Laboratory Evaluation of Technopath Controls on the ARCHITECT Chemistry Analyzers

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Background

Efficient analytical and quality control solution is important for testing laboratories to ensure released results meet the required quality in regard to accuracy and precision. Technopath Manufacturing Ltd. recently introduced multi-constituent controls (MCC) for use with the Abbott ARCHITECT instruments. The performance of the urine and serum chemistry controls were evaluated in comparison to the laboratory's current QC.

Materials and Methods

Technopath Multichem S 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. Sixty analytes are included in this control at three different levels.

Multichem U controls are prepared from human urine to which purified biochemical material (extracts of human and animal origin), chemicals, drugs, preservatives and stabiliers have been added. These controls are provided in liquid form and stored at 2–8°C. Once the material is opened, it should be stored tightly capped at 2–8°C and is stable for 30 days unless otherwise stated in the lot specific data sheets. Thirteen analystes are included in this 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 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 both the ARCHITECT *c*8000 and *c*16000 instruments.

Data presented here are from the following serum analytes: AALT*, AAST*, total bilirubin, Cl, total cholesterol, glucose, K, total protein, Na, triglycerides, and urea; and the following urine analytes: Cl, creatinine, glucose, K, Na, and urea. 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, and Liquichek Urine Chemistry.

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

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 (chloride) to 4.71% (total bilirubin).

The %CV for the 6 assays with the Multichem U control ranged from 0.50 (chloride and potassium) to 5.24% (Urea).

For both controls, the majority of the CVs were less than 2%. The results from the Technopath controls compared favorably with the BioRad Liquichek and BioRad Multiqual serum controls and the BioRad Liquichek Urine control in terms of %CV.

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 0.765 (chloride) to 4.11% (AALT) for S Plus and 1.01 (sodium) to 3.171% (glucose) for Urine.

Summary of Sites and Testing – Multichem S Plus

	France	Italy	Germany
Instruments	2 – *c*8000	2 – *c*8000 1 – *c*16000	2 – *c*8000
AALT	X		X
AAST	X		X
Bilirubin, Total	X	X	X
Chloride	X	X	X
Cholesterol, Total	X	X	X
Creatinine, Enzymatic	X		
Creatinine, Picrate		X	X
Glucose	X	X	X
Potassium	X	X	X
Protein, Total	X	X	X
Sodium	X	X	X
Triglycerides	X	X	X
Urea	X	X	X

Summary of Sites and Testing – Multichem U

	France	Italy	Germany
Instruments	2 – *c*8000	2 – *c*8000 1 – *c*16000	2 – *c*8000
Chloride	X	X	X
Creatinine, Enzymatic	X		
Creatinine, Picrate		X	X
Glucose	X	X	X
Potassium	X	X	X
Sodium	X	X	X
Urea	X	X	X

Multichem S Plus

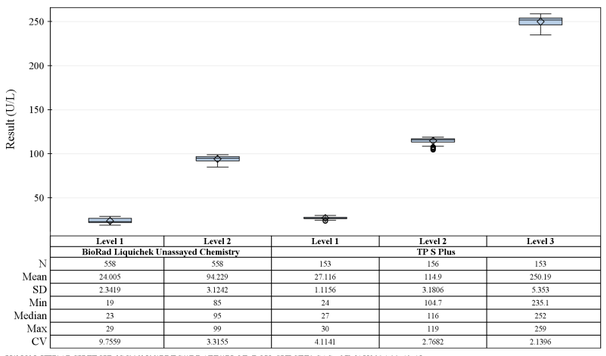
Analyte	Level	Unit	N	Expected Mean	Mean	SD	CV	Expected Range	Observed Range
AALT	1	U/L	153	26.9	27.1	1.12	4.11	21.5–32.3	24.0–30.0
	2		156	114	114.9	3.18	2.77	91.2 – 137	104.7 – 119.0
	3		153	250	250.2	5.35	2.14	200–300	235.1–259.0
AAST	1	U/L	149	45	44.7	1.8	4.04	36.0–54.0	40.0–50.0
	2		150	132	131.9	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

Multichem Urine

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

Results (cont'd)

ABBOTT ARCHITECT Technopath MCC Study – Assay: Activated Alanine Aminotransferase (AALT) (8L92)



	Level 1	Level 2	Level 1	Level 2	Level 3
	BioRad Liquichek Unassayed Chemistry		TP S Plus		
N	558	558	153	156	153
Mean	24.005	94.229	27.116	114.9	250.19
SD	2.3419	3.1242	1.1156	3.1806	5.353
Min	19	85	24	104.7	235.1
Median	23	95	27	116	252
Max	29	99	30	119	259
CV	9.7559	3.3155	4.1141	2.7682	2.1396

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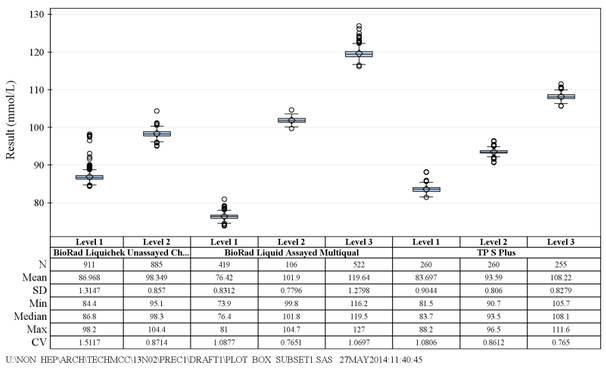
Figure 1: Box and Whisker plots of activated ALT quality control testing for routine controls – BioRad assayed and unassayed Multiconstituent Controls (MCC) – and Technopath S Plus

ABBOTT ARCHITECT Technopath MCC Study – Assay: Chloride (S) (2P32)



	Level 1	Level 2	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
	BioRad Liquichek Ch...		BioRad Liquid Assayed Multiqual			TP S Plus		
N	911	885	419	106	522	260	260	255
Mean	86.968	98.349	76.42	101.9	119.64	83.697	93.59	108.22
SD	1.3147	0.857	0.8312	0.7796	1.2798	0.9044	0.806	0.8279
Min	84.4	95.1	73.9	99.8	116.2	81.5	90.7	105.7
Median	86.8	98.3	76.4	101.8	119.5	83.7	93.5	108.1
Max	98.2	104.4	81	104.7	127	88.2	96.5	111.6
CV	1.5117	0.8714	1.0877	0.7651	1.0697	1.0806	0.8612	0.765

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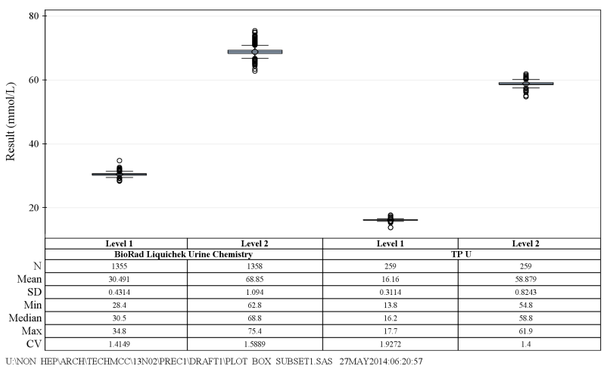
Figure 2: Box and Whisker plots of Chloride quality control testing for routine controls – BioRad assayed and unassayed Multiconstituent Controls (MCC) – and Technopath S Plus

ABBOTT ARCHITECT Technopath MCC Study – Assay: Potassium (U) (2P32)



	Level 1	Level 2	Level 1	Level 2
	BioRad Liquichek Urine Chemistry		TP U	
N	1355	1358	259	259
Mean	30.491	68.85	16.16	58.879
SD	0.4314	1.094	0.3114	0.8243
Min	28.4	62.8	13.8	54.8
Median	30.5	68.8	16.2	58.8
Max	34.8	75.4	17.7	61.9
CV	1.4149	1.5889	1.9272	1.4

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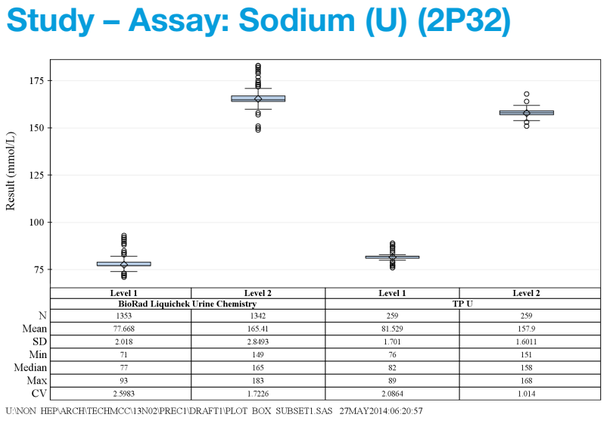
Figure 3: Box and Whisker plots of Urine Potassium quality control testing for routine controls – BioRad Liquichek Urine Chemistry – and Technopath U

ABBOTT ARCHITECT Technopath MCC Study – Assay: Sodium (U) (2P32)



	Level 1	Level 2	Level 1	Level 2
	BioRad Liquichek Urine Chemistry		TP U	
N	1353	1342	259	259
Mean	77.668	165.41	81.529	157.9
SD	2.018	2.8493	1.701	1.6011
Min	71	149	76	151
Median	77	165	82	158
Max	93	183	89	168
CV	2.5983	1.7226	2.0864	1.014

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Figure 4: Box and Whisker plots of Urine Sodium quality control testing for routine controls – BioRad Liquichek urine chemistry controls – and Technopath Multichem U control

AALT Method Decision Chart

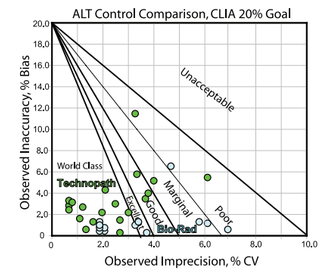

Figure 5. Six Sigma Method Performance comparison of BioRad (○) and Technopath (●) controls for AALT.

Chloride Method Decision Chart

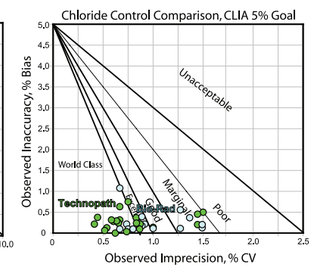

Figure 6. Six Sigma Method performance comparison of BioRad (○) and Technopath (●) controls for chloride.

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**

Urine Potassium Method Decision Chart

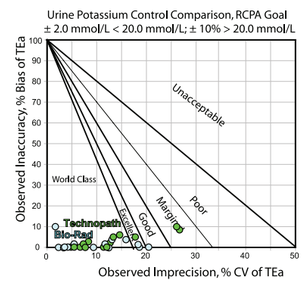

Figure 7. Six Sigma Method performance comparison of BioRad (○) and Technopath (●) controls. For urine Potassium.

Urine Sodium Method Decision Chart

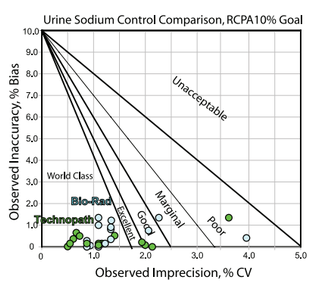

Figure 8. Six Sigma Method performance comparison of BioRad (○) and Technopath (●) controls. For urine Sodium.

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**

Conclusions

The Technopath Multichem S Plus and U 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 having routine metabolites, specific proteins and TDMs consolidated into one control.

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

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