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Comparative Analysis of Alkaline Phosphatase with Two Assays Using Different Buffers; Diethanolamine (DEA) and 2-Amino-2-Methyl-1-Propanol (AMP): Establishing Correlation Factors for Diagnostic Consistency

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Introduction and Objectives

Alkaline phosphatase (ALP) serves as a pivotal biomarker for bone and liver diseases, employing assays utilizing either 2-amino-2-methyl-1-propanol (AMP) (IFCC recommended) or diethanolamine (DEA) buffers, with the latter consistently yielding higher values. This study aimed to develop a correlation factor for ALP reagents using DEA buffer from supplier X, in comparison to routine automated ALP assay at the central laboratory using AMP.

Methods

Twenty-five serum samples were analyzed in the central laboratory assay using AMP buffer in a fully automated analyzer with dedicated reagents and the test assay using DEA buffer on a semi-automated biochemistry analyzer within two hours of receipt. Both assays employed the same biochemical reaction, differing only in buffer composition. The linearity ranges for the test assay with DEA buffer and the routine assay with AMP buffer were determined as 1600 U/L and 800 U/L, respectively.

Results

Patient samples exhibited ALP levels ranging from 0 to 339 U/L by routine assay. The correlation graph demonstrated a satisfactory R²>0.75, indicating adequate number of sample inclusion and quality. A correction factor of 1.2 was calculated for the ALP assay utilizing DEA, compared to the AMP-based assay, employing simple linear regression analysis.

Conclusions

According to the sample availability, only ALP levels up to 339 U/L by AMP-based assay were included. Therefore, the correction factor of 1.2 is applicable only up to an ALP level of 400 U/L with the DEA-based assay, necessitating dilution of samples with higher values for the correlation factor's application. This study indicates a correction factor of 1.2, which is deviated from factors close to 2, observed in literature because of reagents being from different manufacturers and running two assays on two different platforms (automated/ semiautomated). It is important to derive a factor for an ALP assay with DEA buffer to make the results comparable to IFCC recommended AMP buffer used ALP assay.

Keywords

Alkaline phosphatase, 2-Amino-2-Methyl-1-Propanol, Diethanolamine, Buffer