

Section I		
SECTION NC NO: <u>100.</u>	NC NO: <u>HDL/LOL.</u>	
Details of Non-conformance: <u>HDL/LOL 7280 due to low IQC material.</u>		
Immediate action: <u>3 repro samples were selected and run, to ensure patient sample were acceptable before & after new IQC was put in place → see attached patient results</u>		
Classification of NC Major <input type="radio"/> Minor <input type="radio"/>	Reference no of relevant guide/Standard/requirement	Was test halted? Yes <input type="radio"/> NO <input type="radio"/> Signature/Date:
Name of reporter/Identifier: <u>15/02/2021 (Perry)</u>	Date: <u>15/02/2021.</u>	Signature: <u>[Signature]</u>
Section II (Attach Supporting Evidence)		
Root Cause: <u>Root cause was to ensure patient results were not affected therefore, 3 samples were rerun after new IQC was put in use.</u>		
Corrective Action(s) taken: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Date: <u>15/02/21</u>	Sign: <u>[Signature]</u>	(HOS/QO)
Resumption of testing YES <input checked="" type="radio"/> NO <input type="radio"/>		
Date: <u>15/02/21</u>	Sign: <u>[Signature]</u>	(lab director/manager)
Section III (Attach Supporting Evidence)		
Effectiveness Corrective Action effective: YES <input checked="" type="radio"/> NO <input type="radio"/>		
Comment:		
Quality Officer/HOS Signature: <u>[Signature]</u>		Date: <u>15/02/21.</u>

08/15 Feb

Equipment and Analyzer Action Log

Name: AU 480

SIN: 212 1907

Date	Problem	Action Taken	Resolved (Y/N)	Sign
14/02/21	(L1) for urea > 2SD.	10L rerun for urea. → acceptable.	Yes	P
13/02/21	L2 for Fe > 2SD	(L1) + (L2) rerun and results acceptable	Yes	P
10/02/21	AUP (L2) > 2SD	Reagent was almost empty. Replaced reagent and calibrated	Yes	P
11/02/21	CLP - stock-out of reagent. no data points.	All samples sent to a referral lab from the 11/02	Yes	P
15/02/21	LDL+HDL (L1) > 2SD on the 15/2.	There was insufficient Qc. see - QC form for HDL & LDL.	Yes	P
08/02/21	CO2 > 2SD for (L3)	CO2 required to be recalibrated → rerun Qc acceptable	Yes	P
9-10/02	Na (L1) was > 2SD. (L2) was acceptable	Recalibrated. And 10L was acceptable → must monitor Na electrode??	Yes	P

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S.No. P001

Patient Report
Proteus Laboratory

Device No. 2121907
Page. 1

Age Month Serum
S.ID 148974

HDL	0.56	0.90	1.70 mmol/L	L	,	,	2443	6447	2443	6686
LDL	2.19	1.60	3.40 mmol/L	,	,	,	2497	3190	2497	3074
LIP	N			,	,	,				
ICT	N			,	,	,				
HEM	N			,	,	,				

Wp

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S.No. P002

Patient Report
Proteus Laboratory

Device No. 2121907
Page. 2

Age Month Serum
S.ID 148981

HDL	1.18	0.90	1.70	mmol/L	,	,	2443	6447	2443	6686
LDL	3.29	1.60	3.40	mmol/L	,	,	2497	3190	2497	3074
LIP	N				,	,				
ICT	N				,	,				
HEM	N				,	,				

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 S.No. 0022

Patient Report
 Proteus Laboratory

Device No. 2121907
 Page. 1

Female Age Month Serum
 S.ID 148981

ALT	18.1	10.0	45.0 U/L	r	2555	0214	2555	0201
AST	23.2	10.0	40.0 U/L	r	2541	6547	2541	6547
CHOL	4.73	3.00	5.20 mmol/L	r	2557	5545		
TRIG	1.13	0.30	2.00 mmol/L	r	2567	2896	2567	7956
HDL	1.23	0.90	1.70 mmol/L	r	2443	6447	2443	6686
LDL	3.39	1.60	3.40 mmol/L	r	2497	3191	2497	3070
LIP	N			r				
ICT	N			r				
HEM	N			r				

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 S.No. P003

Patient Report
 Proteus Laboratory

Device No. 2121907
 Page. 3

Age Month Serum
 S.ID 148989

		1.70 mmol/L							
HDL	1.14	0.90							
LDL	3.50	1.60	H				2443	6447	2443
LIP	N						2497	3190	2497
ICT	N								3074
HEM	N								

IP

Print Time [02/15/2021 16:53]
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 S.No. 0015

Patient Report
 Proteus Laboratory

Device No. 2121907
 Page. 1

Female Age Month Serum
 S.ID 148989

Na	140.3	135.0	148.0 mmol/L	r				
K	4.41	3.50	5.00 mmol/L	r				
Cl	103.1	98.0	108.0 mmol/L	r				
CO2	22.9	13.0	27.0 mmol/L	r		2596	0408	2592 8040
BUN	3.87	2.50	6.40 mmol/L	r		2592	7739	2592 8040
GGT	80.1	5.0	50.0 U/L	H	r	2557	4366	2557 4394
CHOL	5.21	3.00	5.20 mmol/L	H	r	2557	5545	2567 7956
TRIG	2.56	0.30	2.00 mmol/L	H	r	2567	2896	2567 7956
HDL	1.18	0.90	1.70 mmol/L	r		2443	6447	2443 6686
LDL	3.61	1.60	3.40 mmol/L	H	r	2497	3191	2497 3070
GLUC	3.55	3.90	6.00 mmol/L	L	r	2576	6547	2576 6547
LIP	N			r				
ICT	N			r				
HEM	N			r				
AG	19	8	20 mmol/L	r				

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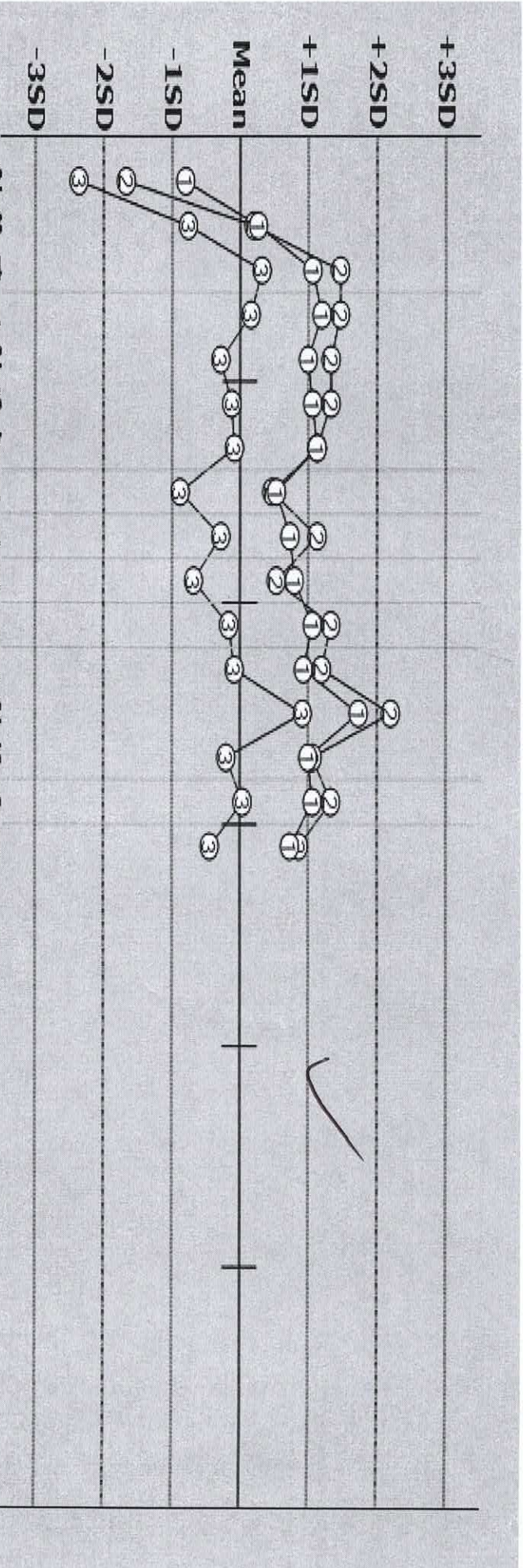
QC Monitor - Daily Chart

Print Time [02/17/2021 21:24]

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Type Serum

38: C02 Graph



02/02/21 CO2 level 3 → 2SD. PC: ? needed calibration.

week 2 Feb 2021

17/02/21 W

QC Monitor - Daily Chart

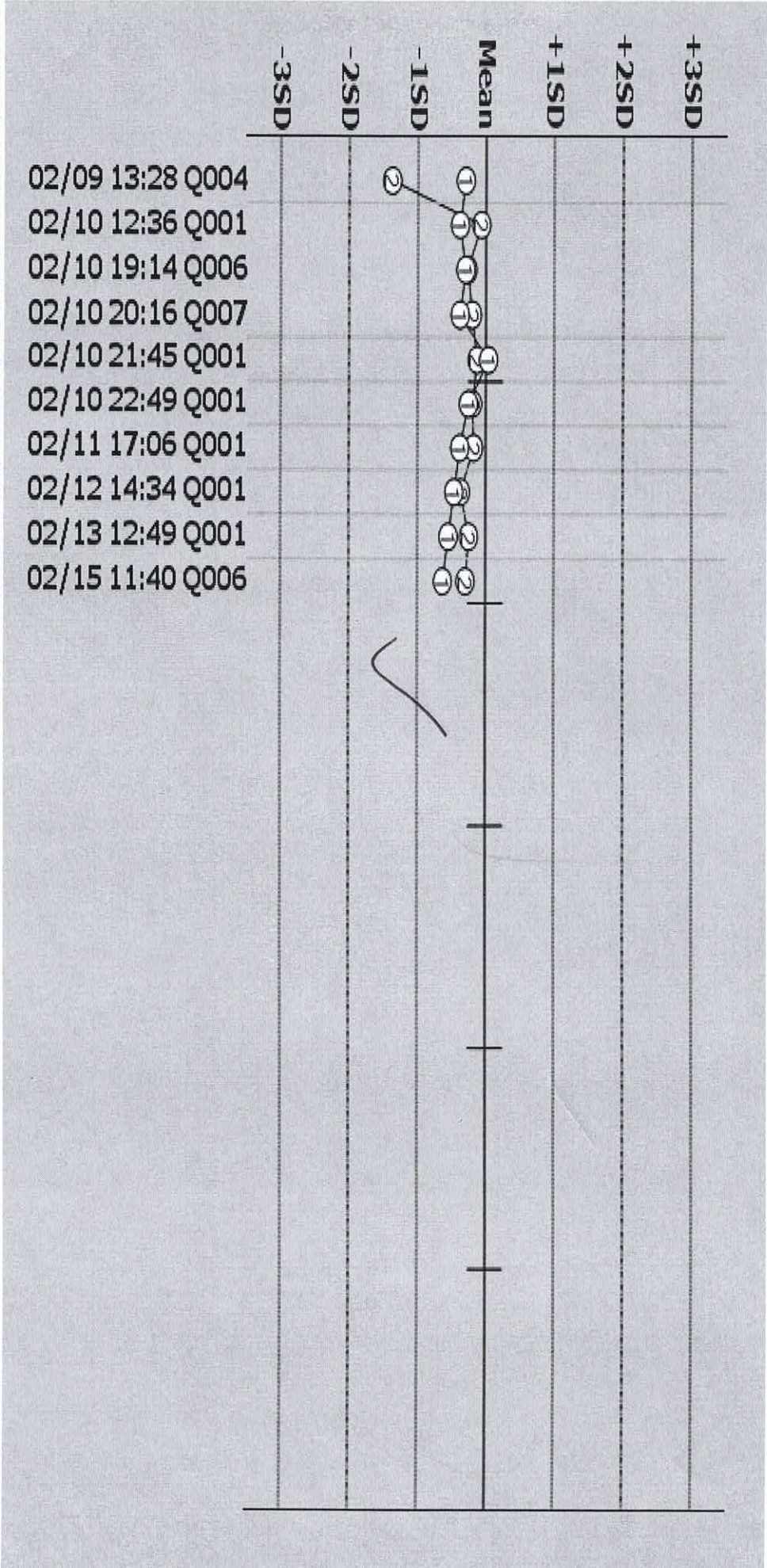
Print Time [02/17/2021 21:24]

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Type

Serum

71.DBILPC
Graph



17/02/21
Lp

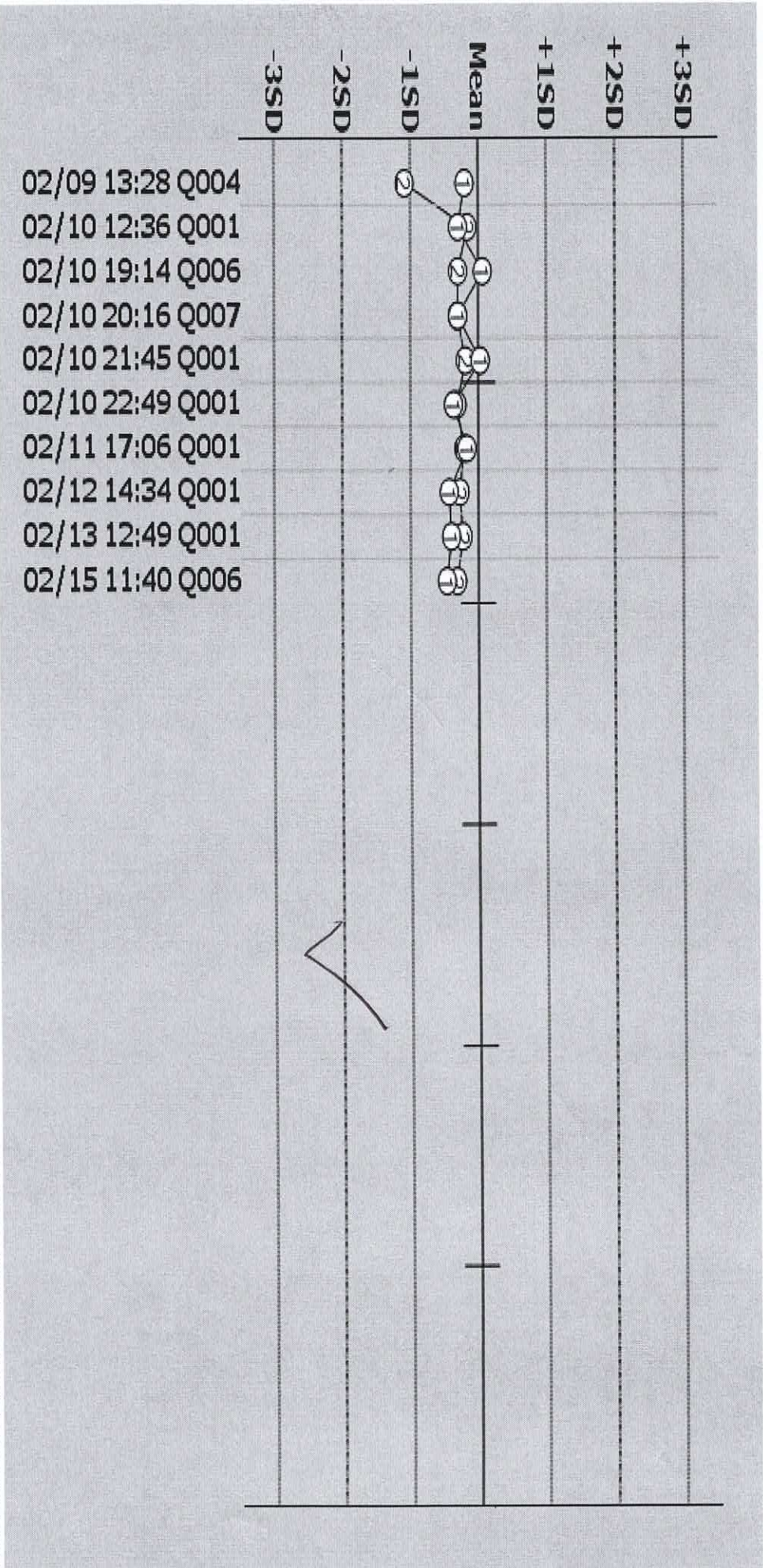
QC Monitor - Daily Chart

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Type Serum

73.TBILPC
Graph



17/02/21 by

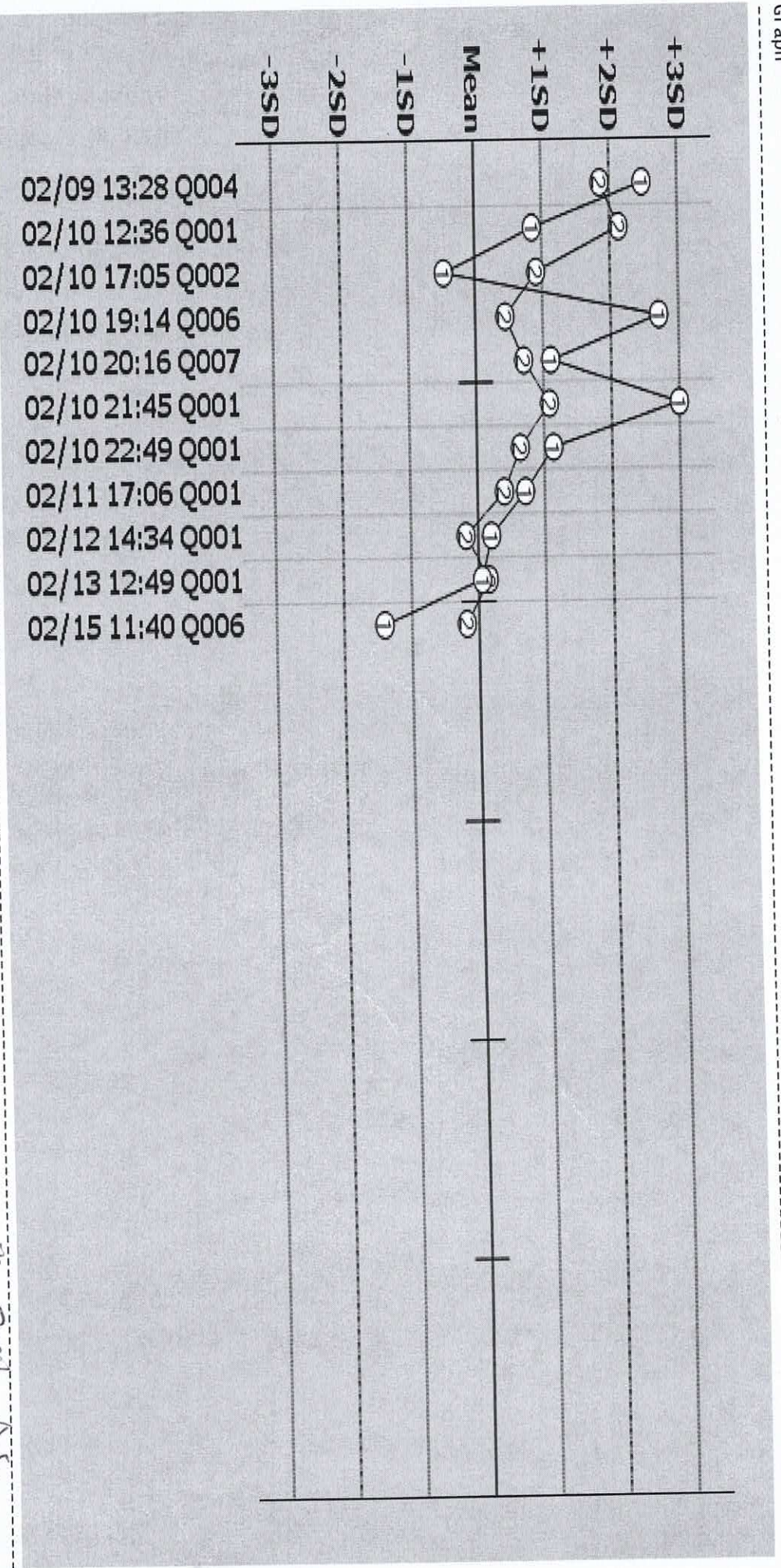
QC Monitor - Daily Chart

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Type

Serum

97.Na
Graph



NGT level 1 shifted on the eqpt. PC? QC fluctuating. Rr was rera with fresh DC and corrected.

17/02/21 dy

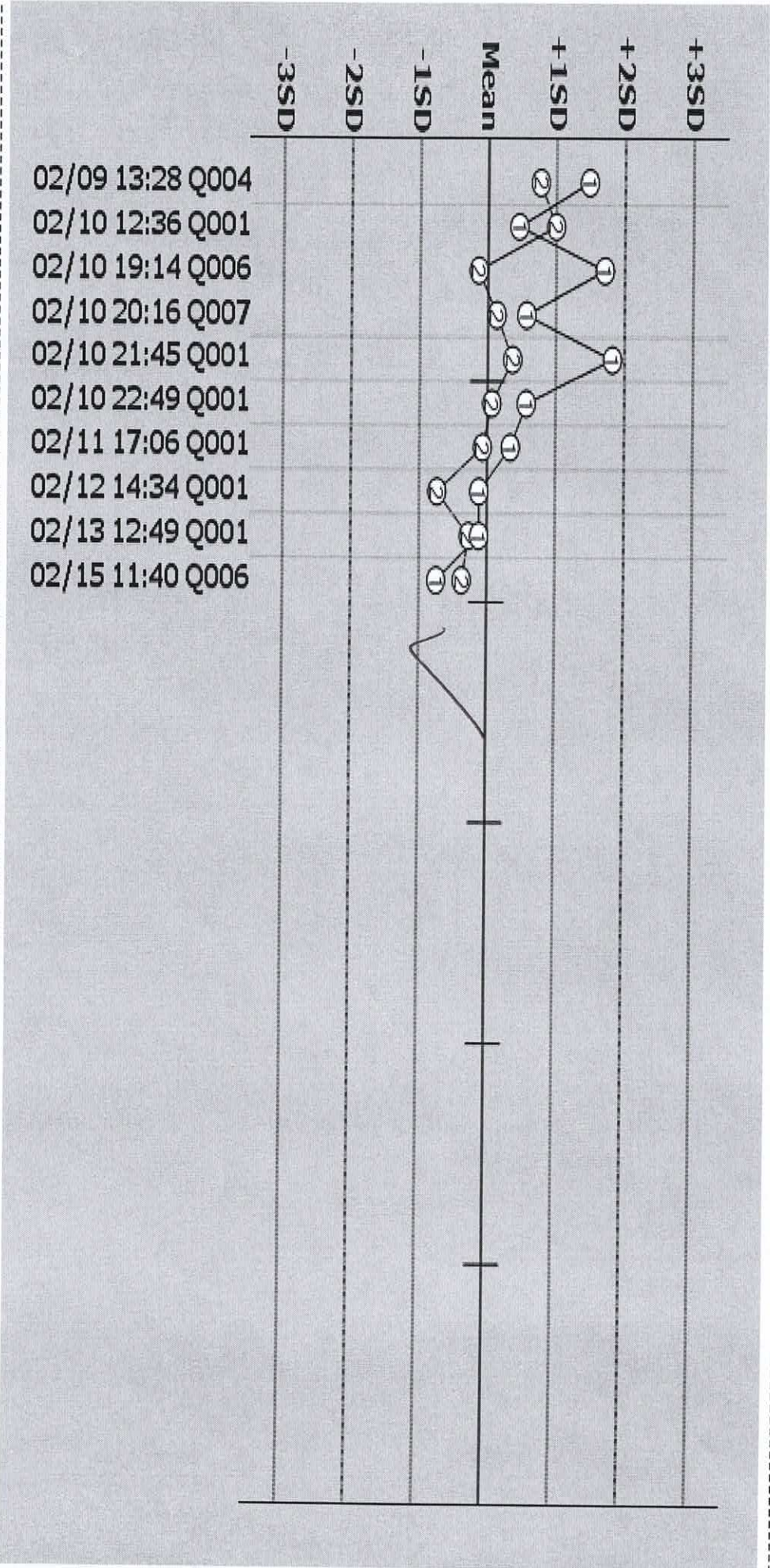
QC Monitor - Daily Chart

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Type Serum

Print Time [02/17/2021 21:24]

98. K
Graph



17/02/21 by

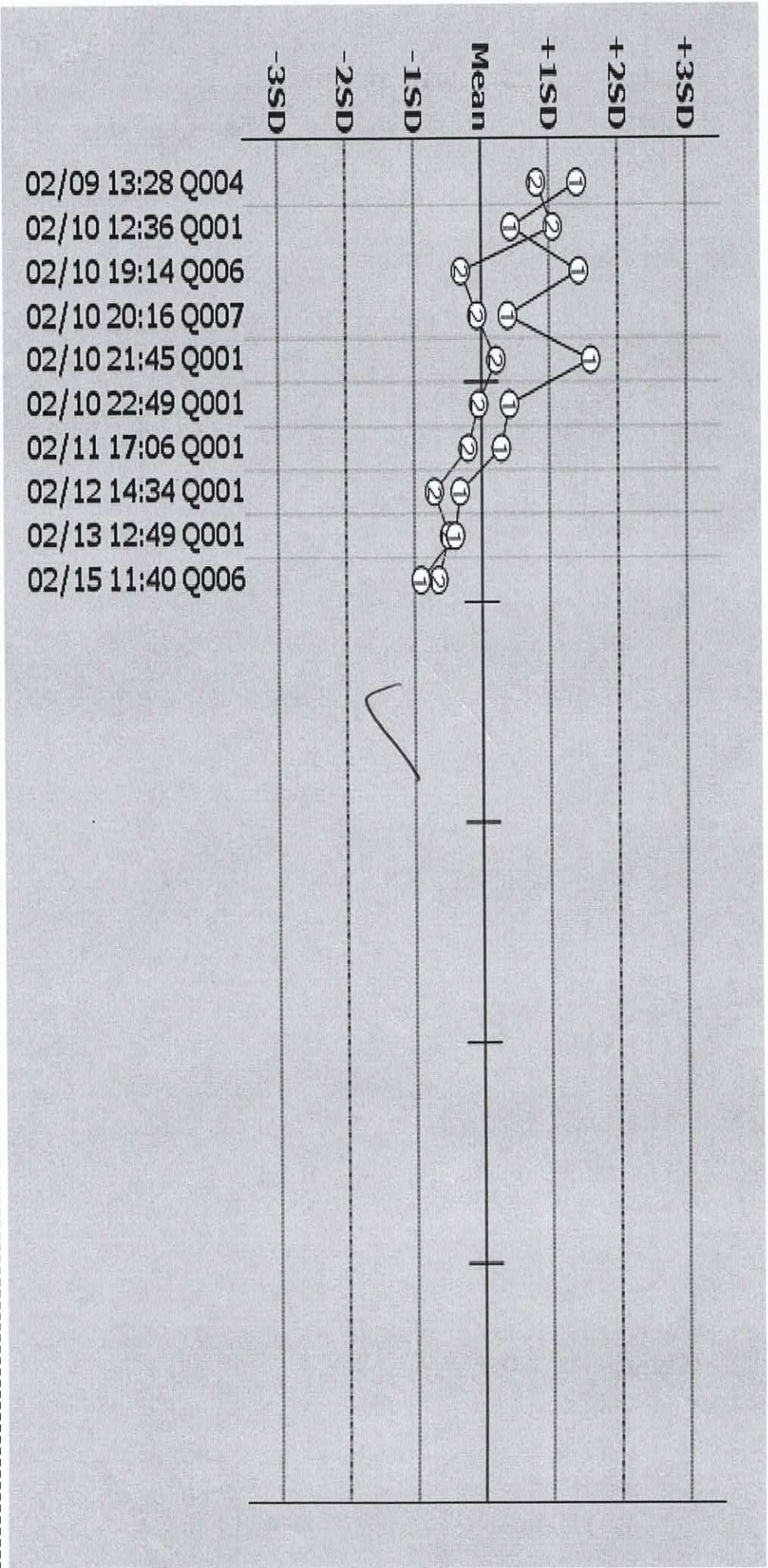
QC Monitor - Daily Chart

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Type Serum

99.C1
Graph



17/02/21

by

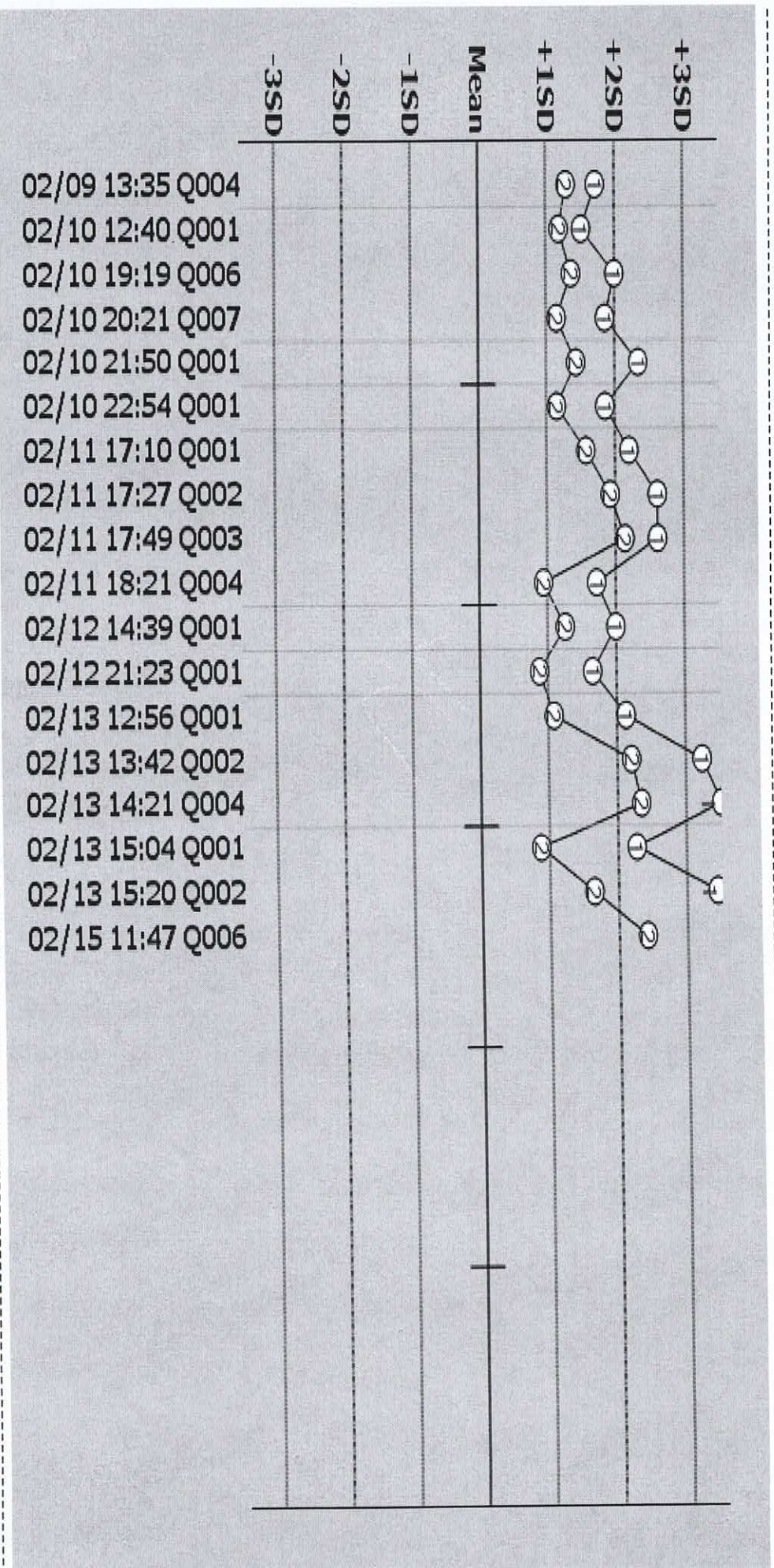
QC Monitor - Daily Chart

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Type Serum

105.LDL
Graph



all level 1 → 28b on the 12th. PC: ?
 Residual- DC mark-11 was log₁₀ and results
 correlation was done and acceptable.

17/02/21 MW

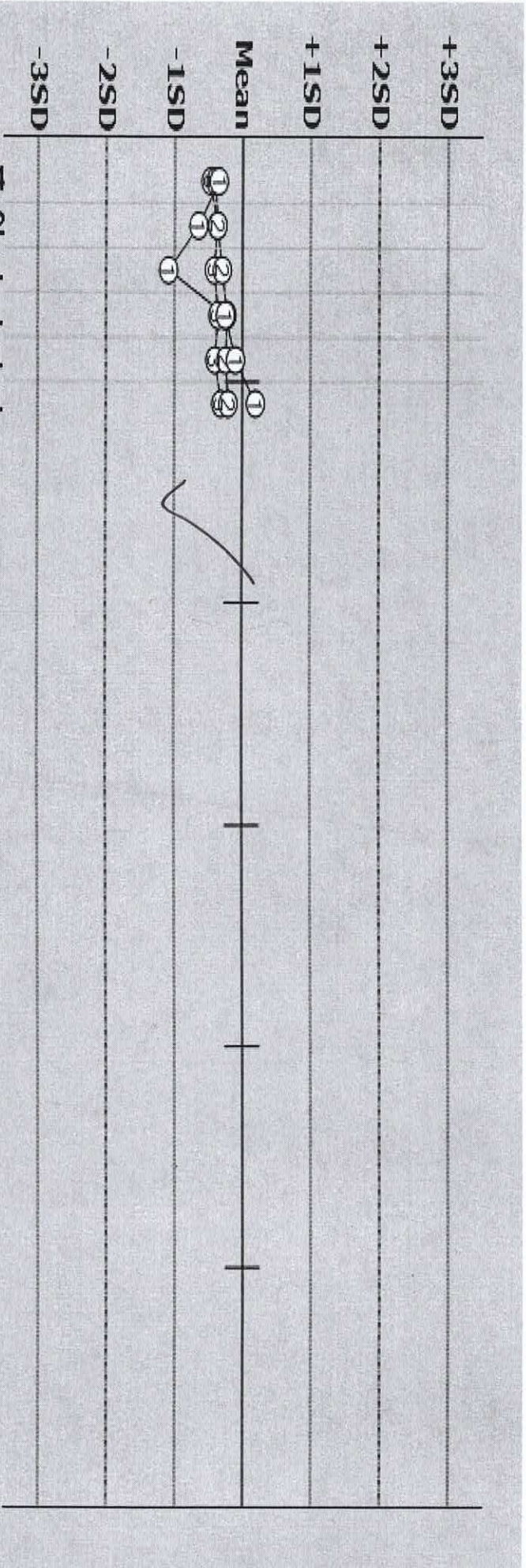
QC Monitor - Daily Chart

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Type Serum

2.RF Graph



Week 2 Feb 2021

17/02/21 W

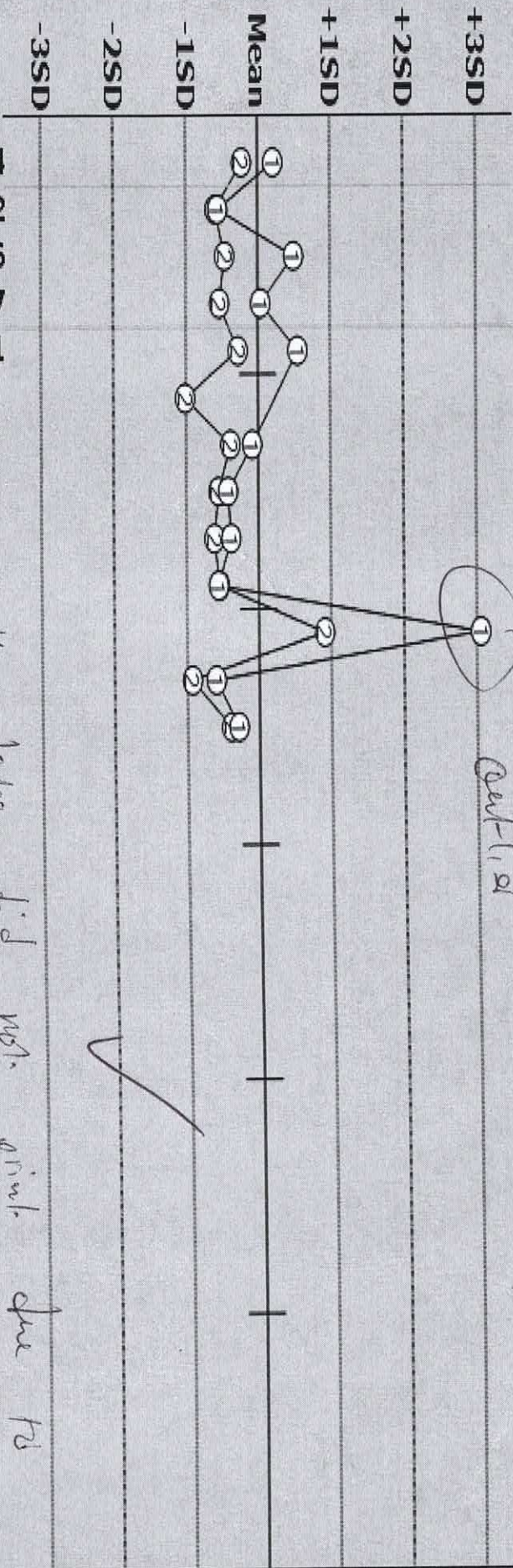
QC Monitor - Daily Chart

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Type Serum

3. BUN
Graph



Other dates had not print due to technical error but the overall QC performance is acceptable.

17/02/21

dy

QC Monitor - Daily Chart

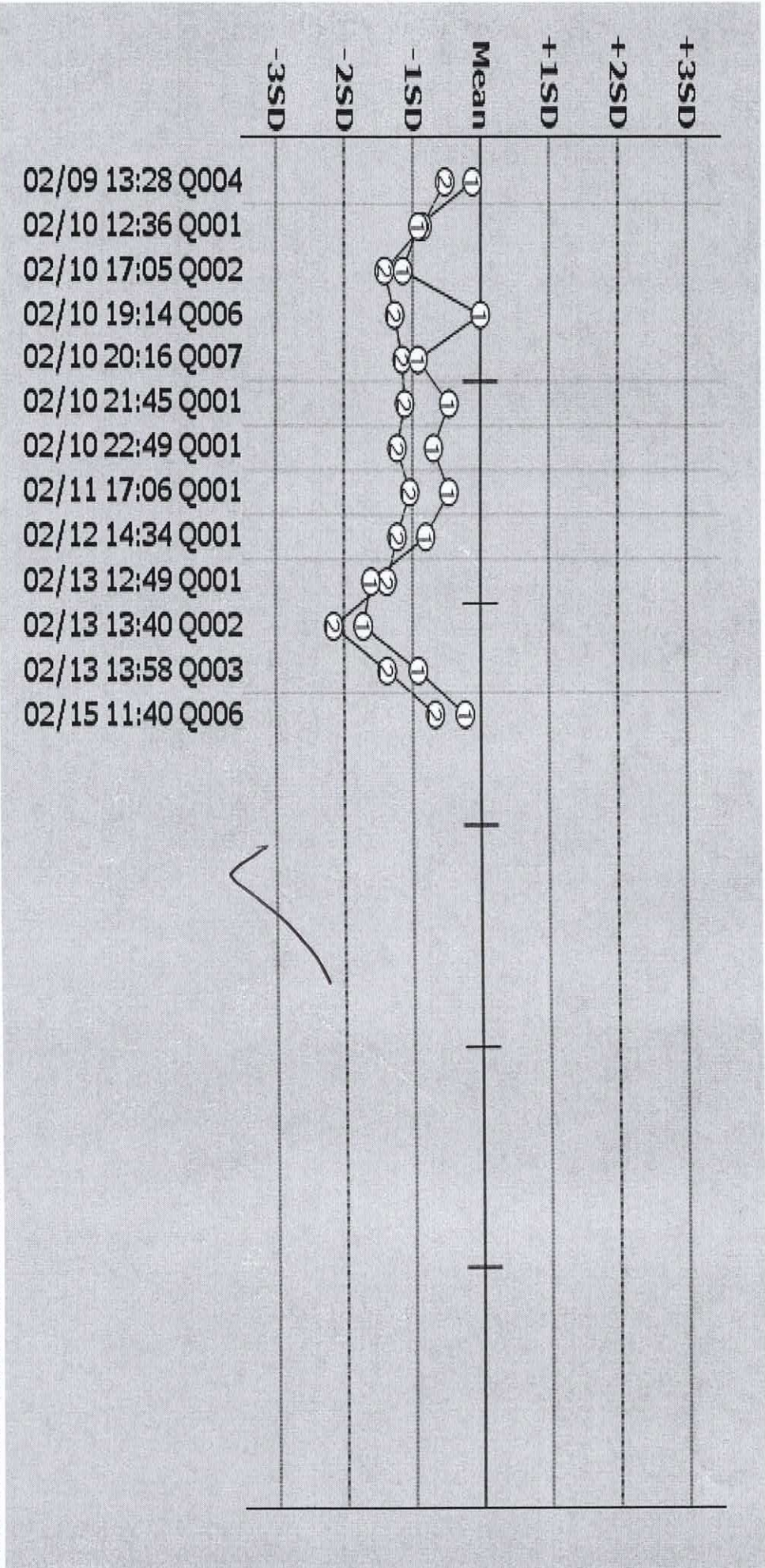
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Type

Serum

4.FE
Graph



✓

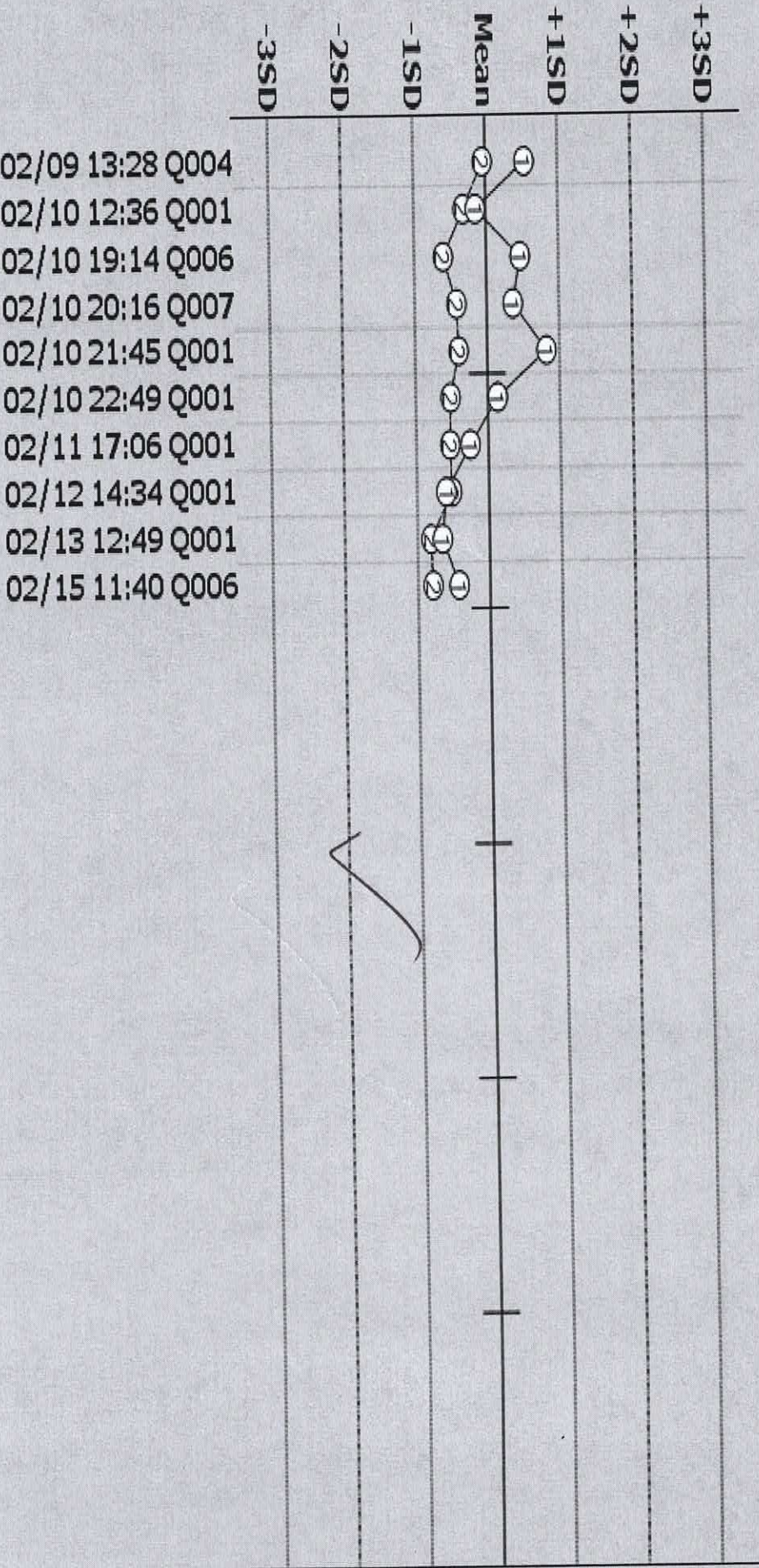
17/02/21
M

QC Monitor - Daily Chart

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Type Serum

6.MG
Graph



17/02/21
Wp

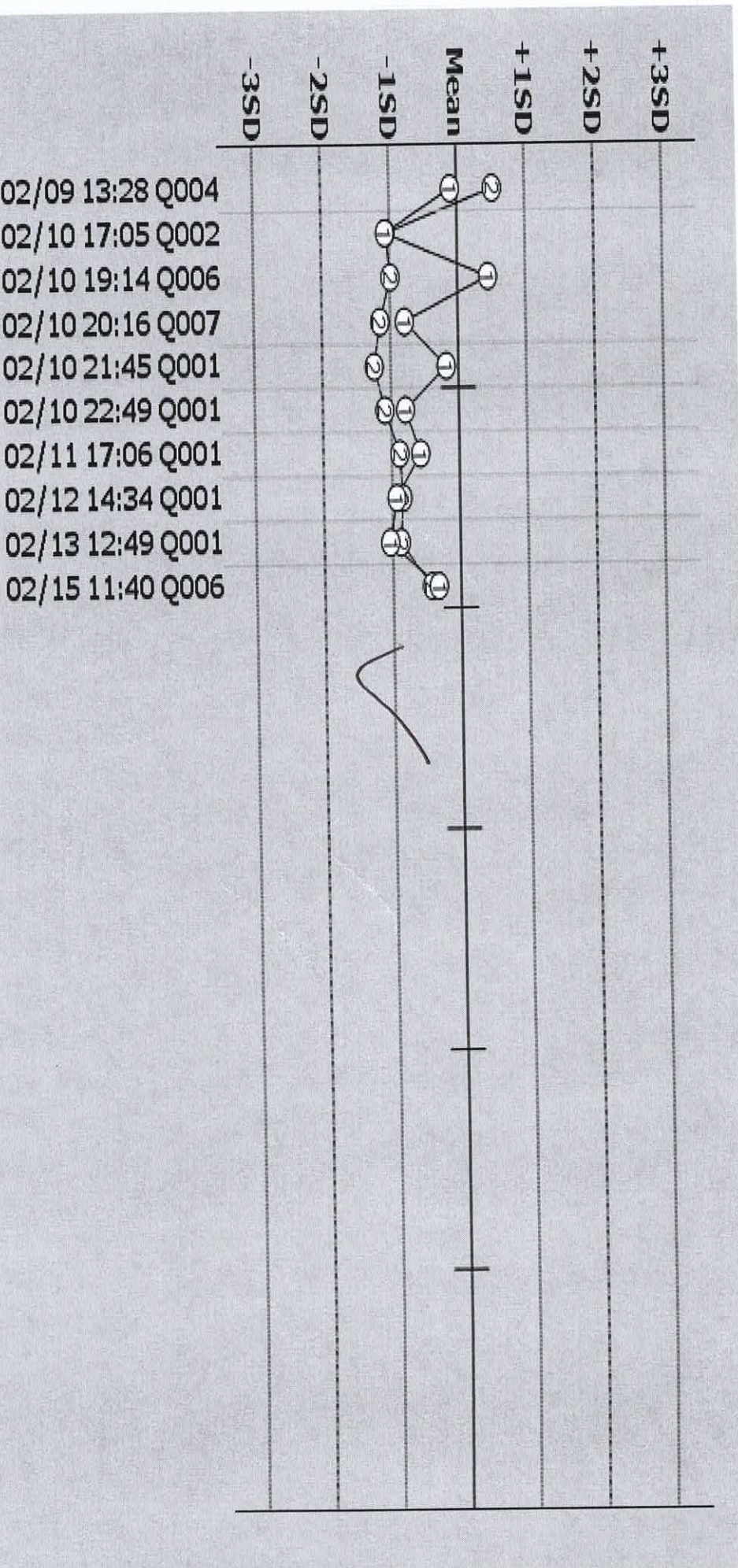
QC Monitor - Daily Chart

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Type Serum

8.P04
Graph



17/02/21
sh

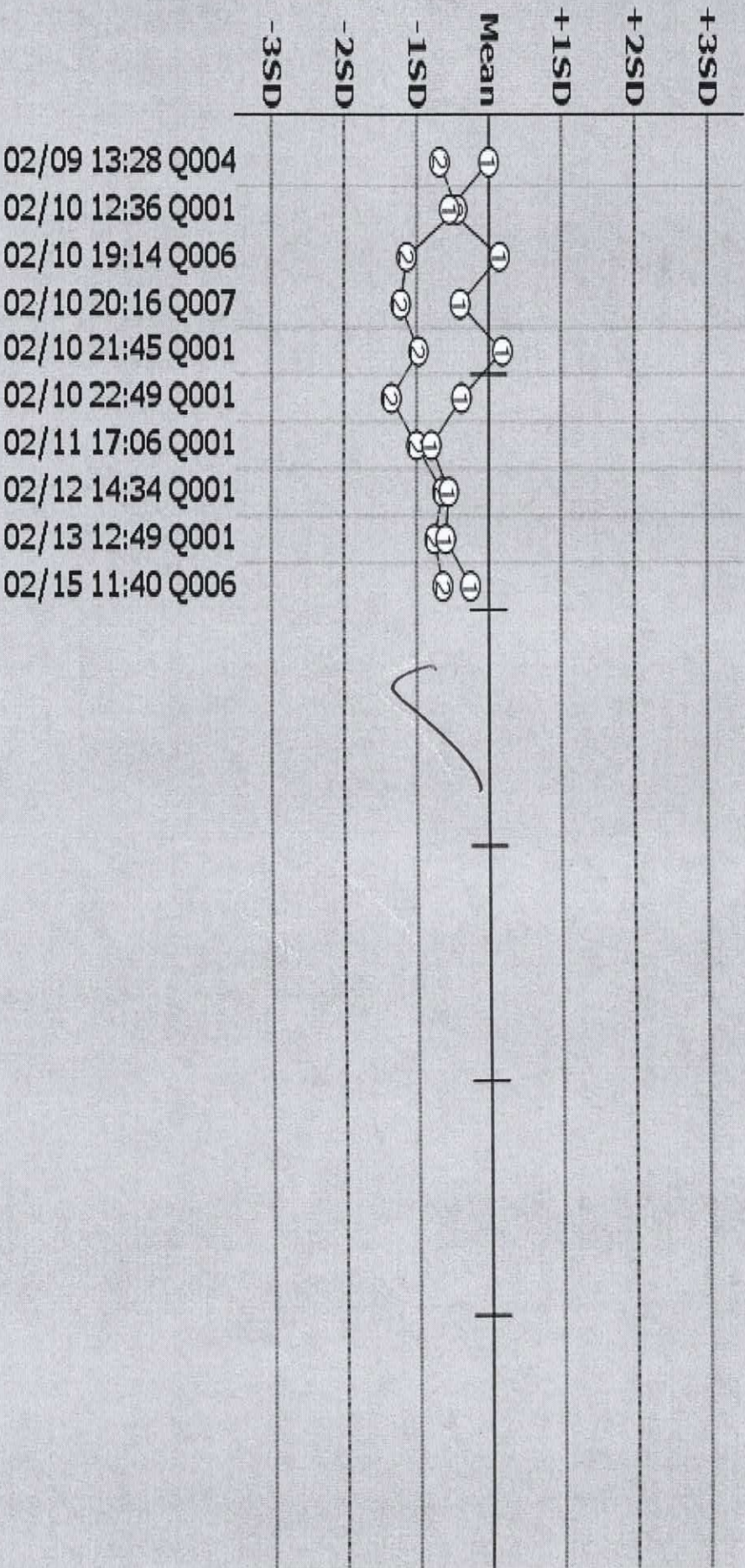
QC Monitor - Daily Chart

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Type Serum

Print Time [02/17/2021 21:24]

12.CA
Graph



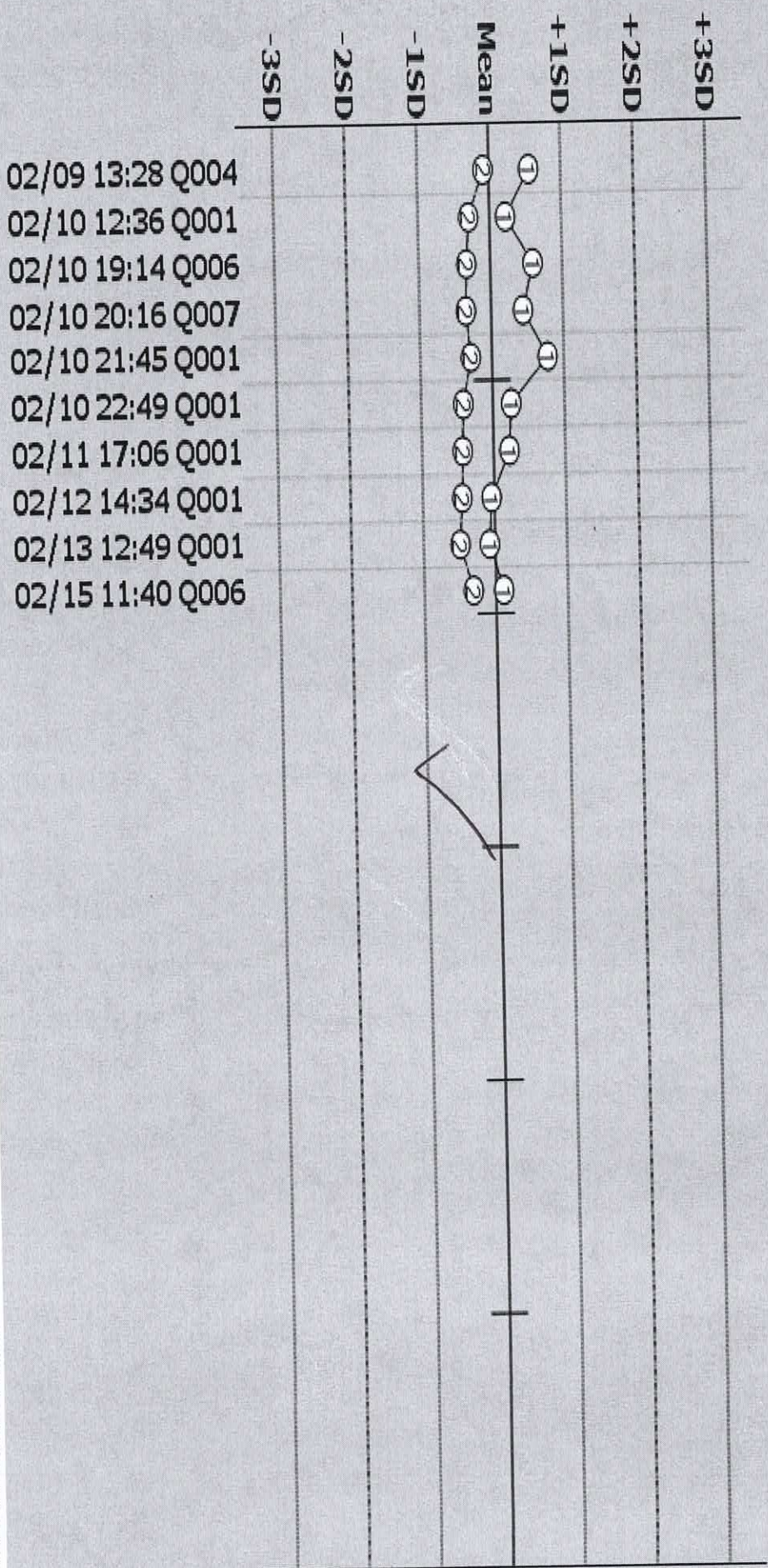
17/02/21
by

QC Monitor - Daily Chart

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Type Serum

13.ALB
Graph



17/02/21
dp

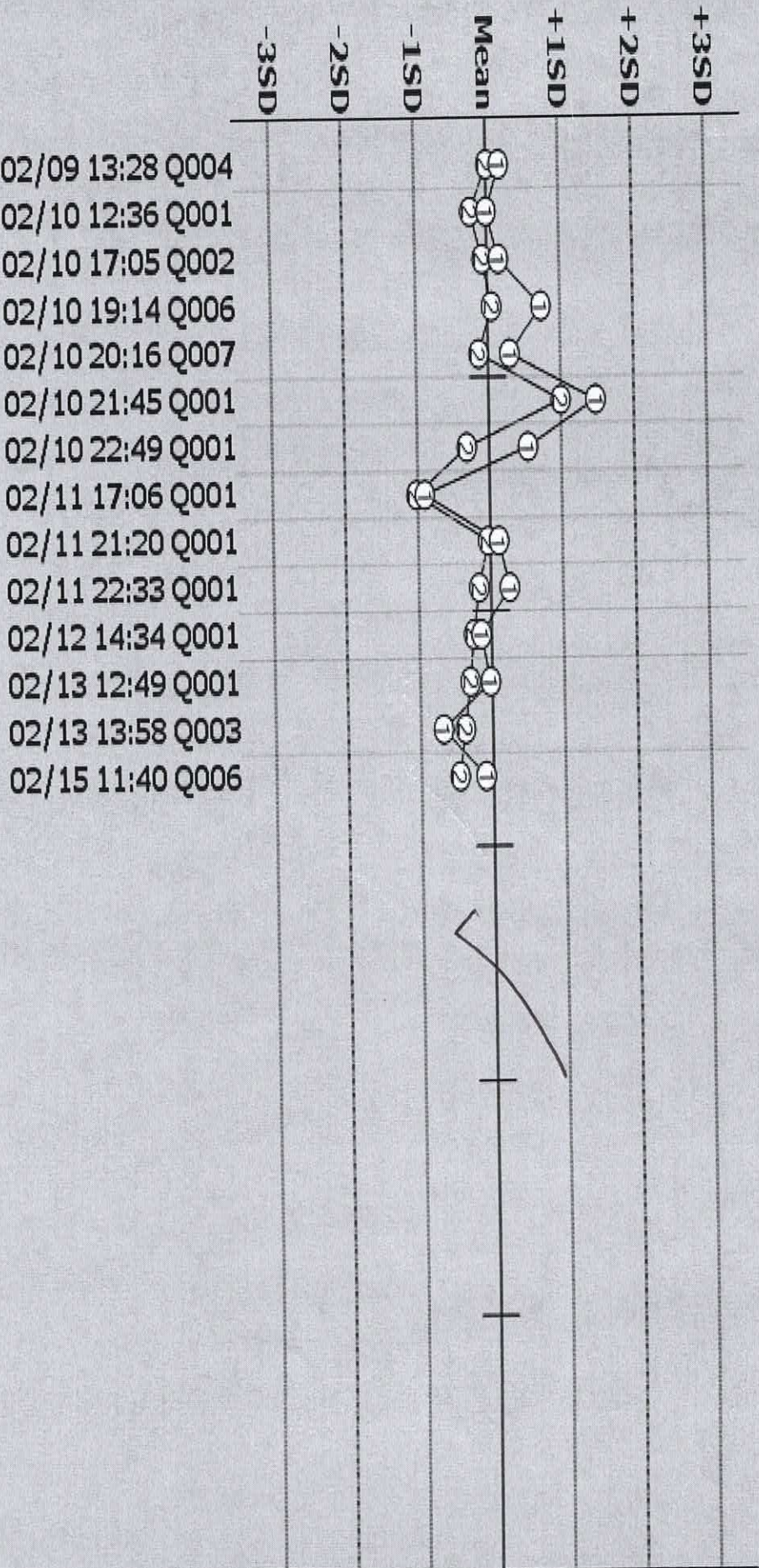
QC Monitor - Daily Chart

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Type Serum

16.ALT
Graph



17/02/21
hp

QC Monitor - Daily Chart

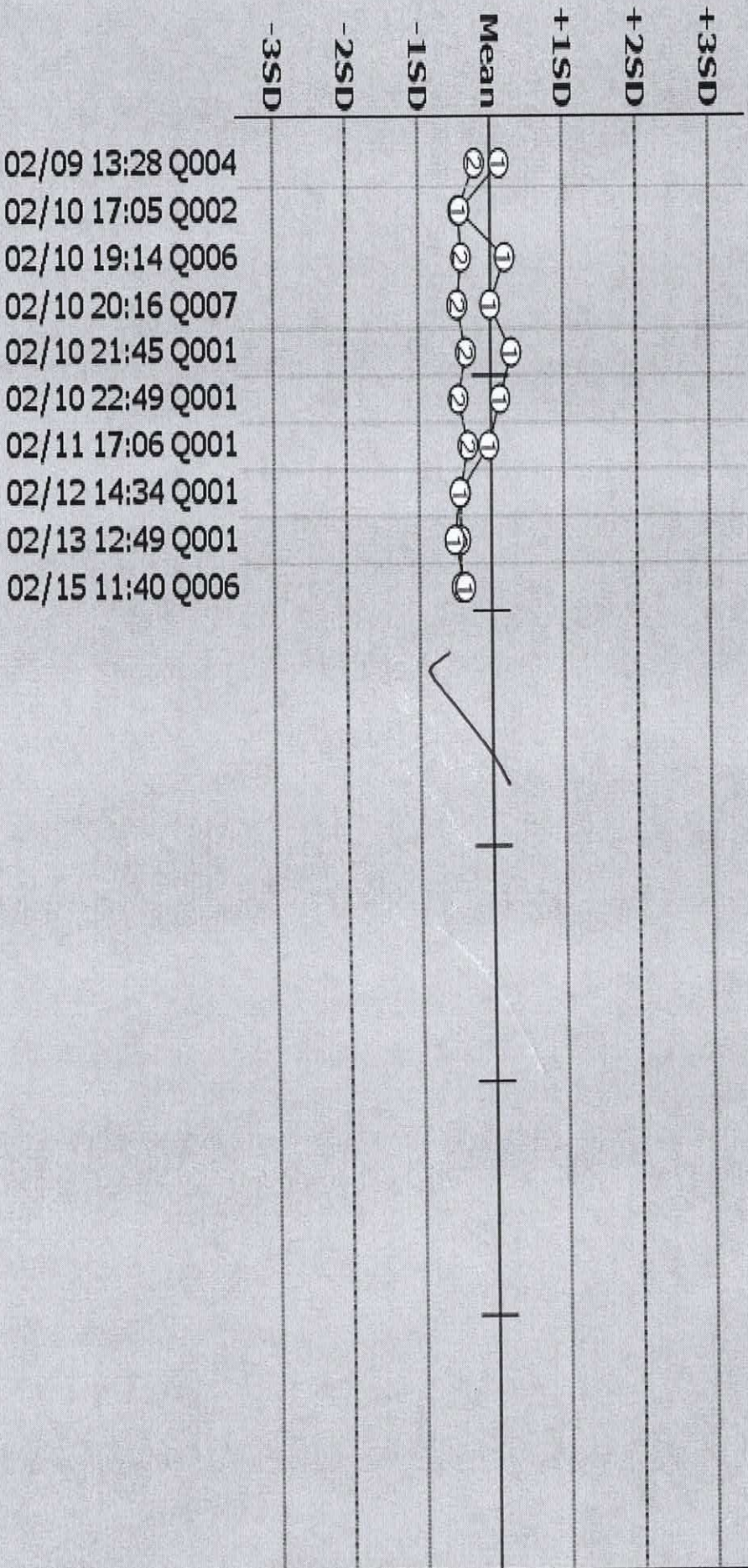
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Type

Serum

17.GGT
Graph



17/02/21

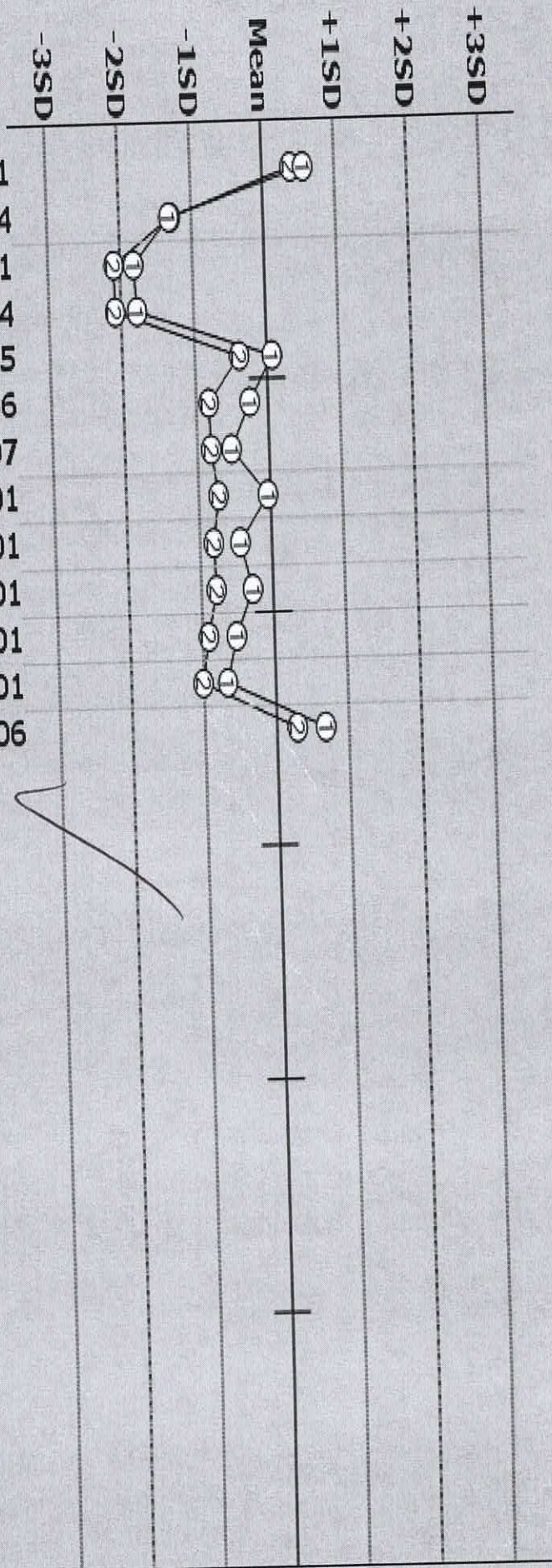
MP

QC Monitor - Daily Chart

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Type Serum

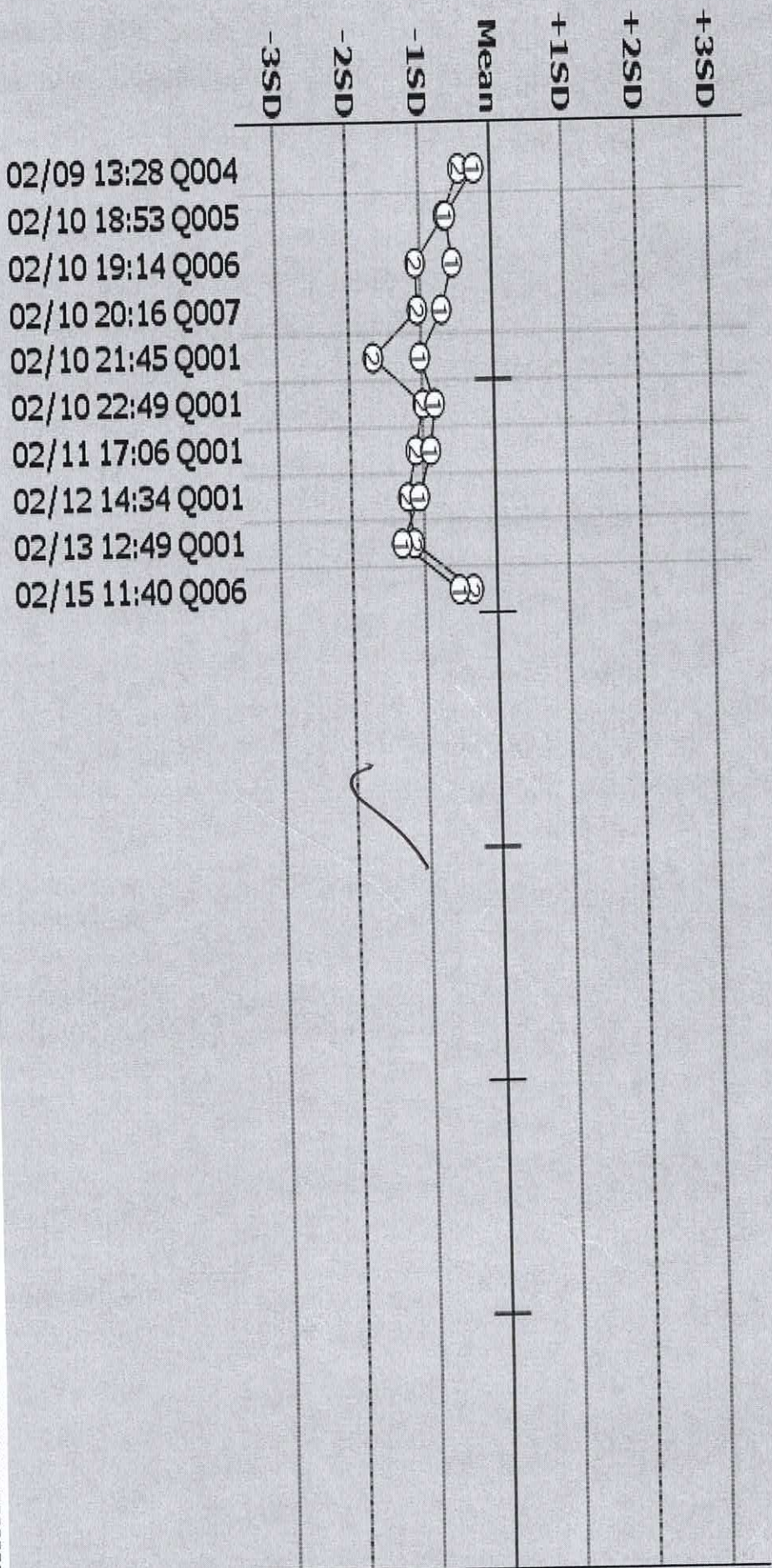
18.ALP Graph



skilt -> 15 b on the 9th and 10th on 25th on the 10th. PC: ? Reagent was nearly empty and it was replaced and calibrated.

17/02/21 by

Type Serum



17/02/21
dms

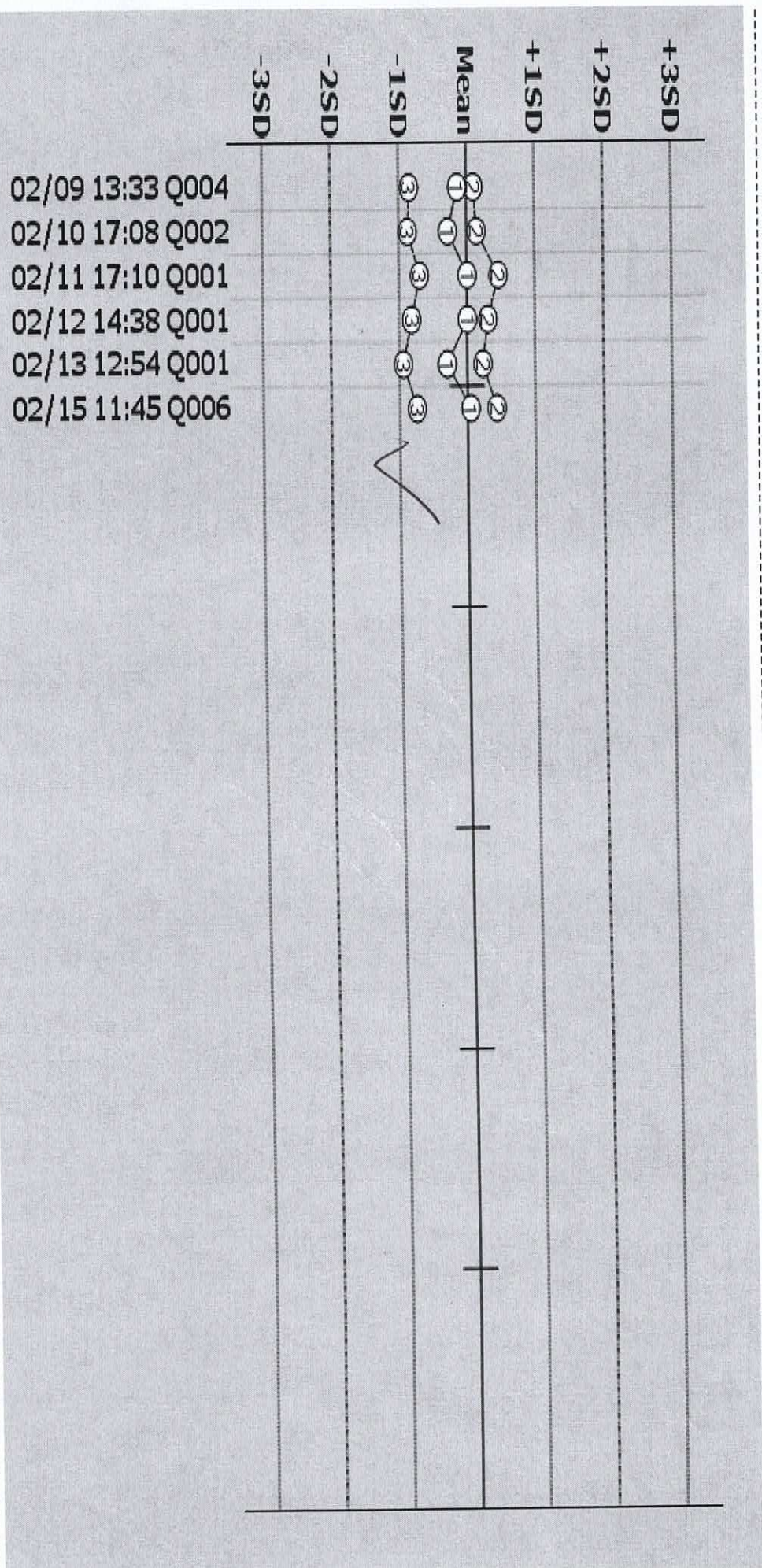
QC Monitor - Daily Chart

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Type Serum

20.TRF
Graph



17/02/21
lp

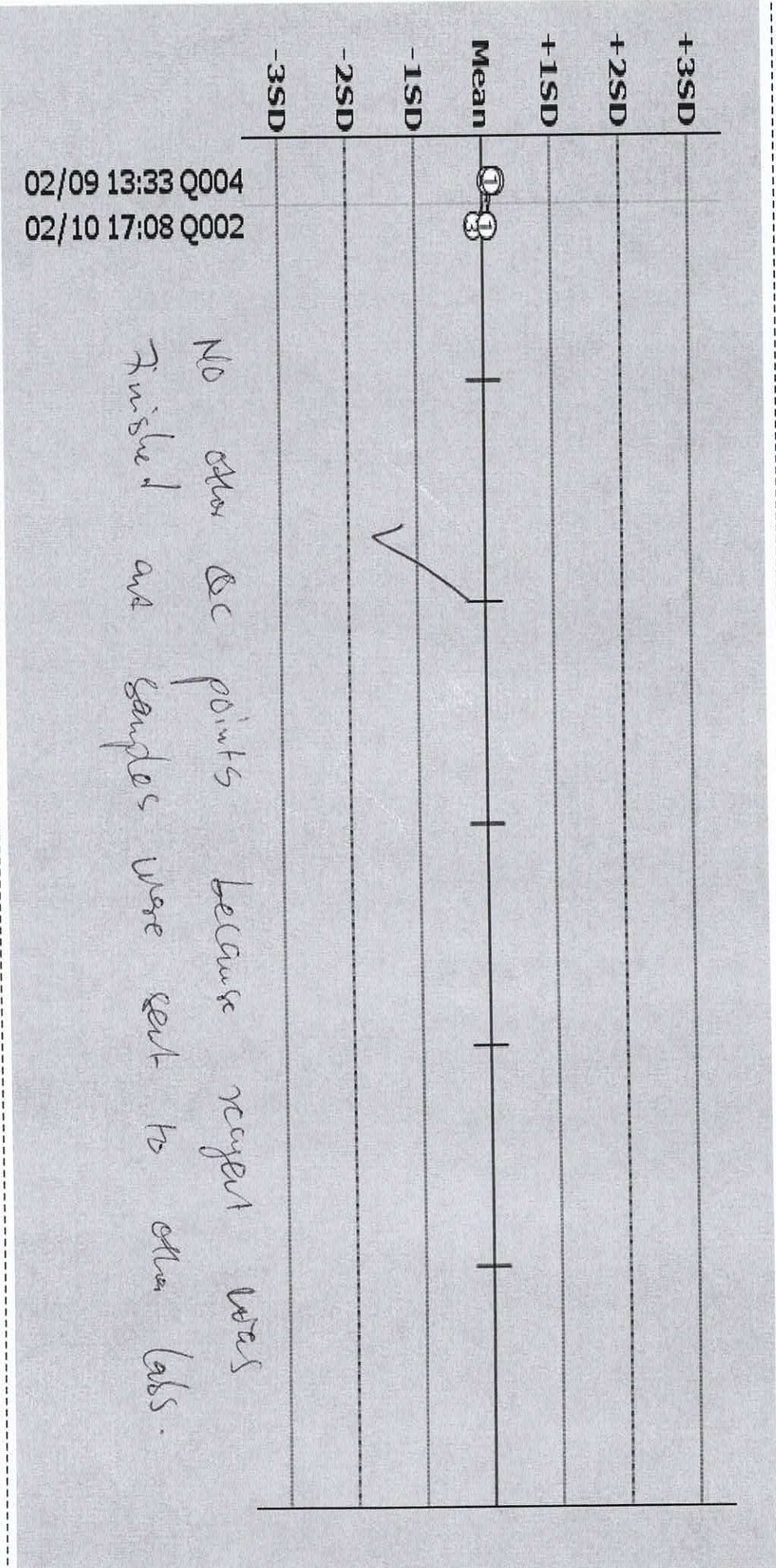
QC Monitor - Daily Chart

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Type Serum

21. CRP Graph



No other QC points because receipt notes finished and samples were sent to other labs.

17/02/21 14

QC Monitor - Daily Chart

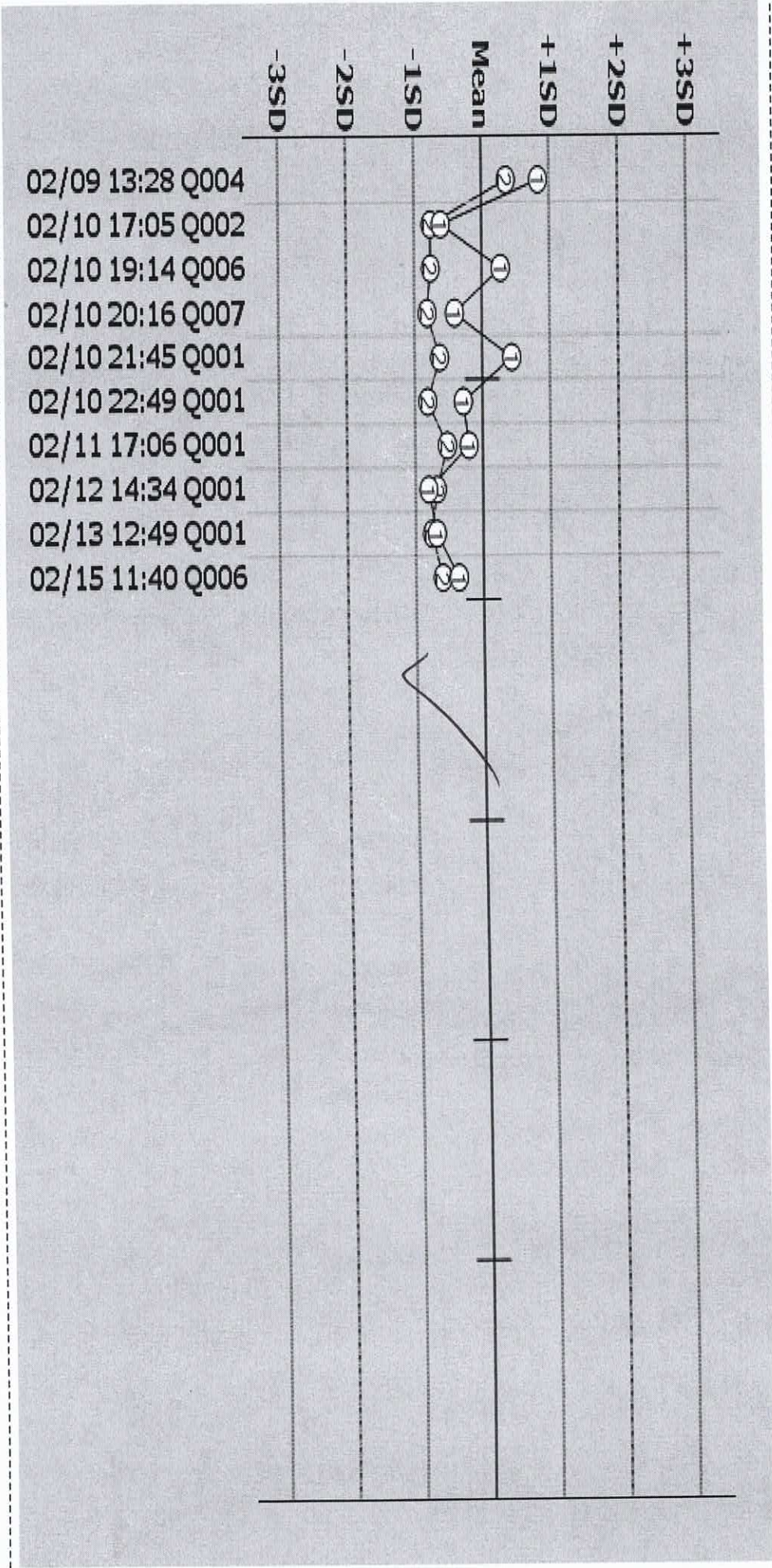
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Type

Serum

22.UA
Graph



17/02/21
W

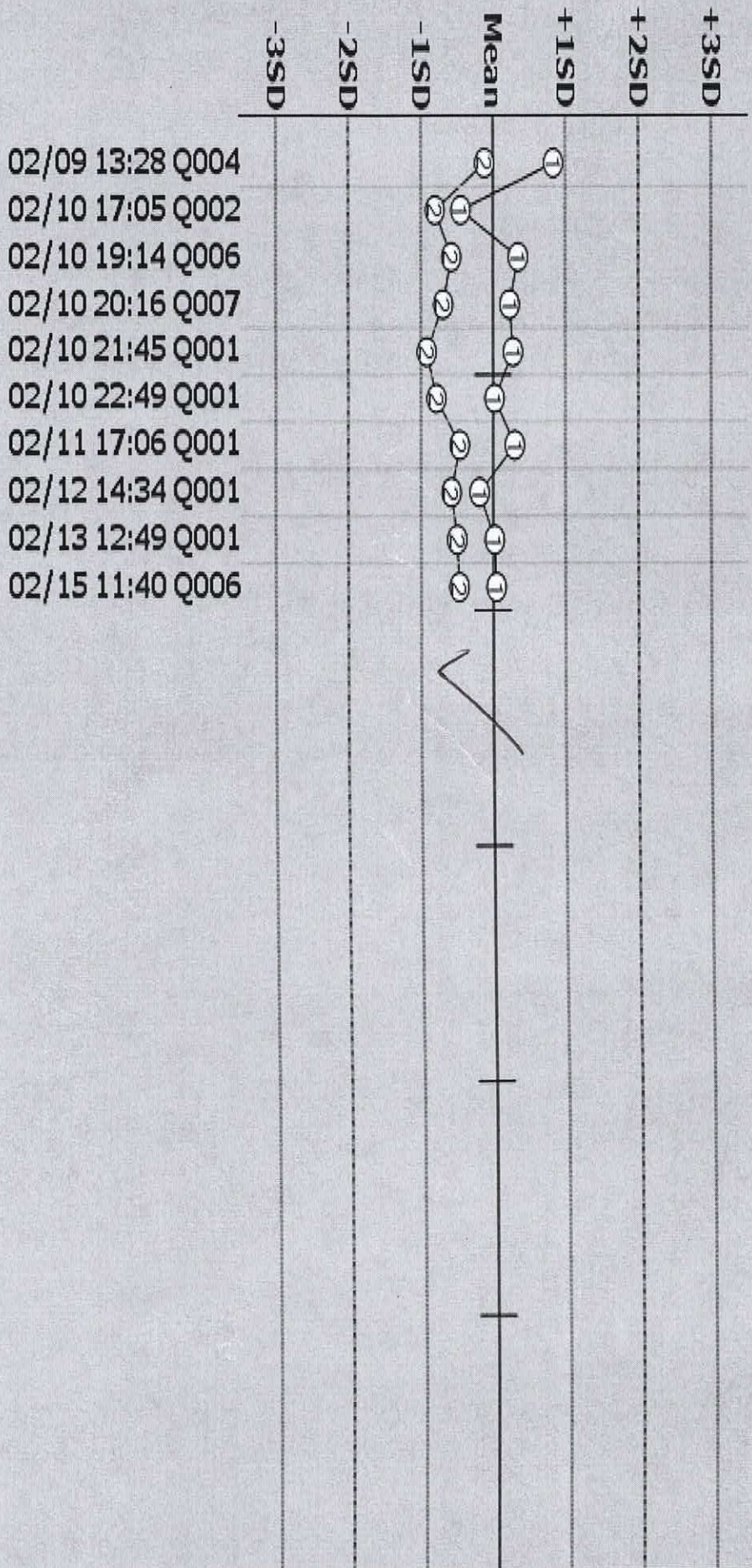
QC Monitor - Daily Chart

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Type Serum

23.GLUC
Graph



17/02/21

W

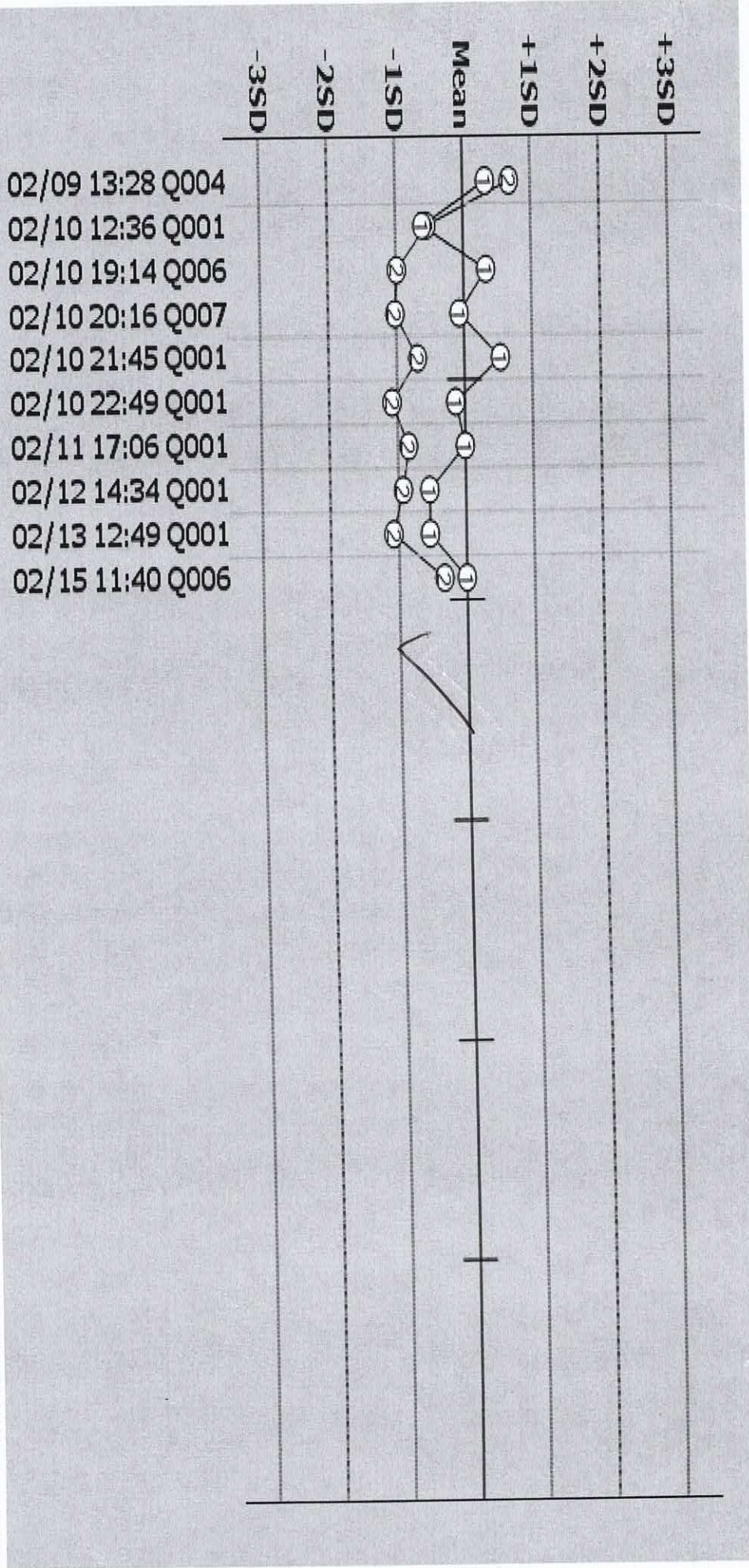
QC Monitor - Daily Chart

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Type Serum

26. TRIG
Graph



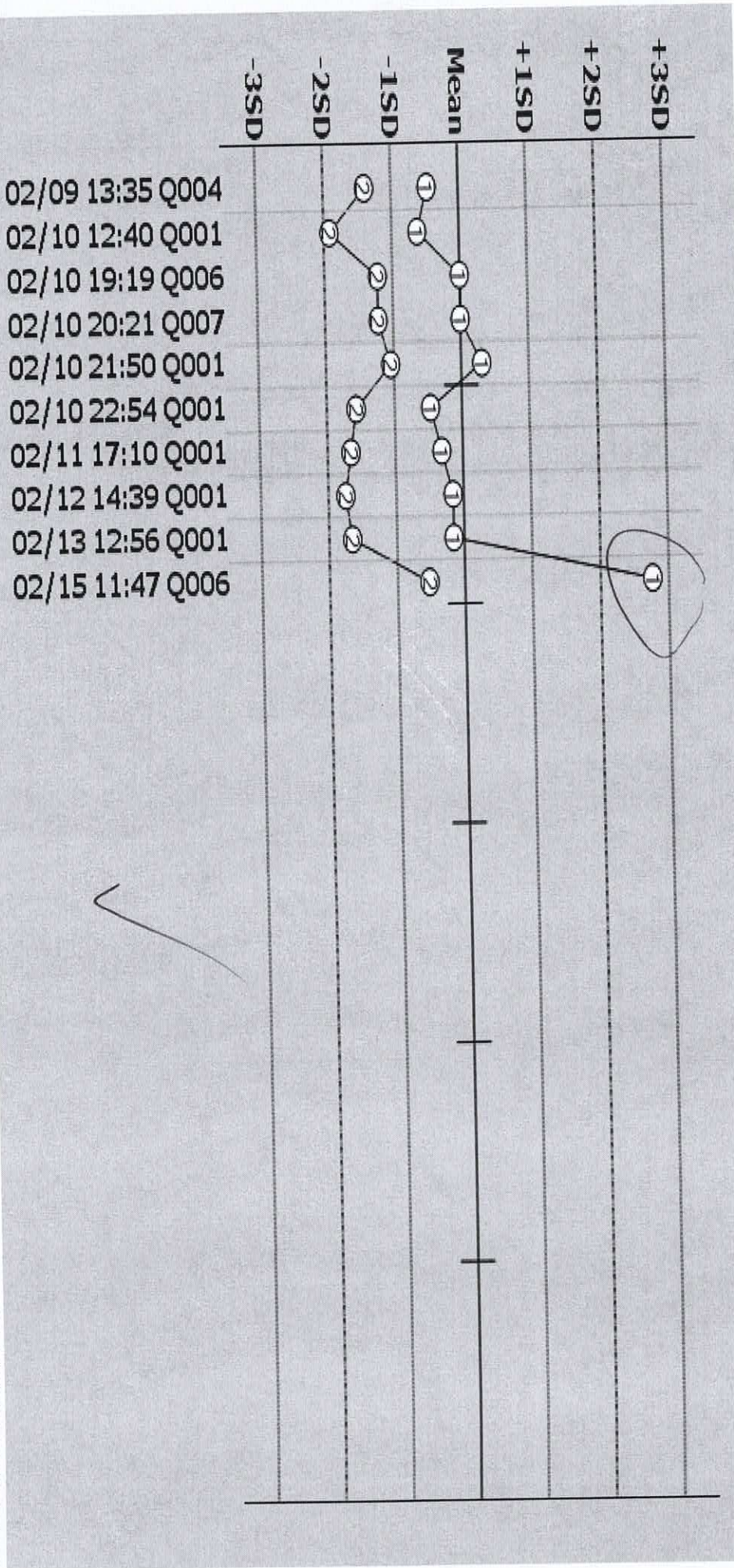
17/02/21 Wp

QC Monitor - Daily Chart

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Type Serum

27.HDL
Graph



02/02/21 HDL level 1 outside 2SD. ReCi? Insufficient QC material. please
 refer to LHL comment.

✓

02/02/21 up

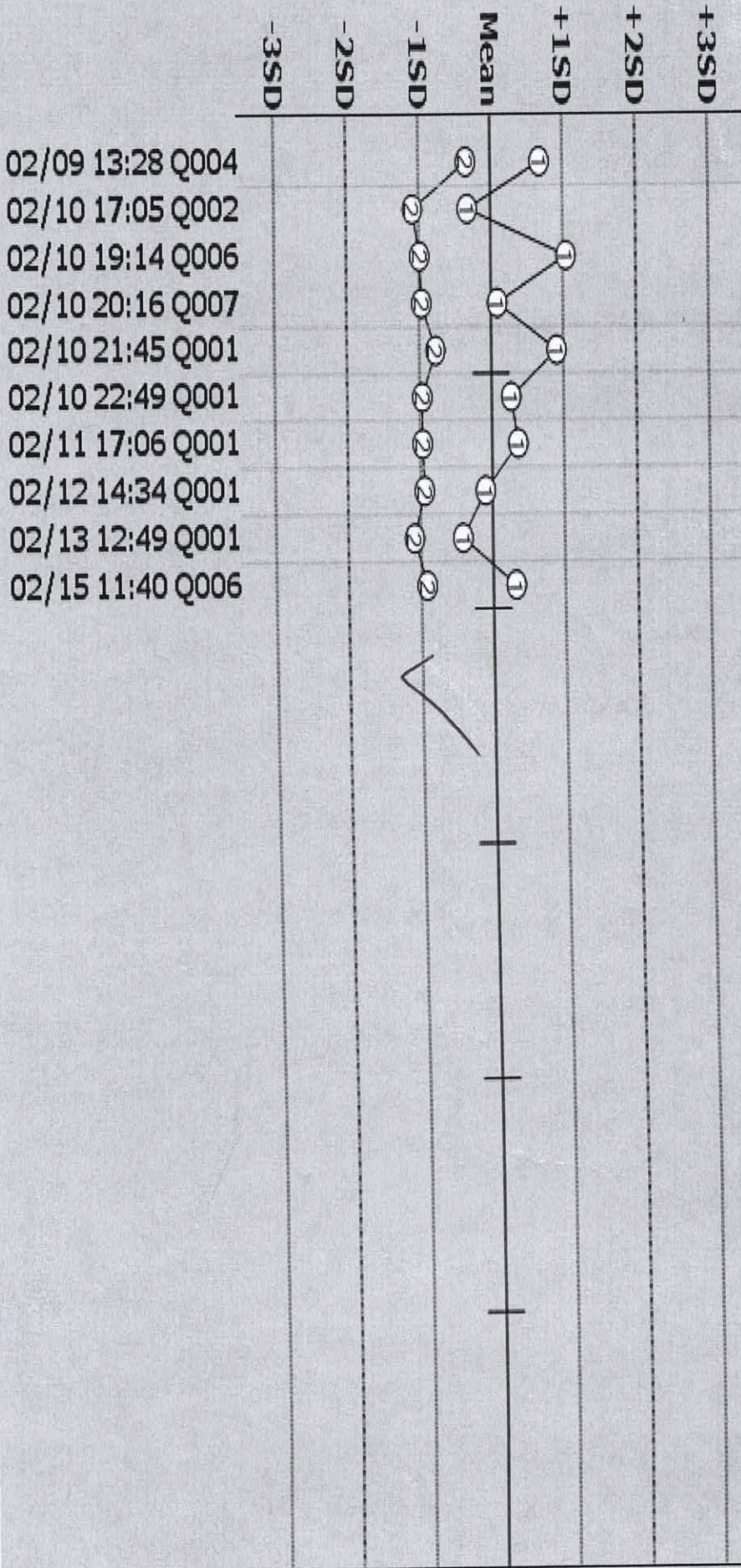
QC Monitor - Daily Chart

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Type Serum

33.TP
Graph



17/02/21 WP

QC Monitor - Daily Chart

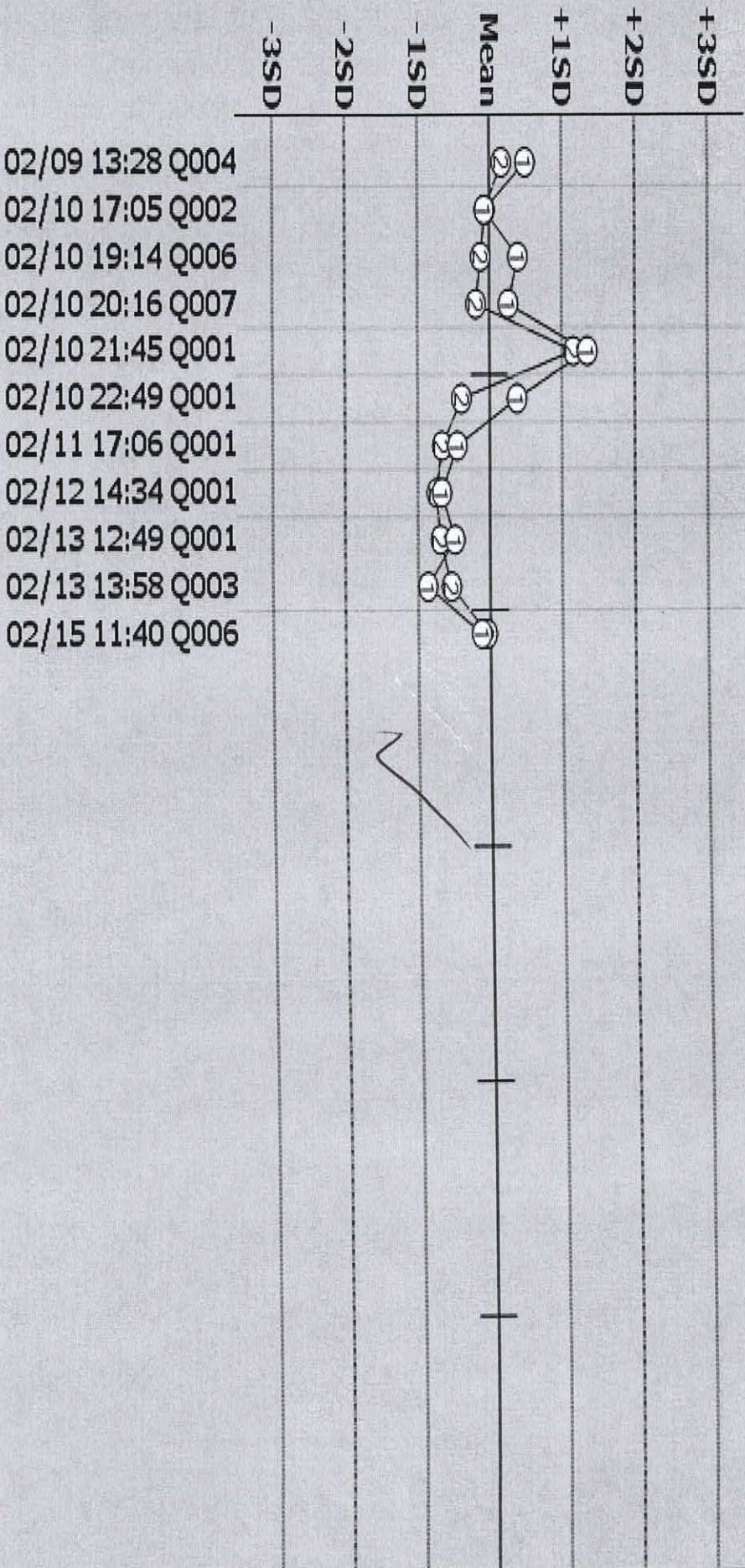
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Type

Serum

34.AST
Graph



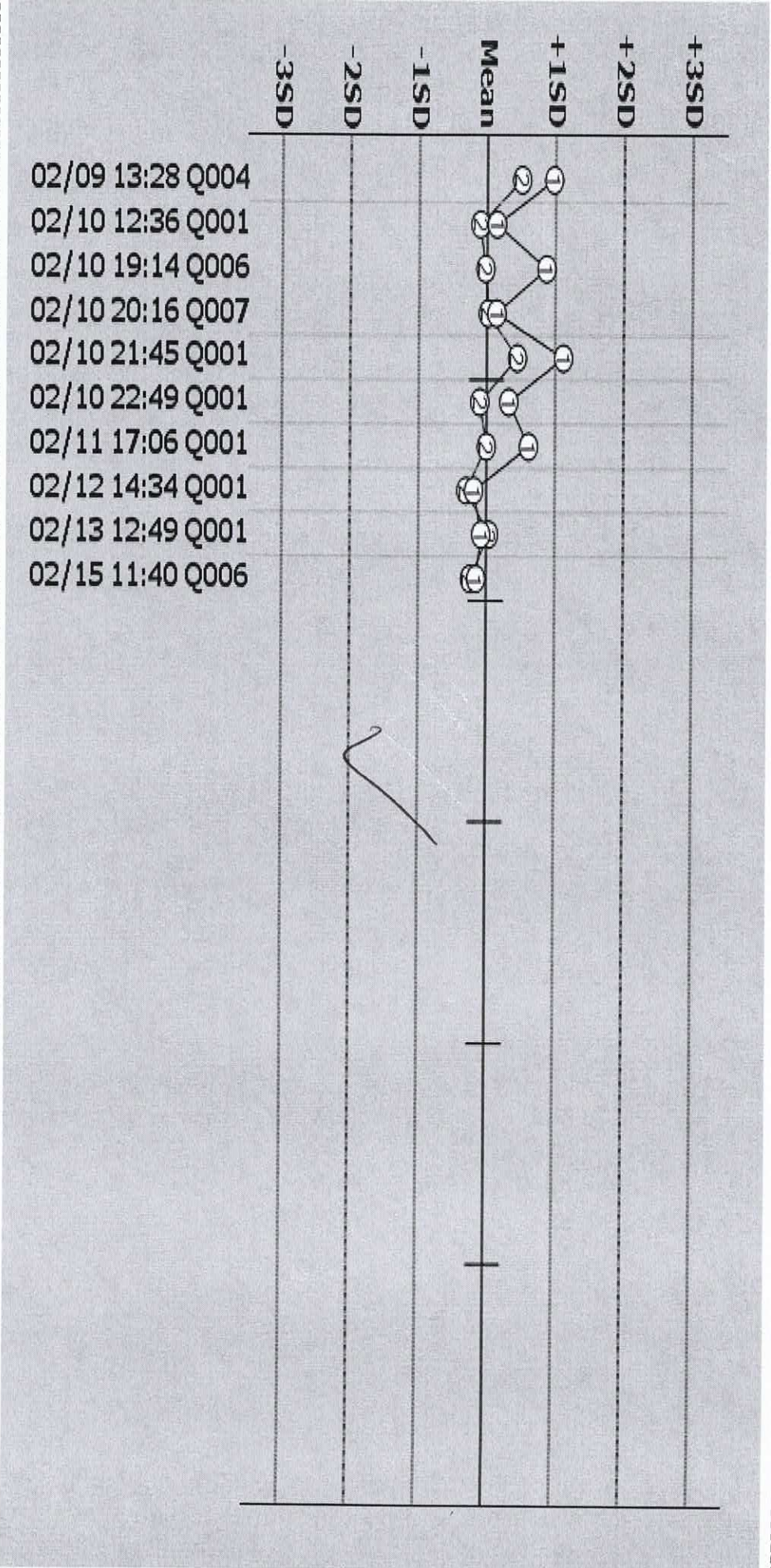
17/02/21
Wp

QC Monitor - Daily Chart

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35.CHOL
Graph

Type Serum



7/02/21 Ma

QC Monitor - Daily Chart

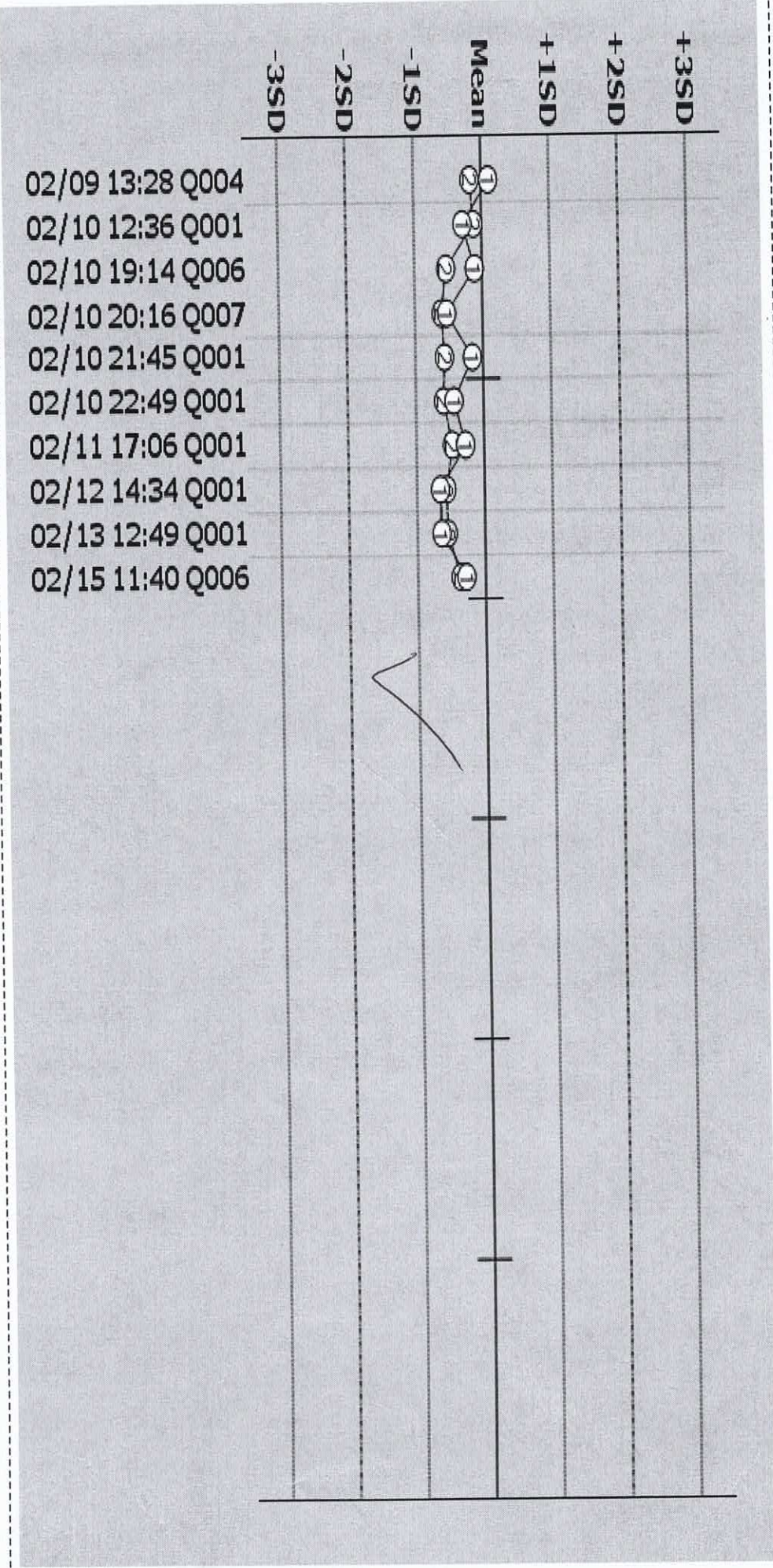
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Type

Serum

36. CRE-E
Graph



17/02/21
WJ