

October 23th, 2014

RE: DEQAS July 2014 25-hydroxyvitamin D positive bias

Dear Valued Customer,

The 25-Hydroxyvitamin DEQAS - July 2014 distribution report indicates that the results obtained with the IDS-iSYS 25-Hydroxy Vitamin D^S assay were outside the $\pm 25\%$ criteria.

Immunodiagnostic Systems launched an internal investigation by verifying the alignment between the IDS-iSYS 25-Hydroxy Vitamin D^S and the ID-LC-/MS/MS 25(OH)D Reference Method Procedure (RMP) using the single donor serum samples from the Vitamin D Standardization Program (VDSP). The DEQAS July 2014 distribution and our internal serum samples panels were also measured in multiple reagent lots and systems.

We have confirmed a bias in DEQAS - July 2014 distribution. The regression slope between the IDS-iSYS assay and the RMP is slightly higher than previously communicated in the Product Notification NIS2700S/04 (1.06 vs. 1.04); the mean % bias is 12% versus -2%. The bias occurred due to the implementing of a new internal serum panel preparation with target value slightly higher than the LC-MS/MS value.

From kit lot 2191 and onward, we have adjusted the internal serum panel target value to correct the bias. The summary of IDS-iSYS 25-Hydroxy Vitamin D^S Traceability is enclosed for your references. The results confirm the alignment against the ID-LC-/MS/MS 25(OH)D Reference Method Procedure (RMP).

Immunodiagnostic Systems strives to provide you with products of the highest quality. We value your business and thank you for your continued support. Please contact your local IDS representative if you have any further questions regarding this information.

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IDS-iSYS 25-Hydroxy Vitamin D^S (ng/mL) VDSP Traceability

The single donor serum samples (n = 70) with RMP ID-LC-MS/MS 25(OH)D target value ranging from 9.0 – 79.2 ng/mL from the Vitamin D Standardization Program (VDSP) were used to verify the IDS-iSYS alignment in May 2014. The same samples were measured in September 2014 to confirm the assay traceability. From kit lot 2191 onward, we have adjusted the internal serum panel target value to correct the bias.

	Passing-Bablok regression	Linear regression	Statistical summary
Product Notification NIS2700S/04 May 2014			<p>The Passing-Bablok regression between the IDS-iSYS (y) and the RMP ID-LC-MS/MS (x) is: IDS-iSYS = 1.04 x (RMP) - 1.6 ng/mL 95 % CI. slope: 0.95 to 1.13 95 % CI. intercept: -4.2 to 0.5 ng/mL Pearson corr. coeff. r: 0.967 (0.948 to 0.980), P<0.0001 Mean %bias: -2.0%</p> <p>The linear regression equation is: IDS-iSYS = 1.00 x (RMP) - 0.8 ng/mL 95 % CI. slope: 0.94 to 1.07 95 % CI. intercept: -3.0 to 1.4 ng/mL</p>
Alignment verification September 2014			<p>Although the Passing-Bablok regression yields a slope >1.05, the slope of linear regression is 0.99.</p> <p>The Passing-Bablok regression is: IDS-iSYS = 1.06 x (RMP) + 1.0 ng/mL 95 % CI. slope: 0.95 to 1.17 95 % CI. intercept: -2.2 to 4.6 ng/mL Pearson corr. coeff. r: 0.954 (0.932 to 0.970), P<0.0001 Mean %bias: 12.0%</p> <p>The linear regression equation is: IDS-iSYS = 0.99 x (RMP) + 3.3 ng/mL 95 % CI. slope: 0.91 to 1.07 95 % CI. intercept: 0.6 to 6.0 ng/mL</p>
Corrected - October 2014			<p>After the correction, the Passing-Bablok regression yields a slope of 1.02 and the linear regression slope is 0.95. The Passing-Bablok regression is: IDS-iSYS = 1.02 x (RMP) - 0.0 ng/mL 95 % CI. slope: 0.91 to 1.11 95 % CI. intercept: -3.0 to 3.0 ng/mL Pearson corr. coeff. r: 0.954 (0.932 to 0.970), P<0.0001 Mean %bias: 3.1%</p> <p>The linear regression equation is: IDS-iSYS = 0.95 x (RMP) + 2.1 ng/mL 95 % CI. slope: 0.87 to 1.02 95 % CI. intercept: -0.5 to 4.7 ng/mL</p>

IDS-iSYS 25-Hydroxy Vitamin D^S (nmol/L) VDSP Traceability

The single donor serum samples (n = 70) with RMP ID-LC-MS/MS 25(OH)D target value ranging from 23 – 198 nmol/L from the Vitamin D Standardization Program (VDSP) were used to verify the IDS-iSYS alignment in May 2014. The same samples were measured in September 2014 to confirm the assay traceability. From kit lot 2191 onward, we have adjusted the internal serum panel target value to correct the bias.

	Passing-Bablok regression	Linear regression	Statistical summary
Product Notification NIS2700S/04 May 2014			<p>The Passing-Bablok regression between the IDS-iSYS (y) and the RMP ID-LC-MS/MS (x) is:</p> <p>IDS-iSYS = 1.04 x (RMP) - 4.0 nmol/L</p> <p>95 % CI. slope: 0.95 to 1.13</p> <p>95 % CI. intercept: -10.5 to 1.4 nmol/L</p> <p>Pearson corr. coeff. r: 0.967 (0.948 to 0.980), P<0.0001</p> <p>Mean %bias: -2.0%</p> <p>The linear regression equation is:</p> <p>IDS-iSYS = 1.00 x (RMP) - 2.0 nmol/L</p> <p>95 % CI. slope: 0.94 to 1.07</p> <p>95 % CI. intercept: -7.6 to 3.5 nmol/L</p>
Alignment verification September 2014			<p>Although the Passing-Bablok regression yields a slope >1.05, the slope of linear regression is 0.99.</p> <p>The Passing-Bablok regression is:</p> <p>IDS-iSYS = 1.06 x (RMP) + 2.6 nmol/L</p> <p>95 % CI. slope: 0.95 to 1.17</p> <p>95 % CI. intercept: -5.4 to 11.5 nmol/L</p> <p>Pearson corr. coeff. r: 0.954 (0.932 to 0.970), P<0.0001</p> <p>Mean %bias: 12.0%</p> <p>The linear regression equation is:</p> <p>IDS-iSYS = 0.99 x (RMP) + 8.2 nmol/L</p> <p>95 % CI. slope: 0.91 to 1.07</p> <p>95 % CI. intercept: 1.5 to 15.0 nmol/L</p>
Corrected - October 2014			<p>After the correction, the Passing-Bablok regression yields a slope of 1.02 and the linear regression slope is 0.95. The Passing-Bablok regression is:</p> <p>IDS-iSYS = 1.02 x (RMP) - 0.0 nmol/L</p> <p>95 % CI. slope: 0.91 to 1.11</p> <p>95 % CI. intercept: -7.6 to 8.8 nmol/L</p> <p>Pearson corr. coeff. r: 0.954 (0.932 to 0.970), P<0.0001</p> <p>Mean %bias: 3.1%</p> <p>The linear regression equation is as follow:</p> <p>IDS-iSYS = 0.95 x (RMP) + 2.1 nmol/L</p> <p>95 % CI. slope: 0.87 to 1.02</p> <p>95 % CI. intercept: -0.5 to 4.7 nmol/L</p>