Research Article

Evaluation of Analytical Precision and linearity of Troponin I, Vitamin B12 and Folic acid on Cobas e411 and Beckman Coulter Access 2 immunoassay analyzers

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Abstract *Background*: Precision, reproducibility, calibration and quality assurance is some of the important requirements that ensure quality pledged services to patients and end-users. *Aim:* In this regard, present study was undertaken to perform comparative precision analysis of Trop I, Vitamin B12 and Folic acid on Cobas e411 (Roche Diagnostics, Basil) and Beckman Coulter Access 2 (Beckman, USA). *Materials and Methods*: Blood samples were collected from 75 patients for Troponin I, 25 anemic patients for each Folic acid and Vitamin B12; and 25 healthy individuals in heparinized tubes. The patients for Troponin I were divided into three groups with 25 patients in each group, according to severity of cardiac conditions. Plasma was separated and analyzed for cTnI, Folic Acid and Vitamin B12 on Cobas e411 using electro-chemiluminescence (ECLi) immunoassay technology (Roche Diagnostics, Basil) and Beckman Coulter Access 2 using chemiluminescence technology (Beckman, USA). Data was compared statistically by using SPSS ver 20.0 (USA), regression correlation analysis and considered significant when $P < 0.05$. *Results:* Analysis of data showed compatible and appreciable precision amongst both instruments for cTnI with regression R^2 ranging from 0.872 to 0.977, representing attuned accuracy of 97.7%, 92.11% and 87.2% on two different instruments. Similarly, Folic acid precision was noted to be 97.1% ($R2 = 0.971$) for anemia patients and 99.2% ($R2$ 0.992) for anemia patients with low Vitamin B12. *Conclusion:* Current data clearly manifested considerable compatibility, precision and accuracy of Beckman Access 2 parameters, viz cTnI, Folic acid and Vitamin B12 when correlation analysis was performed with Cobas E411 immunoassay analyzer. Such compatibility ensures, not only value-added and quality assured services to the end-user and patients and but also benefits organization regarding competitive prices and services.

Keywords Precision, Compatibility, Tropinin I, Cardiac myopathies, Anemia

Introduction

Analytical precision, calibration, reproducibility are some of the components that the end-users from clinical laboratories looks for and wants form an in-vitro diagnostic (IVD) analytical analyzer, either fully automated or semi automatic ones [1-3]. Such is the importance of these needs, mostly for large or even medium scale clinical laboratory that without having all three capabilities or more, management, pathologists, lab professionals and lab scientist just doesn't want to go for the less [4-7]. Having analyzers and system with such capabilities also bound the laboratories to perform quality checks, assurance regiments and precision evaluations, more frequently than ever

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[4,5,8]. Several recent and past studies, both local and international, on precision, reproducibility, calibration, quality assurance studies documented the importance of these requirements to ensure quality pledged services to patients and end-users [1-5, 8, 9]. Present study described comparative precision analysis of Trop I, Vitamin B12 and Folic acid on Cobas e411 (Roche Diagnostics, Basil) and Beckman Coulter Access 2 (Beckman, USA).

Materials and Methods

Study protocol and Patient's selection: Seventy five patients (males = 50; females = 25, age range = 36-55 yrs) with either chest pain, known history of Acute Coronary Syndrome (ACS), Ischemic stroke, myocardial infarction/ necrosis were selected for Troponin I (cTnI) comparative precision analyses, categorizing into three groups. Study period for this prospective study was from August 2018 to Dec 2018. Samples for Folic Acid (Folate) and Vitamin B12 were selected from normal subjects (n =25) and anemic patients (n = 25, with Hemoglobin less than 11.00 gm/dl). The patients who are on steroid therapy, underwent surgery, suffering from renal impairment were excluded from the study. Twenty five samples were also taken from Age-gender matched individuals for each categorized groups and subgroups of Troponin I, Folic acid and Vitamin B12, with no history of any adverse clinical condition.

Precision analysis of cardiac Troponin I, Folic Acid and Vitamin B12 on Immunoassay analyzers
Previously described protocols were followed for standardization [2, 8]. Blood samples were collected from 75 patients for Troponin I, 25 anemic patients for each Folic acid and Vitamin B12; and 25 healthy individuals in heparinized tubes. The patients for Troponin I were divided into three groups with 25 patients in each group, according to severity of cardiac conditions (Fig 2-4). Plasma was separated and analyzed for cTnI, Folic Acid and Vitamin B12 on Cobas e411 using electro-chemiluminescence (ECLi) immunoassay technology (Roche Diagnostics, Basil) and Beckman Coulter Access 2 using chemiluminescence technology (Beckman, USA). Normal reference range of cTnI = < 0.30 ng/ml, Folic acid = 2.7-16.1 ng/ml and Vitamin B12 = 220-925 pg/ml. The data was compared statistically by using SPSS ver 20.0 (USA), regression correlation analysis and considered significant when $P < 0.05$.

Results

Results are summarized in Fig 1 to 8. For Troponin I, patients were divided into three groups with 25 patients in each group, suspected cardiac cases (Fig 2), cardiac patients (Fig 3), and with MI and cardiac myopathies, accordingly (Fig 4). Folic acid (Fig 5,6) and Vitamin B12 (Fig 7,8) samples were categorized separately under anemia and normal subjects. cTnI, Folic acid and Vitamin B12 were analyzed on Cobas e411 using electro-chemiluminescence (ECLi) immunoassay technology (Roche Diagnostics, Basil) and Beckman Coulter Access 2 using chemiluminescence technology (Beckman, USA). Data were compared using SPSS ver 20 with regression correlation equations. Analysis of samples data depicted compatible and appreciable precision amongst both instruments with regression R^2 ranging from 0.872 (Fig 3) to 0.977 (Fig 4), representing attuned accuracy of 97.7% (Fig 4), 92.11% (Fig 2) and 87.2% (Fig 3) for replicated run on two different instruments, in suspected cardiac cases, MI and cardiac myopathies and cardiac patients, respectively. Similarly, Folic acid precision was noted to be 97.1% (R2 = 0.971; Fig 6) for anemia patients and 99.2% (R2 0.992; Fig 8) for anemia patients with low Vitamin B12. The results clearly depicted excellent precision compatibility of Beckman Access 2 with Cobas E411 immunoassay analyzer.
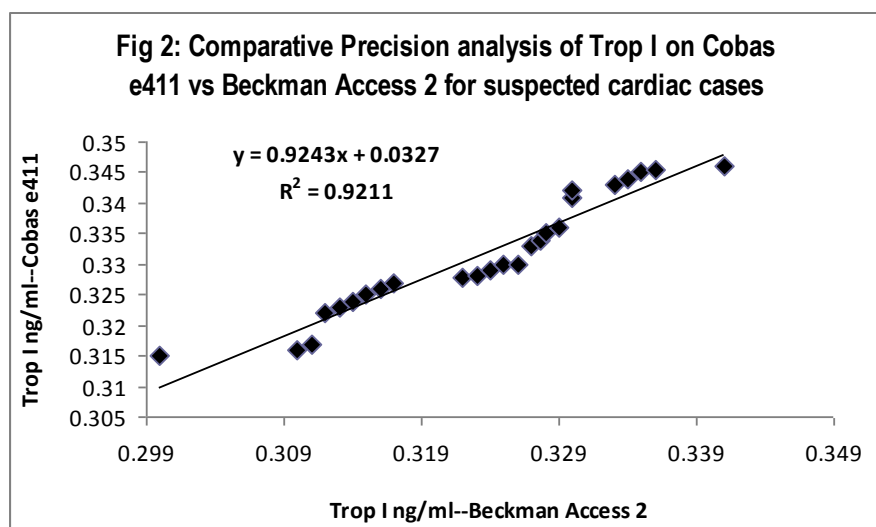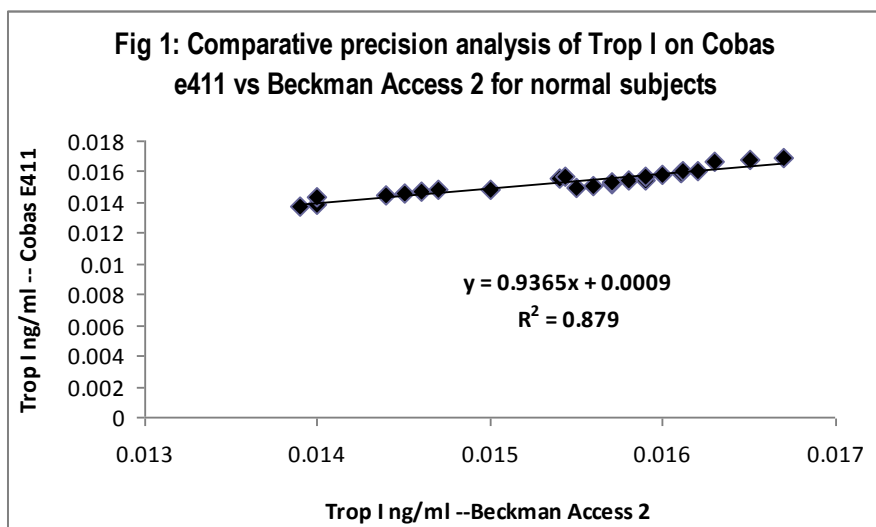
Discussion

Present study described regression correlation analysis of comparative precision of three biomarker parameters, Troponin I, Folic acid and Vitamin B12 on two immunoassay instruments, Cobas E411 and Beckman Access 2. Data analyzed depicted compatible and appreciable precision amongst both instruments with regression R^2 ranging from 0.872 to 0.977, representing accuracy of 97.7% 92.11% and 87.2% for Troponin I, in suspected cardiac cases, MI and cardiac myopathies and cardiac patients, respectively. Similarly, precision of Folic acid was noted to be 97.1% for anemia patients and 99.2% for anemia patients with low Vitamin B12. Precision outcome clearly depicted excellent comparative precision compatibility of Beckman Access 2 with Cobas E411 immunoassay analyzer.
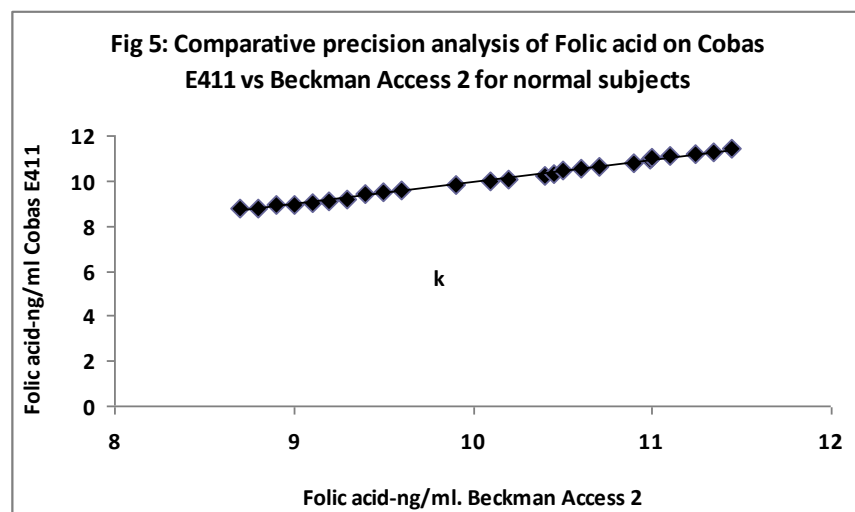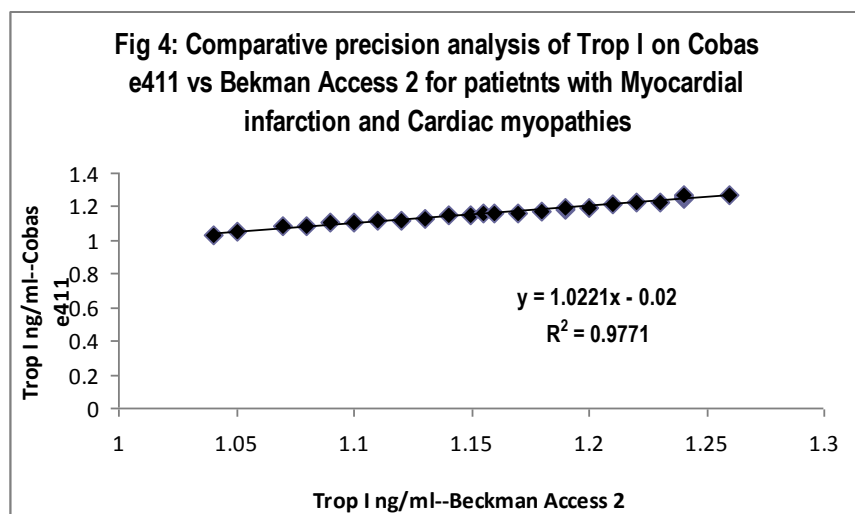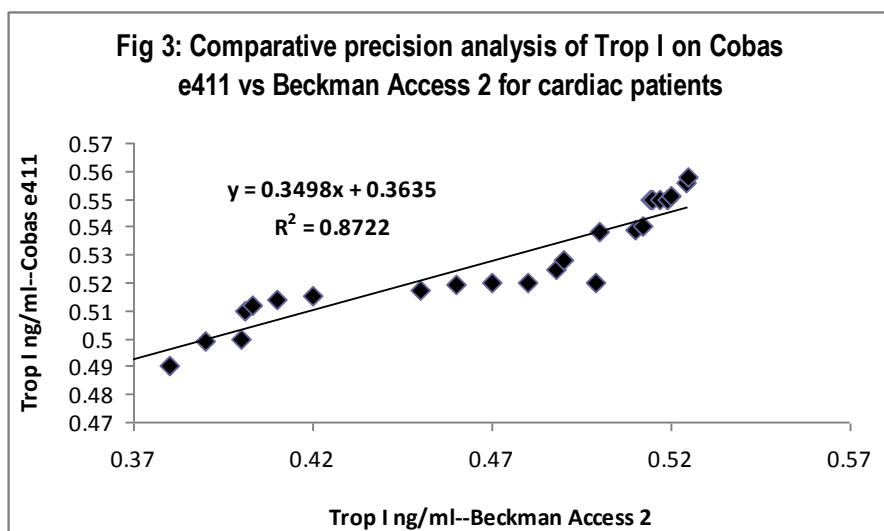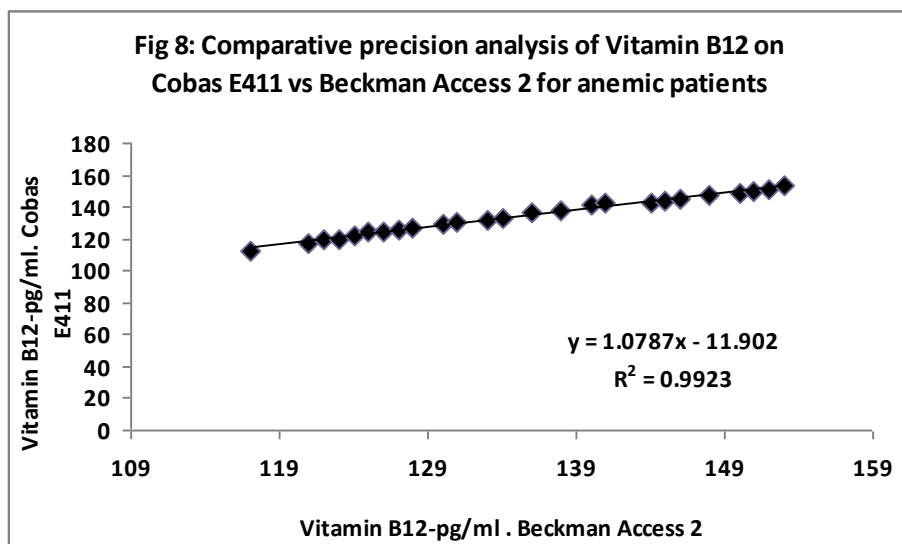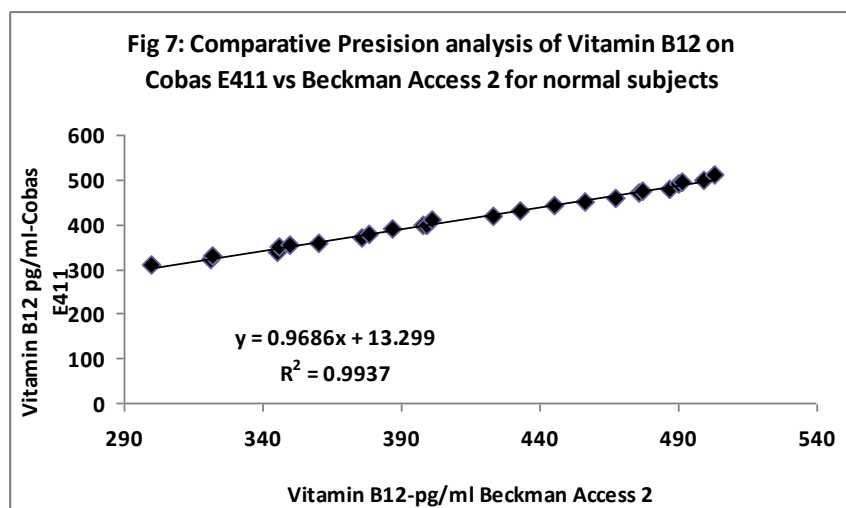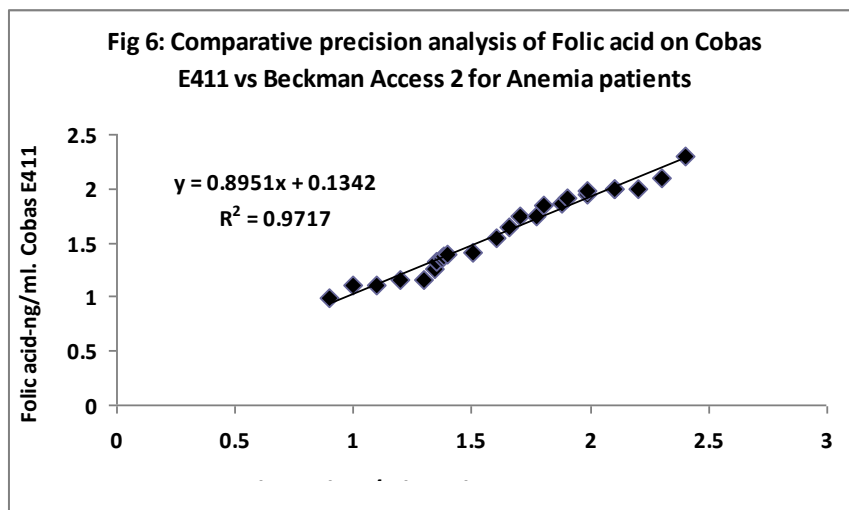
Previous studies also suggested compatible comparability of multiple instruments, both routine chemistry and immunoassays with R2 ranging from 0.79 to 0.82 [4] depicting precision, accuracy, cross reactivity and comparability of serum indices measurement on Abbott Architect c8000, Beckman Coulter AU5800 and Roche Cobas 6000 c501. In another study, comparative precision analysis of controls of LDH and albumin on automated chemistry analyzers were performed and found to be compatible and analytically comparable [1]. Our group also reported several precision analysis and comparative assessment studies regarding instrumental performances of both immunoassay and chemistry analyzers and documented outcome of compatibility and accuracy of results [2, 8].

Conclusion

Current data clearly manifested appreciable compatibility, precision and accuracy of Beckman Access 2 parameters, viz cTnI, Folic acid and Vitamin B12 when correlation analysis was performed with Cobas E411 immunoassay analyzer. It is need of time of clinical laboratories to assess correctness, precision, attuned of multiple instruments from variable manufacturers/brands offering similar biomarker parameters. This ensures value and quality assured services to the end-user and patients and benefits organization as well. Having more than one brand with similar parameters also ensure competitive pricing, services and discourages conflict of interest and monopoly.

Fig 1: Comparative precision analysis of Trop I on Cobas e411 vs Beckman Access 2 for normal subjects

$y = 0.9365x + 0.0009$
$R^2 = 0.879$

Fig 2: Comparative Precision analysis of Trop I on Cobas e411 vs Beckman Access 2 for suspected cardiac cases

$y = 0.9243x + 0.0327$
$R^2 = 0.9211$

Fig 3: Comparative precision analysis of Trop I on Cobas e411 vs Beckman Access 2 for cardiac patients

$y = 0.3498x + 0.3635$

$R^2 = 0.8722$

Fig 4: Comparative precision analysis of Trop I on Cobas e411 vs Bekman Access 2 for patietnts with Myocardial infarction and Cardiac myopathies

$y = 1.0221x - 0.02$

$R^2 = 0.9771$

Fig 5: Comparative precision analysis of Folic acid on Cobas E411 vs Beckman Access 2 for normal subjects

Fig 6: Comparative precision analysis of Folic acid on Cobas E411 vs Beckman Access 2 for Anemia patients

y = 0.8951x + 0.1342
$R^2 = 0.9717$

Folic acid-ng/ml. Cobas E411 (y-axis)

Fig 7: Comparative Presision analysis of Vitamin B12 on Cobas E411 vs Beckman Access 2 for normal subjects

y = 0.9686x + 13.299
$R^2 = 0.9937$

Vitamin B12 pg/ml-Cobas E411 (y-axis)

Vitamin B12-pg/ml Beckman Access 2 (x-axis)

Fig 8: Comparative precision analysis of Vitamin B12 on Cobas E411 vs Beckman Access 2 for anemic patients

y = 1.0787x - 11.902
$R^2 = 0.9923$

Vitamin B12-pg/ml. Cobas E411 (y-axis)

Vitamin B12-pg/ml . Beckman Access 2 (x-axis)

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