Summary

The newly developed CueSee® Coag quality control is packaged in the innovative CueSee® Mix which consists of two compartments as indicated on the vial (see picture). Lyophilized plasma with coagulation factors and red blood cells are contained in compartment 1 and are reconstituted with the diluent held in compartment 2 by simply twisting the bottom gray section. After reconstitution, the matrix is very similar to patient samples therefore giving optimal commutability and best performance on point-of-care (POC) tests.

The purpose of this study was to evaluate the performance and ease of use of this quality control. Prothrombin time (PT), International Normalized Ratio (INR) and/or activated clotting time (ACT) was reported for three different concentration levels. Testing was performed by POC coordinators, quality managers and anticoagulation clinic pharmacists at 23 different locations using 7 different testing platforms.

Table 1 and Figure 1 show the results of this study which demonstrate that the commutability and overall performance is very good. This was confirmed by the survey received from 21 locations indicating participants were impressed by the performance of the control as well as the ease of use and improved safety. The overall score of 4 (out of a maximum score of 5) proves the high satisfaction of the evaluation participants.

The outcome of this study confirms the decision to offer this product for proficiency testing and clinical laboratory use. Utilization of CueSee® Compare, which offers peer data comparison and other statistical data, with CueSee® Coag will give the POC market much confidence in their coagulation testing program. Besides the three levels used for this evaluation two additional levels will be offered making CueSee® Coag ideal for not only routine quality control but also reportable range validation, competency testing, and troubleshooting needs. Next to PT, INR and ACT also activated partial thromboplastin clotting time (aPTT) can be reported for all levels of this quality control.

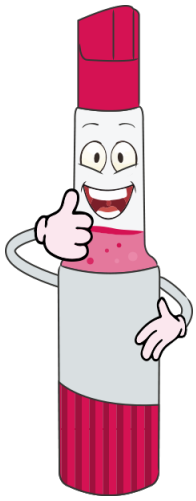

Table 1. Results on coagulation POC systems at 23 locations

PT	(sec)	Roche CoaguChek Pro II	Roche CoaguChek XS	Abbott i-STAT	CoaguSense	Hemochron Signature Elite
Level 1	n	6	1	14	2	20
	AVG	14.9	15.7	13.3	13.7	38.7
	SD	0.13	NA	0.54	1.63	4.82
Level 2	n	6	1	11	2	22
	AVG	35.3	36.1	31.1	29.4	73.7
	SD	1.01	NA	2.29	0.07	13.32
Level 3	n	6	1	12	Not measured	Out of range
	AVG	56.6	56.4	54.7	Not measured	Out of range
	SD	1.91	N/A	4.7	Not measured	Out of range

INR		Roche CoaguChek Pro II	Roche CoaguChek XS	Abbott i-STAT	CoaguSense
Level 1	n	6	9	14	2
	AVG	1.2	1.3	1.1	1.2
	SD	0.04	0.05	0.04	0.14
Level 2	n	6	9	11	2
	AVG	2.9	2.9	2.7	2.7
	SD	0.08	0.07	0.2	0
Level 3	n	6	9	12	Not measured
	AVG	4.7	4.6	4.9	Not measured
	SD	0.15	0.11	0.43	Not measured

ACT	(sec)	Hemochron Signature Elite ACT+	Hemochron Signature Elite ACT-LR	GEM Hemochron 100 ACT+	GEM Hemochron 100 ACT-LR	HMS	Abbott i-STAT Kaolin	Abbott i-STAT Celite
Level 1	n	21	7	5	7	2	37	3
	AVG	201	153	188	153	115	170	139
	SD	41.45	12.91	34.72	12.91	1.41	8.59	6.93
Level 2	n	19	7	5	7	2	37	6
	AVG	351	373	335	373	288	428	354
	SD	18.71	14.8	13.29	14.8	4.95	44.87	10.15
Level 3	n	14	Out of range	5	Out of range	1	34	6
	AVG	380	Out of range	385	Out of range	437	565	467
	SD	22.79	Out of range	21.61	Out of range	NA	40.85	22.44

Figure 1. Graphic representation of results on coagulation POC systems at 23 locations