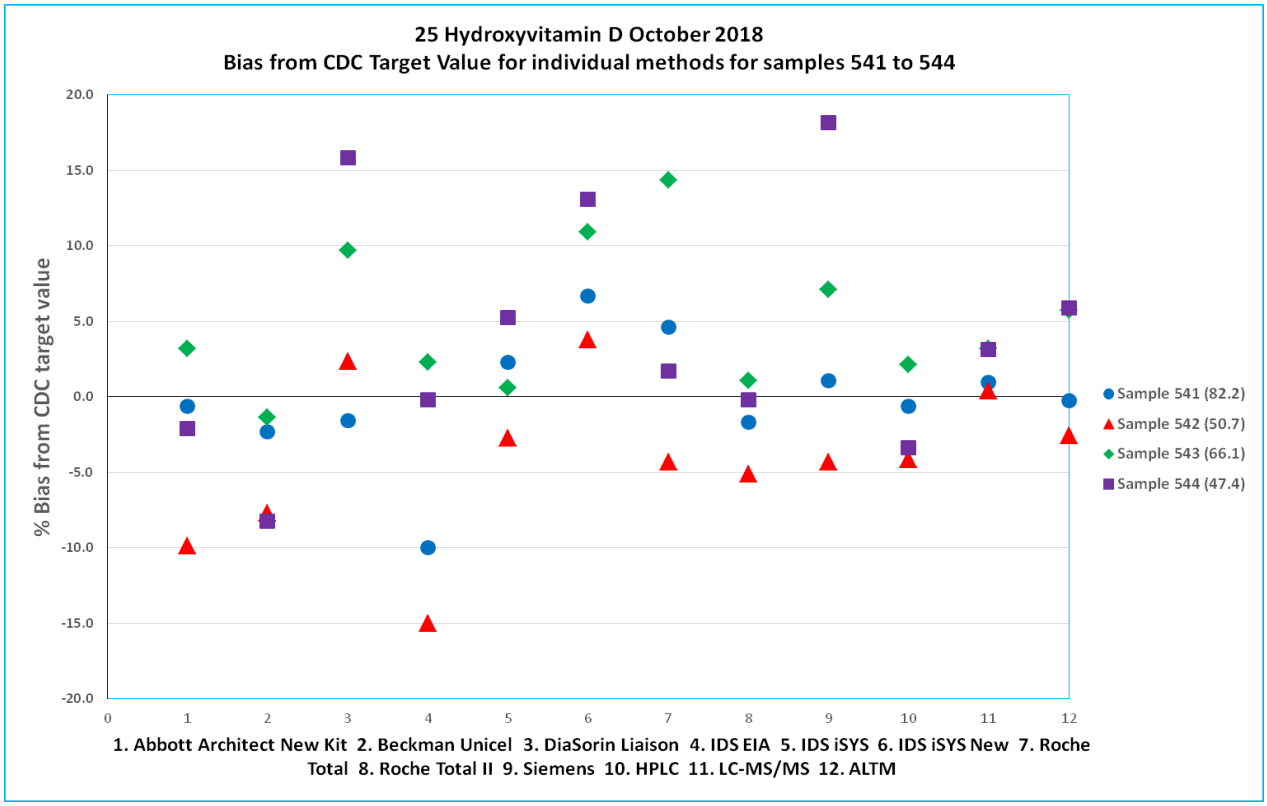
NOTES TO ACCOMPANY THE OCTOBER 2018 25-HYDROXYVITAMIN D REPORT

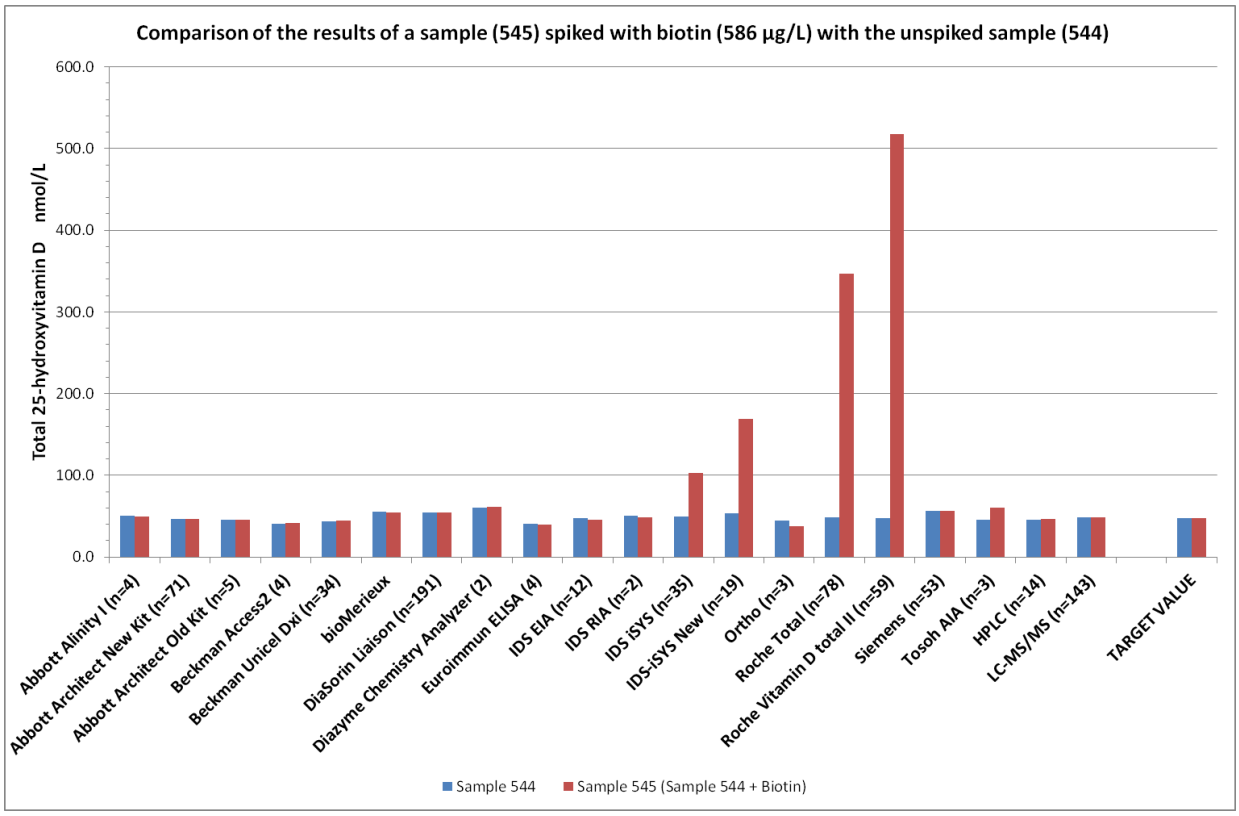
Chart showing between-sample variability of % bias from the target value for samples 541 to 544

Sample 545 has been excluded from the chart due to the high bias from the target value observed for some methods (see note on Sample 545 below).



Legend; Sample numbers (target values nmol/L)

Sample 545



Comments:

1. This was a ***qualitative*** experiment designed to investigate the potential effect of a pharmacological level of exogenous biotin on the measurement of total 25-hydroxyvitamin D by methods used by participating laboratories. The study was prompted by reports in the literature of biotin interference in assays using the biotin-streptavidin detection system within the assay design. Such interference risks misdiagnosis in patients being treated with high-dose biotin, or subjects taking high-dose biotin as a food supplement.
2. Sample 545 was prepared from the same pool of serum as sample 544 but with the addition of an aqueous solution of biotin in sodium carbonate, to give a final concentration of approximately 586 µg/L.
3. The final concentration of sodium carbonate solution was 0.0048% and the same amount was added to the base pool (sample 544).

Conclusions:

Results submitted by DEQAS participants suggest that most methods were unaffected by the addition of a high concentration of biotin to a serum pool, however, a few methods appear to be affected by this high level of exogenous biotin.

DEQAS has previously shown that spiking serum with exogenous metabolites may lead to anomalous results [1]. Nevertheless, the observed interference in some assays is in agreement with the observations made by Piketty et al [2], who showed that assays employing the streptavidin-biotin link in their assay design may be affected by the high biotin concentrations observed in both patients treated with high doses of biotin and healthy volunteers undergoing a pharmacokinetic study.

It should be noted that over-the-counter vitamin food supplements containing lower levels of biotin may not achieve such high levels and are less likely to interfere in the affected assays.

References:

Carter GD, Jones JC, Berry JL. The anomalous behaviour of exogenous 25-hydroxyvitamin D in competitive binding assays. J Steroid Biochem Mol Biol 2007; 103:480-2.

Piketty M-L, Prie D, sedel F, Bernard D hercend C, Chanson P, Souberbeille J-C. high-dose biotin therapy leading to false biochemical endocrine profiles: validation of a simple method to overcome biotin interference. Clin Chem Lab Med 2017;55:817-25.

3-epi-25-hydroxyvitamin D3 results for samples 541 – 545

DEQAS Lab No.	Method	Sample 541 3-epi-25OH-D3 nmol/L	Sample 542 3-epi-25OH-D3 nmol/L	Sample 543 3-epi-25OH-D3 nmol/L	Sample 544 3-epi-25OH-D3 nmol/L	Sample 545 3-epi-25OH-D3 nmol/L
52	LC-MS/MS	6.3	3.7	4.5	3.2	3.1
105	LC-MS/MS	5.0		6.0		
188	LC-MS/MS	4.2	<2.5	4.5	<2.5	<2.5
189	LC-MS/MS	4.7	1.8	3.0	2.2	1.3
255	LC-MS/MS	7.2	3.7	5.0	3.6	1.2
528	LC-MS/MS	6.3	<3.75	5.0	<3.75	<3.75
804	LC-MS/MS	9.5	7.9	7.8	5.2	6.0
1479	LC-MS/MS	4.9	1.6	3.5	2.2	2.1
1684	LC-MS/MS	8.9	10.9	8.8	<2.0	<2.0
1751	LC-MS/MS	5.8	3.5	5.6	3.4	2.8
1864	LC-MS/MS	6.5	3.5	3.8	3.0	<2.8
1919	LC-MS/MS	<6.25	<6.25	<6.25	<6.25	<6.25
1970	LC-MS/MS	9.3	4.0	5.3	2.8	3.1
2017	LC-MS/MS	5.9	1.6	1.5	3.2	3.2
2123	LC-MS/MS	6.0	3.1	4.2	2.2	2.2
2204	LC-MS/MS	7.2	4.0	3.6	1.8	0.9
2258	LC-MS/MS	5.7	3.2	3.9	2.3	2.4
2329	LC-MS/MS	7.2		<6.0		
Median		6.3	3.5	4.5	2.9	2.4
Mean		6.5	3.6	4.7	2.8	2.4
SD		1.33	1.63	1.24	0.55	0.75
CV%		20.7	44.8	26.4	19.5	31.7
CDC value		6.7	2.5*	4.9	3.6	3.9

* Isobaric interference was detected in the 3-epi-25(OH)D3 transition in all preparations of sample 542 and this result should be interpreted with caution.

Comment:

The value provided by CDC for 3-epi-25(OH)D3 was obtained using their routine LC-MS/MS assay and is included as a guide only.

The statistics were calculated on the numeric results only and on trimmed data using our usual trimming process. Clearly, with such a small number of results the summary statistics may be unreliable.
This data is for information purposes only.

24,25-dihydroxyvitamin D results for samples 541 – 545

DEQAS Lab No.	Method	Sample 541 24,25(OH)2-D3 nmol/L	Sample 542 24,25(OH)2-D3 nmol/L	Sample 543 24,25(OH)2-D3 nmol/L	Sample 544 24,25(OH)2-D3 nmol/L	Sample 545 24,25(OH)2-D3 nmol/L
52	LC-MS/MS	6.0	3.6	5.1	3.2	3.2
528	LC-MS/MS	6.5	3.8	6.7	4.1	3.6
1455	LC-MS/MS	7.8	3.4	7.1	4.1	3.9
1479	LC-MS/MS	9.0	3.7	7.0	4.8	6.2
1864	LC-MS/MS	4.8	2.6	4.3	2.4	3.4
2123	LC-MS/MS	7.1	3.3	6.1	3.7	3.7
2258	LC-MS/MS	6.9	3.9	6.4	3.6	3.4
Median		6.9	3.6	6.4	3.7	3.6
Mean		6.9	3.5	6.2	3.7	3.9
SD		1.33	0.44	0.98	0.76	1.03
CV%		19.4	12.6	15.8	20.6	26.4
CDC value		6.4	3.4	6.1	3.4	3.4

Lab Code	541	541	541	542	542	542	543	543	543	544	544	544	545	545	545
	25OH-D3	24,25-D3	Ratio	25OH-D3	24,25-D3	Ratio	25OH-D3	24,25-D3	Ratio	25OH-D3	24,25-D3	Ratio	25OH-D3	24,25-D3	Ratio
52	80.2	6.0	13.4	49.7	3.6	13.8	64.7	5.1	12.7	48.5	3.2	15.2	48.4	3.2	15.1
528	82.3	6.5	12.7	49.3	3.8	13.0	68.5	6.7	10.2	50.0	4.1	12.2	47.8	3.6	13.3
1455	79.0	7.8	10.1	45.9	3.4	13.5	71.9	7.1	10.1	47.4	4.1	11.6	47.9	3.9	12.3
1479	73.2	9.0	8.1	46.2	3.7	12.5	64.5	7.0	9.2	43.4	4.8	9.0	39.5	6.2	6.4
1864	78.3	4.8	16.3	45.5	2.6	17.5	66.3	4.3	15.4	45.0	2.4	18.8	47.0	3.4	13.8
2123	73.0	7.1	10.3	44.9	3.3	13.6	60.8	6.1	10.0	42.1	3.7	11.4	44.2	3.7	11.9
2258	74.2	6.9	10.8	45.4	3.9	11.6	61.2	6.4	9.6	45.4	3.6	12.6	43.0	3.4	12.6
Median	78.3	6.9	10.8	45.9	3.6	13.5	64.7	6.4	10.1	45.4	3.7	12.2	47.0	3.6	12.6
Mean	77.2	6.9	11.7	46.7	3.5	13.6	65.4	6.1	11.0	46.0	3.7	13.0	45.4	3.9	12.2
SD	3.7	1.3	2.7	2.0	0.4	1.9	3.9	1.0	2.2	2.8	0.8	3.1	3.3	1.0	2.8
CV%	4.8	19.4	23.0	4.2	12.6	13.6	6.0	17.1	20.3	6.1	20.6	24.2	7.3	26.4	22.8

Comment:

The value provided by CDC for 24,25-dihydroxyvitamin D was obtained using their routine LC-MS/MS assay and is included as a guide only.

The statistics have been calculated on untrimmed data. Clearly, with such a small number of results the summary statistics may be unreliable. This data is for information purposes only

Free 25-hydroxyvitamin D results for samples 541 – 545 in pmol/L

DEQAS Lab No.	Method	Sample 541	Sample 542	Sample 543	Sample 544	Sample 545
368	DIAsource ELISA	22.4	14.1	24.8	16.1	16.0
2215	In-house ELISA	16.5	9.5	15.0	11.8	11.5
2262	DIAsource ELISA	18.5	12.7	20.3	13.9	14.0

Comment:

This data is for information purposes only.