Evaluation of 5 Automated Immunoassays for the Detection of 25-OH Vitamin D

INTRODUCTION

A study was conducted at a trial site in Belgium in order to compare the accuracy, sensitivity, precision and 25-OH Vitamin D2 specificity of available automated immunoassays from Abbott (ARCHITECT 25-OH Vitamin D), DiaSorin (LIAISON® XL 25-OH Vitamin D TOTAL Assay), IDS (ISYS 25-Hydroxy Vitamin D), Roche (Elecsys Vitamin D total) and Siemens (ADVIA Centaur® Vitamin D Total VI K D) for detection of total 25-OH Vitamin D. All accuracy results (N=10) for each immunoassay test method were compared to a RIA reference method (DiaSorin RIA 25-Hydroxyvitamin D 

METHODS

A total of 109 samples with doses spanning the immunoassay measuring ranges were obtained from the routine workflow at the Belgium trial site, and were aliquoted and frozen (-20°C) until the day of testing. In addition, DiaSorin provided frozen (-20°C) serum aliquots to support precision, sensitivity and 25-OH D2 specificity testing. Precision and sensitivity studies were performed over a 5 day period at the study site using fresh precision panel specimen aliquots on each day of testing. The precision specimens were run in 4 replicates each day for 5 different days [N=20]. Sample serum aliquots containing endogenous 25-OH-D2 were selected by DiaSorin prior to this study and tested by two different reference LC-MS/MS methods (Mayo Clinic and EsoTerix) in the U.S.A.

RESULTS

Figure 2: LCMS Difference Plot of samples containing endogenous 25-OH Vitamin D. The DiaSorin and IDS assays indicate results close to that of LCMS (minimal bias observed), with DiaSorin and the Mayo Clinic LCMS agreeing best with the Esoterix LCMS total values indicating these methods recover 25-OH-D2, and 25-OH-D3 equitably. Both the Abbott and Roche assays demonstrated significant negative bias and low average recovery, and the Siemens assay demonstrated significant positive bias and high average recovery, for samples containing endogenous 25-OH-D2. indicating these 3 assays do not recover 25-OH-D2, and 25-OH-D3 equitably. Abbott’s bias was consistent, but Roche and Siemens increased with dose.

Table 1: Precision and sensitivity. The Siemens assay demonstrated poor total CVs (14.8% to 21.7%) on all sample tested up to 34.6 ng/mL by LCMS, but had acceptable repeatability CVs (all within run < 8.6%), suggesting a significant day to day component of variance in the Siemens assay. The other test methods had very good precision and repeatability CVs, with the Abbott and DiaSorin assays not approaching or exceeding 10% CV until doses < 7.8 ng/mL, by LCMS. The Esoterix LCMS, IDS, Roche and Siemens assays mean doses similar to LCMS (except MP4-MPS which were prepared by spiking 25-OH-D3). Both the Abbott and Siemens assays demonstrated significant negative bias at doses < 9.7 ng/mL by LCMS. The Siemens assay also demonstrated significant negative bias for doses 7.6 to 34.6 ng/mL by LCMS. The Roche assay did not report results for MF1-MF4 (LOQ), or doses > 5.1 ng/mL by LCMS.

CONCLUSION

Varying assay performance was observed between the 5 automated immunoassays as compared to the RIA and LCMS reference methods. The Abbott and Siemens assays indicated clear differences when compared with RIA and LCMS, with DiaSorin, Roche and IDS agreeing best to RIA. When evaluating samples containing endogenous 25-OH-D2 only the DiaSorin and IDS assays agreed with LCMS. Both the Abbott and Siemens assays over-recovered doses in samples containing low concentrations of 25-OH Vitamin D2, and Siemens shows a negative bias for doses < 34 ng/mL by LCMS. Considering the results from all studies the DiaSorin assay continues to be an accurate and sensitive method for the measurement of total 25-OH Vitamin D total.

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