Aligning the ADVIA Centaur Vitamin D Total Assay* to the Vitamin D Standardization Program

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Background

Increased demand for Vitamin D testing has led to more commercially available Vitamin D assays. However, without a universal Vitamin D standard, different assays and methods produce varying results. In an effort to standardize the laboratory measurement of Vitamin D metabolites, the National Institute of Health (NIH), Office of Dietary Supplements and a collaboration with the National Institute of Standards and Technology (NIST), the Centers for Disease Control (CDC), and litre innocently introduced the Vitamin D Standardization Program (DSP). The ADVIA Centaur® Vitamin D Total assay has been re-standardized to align with the Reference Measurement Procedure (RMP) used in the DSP.

Method

The alignment of the ADVIA Vitamin D Total assay aligned to the DSP demonstrated good correlation to the ID-LC/MS/MS Vitamin D RMP yielding a density slope of 0.98, intercept of 1.17 picograms, and regression coefficient of 0.99. Performance of the assay in the October 2013 DSP distributions showed that the restandardized vitamin D assay was within the acceptance criteria (+/- 25% for 80% of samples tested) with the median of 59.5 nmol/L and 58.5 nmol/L and 95% confidence intervals of 24.3 to 99.0 nmol/L and 24.3 to 99.0 nmol/L respectively, showing equivalence between the two groups.

The correlation between the restandardized ADVIA Centaur Vitamin D Total assay reagent lot 1's RLU versus the corresponding ID-LC/MS/MS 25(OH)vitamin D RMP dose.

The correlation between the restandardized ADVIA Centaur Vitamin D Total assay reagent lot 2's RLU versus the corresponding ID-LC/MS/MS 25(OH)vitamin D RMP dose.

The summary of the RLU vs density relationship for each reagent lot in Table 1 was used to generate RLU for reagent standard values of 0.1, 0.2, 0.3, 0.4, 0.5, 1.0, 2.0, and 1.0 was selected. The equation was solved for the RLU associated with the 10 standards.

Method and Results

Standardization of Measurements of 25-Hydroxyvitamin D3 and D2

The Standardization to the Siemens ADVIA Centaur Vitamin D Total assay was achieved by running 177 serum samples with ID-LC/MS/MS 25(OH)vitamin D RMP. Observed ranges for Adult Patients.

The correlation between the restandardized ADVIA Centaur Vitamin D Total assay reagent lot 3's RLU versus the corresponding ID-LC/MS/MS 25(OH)vitamin D RMP dose.

The summary of the RLU vs density relationship for each reagent lot in Table 1 was used to generate RLU for reagent standard values of 0.1, 0.2, 0.3, 0.4, 0.5, 1.0, 2.0, and 1.0 was selected. The equation was solved for the RLU associated with the 10 standards.

Method and Results

The correlation between the restandardized ADVIA Centaur Vitamin D Total assay reagent lot 4's RLU versus the corresponding ID-LC/MS/MS 25(OH)vitamin D RMP dose.

The summary of the RLU vs density relationship for each reagent lot in Table 1 was used to generate RLU for reagent standard values of 0.1, 0.2, 0.3, 0.4, 0.5, 1.0, 2.0, and 1.0 was selected. The equation was solved for the RLU associated with the 10 standards.

Conclusion

The Siemens ADVIA Centaur Vitamin D Total assay* aligned to the ID-LC/MS/MS Vitamin D RMP should be a suitable tool in clinical laboratories for the accurate measurement of vitamin D3 sufficiency in healthy subjects. The assay can be used in both adults and pediatrics.

References


