EVALUATION OF SENTINEL TOTAL ACID PHOSPHATASE AND NON PROSTATIC ACID PHOSPHATASE ASSAY ON BECKMAN COULTER AU50 CHASIS CLINICAL CHEMISTRY ANALYZERS

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Abstract (revised)

Objectives: Evaluation of Total Acid Phosphatase (ACP) and Non Prostatic Acid Phosphatase (ACP-NP) assays from SENTINEL CH. on Beckman Coulter AU400 and AU2700 was performed versus quality specifications based on biological variation, according to Biotest. Materials/Instruments: ACP measurement is based on the hydrolysis in acid medium of o-naphtylphosphate to o-naphtol and phosphate. o-naphtol reacts with diazo-2-chloro-5-toluene (Fast Red TR salt), forming an azo dye compound. Prostatic acid phosphatase activity, inhibited by tartrate, is calculated by subtraction between ACP and ACP-NP. 

Study Design: All study protocols were based on CLSI standard. To meet analytical specifications based on biological variation (TV<10%), at clinical decision level (47 U/L), the following acceptance criteria were adopted: for Total Imprecision CV<5%; linearity has <5% instrument comparison was performed by comparing the results of paired patient versus samples on AU400 vs. Hitachi 912, LX20 vs AU400 and AU640 vs AU2700. On Board reagent stability and calibration stability were also evaluated.

Results: ACP: Overall CV was 2.7% at 19 U/L on AU400 and 1.8% at 8.8 U/L on AU2700. Method Comparison: A) AU400 vs Hitachi 912: n = 70, slope = 1.06, intercept = -0.02 U/L, r = 0.997. B) AU400 vs AU640: n = 60, slope = 0.97, intercept = 0.17 U/L, r = 0.986. Linearity was found from 0.2 up to 72.6 U/L. LOD was 0.13 U/L. ACP-NP: Prostatic acid phosphatase (ACP-P) is inhibited by tartrate and is detected with an indirect method by subtraction between ACP and non-prostatic acid phosphatase (ACP-NP).

Introduction

Acid phosphatases are a group of enzymes that can be found in liver, spleen, erythrocytes, platelets, bone marrow and prostate gland. The ratio between total acid phosphatase and prostatic phosphatase in healthy males is about 1:1. Activity of total acid phosphatase increases in case of Paget’s disease, hyperparathyroidism, bone cancer, Sjögren’s disease, Neumann-Pick disease and myelocytic leukemia. Prostatic acid phosphatase levels increase in case of prostatic cancer. 


Total Imprecision: was performed for 5 days on AU400 and for 6 days on AU2700 with three different control levels, two runs per day, four replicates per run for AU400 and two replicates per run for AU2700. 

Linearity: the “dilution test” performed on at least eleven different concentrations was used to verify the validity of linearity claim. Acceptance criteria were +/- 5.5% or 0.20 U/L in terms of bias.

Sensitivity: Limit of Detection (LOD) is the amount of analyte that can be detected with stated probability (generally 1%). The detection limit was defined as the analyte concentration equivalent to 3 x the SD measured on 20 replicates of saline.

Conclusions: The performance obtained were accomplished within the specified acceptance criteria. The obtained data for both the systems are comparable and all the systems employed the same method comparison between the Beckman Coulter reagent and Sentinel Reagent.

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References


The 2010 update: www.westgard.com/biodatabasel.html

Methodology / Acceptance criteria


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Comparison: This testing was performed on the Beckman Coulter AU400 in comparison to Beckman Coulter Synchron LX20 and to a Roche Hitachi 912. Linear regression analysis was used to determine the degree of agreement between the assay on the different systems.

Biological variability & Desirable Specifications (1)