



Product Information

Date Issued

May 17, 2018

Product

Product Description	List Number	UDI
All ARCHITECT Clinical Chemistry Assays	N/A	N/A
All ARCHITECT Immunoassays	N/A	N/A

Reason

The purpose of this letter is to communicate that an evaluation of ARCHITECT assays did not identify any potential for biotin interference.



There have been several published articles indicating that supplementation and/or treatment with biotin may cause erroneous results due to biotin interference with diagnostic assays which incorporate a streptavidin/biotin format.¹ Biotin supplement usage has increased in recent years and is being utilized by consumers to aid healthy skin, hair and nails; the health benefits are also realized in clinical conditions such as diabetes, multiple sclerosis, inherited metabolic disorders, and may aid in fetal development.

The results of our evaluation are detailed below.

Current Status

No on-market ARCHITECT assay formulations use the free capture streptavidin/biotin assay format referenced in recent articles that have been associated with interference from ingested biotin.

Assessment of each assay design was performed through a comprehensive review of all ARCHITECT assay formats. Although not in the free capture streptavidin/biotin format, five ARCHITECT assays utilize preformed biotin in their assay design: Methotrexate (2P49), Anti-CCP (1P65), Active B12 (3P24), 2nd Generation Testosterone (2P13), and Alere NT-proBNP for ARCHITECT (2R10).

To confirm these five ARCHITECT assays are not impacted by patients taking supplemental high dose biotin, samples spiked with biotin at concentrations from 0ng/mL to 4250ng/mL (or 0µg/L to 4250µg/L) were evaluated. The highest level of biotin tested 4250ng/mL (or 4250µg/L) was selected to exceed the anticipated Clinical and Laboratory Standards Institute (CLSI) guidelines of 3510ng/mL (3510µg/L). See Appendix A showing the concentration and % difference for each sample for the 5 assays tested.

Current Status
continued

The results of the study conclude that ARCHITECT assays which utilize biotin are not impacted by biotin levels as high as 4250ng/mL (or 4250µg/L). The results of the biotin spiked samples within each assay group were consistent with the study sample 0ng/mL (or 0µg/L) as all concentrations were within +/-10% from the 0ng/mL (or 0µg/L) sample with a 95% confidence interval. Abbott had previously tested up to 1000ng/mL and Alere had previously tested up to 100ng/mL with similar results.

¹ Paxton A. *Beauty fad's ugly downside: test interference*, CAP TODAY, September 20, 2016

Action

No action is required. Please retain this letter for your laboratory records.

Contact

If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Support.

Appendix A

Assay	Sample	Biotin (ng/mL or µg/L)	Average Result (µmol/L)	Average Result (µg/mL)	% Diff vs Unspiked (0) Biotin Sample
Methotrexate (2P49) Study 1	1	0	0.051	0.023	
		30	0.050	0.023	-1.78%
		50	0.050	0.023	-1.50%
		500	0.051	0.023	-0.21%
		1000	0.052	0.024	1.28%
	2	0	0.877	0.398	
		30	0.911	0.414	3.94%
		50	0.909	0.413	3.75%
		500	0.909	0.413	3.70%
		1000	0.896	0.407	2.21%

Assay	Sample	Biotin (ng/mL or µg/L)	Average Result (µmol/L)	Average Result (µg/mL)	% Diff vs Unspiked (0) Biotin Sample
Methotrexate (2P49) Study 2	1	0	0.048	0.022	
		1500	0.047	0.021	-0.77%
		2000	0.049	0.022	2.60%
		2500	0.048	0.022	-0.09%
		3550	0.049	0.022	2.50%
		4250	0.048	0.022	1.70%
	2	0	0.902	0.410	
		1500	0.942	0.428	4.45%
		2000	0.946	0.430	4.86%
		2500	0.951	0.432	5.44%
		3550	0.944	0.429	4.68%
		4250	0.977	0.444	8.30%

Assay	Sample	Biotin (ng/mL)	Average Result (U/mL)	% Diff vs Unspiked (0) Biotin Sample
Anti-CCP (1P65) Study 1	1	0	0.66	
		30	0.68	2.64%
		50	0.68	2.69%
		500	0.68	2.98%
		1000	0.67	1.35%
	2	0	10.70	
		30	10.91	1.98%
		50	10.94	2.21%
		500	10.80	0.93%
		1000	10.96	2.40%

Appendix A Continued

Assay	Sample	Biotin (ng/mL)	Average Result (U/mL)	% Diff vs Unspiked (0) Biotin Sample
Anti-CCP (1P65) Study 2	1	0	4.30	
		1500	4.40	2.17%
		2000	4.35	1.19%
		2500	4.29	-0.23%
		3550	4.36	1.47%
		4250	4.35	1.20%
	2	0	14.19	
		1500	14.28	0.64%
		2000	14.30	0.75%
		2500	14.08	-0.81%
		3550	14.52	2.34%
		4250	14.42	1.64%

Assay	Sample	Biotin (ng/mL)	Average Result (pmol/L)	% Diff vs Unspiked (0) Biotin Sample
Active B12 (3P24) Study 1	1	0	87.91	
		30	89.86	2.21%
		50	87.89	-0.02%
		500	86.47	-1.64%
		1000	87.71	-0.22%

Assay	Sample	Biotin (ng/mL)	Average Result (pmol/L)	% Diff vs Unspiked (0) Biotin Sample
Active B12 (3P24) Study 2	1	0	51.33	
		1500	52.51	2.29%
		2000	51.55	0.42%
		2500	52.03	1.35%
		3550	52.18	1.65%
		4250	52.10	1.49%
	2	0	87.30	
		1500	89.28	2.27%
		2000	88.02	0.82%
		2500	89.36	2.36%
		3550	87.76	0.53%
		4250	88.22	1.05%

Appendix A Continued

Assay	Sample	Biotin (ng/mL)	Average Result (nmol/L)	% Diff vs Unspiked (0) Biotin Sample
2nd Generation Testosterone (2P13) Study 1	1	0	6.92	
		30	6.75	-2.59%
		50	6.76	-2.39%
		500	6.86	-0.99%
		1000	6.74	-2.68%
	2	0	21.36	
		30	20.85	-2.37%
		50	20.88	-2.27%
		500	21.20	-0.74%
		1000	21.32	-0.17%

Assay	Sample	Biotin (ng/mL)	Average Result (nmol/L)	Average Result (ng/dL)	Average Result (ng/mL)	% Diff vs Unspiked (0) Biotin Sample
2nd Generation Testosterone (2P13) Study 2	1	0	8.48	244.52	2.45	
		1500	8.04	231.98	2.32	-5.13%
		2000	8.00	230.84	2.31	-5.59%
		2500	7.94	228.99	2.29	-6.35%
		3550	7.92	228.33	2.28	-6.62%
		4250	8.04	231.80	2.32	-5.20%
	2	0	32.37	933.47	9.33	
		1500	30.76	887.03	8.87	-4.98%
		2000	30.48	878.90	8.79	-5.85%
		2500	30.83	889.23	8.89	-4.74%
		3550	30.68	884.80	8.85	-5.21%
		4250	31.00	893.93	8.94	-4.24%

Appendix A Continued

Assay	Sample	Biotin (ng/mL)	Average Result (pg/mL)	Average Result (pmol/L)	% Diff vs Unspiked (0) Biotin Sample
Alere NT-proBNP for ARCHITECT (2R10)	1	0	79.30	9.36	
		531.3	79.43	9.37	0.17%
		1062.5	78.44	9.26	-1.09%
		1593.8	79.89	9.43	0.74%
		2125	78.54	9.27	-0.96%
		2656.3	80.24	9.47	1.18%
		3187.5	78.79	9.30	-0.65%
		3718.8	78.80	9.30	-0.64%
		4250	79.74	9.41	0.55%
	2	0	1815.26	214.20	
		531.3	1760.91	207.79	-2.99%
		1062.5	1759.66	207.64	-3.06%
		1593.8	1777.98	209.80	-2.05%
		2125	1797.01	212.05	-1.01%
		2656.3	1804.90	212.98	-0.57%
		3187.5	1783.38	210.44	-1.76%
		3718.8	1765.07	208.28	-2.76%
		4250	1830.18	215.96	0.82%