EXTERNAL QUALITY CONTROL RESULTS FOR POCT INR TESTING.

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Anticoagulation management

Narrow therapeutic windows

INR target ranges are specified by patient populations

- **General therapeutic window: INR = 1.5 – 4.5**
- **Prophylactic therapy for DVT: INR= 2.0 – 3.0**
- **Artificial heart valve: INR=2.5 – 3.5**
- **Other ranges on a patient by patient basis**

Clinical safety

- **Below target: Thrombosis**
- **Above target: Bleeding**

Accurate INR measurement

Anticoagulation control by patient self-testing, patient self-management or near-patient testing

- At least as efficient as control by AC with standard laboratory testing
  (% INR within range ; % Time within target)
- It shows less complications
- Significant improvement of Quality of Life

How to assure accurate INR measurement?

<u>External Quality Control (EQC)</u>:

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

Accuracy : **Correct result**

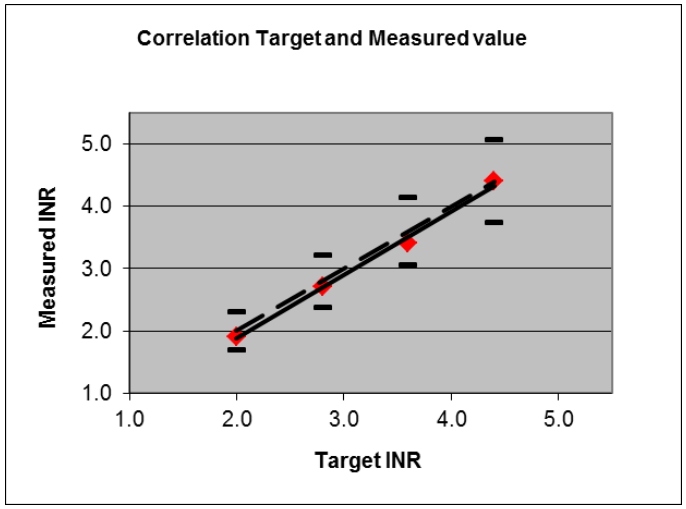
Reproducibility: **Variation between monitors**

External Quality Control with samples with assigned values.

Quality Control Set:

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

Acceptance Criteria	Criterion
QC sample	± 15% of target
No. Of QC samples within target	4
Slope	0.80 – 1.20
Intercept	-0.50 – +0.50
Corr. Coef	> 0.950



VALUE ASSESSMENT OF QC SAMPLES

Measurement of INR with different CoaguCheks, different lot.no. of test strips, different days.

Within-day variability	**:**	**< 2%**
Between-day variability	**:**	**< 2%**
Between-monitor variability	**:**	**< 2.5%**
Between-lot variability	**:**	**< 3%**

- **The value assignment is performed in the Dutch Reference Laboratory for Anticoagulation.**
- **One of the lot.no. of test strips used for the value assignement is calibrated against the WHO standard for rh-Thromboplastin.**

VALUE ASSESSMENT OF QC SAMPLES

QC sample	1	2	3	4
Lot. no. 211B00				
Assigned INR value	1.9	2.7	3.9	4.1
SD	0.09	0.00	0.10	0.07
Uncertainty (%)	1.0	0.0	0.6	0.4
Lot. no. 221B00				
Assigned INR value	2.1	2.8	3.6	4.4
SD	0.04	0.07	0.08	0.18
Uncertainty (%)	0.6	0.8	0.8	1.3
Lot. no. 241B00				
Assigned INR value	2.1	2.7	3.8	4.3
SD	0.05	0.05	0.07	0.13
Uncertainty (%)	0.8	0.6	0.6	0.9

STABILITY OF QC SAMPLES

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**

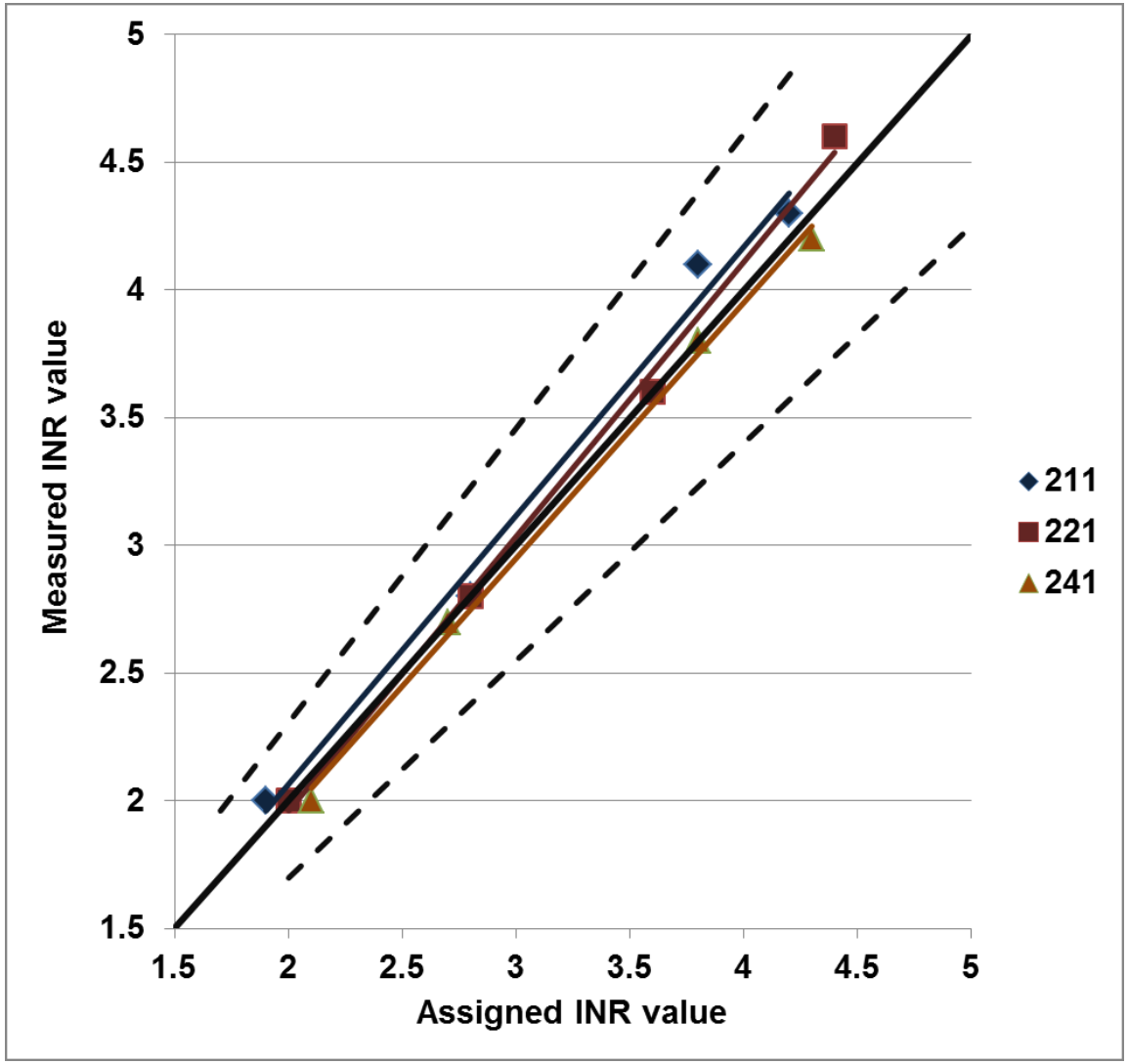
SUMMARY OF EVALUATED MONITORS

Lot. No QC set	211B00	221B00	241B00
No. of evaluated monitors	163	812	239
No. of monitors passing QC	139	758	231
No. of monitors with systematic error *	19	28	4
No. of monitors fail in QC	5	26	4
Failure rate	3.5%	3.3%	1.7%

SUMMARY OF MEASURED INR RESULTS

Control Set		Sample 1	Sample 2	Sample 3	Sample 4
Batch 211B00 number of monitors: 144	Assigned Value	1.9	2.8	3.8	4.2
	Mean	2.0	2.8	4.1	4.3
	Coeff. Variation	6.3%	2.5%	3.9%	3.0%
	Average regression line	Y = 1.06 X – 0.07 (corr. coeff.: 0.985)			
Batch 221B00 number of monitors: 784	Assigned Value	2.0	2.8	3.6	4.4
	Mean	2.0	2.8	3.6	4.6
	Coeff. Variation	2.9%	3.2%	4.2%	3.6%
	Average regression line	Y = 1.08 X – 0.20 (corr. coeff.: 0.994)			
Batch 241B00 number of monitors: 235	Assigned Value	2.1	2.7	3.8	4.3
	Mean	2.0	2.7	3.8	4.2
	Coeff. Variation	3.6%	3.1%	3.6%	3.8%
	Average regression line	Y = 0.99 X – 0.01 (corr. coeff.: 0.995)			

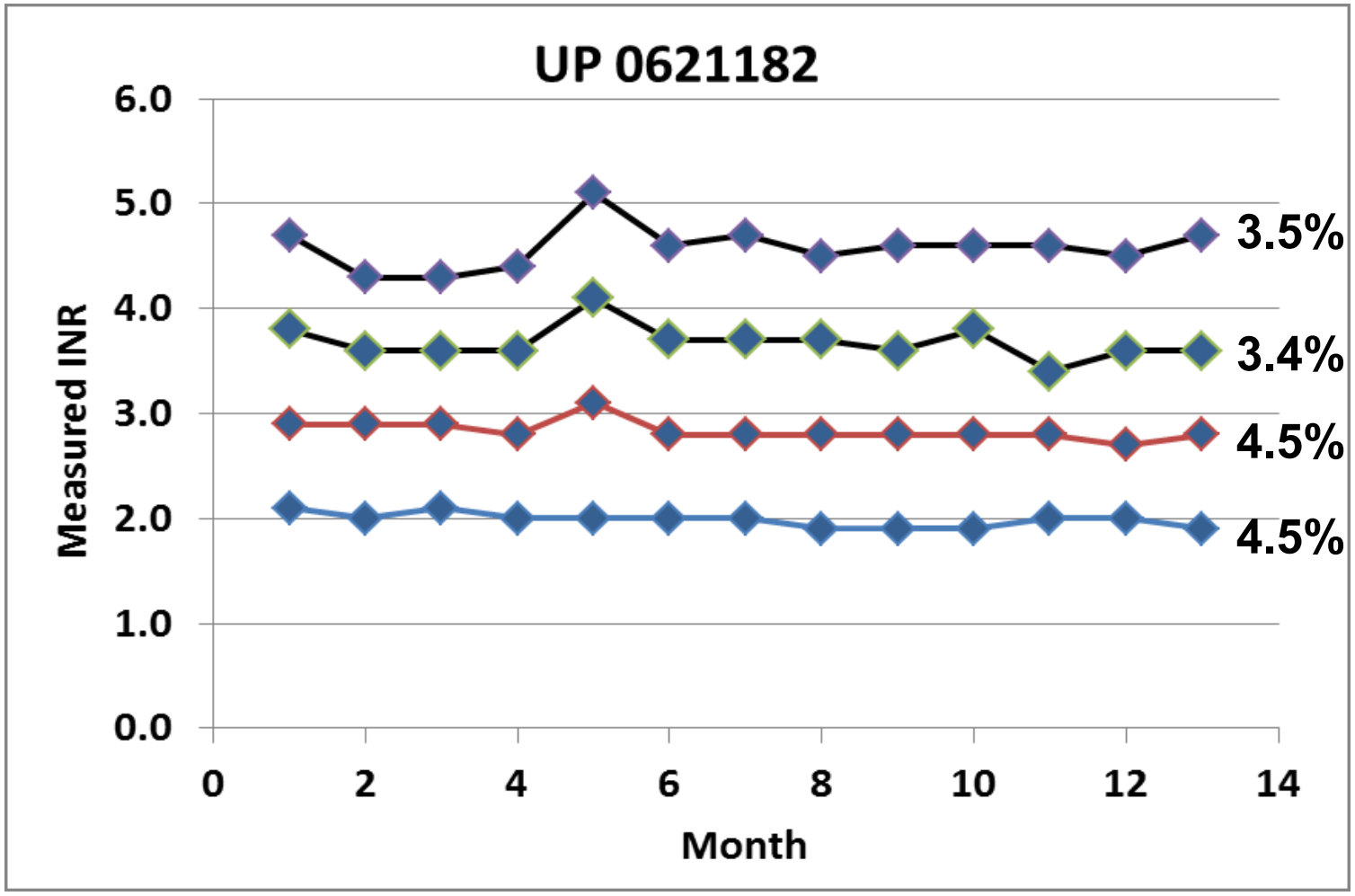
SUMMARY OF MEASURED INR RESULTS



INR RESULTS (DIFFERENT LOT.NO.)

Batch: 221		Sample 1		Sample 2		Sample 3		Sample 4	
Assigned Value		**2.0**		**2.8**		**3.6**		**4.4**	
Code test strip	No. monitors	**Mean**	/ CV (%)	**Mean**	/ CV (%)	**Mean**	/ CV (%)	**Mean**	/ CV (%)
23	97	**2.0**	2.0	**2.9**	1.7	**3.7**	1.4	**4.6**	2.4
32	40	**1.9**	2.0	**2.7**	1.6	**3.5**	2.3	**4.5**	1.8
41	140	**2.0**	2.0	**2.7**	2.2	**3.5**	1.8	**4.5**	2.0
446	47	**2.0**	2.3	**2.8**	2.3	**3.6**	2.4	**4.4**	3.0
451	20	**2.0**	3.3	**2.9**	2.1	**3.7**	3.0	**4.5**	2.4
477	47	**2.0**	2.5	**2.9**	2.9	**3.6**	2.5	**4.6**	3.5
495	33	**1.9**	2.2	**2.8**	3.3	**3.6**	1.6	**4.6**	2.2

LONG-TERM PERFORMANCE



COMMENT

- 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
- Starting in 2015 a webtool will be available for immediate evaluation.

CONCLUSION

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

CoaguChek XS INR monitors show accurate and stable performance with minimal differences between different lot numbers of test strips.