EVALUATION OF THE TOSOH 25-OH VITAMIN D ASSAY IN AN INTEGRATED HIGH AUTOMATION CORE LAB PLATFORM

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BACKGROUND

A marked increase in laboratory testing for 25-hydroxyvitamin D (25-OH-D) has been fueled by an increased focus on the diagnosis and treatment of osteoporosis, the demonstration of a high prevalence of vitamin D deficiency in many populations, and the discovery that the biological significance of vitamin D extends far beyond its classic role in the regulation of bone and mineral metabolism. The increased demand for 25-OH-D testing has led to the introduction of new methods.

MATERIALS and METHODS

The TOSOH AIA-PACK 25-OH Vitamin D assay is a one step competitive immuno assay; we evaluated this assay on two TOSOH AIA 2000 analyzers connected with a Thermo EnGen automation. In this study we evaluated the following analytical characteristics using CLSI evaluation protocols for testing precision (EP5), accuracy (EP15), linearity (EP6), as well as protocols for evaluating quantitative and qualitative methods (EP10, EP12), for estimating bias (EP9), and estimating total analytical error (EP21). The method comparison study was performed versus the assay previously adopted in our Laboratory (DiaSorin Liaison 25-OH Vitamin D).

RESULTS

Intra and inter assays precision did not exceeded 8%, these data were reported in *Figure 1a*. Linearity from 10 to 225 ng/mL was satisfactory as reported in *Figure 1b*.

Figure 1a: Imprecision

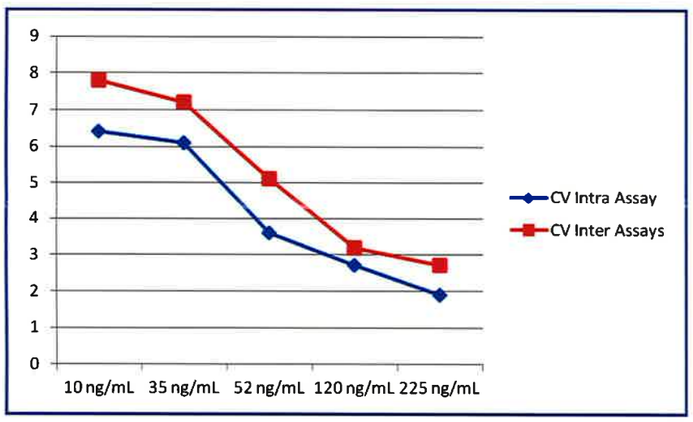
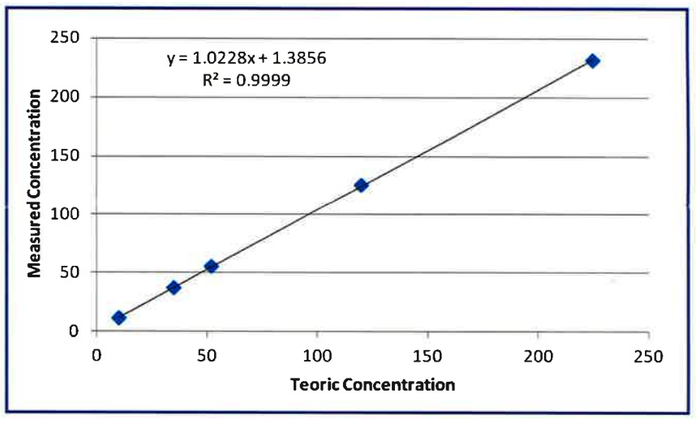


Figure 1b: Linearity



As reported in *Figure 2a* and *2b* we observed a satisfactory correlation of this assay with the method previously adopted in our Laboratory.

Figure 2a: Assays Comparison Linear Regression

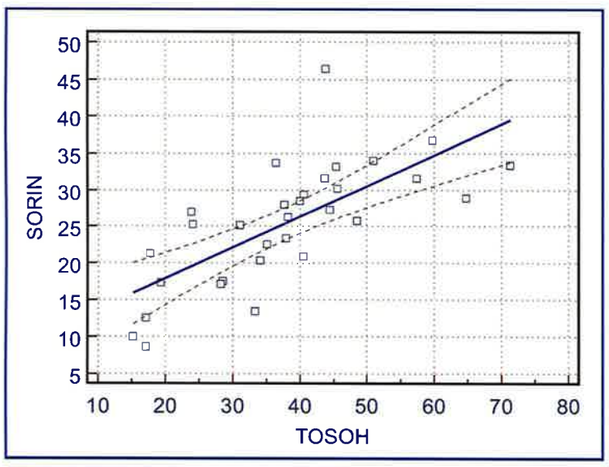
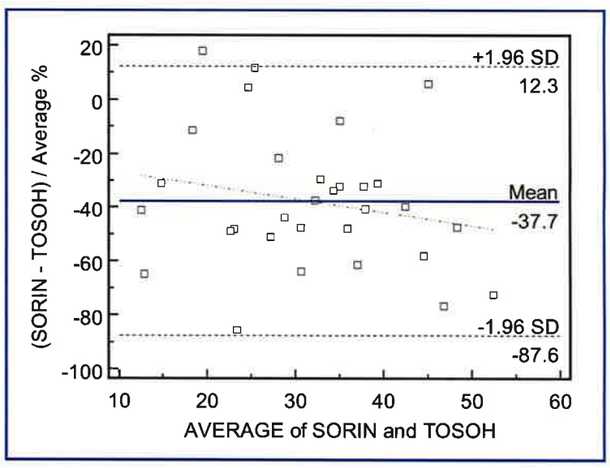


Figure 2b: Assays Comparison Bland-Altman plot



CONCLUSIONS

Vitamin D testing continues to be a challenge for the clinical laboratory, which is expected to provide reliable results in a timely manner for this high volume assay. The ideal vitamin D assay is one that is precise, accurate, and timely; most available assays could benefit from improvements in these desired traits. Vitamin D is not an easy analyte to measure. Some key issues for immunoassays include lot-to-lot variation, human antianimal antibody interferences, interferences from other hydroxylated vitamin D metabolites, and the ability to separate 25-OH-D from its binding protein. In this study, the TOSOH AIA-PACK 25-OH Vitamin D assay demonstrated good linearity (0.99) and imprecision, both within run (CV<6.5%) than inter runs (CV<8%). Moreover this assay, in our Laboratory, has been implemented, without any difficulty, in a high automatomation Core-Lab area.