External quality control for CoaguChek XS INR monitors.

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Introduction

External Quality Control (EQC):

Independent assessment of the quality of performance of an analytical test system.

Introduction

External Quality Control (EQC):

Accuracy : Correct result

Reproducibility : Variation between monitors

ECAT Quality Control for CoaguChek XS

Point-of-care monitoring of vitamin K-antagonists: validation of CoaguChek XS test strips with International Standard thromboplastin

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Table 1 Validation of CoaguChek XS reference lots with International Standard thromboplastin, human, recombinant

CoaguChek XS reference lot number	International Standard	N	Mean INR deviation (%)	*a*	*b*	p Value (Bland-Altman plot)	MRD (%)
20148535	rTF/95	59	−4.8	0.1838	0.8690	0.001	6.8
20150735	rTF/95	73	+0.7	0.1637	0.8422	<0.001	5.3
20162931	rTF/95	57	−3.9	0.0441	0.9972	0.329	5.7
20171134	rTF/95	60	−7.3	0.1266	0.9479	0.569	8.0
20179634	rTF/95	58	−2.3	0.0925	0.9345	0.105	4.2
20318112	rTF/09	56	+1.8	−0.1542	1.1509	0.002	5.9

Table 2 Mean relative INR deviation and MRD from International Standard for consecutive CoaguChek XS test strip lots grouped according to the reference lot with which they were compared

CoaguChek XS reference lot number	Number of consecutive lots compared to reference lot	Mean relative deviation of INR for consecutive test strip lots			MRD		
		Median (%)	Minimum (%)	Maximum (%)	Median (%)	Minimum (%)	Maximum (%)
20148535	4	−3.7	−5.4	−1.9	4.7	3.6	5.7
20150735	9	−1.6	−5.9	+4.0	4.9	2.5	6.1
20162931	8	−1.0	−5.8	+1.6	4.0	2.4	6.3
20171134	10	−4.8	−8.1	−2.8	5.3	3.2	8.1
20179634	14	−3.7	−6.3	−1.7	4.5	3.2	6.5
20318112	6	−0.5	−2.2	+2.5	4.3	3.3	5.6
All	51	−3.4	−8.1	+4.0	4.5	2.4	8.1

INR, International Normalised Ratio; MRD, mean absolute value of relative deviation.

Quality Control Set:

- 4 different QC samples (INR 2 – 4.5)
- 4 vials of water
- 4 vials of calciumchloride
- plastic pipettes
- instructions

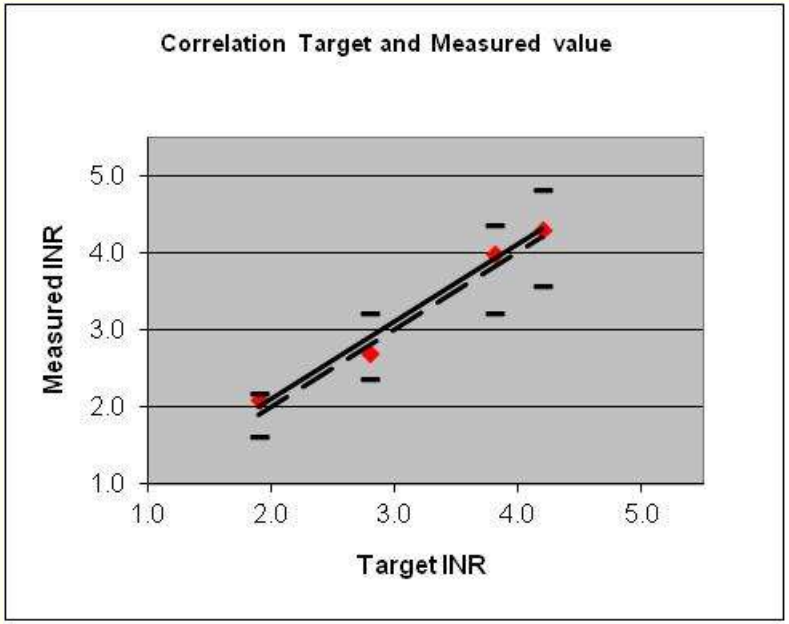
2.

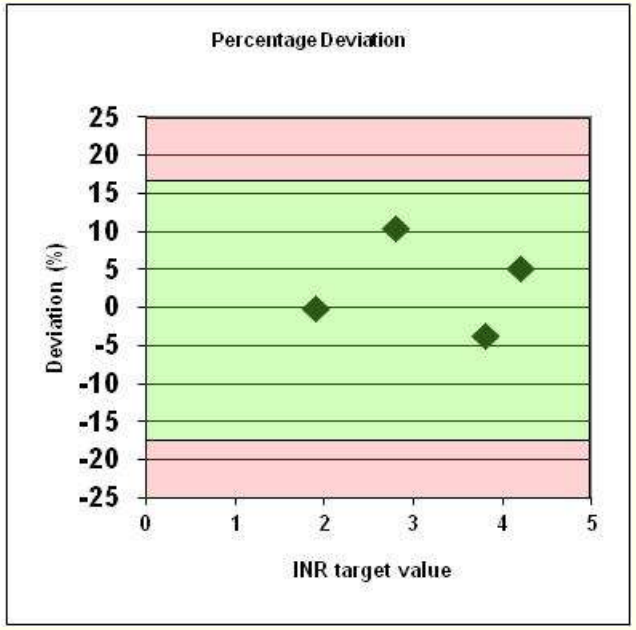
The package contains 4 small bottles with **control sample** that can be recognised from the number on the label (**no. 1: green; no. 2: yellow; no. 3: red; no. 4: brown)**. It also contains 4 bottles of **water (blue cap)** for dissolving the control samples and a 4 bottles of **calcium chloride (white cap)**. Plastic pipettes are supplied for, for instance, dissolving the control samples.

3.

First of all the control samples are dissolved. To do this add the whole content of a bottle of water to a bottle of control sample. Do this for each bottle in turn, so that the caps of the different bottles cannot be put back on the wrong bottle by mistake. This should be done as follows:

- Unscrew the top of the bottle of water (blue cap) and control sample 1 (green cap) and remove, when needed, the grey rubber stopper. Do not touch the bottom of the rubber stopper.
- Take a plastic pipette and squeeze the balloon at the top completely.
- Place the tip of the pipette at the bottom of the bottle of water. Keep the balloon firmly squeezed while doing this.





Sample	Target	Target Range	Measured	%D	Conclusion
1	1.9	1.6 - 2.2	2.1	10.5	OK
2	2.8	2.4 - 3.2	2.7	-3.6	OK
3	3.8	3.2 - 4.3	4.0	5.3	OK
4	4.2	3.6 - 4.9	4.3	2.4	OK

		Conclucion
Correlation	0.982	OK
Slope	1.00	OK
Intercept	0.09	OK
Correct QC results	4	OK

Target Values

Strip No.	Sample 1	Sample 2	Sample 3	Sample 4
Relac	302	1.90	2.68	3.90	4.10
Relac	367	1.80	2.60	3.80	4.06
Relac	374	1.88	2.70	3.88	4.26
Producer	338	1.85	2.68	3.65	4.23
Producer	342	1.98	2.90	3.75	4.23
Mean		**1.9**	**2.7**	**3.8**	**4.2**
SD		0.06	0.11	0.10	0.09
CV (%)		**3.4**	**4.1**	**2.7**	**2.1**

Reproducibility I (within-day)

Monitor no. UP0019809

Strip No. 302

	Sample 1	Sample 2	Sample 3	Sample 4
Measurement 1	1.9	2.7	3.9	4.1
Measurement 2	1.9	2.7	3.9	4.1
Measurement 3	1.9	2.6	3.9	4.1
Measurement 4	1.9	2.7	3.9	4.1
Measurement 5	1.9	2.7	3.9	4.1
Mean	1.90	2.68	3.90	4.10
SD	0.00	0.04	0.00	0.00
CV (%)	0.0	1.7	0.0	0.0

Reproducibility II (between-day)

Monitor No. UP0019809

Strip No.: 367

	Sample 1	Sample 2	Sample 3	Sample 4
Day 1	1.9	2.7	3.8	4.1
Day 2	1.9	2.7	3.8	4.1
Day 3	1.9	2.7	3.8	4.1
Day 4	2.0	2.7	3.8	4.1
Day 5	1.9	2.7	3.8	4.1
Mean	1.92	2.70	3.80	4.10
SD	0.04	0.00	0.00	0.00
CV (%)	2.3	0.0	0.0	0.0

Reproducibility III (between-monitor)

	Sample 1	Sample 2	Sample 3	Sample 4
Monitor				
UP0019809	1.9	2.7	3.9	4.1
UP0019805	2.0	2.7	4.0	4.2
UP0282198	2.0	2.7	4.0	4.1
Mean	1.95	2.69	3.95	4.13
SD	0.05	0.01	0.05	0.03
CV (%)	2.6	0.4	1.3	0.7

Stability

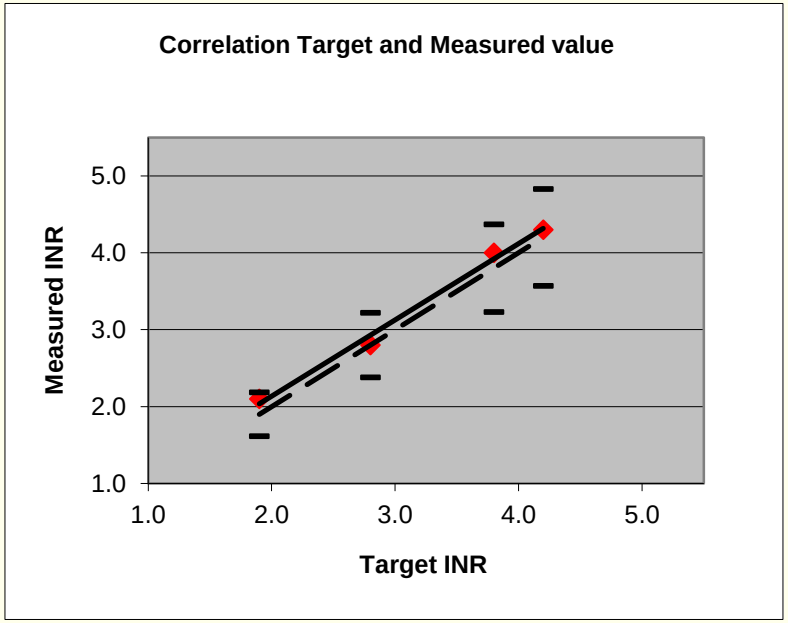
Monitor: UP 0135631 UP 0621240

Strip No.: 416 429

Time (hr)	level 1	level2	level3	level4		level 1	level2	level3	level4
0:00	1.9	2.8	4.0	4.3		1.9	2.8	4.0	4.3
0:10	1.9	2.8	4.0	4.3		1.9	2.8	3.9	4.2
2:00	2.0	2.7	4.0	4.3		1.9	2.7	4.0	4.3
3:00	2.0	2.8	4.1	4.4		1.9	2.7	4.0	4.3
4:00	2.0	2.7	4.1	4.3		1.9	2.8	4.1	4.4
5:00	1.9	2.7	4.0	4.3		2.0	2.8	4.1	4.4
6:00	2.0	2.8	4.1	4.4		1.9	2.9	4.0	4.3
Mean	**2.0**	**2.8**	**4.0**	**4.3**		**1.9**	**2.8**	**4.0**	**4.3**
SD	**0.05**	**0.05**	**0.05**	**0.05**		**0.04**	**0.07**	**0.07**	**0.07**
CV (%)	**2.7**	**1.9**	**1.3**	**1.1**		**2.0**	**2.5**	**1.7**	**1.6**

Criteria for evaluation

QC-plasma	Target	-15%	+ 15%		Min	Max
1	1.9	1.6	2.2	Slope	0.77	1.79
2	2.8	2.4	3.2	Intercept	-1.78	0.72
3	3.8	3.2	4.4	Corr. Coeff.	> 0.900	
4	4.2	3.6	4.8			



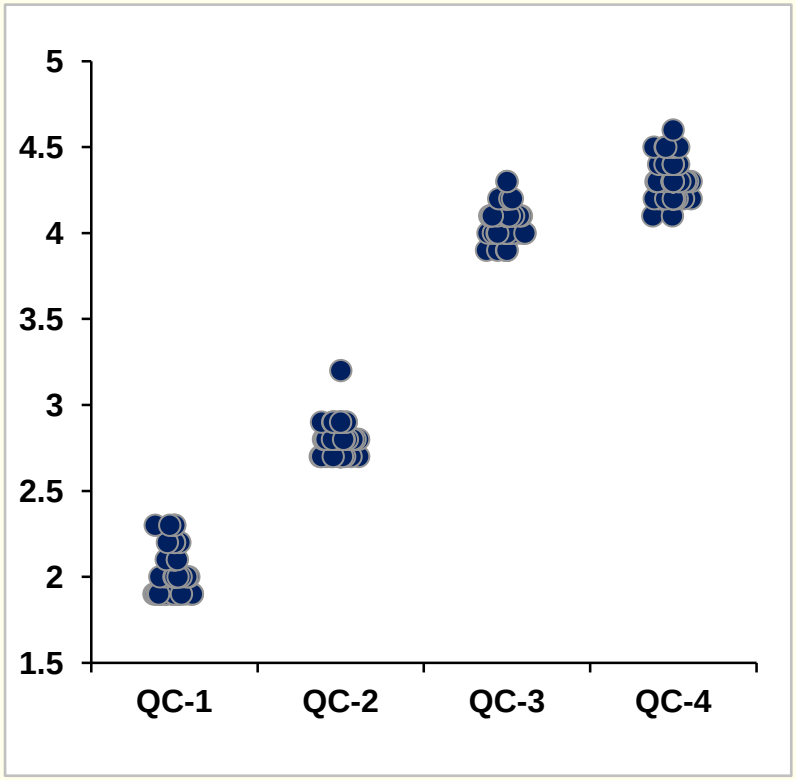
Results 1

103 monitors tested

5 excluded because of error in 1 particular sample.

From the remaining 98 monitors 94 pass QC = 96%

Results 2



N = 98

	S1	S2	S3	S4
Mean	2.0	2.8	4.1	4.3
Min	1.9	2.7	3.9	4.1
Max	2.3	2.9	4.3	4.6
SD	0.10	0.06	0.10	0.10
CV (%)	5.3	2.1	2.3	2.4

Result 3

	Sample 1	Sample 2	Sample 3	Sample 4
Target	1.9 (1.78 – 2.02)	2.7 (2.48 – 2.92)	3.8 (3.60 – 4.00)	4.2 (4.02 – 4.38)
Observed	2.0 (1.80 – 2.20)	2.8 (2.68 – 2.92)	4.1 (3.90 – 4.30)	4.3 (4.10 – 4.50)

Results 4

Strip No.	N	Sample 1	Sample 2	Sample 3	Sample 4
402	9	2.0	2.8	4.0	4.3
413	42	2.0	2.8	4.1	4.3
416	7	2.0	2.8	4.1	4.3
424	17	2.1	2.8	4.2	4.4

Results 5

	Min	Max
Slope	0.77	1.79
Intercept	-1.78	0.72
Correlation	0.900	

Mean	SD	Min	Max
1.037	0.048	0.928	1.154
- 0.018	0.153	-0.340	0.329
0.989	0.007	0.973	1.000

Comments

- QC samples are prepared from pools of patient samples
- High reproducibility
- High stability
- Good inter-monitor comparability
- Integrated evaluation of QC samples provides insight in the measurement accuracy over the entire clinically important INR range (2.0 – 4.5)
- Can be performed at any time

Conclusion

The ECAT Quality Control Sets are a reliable tool for external assessment of the quality of the performance of CoaguChek XS INR monitors.