Evaluation of Technopath Controls on the ARCHITECT Family of Instruments

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Abstract

Introduction: Quality controls are important for laboratories to ensure that released results meet the required quality in regard to accuracy and precision. Consolidation of controls is an important trend in laboratories to simplify QC testing. Recently, multi-constituent controls (MCCs) have been introduced by Technopath Manufacturing Ltd (Ballina, Ireland) that cover a wide range of clinical chemistry and immunoassay analytes.

Objective: The goal of this study was to evaluate the performance of the Multichem S Plus, Multichem IA Plus and Multichem U controls on the ARCHITECT family of instruments. Precision and accuracy compared to the target value were evaluated.

Methods: Three European sites (Paris, France; Stuttgart, Germany; Sondrio, Italy) used the three controls for a minimum of 30 days in parallel with the lab's routine QC controls. Testing was performed on the ARCHITECT *c*8000, *c*16000, *i*1000$_{SR}$ and *i*2000$_{SR}$ instruments. Data presented here are from the following serum clinical chemistry analytes: (A)ALT, (A)AST, total bilirubin, chloride, total cholesterol, creatinine (enzymatic and picrate), glucose, potassium, total protein, sodium, triglycerides and urea; the following immunoassays: CA 19-9, CEA, total PSA, free T3, free T4, TSH, troponin-I, total beta HCG, testosterone, estradiol and FSH; and on the following urine assays: chloride, creatinine (enzymatic and picrate), glucose, potassium, sodium and urea. The Multichem S Plus and IA Plus are serum based with three control levels; the Multichem U is prepared from human urine with two control levels. All data were collected via AbbottLink for automated data retrieval. Means, standard deviations and ranges were calculated for all controls. Assay reagent lots and calibrator lots varied across the sites and within the sites.

Results: The results from 12 frequently performed clinical chemistry assays were analyzed. The %CV for the 12 assays with the Multichem S Plus control ranged from 0.42 to 4.71% at the individual sites. The %CV for the six assays with the Multichem U control ranged from 0.50 to 5.24% at the individual sites. For both controls, the majority of the CVs were less than 2%. The results from these 11 frequently performed immunoassays were analyzed. The %CV for the 11 assays with the Multichem IA Plus control ranged from 1.82 to 14.94% at the individual sites; however the majority of the CVs were less than 5%. Overall little variation was seen instrument to instrument, site to site or reagent lot to reagent lot.

Conclusions: The Technopath S Plus, IA Plus and U controls demonstrated similar performance to the routine internal laboratory quality controls. The use of these MCCs reduce the number of controls required for the analytical quality control testing of both clinical chemistry and immunoassay analytes with no compromise on quality.

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 five controls to be used for the majority of the assays available in the routine lab on the ARCHITECT instruments. The performance of the Technopath Multichem S Plus, Urine IA Plus controls were evaluated in comparison to the laboratory's current QC methods in three European laboratories.

Materials and Methods

Technopath Multichem S Plus, U and IA Plus controls are prepared from human serum or urine to which purified biochemical material (extracts of human and animal origin), chemicals. The S Plus controls have three levels covering 60 analytes. The IA Plus overs 45 analytes with three control levels. Thirteen analytes are included in the U control at two different levels.

Three European sites (Paris, France; Stuttgart, Germany; Sondrio, Italy) evaluated the Technopath Multichem S Plus and Multichem U controls for a minimum of 30 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 *c*8000, *c*16000, *i*1000$_{SR}$ and *i*2000$_{SR}$ instruments.

Data presented here are from the following serum clinical chemistry analytes: (A)ALT*, (A)AST*, total bilirubin, Cl, total cholesterol, glucose, K, total protein, Na, triglycerides, and urea; the following urine analytes: Cl, creatinine, glucose, K, Na, and urea; and the following immunoassay 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 evaluated included BioRad Liquichek Unassayed Chemistry controls, Liquichek Lipids, Liquichek Ethanol/Ammonia, Liquid Assay Multiqual, Liquichek Urine Chemistry, Liquichek Immunoassay Plus, and Liquichek Cardiac Marker.

Sigma metrics were calculated using peer means and CVs and TEas from the literature according to the following equation: Sigma metric = (TEa – Bias)/CV.

Results

Little variation was seen instrument to instrument or even site to site. When all the data was consolidated by analyte across multiple reagent lots and instruments, the overall %CV ranged from 0.76 (chloride) to 4.11% (ALT) for S Plus and 1.01 (sodium) to 3.17% (glucose) for Urine.

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%.

World class Six Sigma performance was seen with both Technopath and BioRad controls on the majority of analytes evaluated. The Sigma metrics for each analyte are shown in the tables. The comparison of Techopath and BioRad Sigma metrics are summarized in the figures.

Results (cont'd)

Summary of Multichem S Plus Results

Analyte	Level	Unit	N	Expected Mean	Mean	SD	CV	Expected Range	Observed Range
AALT	1	U/L	153	26.9	27.1	1.12	4.11	21.5-32.3	24.0-30.0
	2		156	114	114.9	3.18	2.77	91.2 - 137	104.7 – 119.0
	3		153	250	250.2	5.35	2.14	200-300	235.1-259.0
AAST	1	U/L	149	45	44.7	1.8	4.04	36.0-54.0	40.0-50.0
	2		150	132	131.9	3.35	2.54	106-158	122.0-142.0
	3		149	261	264.7	4.52	1.71	209-313	255.0-281.0
Bilirubin	1	µmol/L	267	17.2	16.98	0.684	4.03	13.8 - 20.6	14.54 - 19.15
	2		266	45.6	44.8	1.284	2.87	36.5 - 54.7	39.84 - 48.22
	3		259	95.7	91.89	3.611	3.93	76.6 - 115	80.37 - 98.15
Chloride	1	mmol/L	260	85.1	83.7	0.904	1.08	76.6 - 93.6	81.50 - 88.20
	2		260	95.6	93.59	0.806	0.86	86.0 - 105	90.70 - 96.50
	3		255	110	108.22	0.828	0.76	99.0 - 121	105.70 - 111.60
Cholesterol	1	mmol/L	248	2.66	2.7	0.042	1.54	2.13 - 3.19	2.50 - 2.83
	2		244	4.06	4.09	0.087	2.12	3.25 - 4.87	3.61 - 4.37
	3		238	6.43	6.49	0.109	1.68	5.14 - 7.72	6.14 - 6.73
Creatinine, E	1	µmol/L	85	69.4	69.2	2.11	3.05	55.5 - 83.3	62.7 - 72.5
	2		90	175	176.2	3.18	1.8	140 - 210	167.6 - 183.8
	3		89	519	525.2	6.35	1.21	415 - 623	512.6 - 551.7
Creatinine, P	1	mg/dL	148	0.697	0.7	0.023	3.32	0.558 - 0.837	0.64 - 0.79
	2		147	1.97	1.98	0.062	3.12	1.57 - 2.36	1.69 - 2.26
	3		145	5.02	6.13	0.11	1.79	4.82 - 7.23	5.92 - 6.63
Glucose	1	mmol/L	259	2.82	2.84	0.049	1.72	2.26 - 3.38	2.70 - 3.02
	2		258	7.37	7.4	0.134	1.81	5.90 - 8.84	6.93 - 7.89
	3		253	16.2	16.21	0.236	1.46	13.0 - 19.4	15.46 - 17.05
Potassium	1	mmol/L	262	2.42	2.45	0.051	2.07	2.18 - 2.66	2.30 - 2.59
	2		260	3.77	3.8	0.058	1.52	3.39 - 4.15	3.69 - 3.94
	3		257	6.76	6.75	0.072	1.07	6.08 - 7.44	6.45 - 7.06
Protein, T	1	g/L	190	46.1	45.66	0.961	2.11	36.9 - 55.3	41.70 - 48.30
	2		190	65.2	64.9	1.329	2.05	52.2 - 78.2	60.10 - 68.70
	3		189	87.5	87.83	1.067	1.21	70.0 - 105	81.40 - 92.60
Sodium	1	mmol/L	259	121	120.68	1.068	0.88	109 - 133	117.60 - 125.00
	2		259	141	139.88	1.199	0.86	127 - 155	134.80 - 144.50
	3		256	161	160.39	1.264	0.79	145 - 177	156.90 - 165.00
Triglycerides	1	mmol/L	194	0.625	0.63	0.019	2.98	0.500 - 0.750	0.56 - 0.68
	2		190	1.5	1.47	0.037	2.53	1.20 - 1.80	1.36 - 1.55
	3		188	2.52	2.48	0.046	1.84	2.02 - 3.02	2.30 - 2.59
Urea	1	mmol/L	78	3.05	3	0.09	3.05	2.44 - 3.66	2.8 - 3.2
	2		80	14	13.7	0.29	2.11	11.2 - 16.8	12.7 - 14.8
	3		78	22.8	22.3	0.49	2.19	18.2 - 27.4	20.7 - 23.7

Summary of Multichem Urine Results

Analyte	Level	Unit	N	Expected Mean	Mean	SD	CV	Expected Range	Observed Range
Chloride	1	mmol/L	263	87.2	87.9	1.59	1.8	78.5 - 95.9	78.0 - 96.0
	2		256	193	189.4	2.22	1.17	174 - 212	181.0 - 201.0
Creatinine, E	1	mmol/L	89	6.42	6.05	0.11	1.81	5.14 - 7.70	5.73 - 6.37
	2		88	12.9	11.99	0.205	1.71	10.3 - 15.5	11.51 - 12.72
Creatinine, P	1	mg/dL	72	66.1	66.06	1.598	2.42	52.8 - 79.3	63.31 - 72.02
	2		71	135	131.63	2.302	1.75	108 - 162	125.60 - 136.63
Glucose	1	mmol/L	262	1.99	2.03	0.064	3.17	1.59 - 2.39	1.71 - 2.23
	2		264	20	20.41	0.543	2.66	16.0 - 24.0	17.38 - 21.69
Potassium	1	mmol/L	259	16.2	16.2	0.31	1.93	14.6 - 17.8	13.8 - 17.7
	2		259	58.8	58.9	0.82	1.4	52.9 - 64.7	54.8 - 61.9
Sodium	1	mmol/L	259	81.8	81.5	1.7	2.09	73.6 - 90.0	76.0 - 89.0
	2		259	158	157.9	1.6	1.01	142 - 174	151.0 - 168.0
Urea	1	mmol/L	79	153	151.4	2.97	1.96	122 - 184	145.3 - 162.4
	2		79	358	347.4	7.59	2.18	286 - 430	329.4 - 371.6

Summary of Multichem IA Plus 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	0.0801 - 0.1161
	2		226	4.35	4.16	0.191	4.6	3.48 - 5.22	3.4529 - 4.7483
	3		223	23.1	22.42	0.875	3.9	18.5 - 27.7	19.8737 - 24.7673

Conclusions

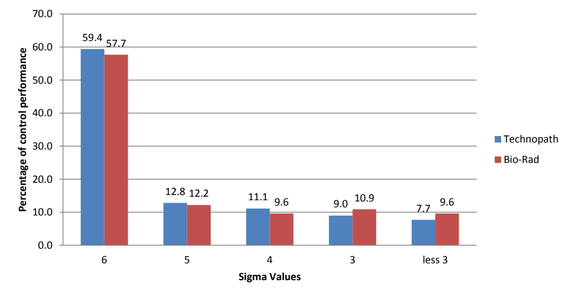
The Technopath Multichem S Plus, U and IA Plus controls showed comparable performance to the routine QC solution at the three sites.

The new MCCs allow the optimization of day-to-day analytical QC testing by consolidation of analytes into a fewer number of controls.

Sigma Metric Summary: Multichem S Plus

	Sigma Metric – Technopath					Sigma Metric – BioRad				
Analyte	6	5	4	3	<3	6	5	4	3	<3
AALT	15	3	2		1	6	3		1	4
AAST	19		2			12	1	1		
Bilirubin, Total	14	4	3			9	4	1		
Chloride	12	5	1	3		5	3	2	4	
Cholesterol	7	3	5	3		9	2	2		
Creatinine E	5			1		3	1			
Creatinine P	10		1	1		7	1			
Glucose	13	5	1	2		9	2	1	2	
Potassium	18	2	1			10	1	1	2	
Sodium		6	3	5	7			3	7	4
Total Protein	10		3	1	1	8		1		
Triglycerides	15					10				
Urea	1	2	4	5	9		1	3	3	7
Total	139	30	26	21	18	88	19	15	19	15
%	**59.4**	**12.8**	**11.1**	**9**	**7.7**	**56.4**	**12.2**	**9.6**	**12.2**	**9.6**

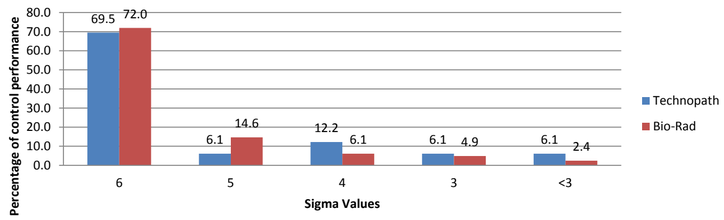
Sigma Metric Comparison of Chemistry Controls



Sigma Metric Summary: Multichem U

	Sigma Metric – Technopath					Sigma Metric – BioRad				
Analyte	6	5	4	3	<3	6	5	4	3	<3
Chloride	11	1	1	1	0	13	1		0	0
Creatinine E	2		2			2	1	1		
Creatinine P	3	1	2		2	3	0	2	2	1
Glucose	8	1	2	1	2	10	4	0	0	
Potassium	11	1	0	2		10	4	0		
Sodium	10		3	0	1	11	0	1	1	1
Urea	12	1	0	1		10	2	1	1	
Total	57	5	10	5	5	59	12	5	4	2
%	**69.5**	**6.1**	**12.2**	**6.1**	**6.1**	**72**	**14.6**	**6.1**	**4.9**	**2.4**

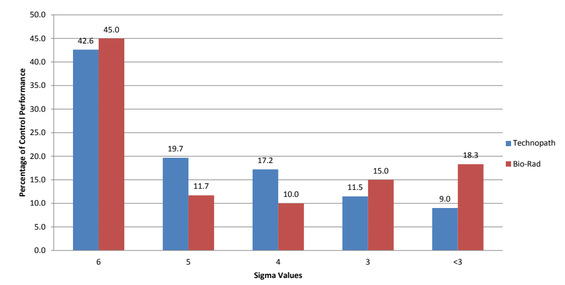
Sigma Metric Comparison of Urine Controls



Sigma Metric Summary: Multichem IA Plus

	Sigma Metric – Technopath					Sigma Metric – BioRad				
Analyte	6	5	4	3	<3	6	5	4	3	<3
Testosterone	1	0	2	1	2	0	0	1	1	0
CEA	3	3	0	2	1	1	1			2
Estradiol	5	2	1	1		5	1			2
FSH	6	3				1	0	1	1	2
Free T3	3	4	5	2	1	1		1	1	2
Free T4	4	4	3	2		5	1	1		
TSH	10	2	4	2		3	2	1	1	
Total PSA	10	2				2	1		2	
beta hCG	4	2		2	3	2	1		2	1
Troponin I	5	2	5	2	4	5			1	4
Vitamin D	1		1			2		1		
Total	52	24	21	14	11	27	6	7	9	12
%	**42.6**	**19.7**	**17.2**	**11.5**	**9**	**45**	**11.7**	**10**	**15**	**18.3**

Sigma Metric Comparison of IA Controls



*These assays are not available in the U.S.