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Evaluation of precision performance of the IMx CEA and CA 15-3 assays

Key words: Precision; CA 15-3; CEA

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Manual enzyme immunoassay (EIA) for CEA and CA 15-3 typically require several pipetting steps, strict control of incubation temperature, time, which contribute to the relative imprecision (inter assay coefficient of variation 7-18%) of these assays. IMx manufactured by ABBOTT is a fully automated non-isotopic microparticle capture enzyme immunoassays which utilizes a dual monoclonal antibody. The assay requires 150 ml of serum. IMx is analyzer with maximum assay capacity of 24 samples in singleton. Results for a full run are available in 40 minutes.

Assay precision was determined by using two commercial controls of ABBOTT within run in replication of ten and between run. Precision data are shown below:

These results show that coefficient of variation for both assays was less than 5% and both assay show excellent precision and reproducibility.

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Table 1. Precision of CEA and CA 15-3 assays

CEA PRECISION						
WITHIN RUN N = 10				BETWEEN RUN N = 10		
IMx CEA CONTROL	MEAN VALUE ng/ml	SD ±	CV %	MEAN VALUE ng/ml	SD ±	CV %
LOW	4,64	0,18	3,89	5,36	0,25	4,67
HIGH	106,4	2,69	2,50	109,55	5,13	4,68
CA 15-3 PRECISION						
WITHIN RUN N = 10				BETWEEN RUN N = 10		
IMx CA 15-3 CONTROL	MEAN VALUE n/ml	SD ±	CV %	MEAN VALUE n/ml	SD ±	CV %
LOW	34,64	0,85	2,41	35,23	1,44	3,24
HIGH	127,83	3,35	2,62	126,27	5,76	4,23

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