

Laboratory Evaluation of Technopath Controls on the ARCHITECT Immunoassay Analyzers

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Background

Efficient analytical and quality control is important for testing laboratories to ensure that released results meet the required quality in regards to accuracy and precision. Consolidation of quality controls simplifies workflow in the laboratory. However, changing of quality controls necessitates careful evaluation by the laboratory. Technopath Manufacturing Ltd (Ballina, Ireland) recently introduced multi-constituent controls (MCC) for use with the Abbott ARCHITECT instruments that allows one control to be used for the majority of the assays available in the routine lab on the ARCHITECT instruments. The performance of the Technopath Multichem IA plus immunoassay controls was evaluated in comparison to the laboratory's current QC methods in three European laboratories.

Results (cont'd)

Summary of Sites and Testing

	France	Italy	Germany
Instruments	2 – i2000 _{SR}	3 – i2000 _{SR}	2 – i2000 _{SR}
CA 19-9	X	X	X
CEA	X	X	X
Estradiol	X	X	X
FSH		X	X
Free T3	X	X	X
Free T4	X	X	X
Testosterone		X	X
Total PSA	X	X	X
Total βHCG	X	X	X
Troponin I	X	X	X
TSH	X	X	X

Overall Results

Analyte	Level	Unit	N	Expected Mean	Mean	SD	CV	Expected Range	Observed Range
CA 19-9	1	U/L	45	N/A	17.52	2.396	13.67	N/A	12.48 – 21.75
	2		123	37.4	35.94	3.496	9.73	26.2 – 48.6	26.41 – 43.56
	3		123	140	139.55	8.543	6.12	98.0 – 182	115.17 – 159.69
CEA	1	ng/mL	111	3.22	3.12	0.234	7.52	2.58 – 3.86	2.46 – 3.81
	2		109	19.2	18.06	0.753	4.17	15.4 – 23.0	15.83 – 19.63
	3		109	52	49.25	1.784	3.62	41.6 – 62.4	44.63 – 53.53
Estradiol	1	pg/mL	107	55.8	54.9	3.67	6.68	39.1 – 72.5	45.0 – 63.0
	2		110	173	172.7	7.43	4.3	121 – 225	160.0 – 210.0
	3		105	444	431.3	15.24	3.53	311 – 577	391.0 – 456.0
FSH	1	U/L	110	5.55	5.32	0.16	3.01	4.44 – 6.66	5.01 – 5.79
	2		108	18.7	17.67	0.632	3.57	15.0 – 22.4	16.08 – 19.89
	3		106	41.9	39.98	1.547	3.87	33.5 – 50.3	35.98 – 43.23
Free T3	1	pg/mL	236	2.88	2.97	0.179	6.03	2.02 – 3.74	2.45 – 3.59
	2		230	3.98	4.14	0.192	4.63	2.79 – 5.17	3.53 – 5.06
	3		228	8.59	9.14	0.39	4.27	6.01 – 11.2	8.34 – 10.49
Free T4	1	ng/dL	183	0.581	0.59	0.032	5.44	0.407 – 0.755	0.51 – 0.66
	2		147	1.61	1.69	0.065	3.88	1.13 – 2.09	1.48 – 1.85
	3		152	2.76	2.89	0.133	4.62	1.93 – 3.59	2.60 – 3.25
Testosterone	1	ng/mL	76	0.297	0.32	0.032	10.12	0.208 – 0.386	0.26 – 0.40
	2		72	4.5	4.97	0.368	7.42	3.60 – 5.40	4.31 – 5.69
	3		104	9.31	10.31	0.51	4.95	6.52 – 12.1	9.42 – 11.68
Total PSA	1	ng/mL	155	0.551	0.564	0.0256	4.53	0.441 – 0.661	0.510 – 0.634
	2		153	4.26	4.051	0.1802	4.45	3.41 – 5.11	3.413 – 4.644
	3		148	23.7	23.008	1.2152	5.28	19.0 – 28.4	20.054 – 26.486
Total βHCG	1	mIU/mL	135	5.78	5.43	0.553	10.18	4.05 – 7.51	4.03 – 7.20
	2		74	N/A	18	1.451	8.06	N/A	15.37 – 22.00
	3		134	505	490.75	28.966	5.9	404 – 606	434.89 – 563.51
Troponin-I	1	ng/mL	205	0.064	0.063	0.0069	10.95	0.045 – 0.083	0.044 – 0.082
	2		224	0.513	0.527	0.0296	5.63	0.410 – 0.616	0.456 – 0.596
	3		220	4.72	4.768	0.2534	5.31	3.78 – 5.66	4.106 – 5.422
TSH	1	μIU/mL	232	0.102	0.099	0.006	6.09	0.071 – 0.133	0.080 – 0.116
	2		226	4.35	4.16	0.191	4.6	3.48 – 5.22	3.45 – 4.75
	3		223	23.1	22.42	0.875	3.9	18.5 – 27.7	19.87 – 24.77

Materials and Methods

Technopath Multichem IA Plus controls are prepared from human serum to which purified biochemical material (extracts of human and animal origin), chemicals, drugs, preservatives and stabilizers are added. These controls are provided in liquid form and stored frozen (-20 to -80°C) until use. Once thawed, the material is stored at 2-8°C and stable for 10 days unless otherwise stated in the lot specific data sheets. Forty-five analytes are included in this control at three different levels.

Three European sites (Paris, France; Stuttgart, Germany; Sondrio, Italy) evaluated the Technopath Multichem IA Plus MCCs for a minimum of thirty days in parallel with the lab's routine QC controls including single constituent controls (SCC) and MCC for assays on their routine menus. Testing was performed with the ARCHITECT i2000_{SR} instrument.

Data presented here are from the following serum analytes: CA 19-9, CEA, estradiol, FSH, free T3, free T4, TSH, testosterone, total beta HCG, total PSA, and troponin-I. All data were collected via AbbottLink for automated data retrieval. Means, standard deviation and range were calculated for all controls. Assay reagent lots and calibrator lots varied across the sites and within the sites.

Other controls tested included BioRad Liquichek Immunoassay Plus, BioRad Liquichek Cardiac Marker, Abbott SCC (single constituent control) and Abbott/BioRad MCC.

Results

The results from these eleven frequently performed immunoassays were analyzed. The %CV for the 11 assays with the Multichem IA Plus control ranged from 1.82 (Estradiol) to 14.94% (Troponin) at the individual sites; however the majority of the CVs were less than 5%. The results from the Technopath IA Plus control compared favorably with routinely used MCCs and SCCs in terms of %CV. Little variation was seen instrument to instrument, site to site or reagent lot to reagent lot. When all the data was consolidated by analyte across multiple reagent lots and instruments, the overall %CV ranged from 3.01 (FSH) to 10.95% (Troponin) for the Multichem IA Plus control with the majority demonstrating a %CV of less than 7.5%.

ABBOTT ARCHITECT Technopath MCC Study Assay: FSH (7K75)

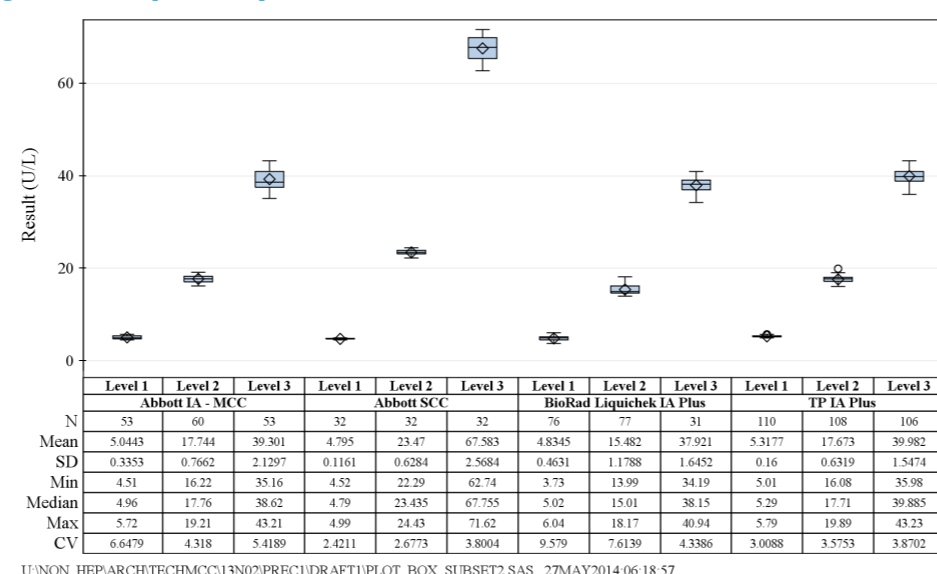


Figure 1: Box and Whisker plots of FSH quality control testing for routine controls – BioRad and Abbott Multiconstituent Controls (MCC) and Single Constituent Controls (SCC) – and Technopath IA Plus.

ABBOTT ARCHITECT Technopath MCC Study Assay: Troponin I (2K41)

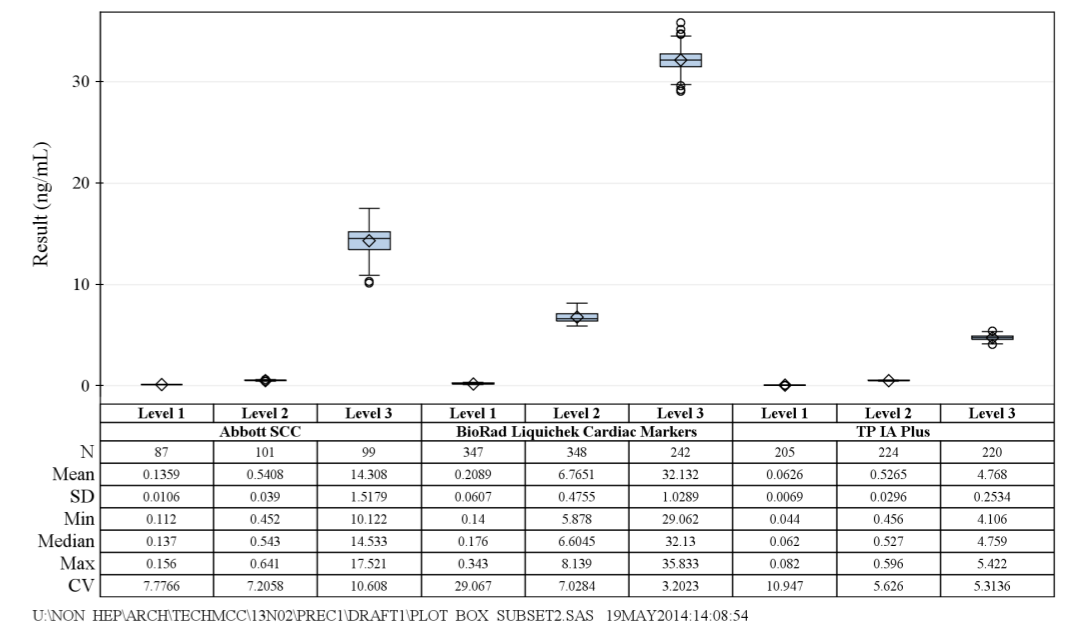
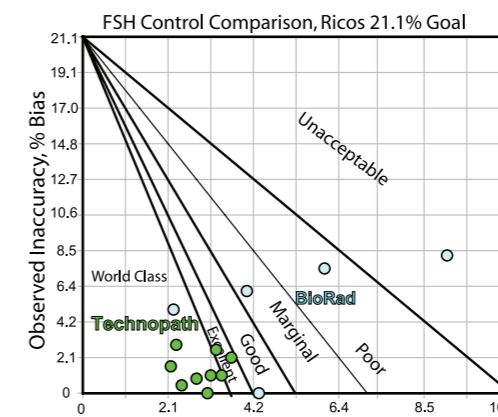


Figure 2: Box and Whisker plots of Troponin (cTnI) quality control testing for routine controls – BioRad Liquichek cardiac marker and Abbott Single Constituent Controls (SCC) – and Technopath IA Plus.

FSH Method Decision Chart



TnI Method Decision Chart

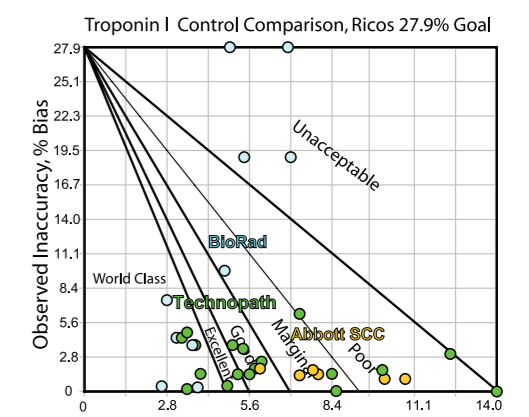


Figure 3: Six Sigma Method performance comparison of BioRad (○) and Technopath (●) controls for FSH. Few data points for BioRad controls were available.

Sigma Metrics were calculated using peer means and CVs and TEAs from the literature according to the following equation: Sigma Metric = (TEA – Bias)/CV.

Sigma Metric Summary: Multichem IA Plus

Analyte	Sigma Metric – Technopath					Sigma Metric – BioRad				
	6	5	4	3	<3	6	5	4	3	<3
CEA	3	3	0	2	1	1	1	0	0	2
Estradiol	5	2	1	1	0	5	1	0	0	2
FSH	6	3	0	0	0	1	0	1	1	2
Free T3	3	4	5	2	1	1	0	1	1	2
Free T4	4	4	3	2		5	1	1	0	0
Testosterone	1	0	2	1	2		0	1	1	0
Total PSA	10	2	0	0	0	2	1	0	2	0
Total βHCG	4	2		2	3	2	1		2	1
Troponin I	5	2	5	2	4	5	0	0	1	4
TSH	10	2	4	2	0	3	2	1	1	0
Total	51	24	20	14	11	25	7	5	9	11
%	42.5	20	16.7	11.7	9.2	43.9	12.3	8.8	15.8	19.3

% Sigma-metric comparison of controls

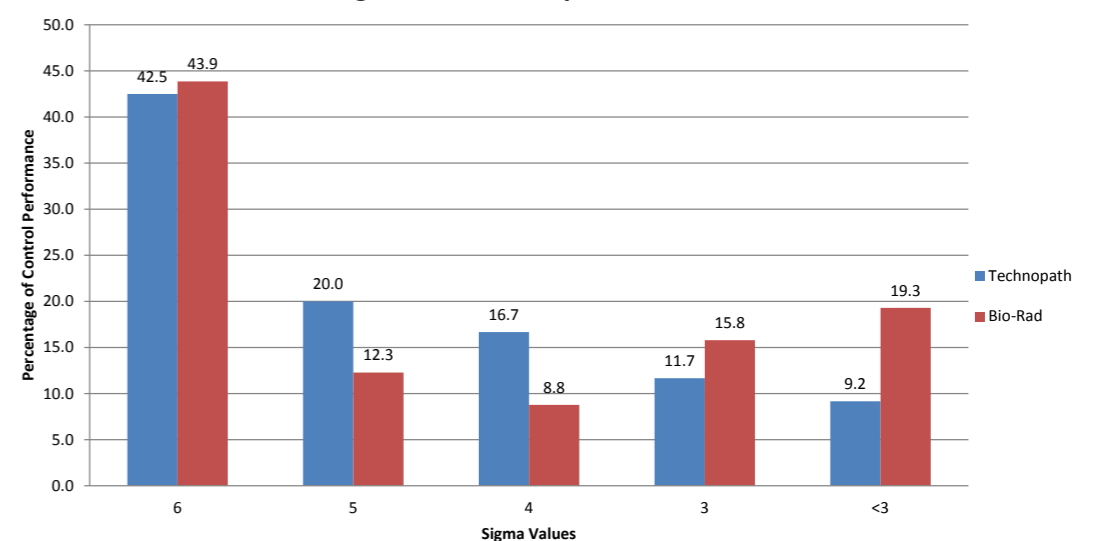


Figure 5: Summary of the comparison of Sigma Metrics for Technopath and BioRad. CA 19-9 was excluded since no BioRad controls were run. There was no statistical difference in performance between the two controls.

Conclusions

The Technopath Multichem IA Plus control demonstrated similar performance to the routine laboratory quality control solutions. The Technopath Multichem IA Plus controls allow a reduction in the number of controls required for the analytical quality control testing of immunoassays.

ABBOTT ARCHITECT i2000_{SR} is a trademark of Abbott Laboratories.