



# ANALYTICAL IMPACT OF METHOD-DEPENDENT VARIABILITY IN BONE ALKALINE PHOSPHATASE IMMUNOASSAYS

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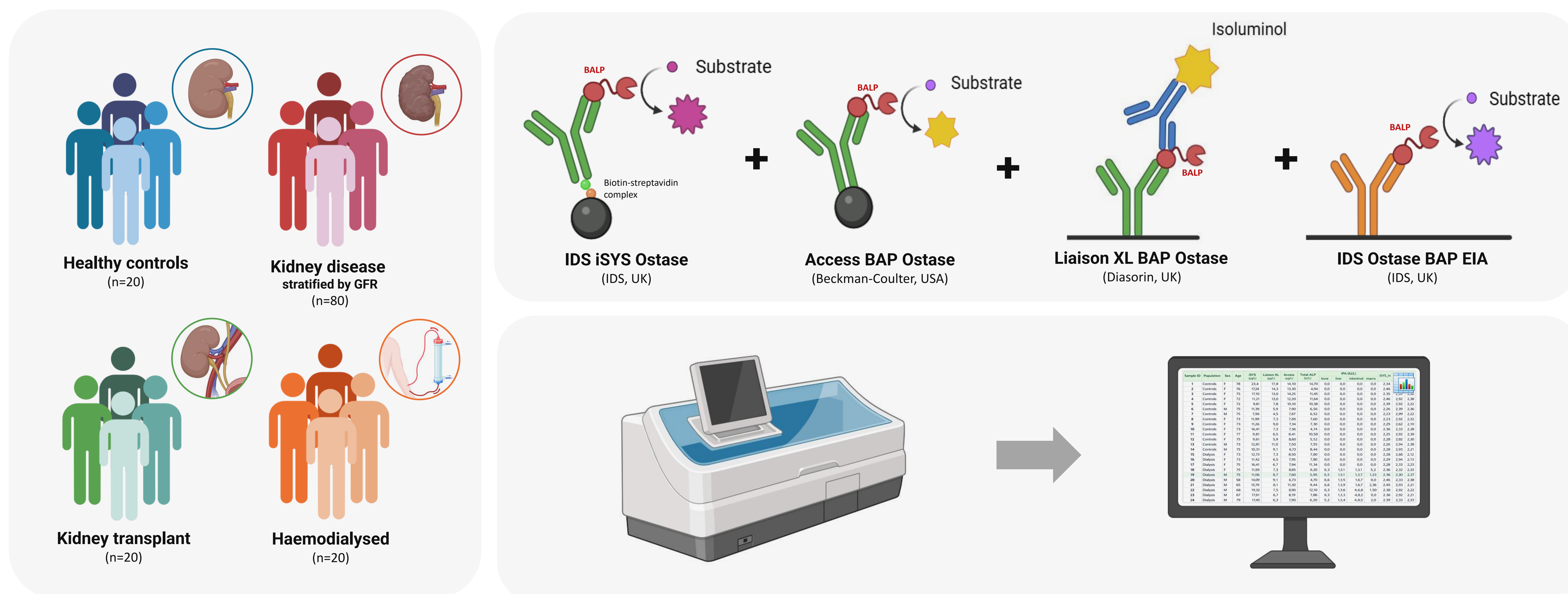
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## Introduction

**Bone-specific alkaline phosphatase (BALP)**, is one of the biomarkers recommended by the **KDIGO guidelines** for the assessment of bone turnover in CKD-MBD and has recently been proposed by the **ESCEO/IOF/IFCC consensus** as a **reference marker** of bone formation in CKD-associated osteoporosis, notably because it is not cleared by the kidney. BALP measurement is routinely performed worldwide. However, the availability of multiple commercial BALP immunoassays may lead to discrepancies in patient results. This study compared the analytical performance and clinical agreement of four BALP immunoassays across distinct patient subgroups.

## Materials and Methods

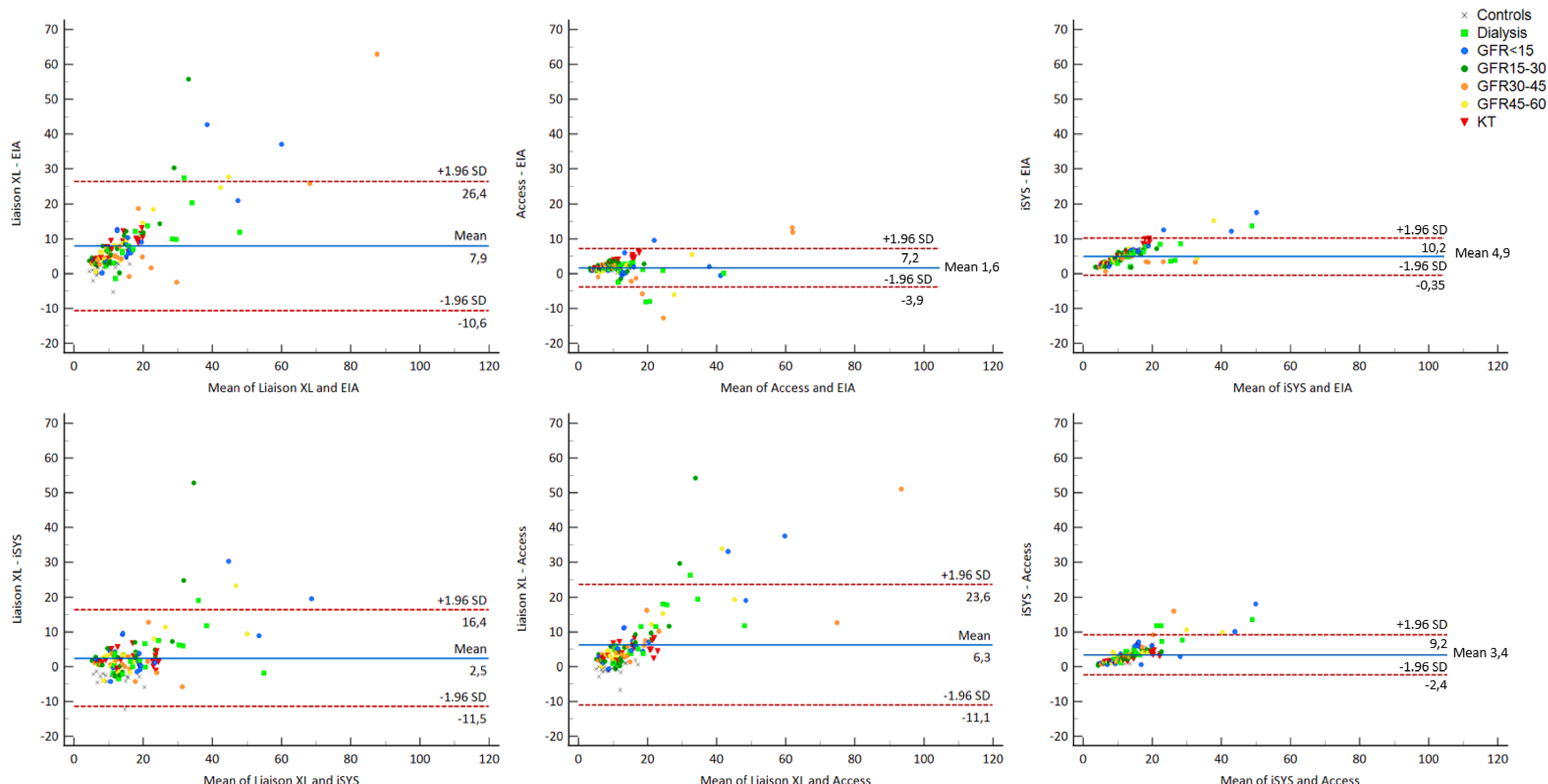


## Results

Significant correlation was found for all assays pairs (Spearman's  $\rho = 0.816-0.984$ ).

Bland Altman plots revealed systematic biases between methods, with largest difference involving the Liaison XL assay.

Some method pairs showed significantly higher bias in CKD, dialysis or kidney transplant patients compared with controls. (Kruskal-Wallis)



## Conclusion

Although correlations between methods are statistically significant, the observed biases indicate that the **assays are not interchangeable**. The larger biases observed in CKD, dialysis and kidney-transplanted patients further underscore the need for careful clinical interpretation. These findings reinforce the **importance of assay harmonization** and the **need for standardization**.

## Perspectives

The development of sensitive and highly specific methods is crucial to overcome current assay limitations. **High-performance liquid chromatography coupled with mass spectrometry** represents a promising approach for the precise and reproducible quantification of BALP and BALP isoforms, ensuring improved diagnostic reliability and facilitating **standardization** efforts.