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Research Article

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Effects of Storage Temperature on Accuracy and Precision of Hepatic Enzymes Levels

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Abstract
This is a known and documented fact that several pre-analytical steps are essential and mandatory for accurate and precise analysis of enzymes and biomarkers such as correct container, volume, collection, and transport and storage temperature. Our present study described the effects of storage temperature conditions on accuracy and precision of four hepatic enzymes, ALT, AST, ALP, γGT. concentrations. All blood samples were subjected to one room temperature condition, assess at zero and 24 hours for deviations. Data obtained showed considerable deviation in analytes concentration at storage room temperatures timed at zero hr. and 24 hours with precision of only 53%, 54%, 38% and 37%, for ALT, AST, γGT and ALP, respectively. Hepatic enzymes are critical care biomarker, and its accurate and precise analysis is significantly important to ensure correct diagnosis and assessment of progression of treatments. Clinical laboratory thus needs to safeguard the documented standards and protocols and ensure its implementation when hepatic enzyme test is requested.

Keywords: Hepatic enzymes, Accuracy, Precision

1. Introduction

Chronic diseases, such as hepatic anomalies, neuropathy, diabetes, inherent metabolic disorders, and renal insufficiency are getting more common since start of current decade and more and more adult population seems to be suffering from either of the mentioned clinical conditions or multiple syndromes [1]. In order to diagnose the individuals, who developed such diseases and in danger of having complications, hospitals, clinics and care givers must have proper diagnostic tools to identify the actual ailment and possible treatment regiments [2,3]. Identifying or suggesting biomarkers that can provide information about etiology and/or progression of a disease is as important as its treatment. Collecting blood or fluid at time of natural history or progression of disease is done either at clinics, wards, Lab collections centers and transported and stored as per standardized procedures. Transport and storage of biological samples, from which an intended, clinically significant biomarker is needed to be analyzed, is very important for the correct, accurate results [4,5]. Accurate diagnosis of an intended blood parameter(s), such as urea, creatinine, electrolytes, liver function test profile, hepatic and muscle enzymes etc as well urinary components e.g

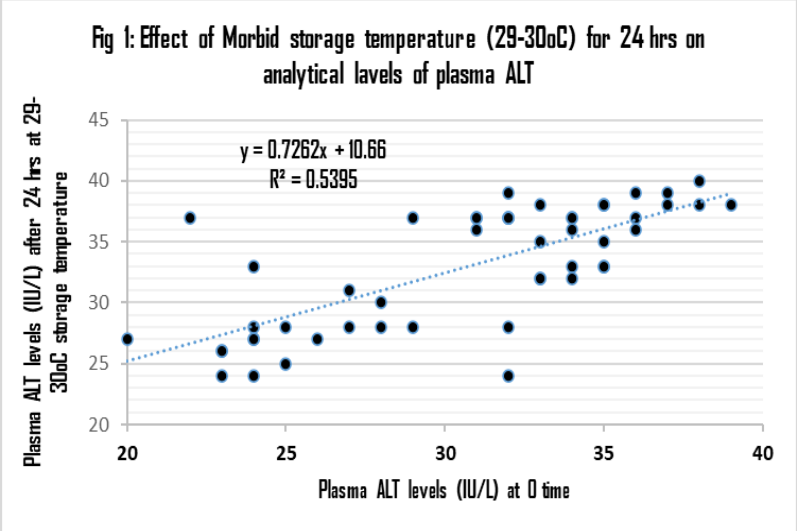
sugar, protein, albumin, oxalate, citrate and urinary micro-albumin is very important in clinical decision making and correct treatment by physicians [6]. Several special chemistry profiled parameters such as Troponin I, pro-BNP, and tumor markers also needed to be assesses urgently and with accuracy to ensure proper diagnosis and long term prognosis [7-10]. This is a known and documented fact that several pre-analytical steps are essential and mandatory for accurate and precise analysis of biomarkers such as correct container, volume, collection, transport and storage. Any deviation in mentioned steps and requirement cause inaccuracy and deviation in expected true results. Our present study described the effects of storage temperature conditions on accuracy and precision of hepatic enzymes analysis and concentrations.

2. Materials and Methods

Fifty healthy individuals were selected for this study to avoid analytical biases and to avoid clinical disagreements. Two types of untoward condition were created to check effects of storage length and temperature on hepatic enzymes concentrations. For each enzyme, same day was selected to collect samples from same 50 individuals, which were dedicated for both Conditions. Condition 1: N = 50, where samples were subjected to zero and 24 hrs storage at room temperature and analyzed. Condition 2: N = 50, where samples subjected to room temperature 29OC to 30OC storage. Details are described in results and in Figures 1-4 as well. Plasma was separated, aliquot were made and analyzed on both instruments, standalone Cobas c501 and TLA Cobas c503 simultaneously for ALT, AST, ALP, LDH, CPK and □GT. Analytical methods were standard as per protocols used earlier [9-11]. Condition were detailed in title of the figures whereas Y and X plotted as per regression correlation analyses.

3. Results

Results are summarized in Fig1 to 4. Routine protocol for transport, storage and analysis of hepatic enzymes were followed. In this study, samples were subjected to long hrs storage at room temperature, which is not advisable, although sample collected, transported properly within time limit, while storing at 29 to 30OC. Comparative analysis done amongst scenarios showed variable deviation in obtained results depicted in Fig 1 to 4. Technical and analytical precision is thus very significant factor in ensuring sustainable accuracy, patients care and trust of end-users and clinicians. Comparative analysis of both storage time period at zero and 24 hrs showed considerable downward trend in concentration of all four hepatic enzymes from as low as 37% (Fig 4) only upto only 54% (Fig 2) maximum. Regression data analyzed in the form of X and Y intercept are as follows ALT (Fig 1) Y = 0.7262x +1.66 R2 0.5395, AST (Fig 2) Y = 0.8433x + 6.4052 R2 0.5429, □GT (Fig 3) Y = 0.7805x +8.285 R2 0.3824 and ALP (Fig 4) Y = 0.362x + 67.11 R2 0.3745, manifesting with downgraded comparative precision and reproducible results at 53.95%, 54.29%, 38.24% and 37.45% respectively.



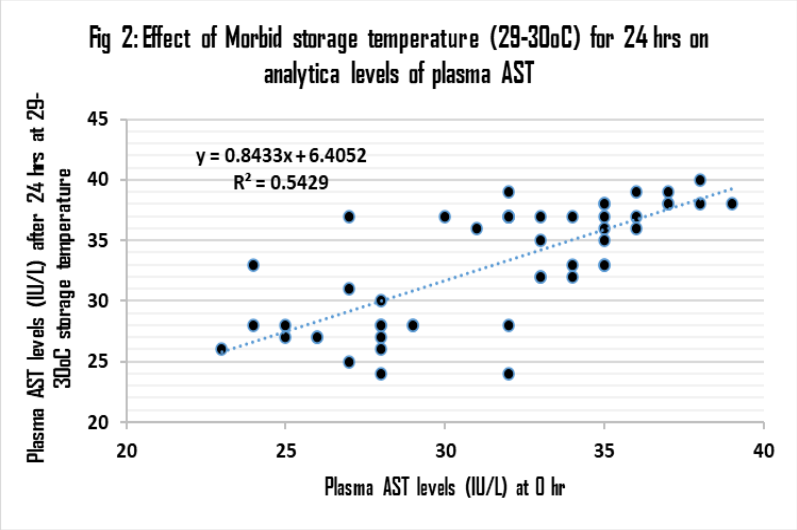


Fig 2: Effect of Morbid storage temperature (29-30oC) for 24 hrs on analytica levels of plasma AST
y = 0.8433x + 6.4052
R² = 0.5429
Plasma AST levels (IU/L) after 24 hrs at 29-30oC storage temperature
Plasma AST levels (IU/L) at 0 hr
20
25
30
35
40
45

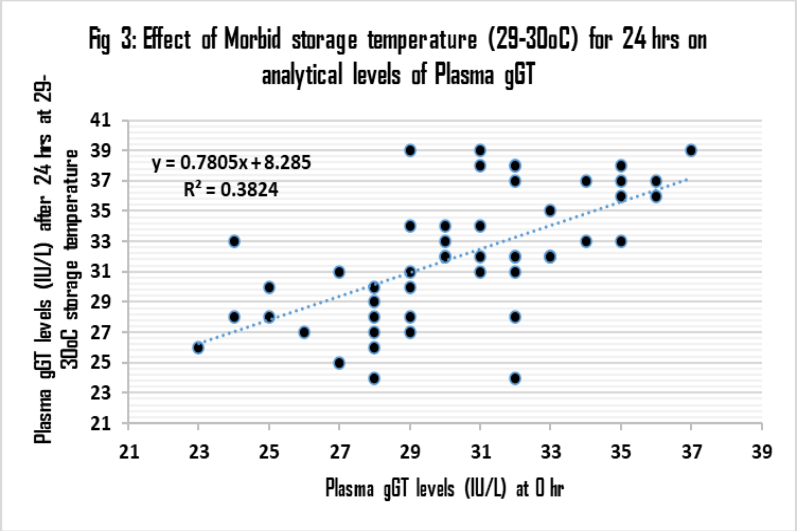


Fig 3: Effect of Morbid storage temperature (29-30oC) for 24 hrs on analytical levels of Plasma gGT
y = 0.7805x + 8.285
R² = 0.3824
Plasma gGT levels (IU/L) after 24 hrs at 29-30oC storage temperature
Plasma gGT levels (IU/L) at 0 hr
21
23
25
27
29
31
33
35
37
39
41

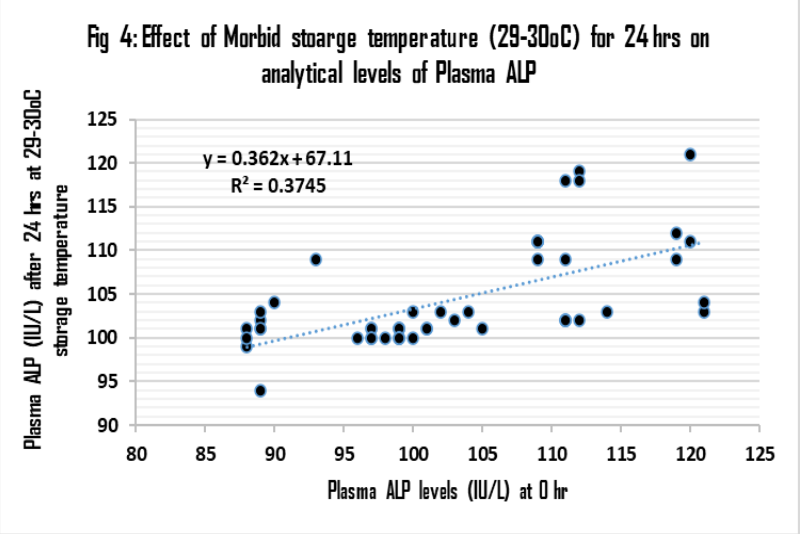


Fig 4: Effect of Morbid stoarge temperature (29-30oC) for 24 hrs on analytical levels of Plasma ALP
y = 0.362x + 67.11
R² = 0.3745
Plasma ALP (IU/L) after 24 hrs at 29-30oC storage temperature
Plasma ALP levels (IU/L) at 0 hr
80
85
90
95
100
105
110
115
120
125

4. Discussion

What transpired in recent years is the significant urge in requirements of urgent testing, with accurate results, precise, standardized, that can help, and support quick medical decision and prompt patient care [6-8, 11]. In today's world of health care industry, space limitation, qualified staff, financial constraints, procurement of latest technologies and/or kits, chemicals are some of the components, either one of it or all, that can induce pressure to have further enhanced and robust analytical systems that has the ability to perform with precision and accuracy for better patient care and trust [6-8]. Regardless of the financial cost, it has been advocated many times that the aim should be a robust analytical testing system for patients care with efficient turnaround time (TAT), minimal blood or sample volume, readily accessible results and desirable outcome. Moreover with more efficient precision and analytical performance, maintenance of high tech instruments is also now becoming essential and mandatory. To have periodic preventative maintenance (PPM) system, is always beneficial for long term sustainable and standardized laboratory services.

In this study, samples were subjected to long hr storage at room temperature, which is not advisable, although sample collected, transported properly within time limit, while storing at 29 to 30OC. Comparative analysis done amongst scenarios showed variable deviation in obtained results depicted in Figures. Technical and analytical precision is thus very significant factor in ensuring sustainable accuracy, patients care and trust of end-users and clinicians. Comparative analysis of both storage time period at zero and 24 hrs showed considerable downward trend in concentration of all four hepatic enzymes from as low as 37% (Fig 4) only upto only 54% (Fig 2) maximum. Regression data manifested downgraded comparative precision and reproducible results at 53.95%, 54.29%, 38.24% and 37.45% respectively.

5. Conclusion

Our present study demonstrated the effects of long-term storage on high room temperature on accuracy and precision of hepatic enzymes and concentrations. Clinical laboratory thus needs to safeguard the documented standards and protocols and ensure its implementation when liver function test is requested. Technical and analytical precision is thus very significant factor in ensuring sustainable accuracy, patients care and trust of end-users and clinicians. Comparative analysis of both storage time period at zero and 24 hrs at room temperature 29 to 30OC showed considerable downward trend in concentration of all four hepatic enzymes from as low as 37% to only upto only 54% maximum accuracy.

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