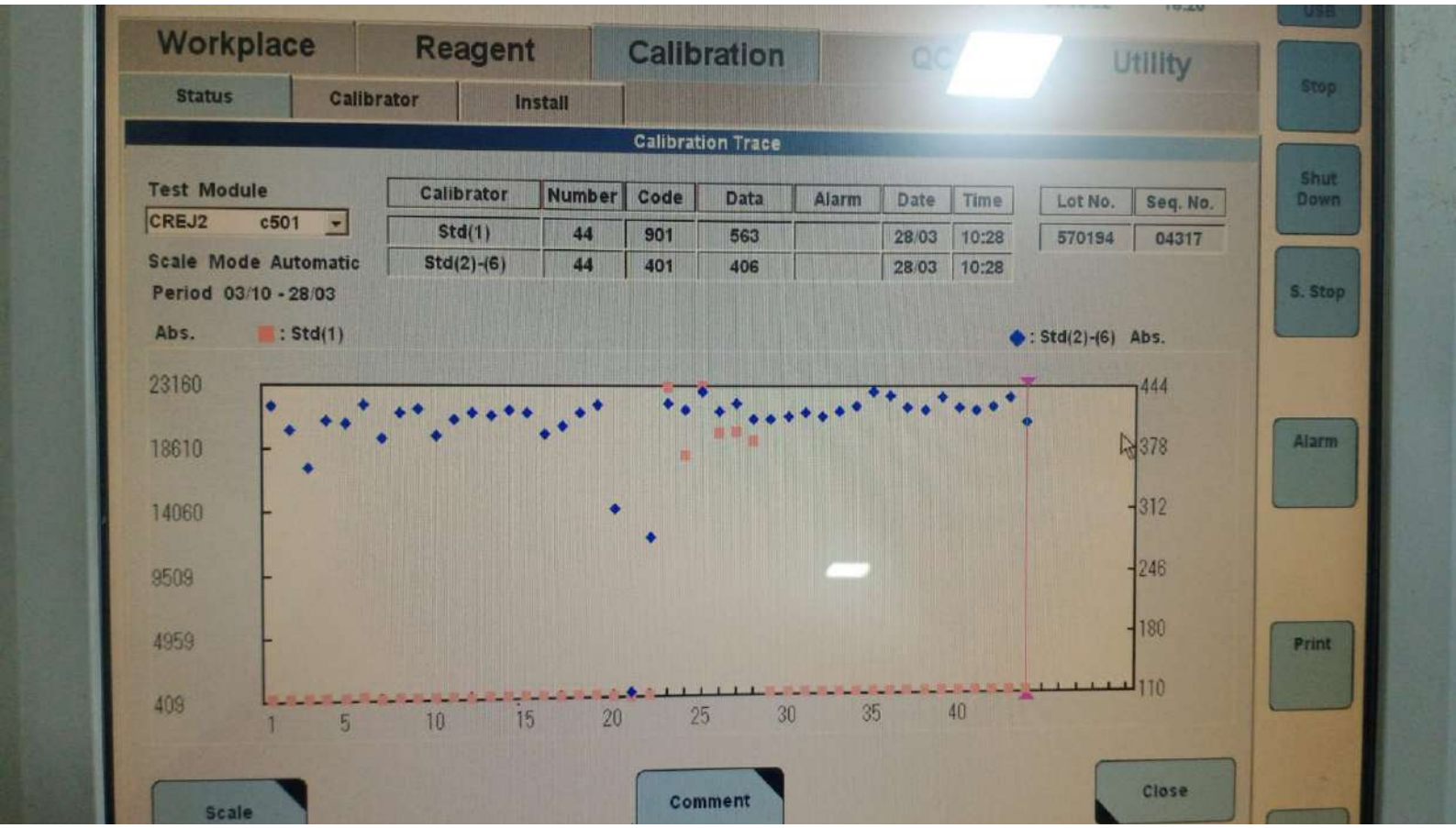
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QC
Utility
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Calibrator
Install
Stop
Shut Down
S. Stop
Alarm
Print
Calibration Trace
Test Module
CREJ2 c501
Scale Mode Automatic
Period 03/10 - 28/03
Calibrator | Number | Code | Data | Alarm | Date | Time | Lot No. | Seq. No.
Std(1) | 44 | 901 | 563 | | 28/03 | 10:28 | 570194 | 04317
Std(2)-(6) | 44 | 401 | 406 | | 28/03 | 10:28
Abs.
: Std(1)
: Std(2)-(6) Abs.
23160
18610
14060
9509
4959
409
444
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312
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110
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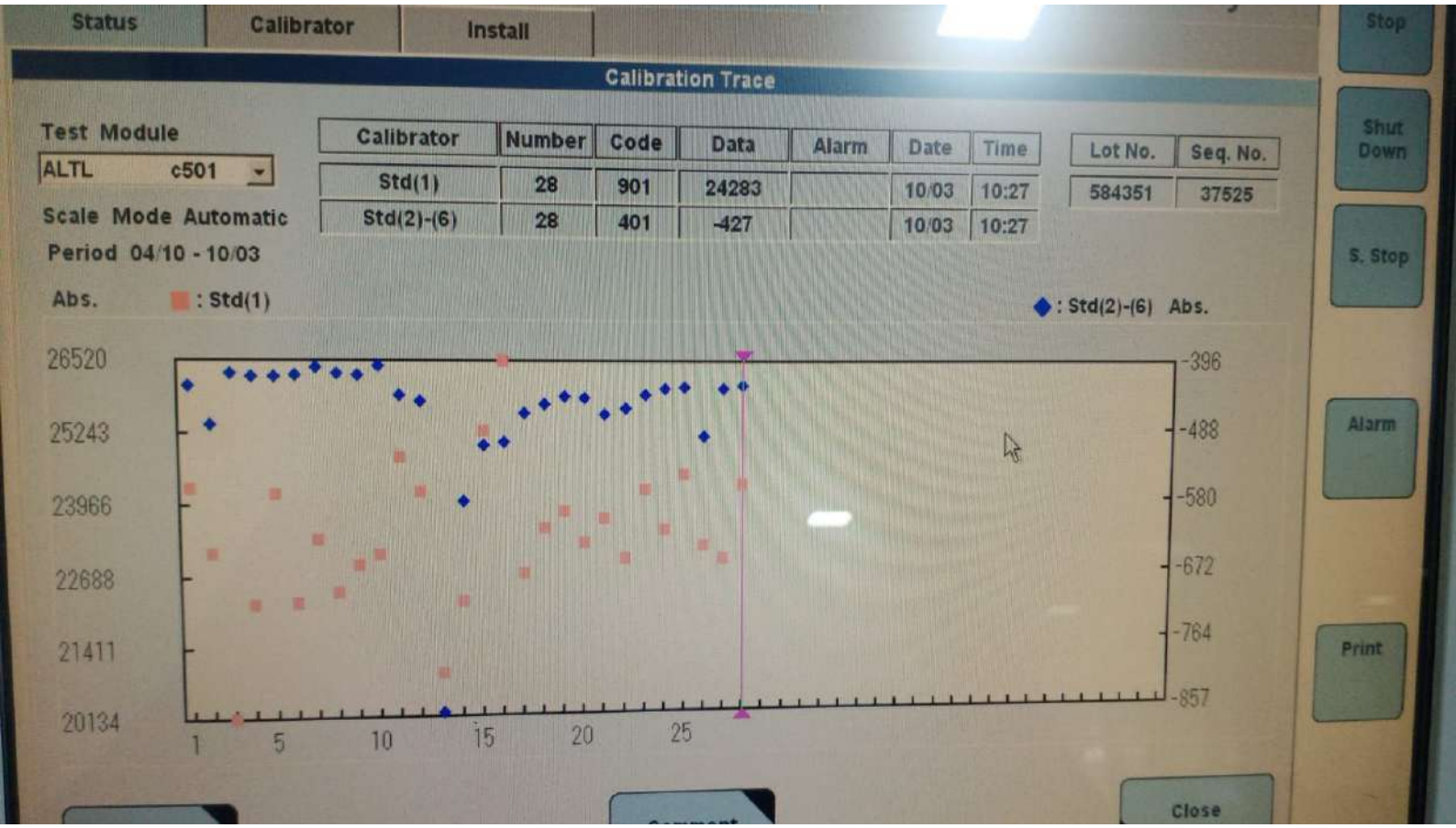
15
20
25
30
35
40
Scale
Comment
Close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Stop
Calibration Trace
Test Module
ALTL c501
Scale Mode Automatic
Period 04/10 - 10/03
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 28 | 901 | 24283 | | 10/03 | 10:27
Std(2)-(6) | 28 | 401 | -427 | | 10/03 | 10:27
Lot No. | Seq. No.
584351 | 37525
Shut Down
S. Stop
Alarm
Print
Abs.
: Std(1)
: Std(2)-(6) Abs.
26520
25243
23966
22688
21411
20134
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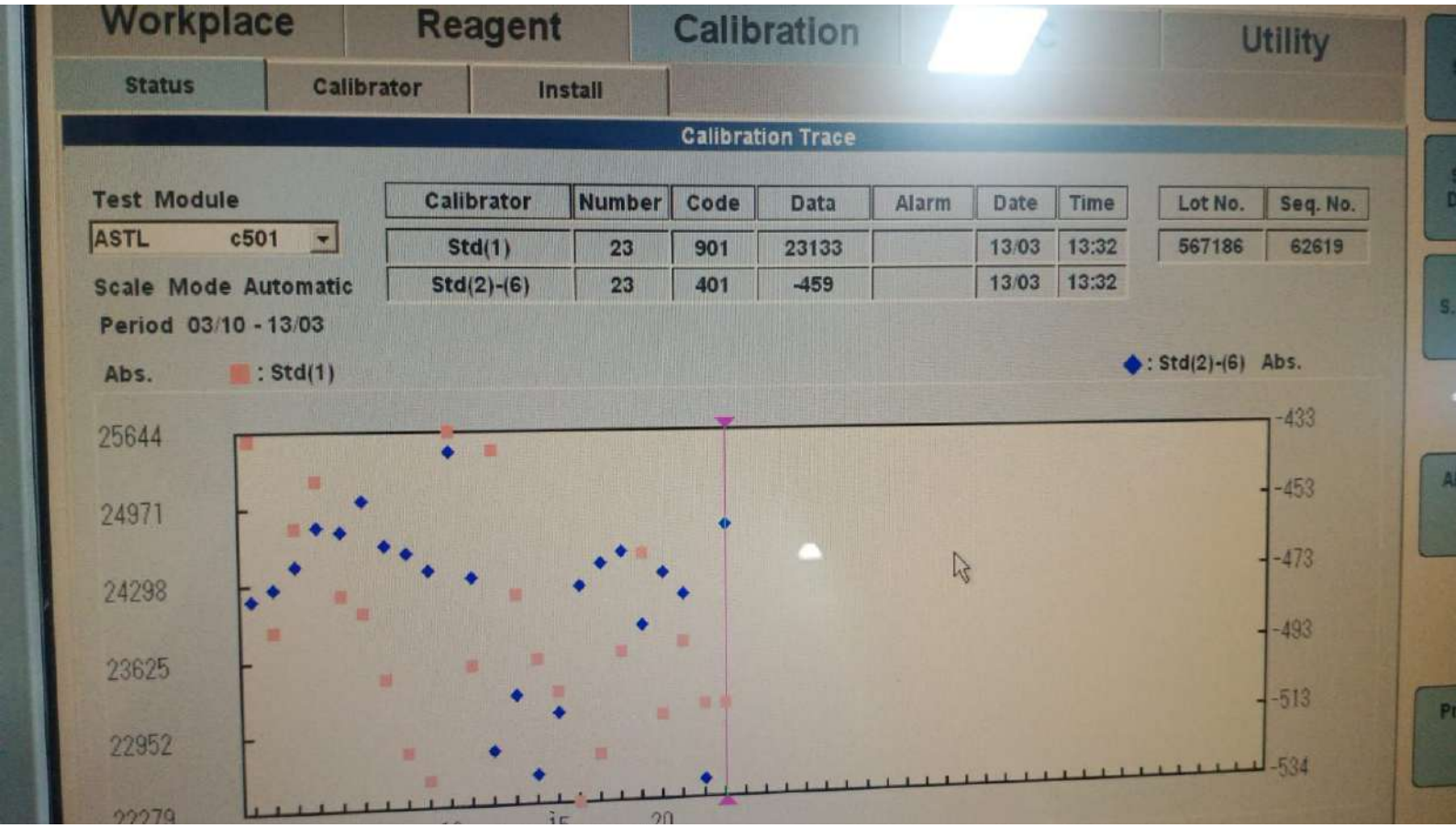
-672
-764
-857
1
5
10
15
20
25
Close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Reagent
Calibration
Utility
Status
Calibrator
Install
Calibration Trace
Test Module
ASTL c501
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Period 03/10 - 13/03
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Std(1) | 23 | 901 | 23133 | | 13/03 | 13:32 | 567186 | 62619
Std(2)-(6) | 23 | 401 | -459 | | 13/03 | 13:32
Abs.
: Std(1)
: Std(2)-(6) Abs.
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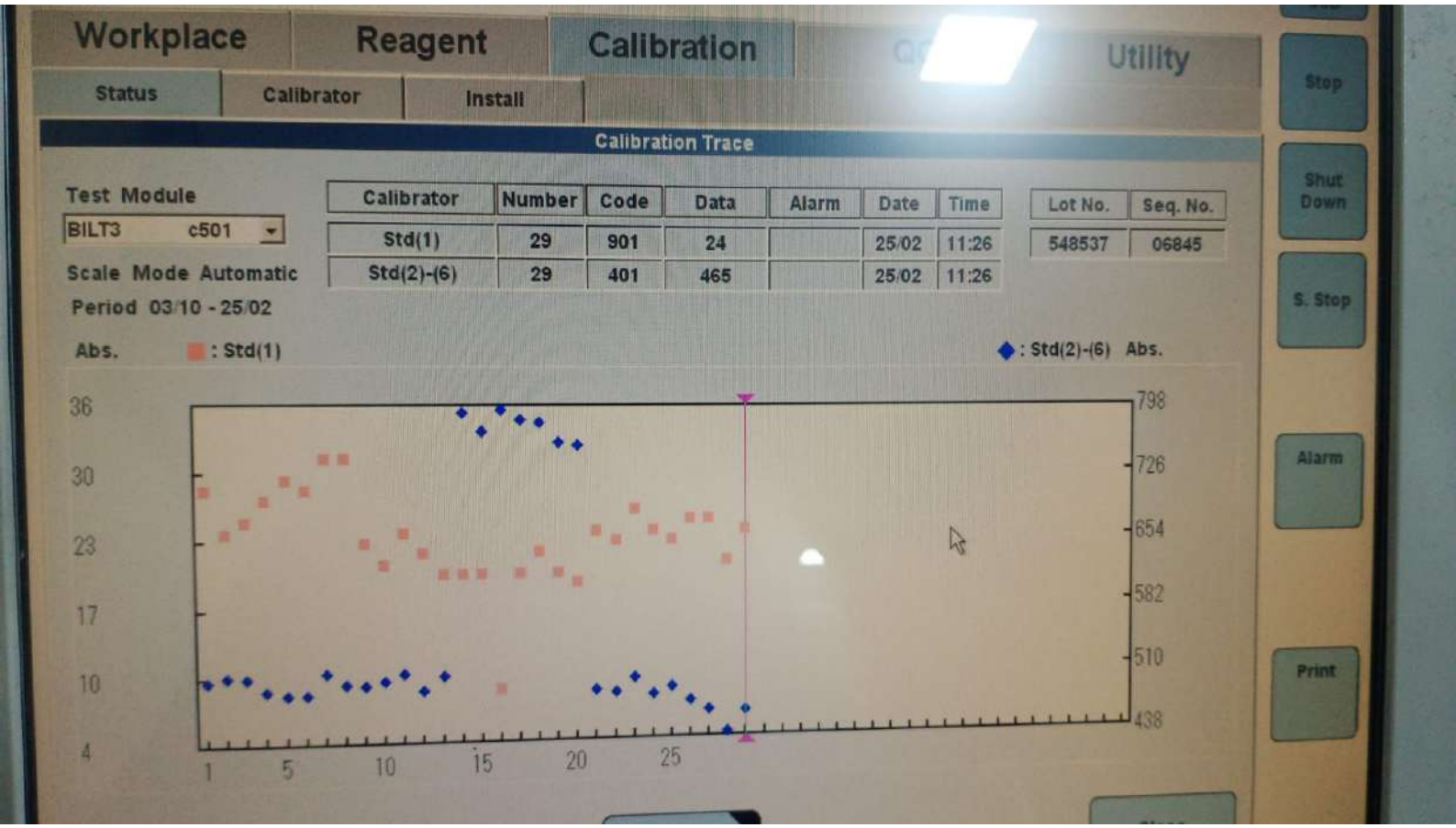
-433
-453
-473
-493
-513
-534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Reagent
Calibration
Utility
Status
Calibrator
Install
Stop
Shut Down
S. Stop
Alarm
Print
Calibration Trace
Test Module
BILT3 c501
Scale Mode Automatic
Period 03/10 - 25/02
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 29 | 901 | 24 | | 25/02 | 11:26
Std(2)-(6) | 29 | 401 | 465 | | 25/02 | 11:26
Lot No. | Seq. No.
548537 | 06845
Abs.
: Std(1)
: Std(2)-(6) Abs.
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23
17
10
4
798
726
654
582
510
438
1
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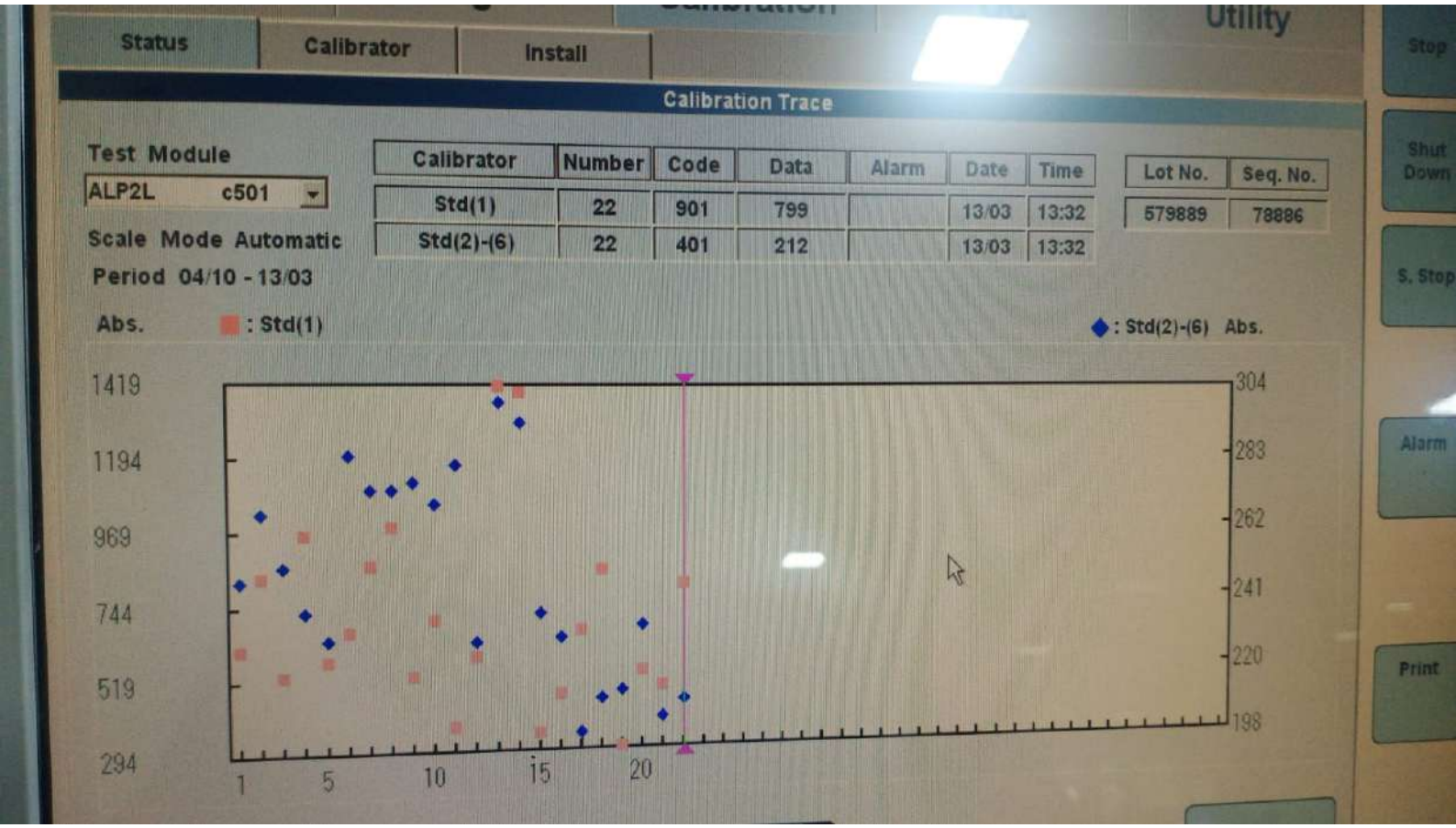
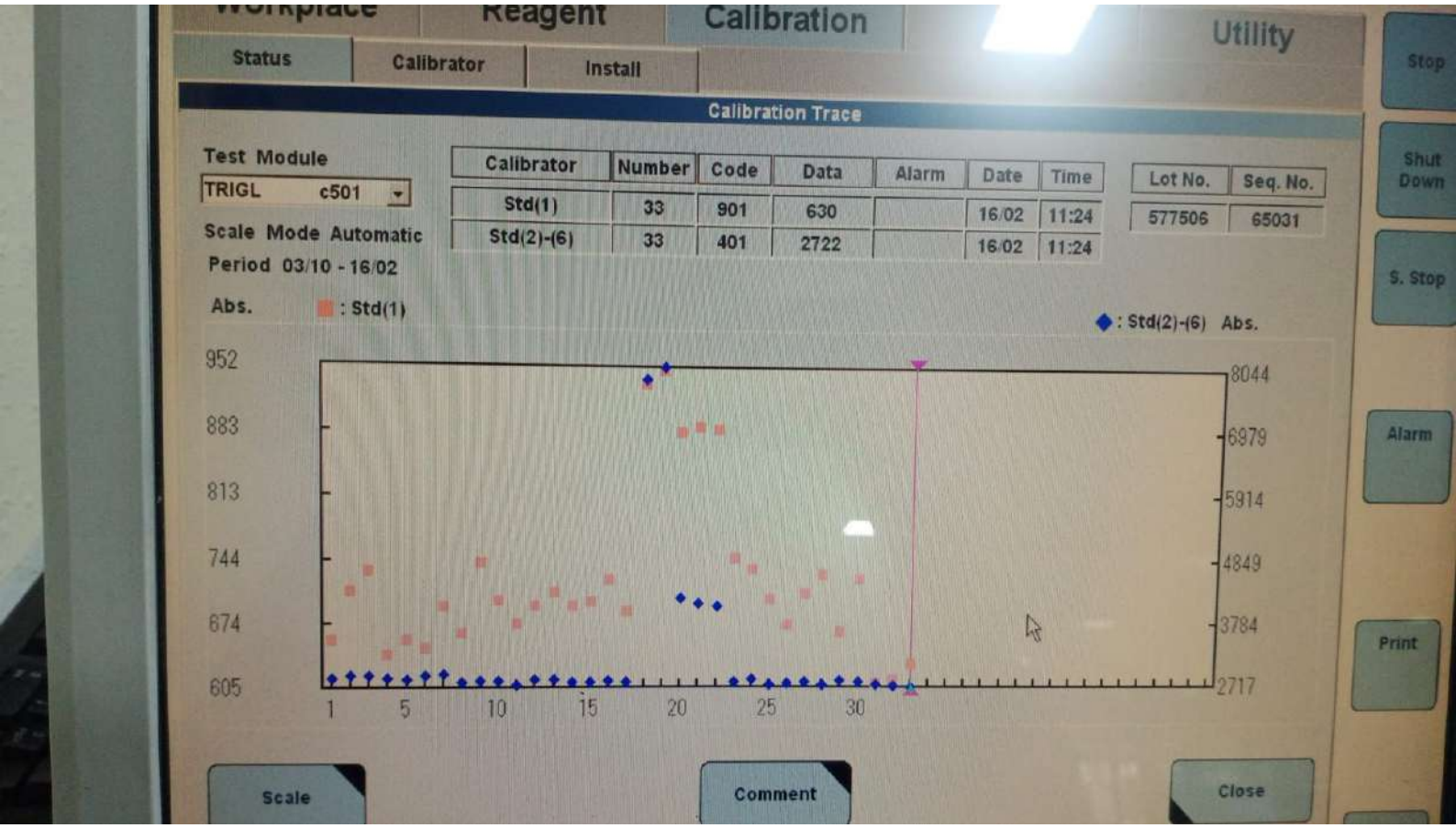

Status
Calibrator
Install
Utility
Stop
Shut Down
S. Stop
Alarm
Print
Calibration Trace
Test Module
ALP2L c501
Scale Mode Automatic
Period 04/10 - 13/03
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 22 | 901 | 799 | | 13/03 | 13:32
Std(2)-(6) | 22 | 401 | 212 | | 13/03 | 13:32
Lot No. | Seq. No.
579889 | 78886
Abs.
: Std(1)
: Std(2)-(6) Abs.
1419
1194
969
744
519
294
304
283
262
241
220
198
1
5
10
15
20


Workplace
Reagent
Calibration
Utility
Status
Calibrator
Install
Stop
Shut Down
S. Stop
Alarm
Print
Calibration Trace
Test Module
TRIGL c501
Scale Mode Automatic
Period 03/10 - 16/02
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 33 | 901 | 630 | | 16/02 | 11:24
Std(2)-(6) | 33 | 401 | 2722 | | 16/02 | 11:24
Lot No. | Seq. No.
577506 | 65031
Abs. : Std(1)
: Std(2)-(6) Abs.
952
883
813
744
674
605
8044
6979
5914
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Scale
Comment
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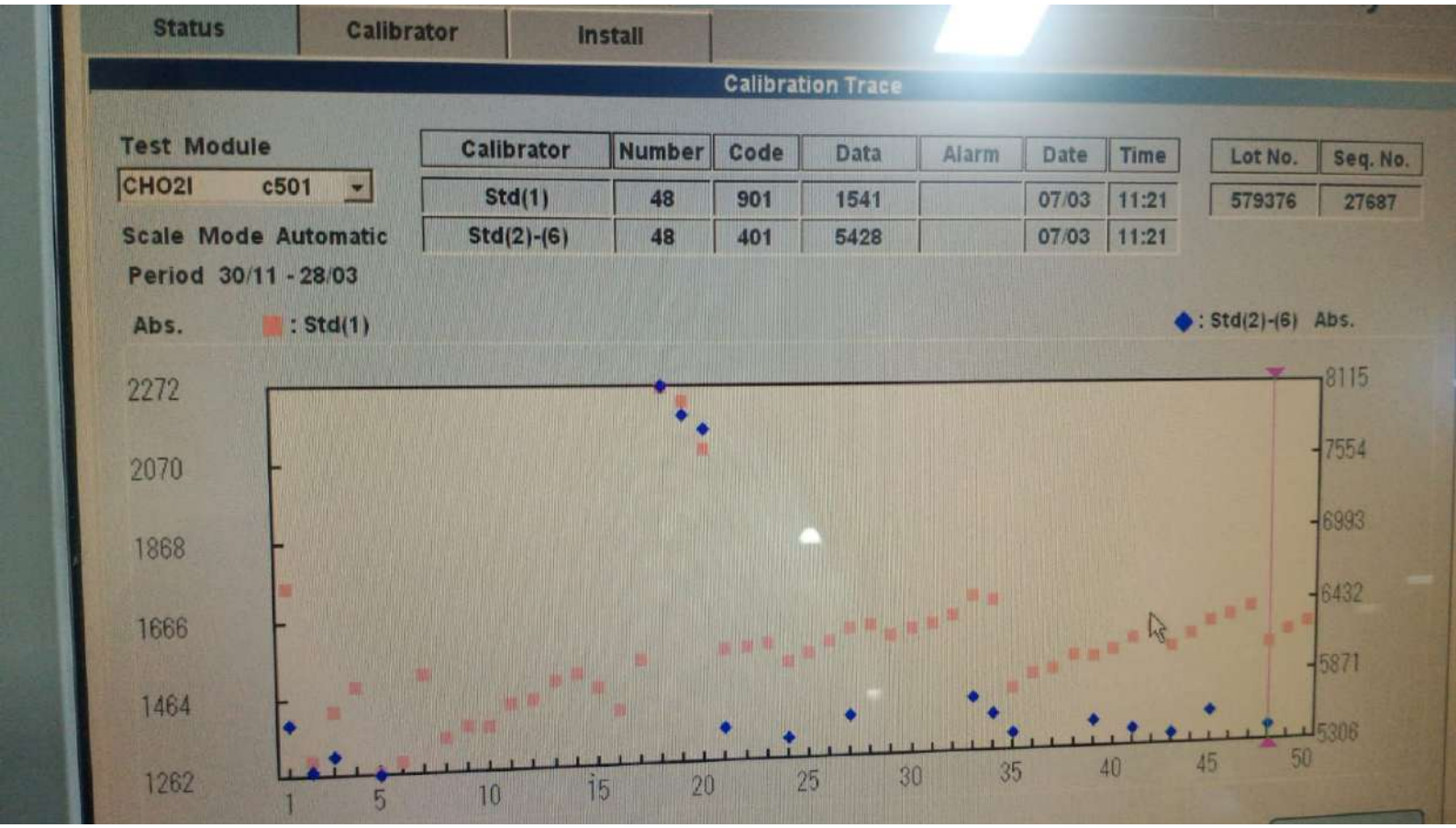
Status
Calibrator
Install
Calibration Trace
Test Module
CHO2I c501
Scale Mode Automatic
Period 30/11 - 28/03
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 48 | 901 | 1541 | | 07/03 | 11:21
Std(2)-(6) | 48 | 401 | 5428 | | 07/03 | 11:21
Lot No. | Seq. No.
579376 | 27687
Abs.
: Std(1)
: Std(2)-(6) Abs.
2272
2070
1868
1666
1464
1262
8115
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6432
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45
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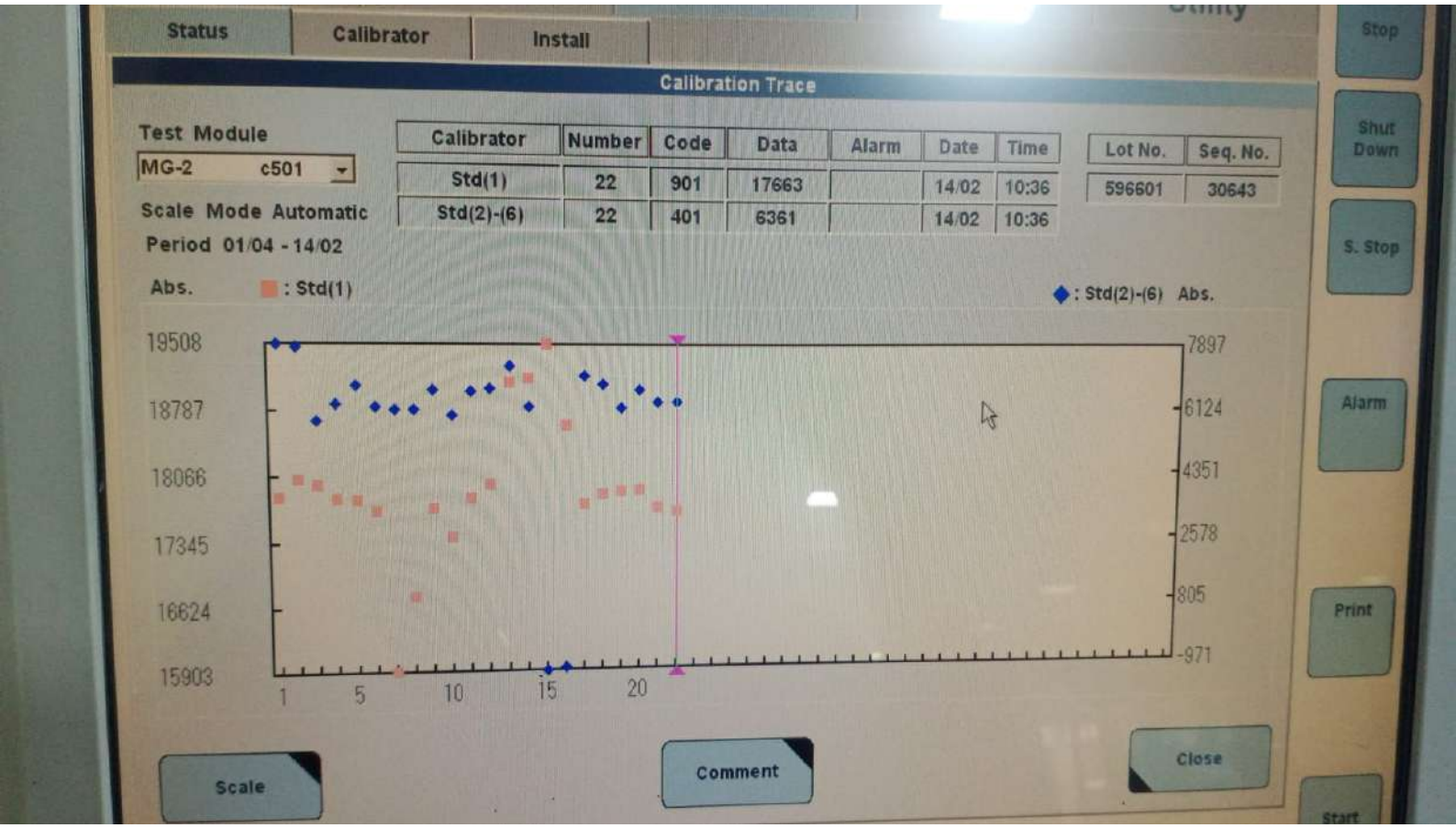
Status
Calibrator
Install
Stop
Calibration Trace
Test Module
MG-2 c501
Scale Mode Automatic
Period 01/04 - 14/02
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 22 | 901 | 17663 | | 14/02 | 10:36
Std(2)-(6) | 22 | 401 | 6361 | | 14/02 | 10:36
Lot No. | Seq. No.
596601 | 30643
Shut Down
S. Stop
Abs.
: Std(1)
: Std(2)-(6) Abs.
19508
18787
18066
17345
16624
15903
7897
6124
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2578
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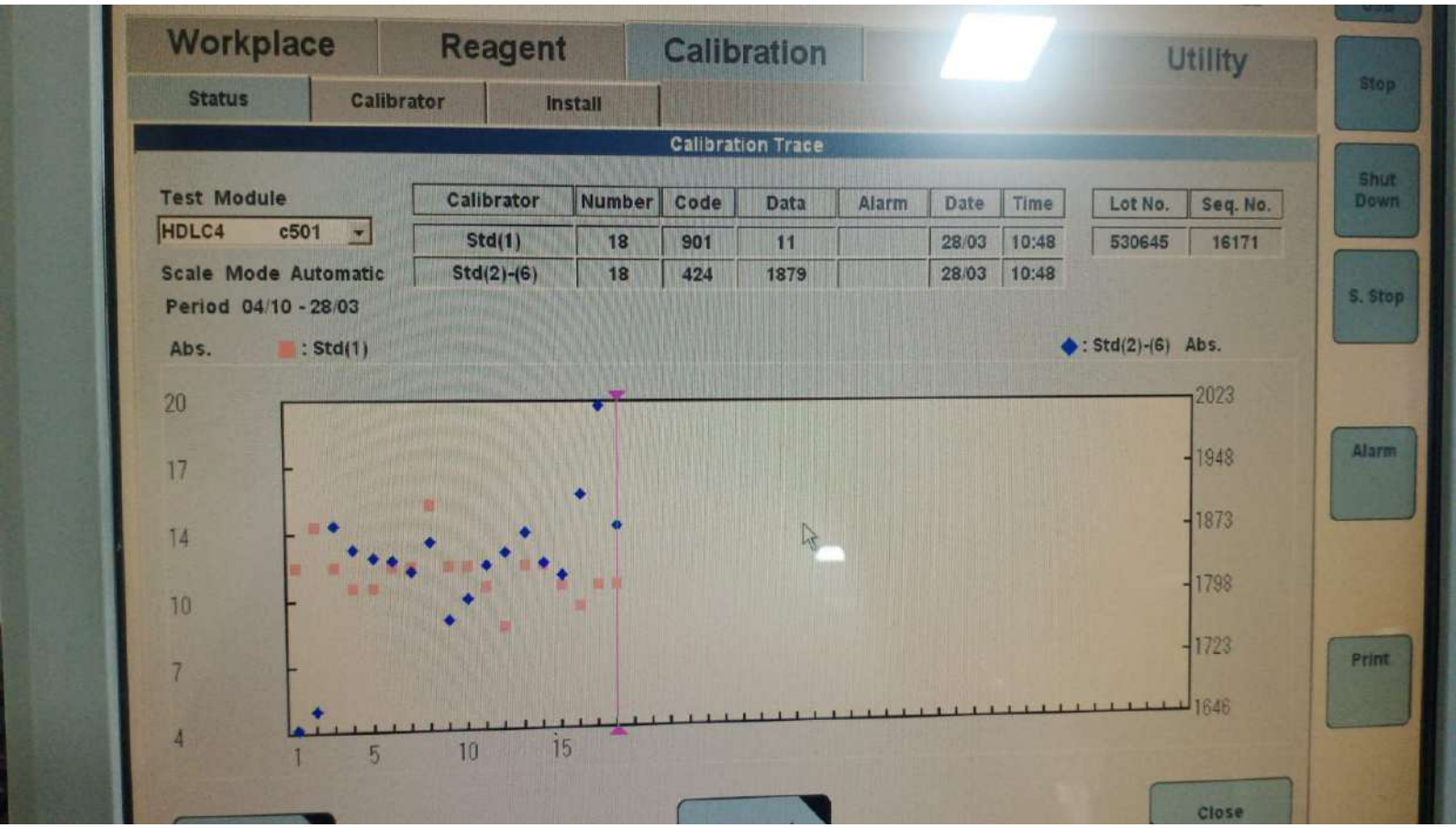
1
5
10
15
20
Alarm
Print
Scale
Comment
Close
Start


Workplace
Reagent
Calibration
Utility
Status
Calibrator
Install
Calibration Trace
Test Module
HDLC4 c501
Scale Mode Automatic
Period 04/10 - 28/03
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 18 | 901 | 11 | | 28/03 | 10:48
Std(2)-(6) | 18 | 424 | 1879 | | 28/03 | 10:48
Lot No. | Seq. No.
530645 | 16171
Abs. : Std(1)
: Std(2)-(6) Abs.
20
17
14
10
7
4
2023
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1873
1798
1723
1646
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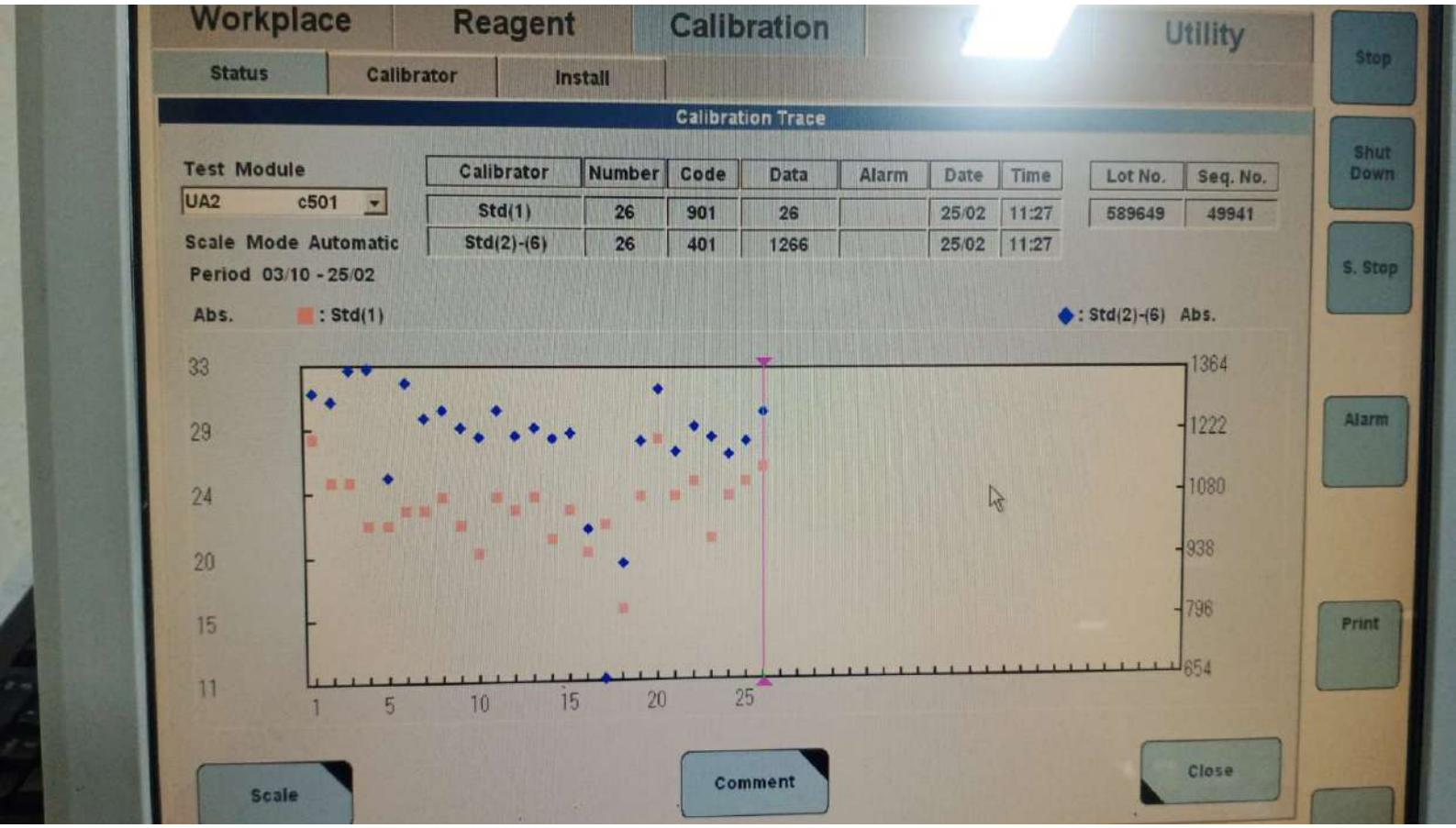
15
Stop
Shut Down
S. Stop
Alarm
Print
Close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Reagent
Calibration
Utility
Status
Calibrator
Install
Calibration Trace
Test Module
UA2 c501
Scale Mode Automatic
Period 03/10 - 25/02
Calibrator | Number | Code | Data | Alarm | Date | Time | Lot No. | Seq. No.
Std(1) | 26 | 901 | 26 | | 25/02 | 11:27 | 589649 | 49941
Std(2)-(6) | 26 | 401 | 1266 | | 25/02 | 11:27
Abs. : Std(1)
: Std(2)-(6) Abs.
33
29
24
20
15
11
1364
1222
1080
938
796
654
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15
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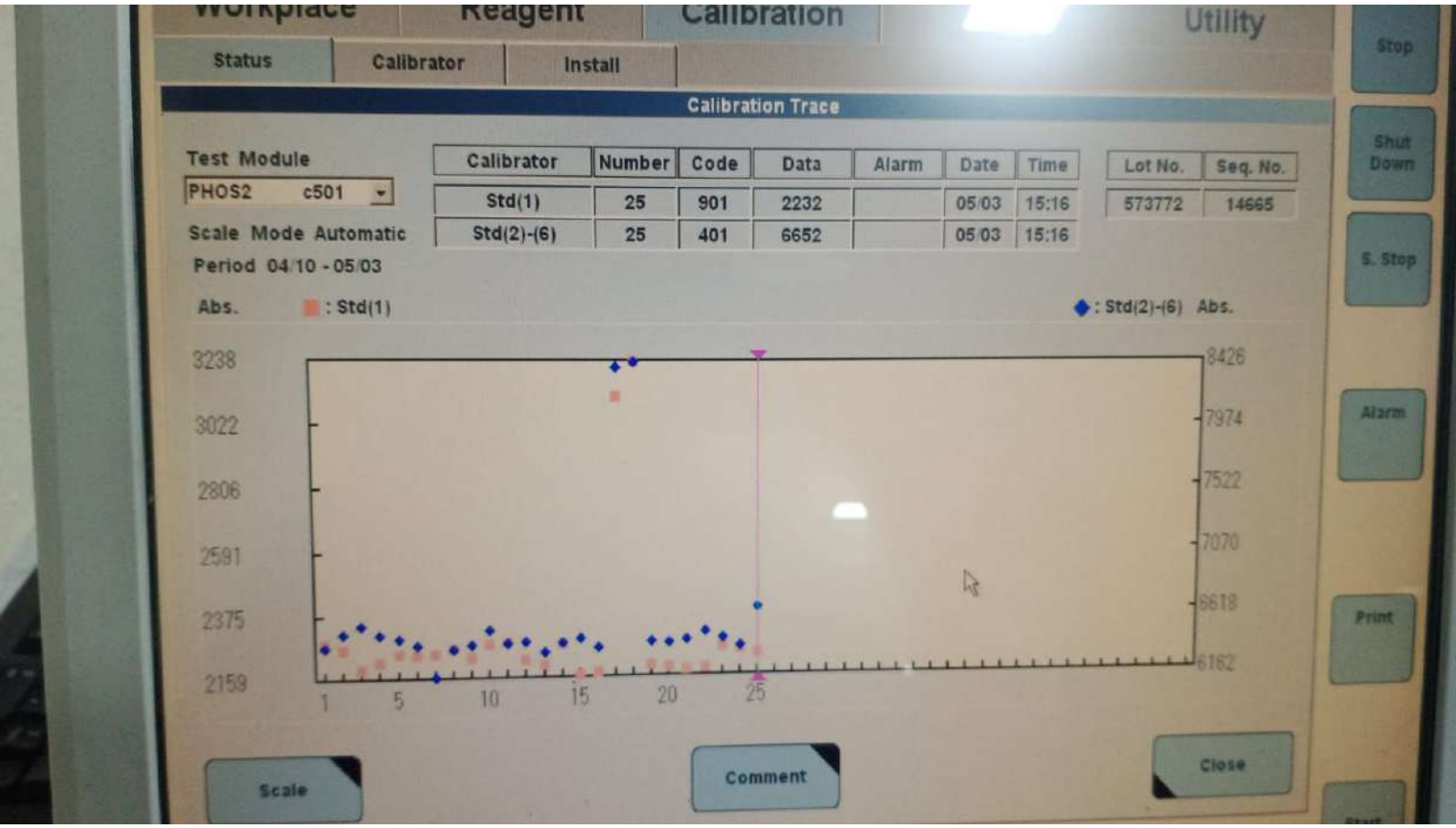
25
Stop
Shut Down
S. Stop
Alarm
Print
Scale
Comment
Close


Workplace
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Calibration
Utility
Status
Calibrator
Install
Stop
Shut Down
S. Stop
Alarm
Print
Calibration Trace
Test Module
PHOS2 c501
Scale Mode Automatic
Period 04/10 - 05/03
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 25 | 901 | 2232 | | 05/03 | 15:16
Std(2)-(6) | 25 | 401 | 6652 | | 05/03 | 15:16
Lot No. | Seq. No.
573772 | 14665
Abs.
: Std(1)
: Std(2)-(6) Abs.
3238
3022
2806
2591
2375
2159
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7974
7522
7070
6618
6162
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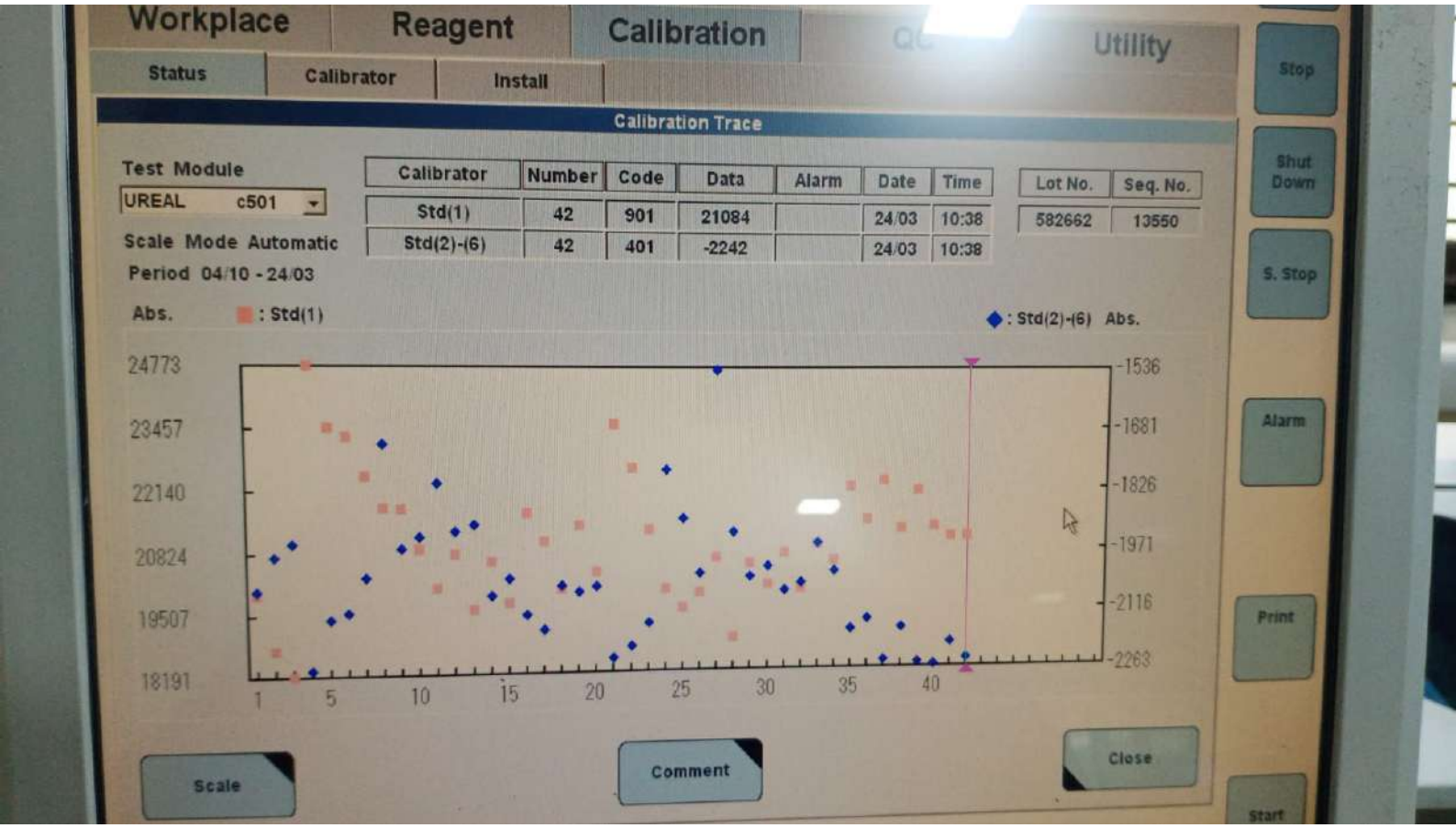
5
10
15
20
25
Scale
Comment
Close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Utility
Status
Calibrator
Install
Stop
Shut Down
S. Stop
Alarm
Print
Calibration Trace
Test Module
UREAL c501
Scale Mode Automatic
Period 04/10 - 24/03
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 42 | 901 | 21084 | | 24/03 | 10:38
Std(2)-(6) | 42 | 401 | -2242 | | 24/03 | 10:38
Lot No. | Seq. No.
582662 | 13550
Abs. : Std(1)
: Std(2)-(6) Abs.
24773
23457
22140
20824
19507
18191
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-1681
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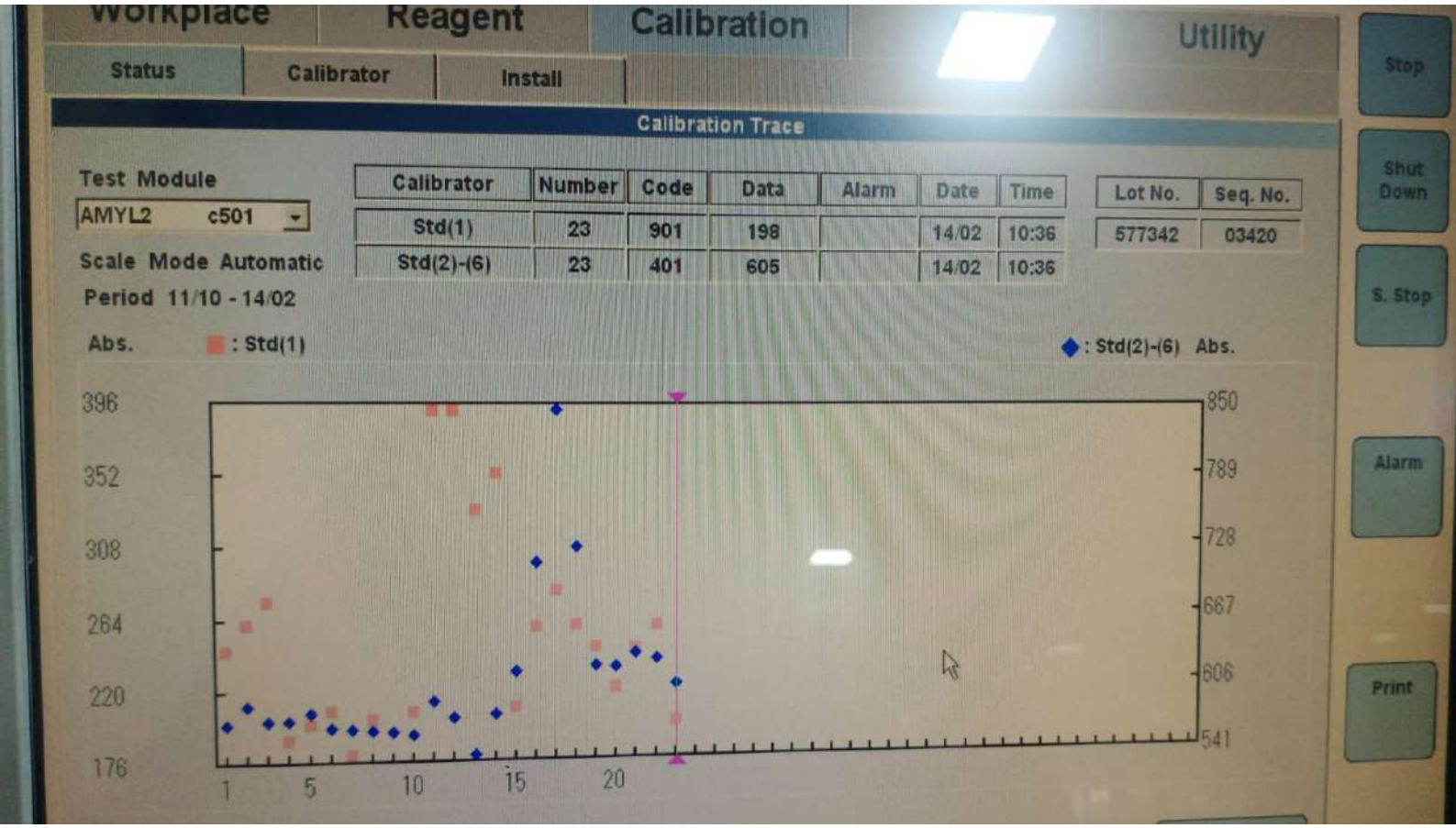
-2116
-2263
1 5 10 15 20 25 30 35 40
Scale
Comment
Close
Start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Calibration
Utility
Status
Calibrator
Install
Stop
Shut Down
S. Stop
Alarm
Print
Calibration Trace
Test Module
AMYL2 c501
Scale Mode Automatic
Period 11/10 - 14/02
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 23 | 901 | 198 | | 14/02 | 10:36
Std(2)-(6) | 23 | 401 | 605 | | 14/02 | 10:36
Lot No. | Seq. No.
577342 | 03420
Abs. : Std(1)
: Std(2)-(6) Abs.
396
352
308
264
220
176
850
789
728
667
606
541
1
5
10
15
20

Status | Calibrator | Install

Calibration Trace

Test Module

CA2 c501

Scale Mode Automatic

Period 04/10 - 13/03

Calibrator	Number	Code	Data	Alarm	Date	Time	Lot No.	Seq. No.
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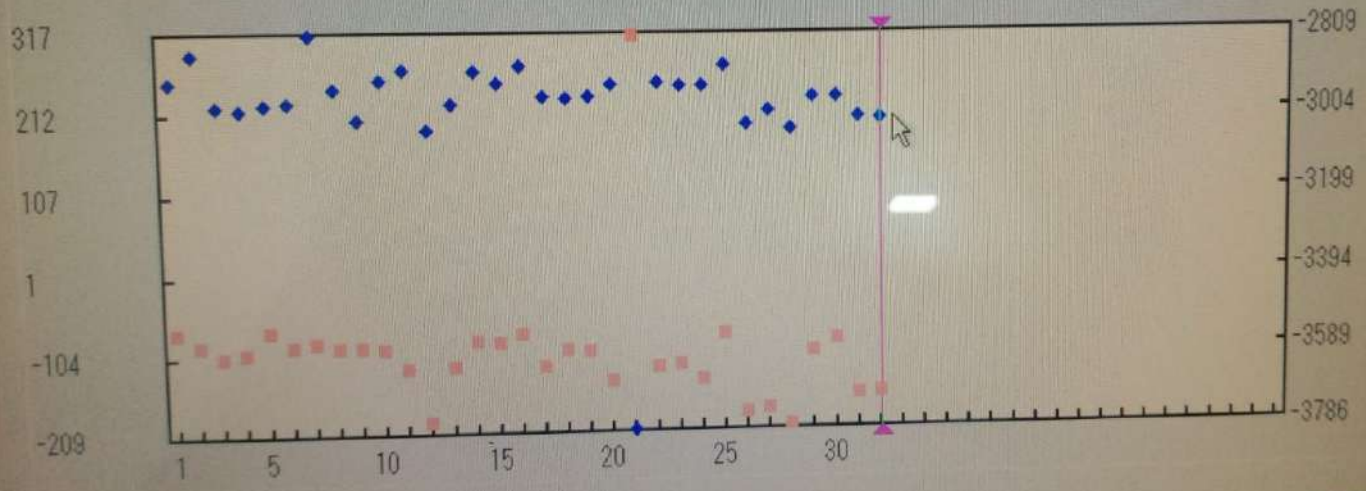
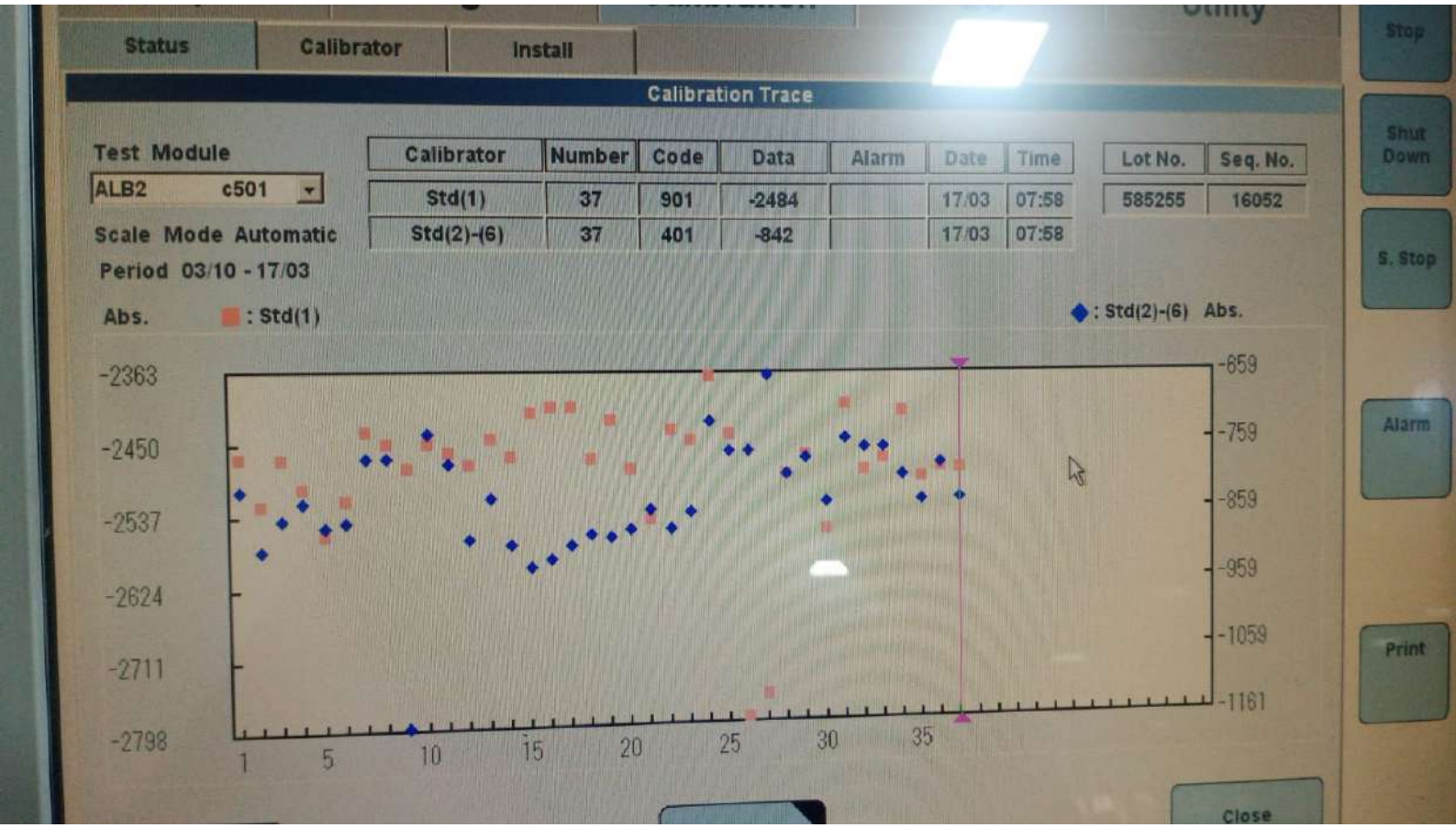
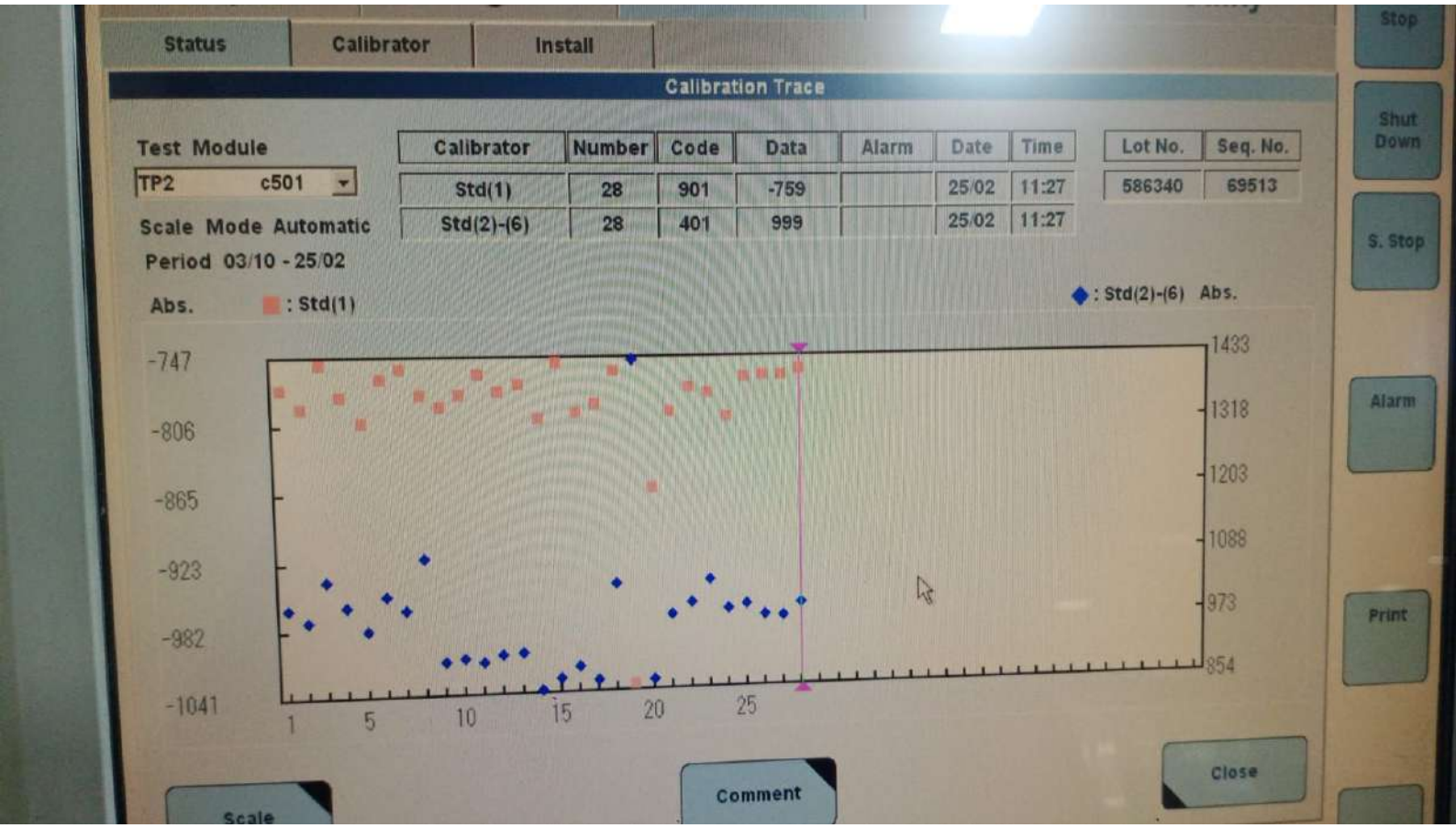
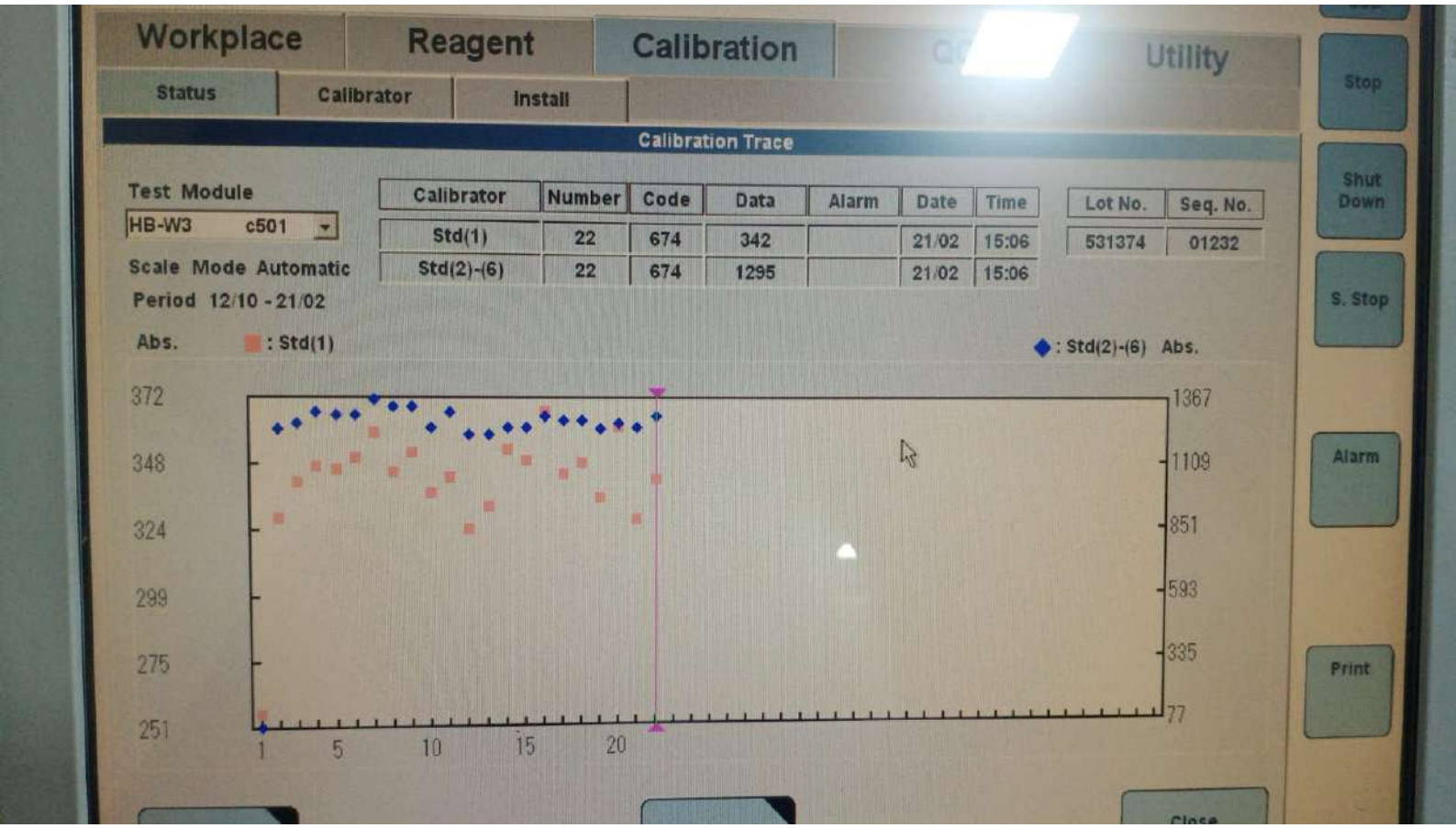
Std(2)-(6)	32	401	-3021		13/03	13:32		




Status
Calibrator
Install
Calibration Trace
Test Module
ALB2 c501
Scale Mode Automatic
Period 03/10 - 17/03
Calibrator
Number
Code
Data
Alarm
Date
Time
Std(1)
37
901
-2484
17/03
07:58
Std(2)-(6)
37
401
-842
17/03
07:58
Lot No.
Seq. No.
585255
16052
Abs.
: Std(1)
: Std(2)-(6) Abs.
-2363
-2450
-2537
-2624
-2711
-2798
-659
-759
-859
-959
-1059
-1161
1
5
10
15
20
25
30
35
Stop
Shut Down
S. Stop
Alarm
Print
Close


Status
Calibrator
Install
Stop
Calibration Trace
Shut Down
Test Module
TP2 c501
Scale Mode Automatic
Period 03/10 - 25/02
S. Stop
Calibrator | Number | Code | Data | Alarm | Date | Time | Lot No. | Seq. No.
Std(1) | 28 | 901 | -759 | | 25/02 | 11:27 | 586340 | 69513
Std(2)-(6) | 28 | 401 | 999 | | 25/02 | 11:27
Abs.
: Std(1)
: Std(2)-(6) Abs.
-747
-806
-865
-923
-982
-1041
1433
1318
1203
1088
973
854
1
5
10
15
20
25
Alarm
Print
Close
Comment
Scale


Workplace
Reagent
Calibration
Utility
Status
Calibrator
Install
Calibration Trace
Test Module
HB-W3 c501
Scale Mode Automatic
Period 12/10 - 21/02
Calibrator | Number | Code | Data | Alarm | Date | Time
Std(1) | 22 | 674 | 342 | | 21/02 | 15:06
Std(2)-(6) | 22 | 674 | 1295 | | 21/02 | 15:06
Lot No. | Seq. No.
531374 | 01232
Abs.
: Std(1)
: Std(2)-(6) Abs.
372
348
324
299
275
251
1367
1109
851
593
335
77
1
5
10
15
20
Stop
Shut Down
S. Stop
Alarm
Print
Close