

Technical Review

# Evaluation of the DIAsource 250H Vitamin D Total RIA assay according to the Vitamin D Standardization Program (VDSP)

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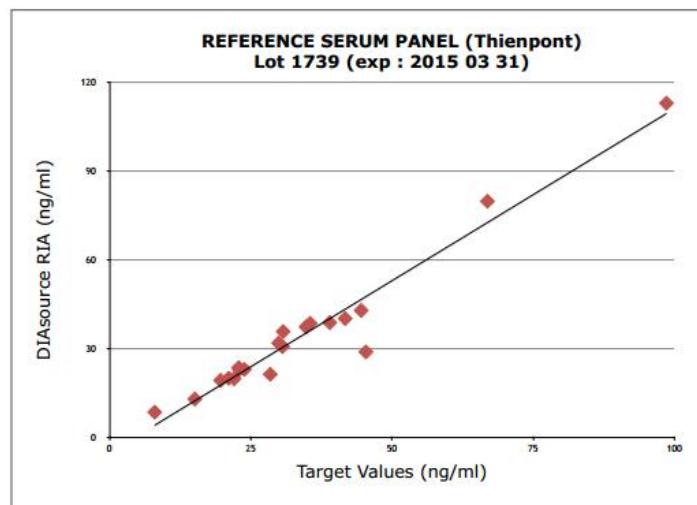
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## 1. INTRODUCTION

The DIAsource 25OH Vitamin D Total RIA assay shows very competitive sensitivity, precision and performance characteristics to all other immunoassays in the market but uses a novel and extremely easy pre-treatment step directly in the coated tubes. The assay is calibrated against the reference method ID-LC/MS-MS (Ghent University) according to the VDSP - Vitamin D Standardization Program (Figure 1).<sup>1</sup>

Figure 1. Linear regression of DIAsource 25OH Vitamin D Total RIA against ID-LC/MS-MS (Ghent University). The regression analysis demonstrated a slope of 1.16, an intercept of -5,21 ng/mL and a correlation of R= 0.97



As an additional initiative to further validate the calibration of the DIAsource 25OH Vitamin D Total RIA assay we enrolled into the Vitamin D Standardization Certification Program (VDSCP) – Phase I.

In VDSCP – Phase 1, participants receive 40 single-donor human serum samples with blinded concentrations assigned by the reference laboratory. The participants use these 40 samples to perform a bias assessment and adjust their calibration if required.

<sup>1</sup> <http://ods.od.nih.gov/Research/VitaminD.aspx#vdsp>

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## 2. MATERIAL and METHODS

### 2.1. Samples

The materials used for method comparison and bias estimation are non-pooled sera from single donors obtained following the protocol from the Clinical and Laboratory Standards Institute (CLSI) C37-A. Sera prepared according to this protocol have shown to be commutable and were recommended for use in trueness control and calibration studies.

The materials underwent two freeze-thaw cycles and are approximately within the range of 25(OH)D commonly observed in most populations.

### 2.2. Measurement of 25OH Vitamin D

Samples were measured using the DIASource 25OH Vitamin D Total RIA assay according to the package insert instructions. The total amount of 40 samples were measured in duplicate. Two kit controls were included into the run and fell within their acceptance criteria.

Reference values were assigned to the sera by the reference laboratory, which uses ID-LC/MS-MS and certified primary standards from the National Institute for Standards and Technology. The method is recognized by the Joint Committee for Traceability in Laboratory Medicine (JCTLM) as a reference measurement procedure (RMPs) of a higher-order. Therefore, these samples are traceable as described in ISO 17511.

### 2.3. Analysis of results

For the DIASource 25OH Vitamin D Total RIA assay, samples and controls concentrations were calculated by interpolation from the standard curve using a 4 parameter logistic nonlinear regression model.

We used the linear regression model and regression models were built for the total number of samples (n = 40). All linear regressions were performed with Microsoft Excel 2013.

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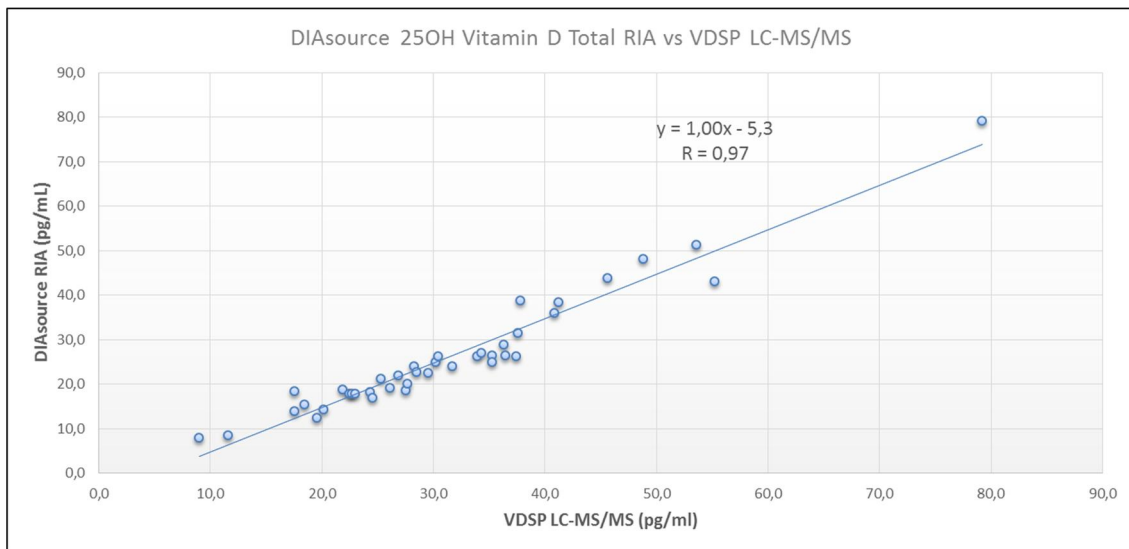
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### 3. RESULTS

When reference LC-MS concentrations were plotted on the X axis, and DIAsource RIA on the Y axis, a slope of 1.00, an intercept of -5.3ng/mL and a correlation coefficient of  $R = 0.97$  were observed (Figure 2).

Figure 2. Linear regression of DIAsource 25OH Vitamin D Total RIA against LC-MS 25OH Vitamin D (n = 40)



### 4. CONCLUSION

The DIAsource 25OH Vitamin D Total RIA assay shows excellent performances against the reference LC-MS method using VDSCP – Phase I certified samples. Although this unique assay features a novel and extremely easy pre-treatment step directly in the coated tubes, it fully meets the performance requirements of contemporary Vitamin D testing. Thanks to its user-friendly protocol and to its performance characteristics, the DIAsource 25OH Vitamin D Total RIA is a valuable tool for the assessment of 25OH Vitamin D in clinical laboratories.

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## Ordering Information

Description	Article code	Format
25OH Vitamin D Total ELISA	KAP1971	ELISA
25OH Vitamin D Total RIA	KIP1971	RIA
25OH Vitamin D3 RIA	KIP1961	RIA
Rat 25OH Vitamin D Total ELISA (RUO)	KRR1971	ELISA
Free 25OH Vitamin D ELISA (RUO)	KARF1991	ELISA
1,25(OH) <sub>2</sub> Vitamin D ELISA	KAP1921	ELISA
1,25(OH) <sub>2</sub> Vitamin D RIA	KIP1929	RIA



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