VALIDATION OF THE ABBOTT ARCHITECT 25OH-VITAMIN D ASSAY.

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Background. To validate the Abbott Architect 25-OH vitamin D assay, a new method for 25(OH)D determination.
Methods. Determination of repeatability, reproducibility, functional sensitivity, recovery, linearity, accuracy profile and determination of 25(OH)-vitamin D2 recovery with native samples. Comparison with DiaSorin Liaison and RIA.
Results. Intra and inter-assay CVs: <6% at 10.1 ng/mL and 2.1% at 92.6 ng/mL. Detection limit: 2.0 ng/mL and functional sensitivity: 9 ng/mL. Mean recovery and linearity estimated according the CLSI Guidelines 96.4±5.2%. Between 9.3 and 92.6 ng/mL, the accuracy profile shows that the risk that one result falls out of the ±20% acceptance limits is <5%, indicating that the method is completely validated. The recovery of 25(OH)D2 is 75,8% (95% CI: 61,9 to 89,7%).
On 253 samples, the regression equation with the DiaSorin RIA and Liaison were respectively Architect =1.02XDiaSorin_RIA+ 1.2 (r^2=0.78) and Architect= 1.07X DiaSorin_Liaison+3.7 (r^2=0.875). Bland-Altman plots show that for values >50 ng/mL, the Architect and the Liaison tend to systematically overestimate the 25(OH)D levels obtained with the DiaSorin RIA. On the samples distributed for the October DEQAS distribution, the Architect levels were in accordance with the mean of LCMSMS users, except an overestimation of 10% of the samples presenting the highest level (40 ng/mL).
Conclusions. Abbott Architect 25OH-vitamin D is a robust method, with good CVs, linearity, recovery and good agreement with DiaSorin RIA for values <50 ng/mL. The accuracy profile shows that the method is completely validated between 9.3 and 96.2 ng/mL. Even if not 100%, the recovery of the 25(OH)D2 remains acceptable.

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