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Research Article

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Comparative Performance and Precision evaluation of Thyroid Hormones on ECL Cobas e411 during two different shifts

Junaid Mahmood Alam, Humaira Ali, Shazia Naureen, Qurat-ul-Ain, Sadaf Naz, Junaid Ahmed, Shoukat Ali

Department of Biochemistry lab services and Chemical Pathology, and Liaquat National Hospital and Medical College, Karachi. Pakistan
Corresponding author: Dr Junaid Mahmood Alam, dr_jmalam@hotmail.com

Abstract Laboratory reports of clinical significance such as cardiac markers, ABGs and even Thyroid profile in infants and adults comes after a lot of quality assured and quality-controlled steps and processes. In last one-decade, strong emphasis was given to introduce precision, accuracy, standardization and reproducibility in tests performed on variable instruments, group of staff and even in different shifts. Present study describe comparative performance and precision evaluation of thyroid hormones, T3, T4, FT3, FT4 on electro-chemi luminesce ECL Cobas e411(Roche Diagnostics, Basil) during two different shifts, morning and evening. Data depicted excellent precision and accuracy of performance amongst staff, working in two different shifts (morning and evening). Similar set of samples were analyzed by both groups and given precision of 98.22% for T3, 95.41% for T4, 94.81% for FT3 and 97.01% for FT4. This shows that the staff, whether in different shifts are well trained, skilled with understanding of instrumentation, quality assurance and standardized protocols.

Keywords Precision, Accuracy, Standardization
Short title: Comparative Precision analysis of Thyroid hormones

Introduction

Thyroid hormone assays are now mandatory requirement for infants and for those patients suffering from thyroid diseases or cardiac abnormalities. Having laboratory reports of such clinical significance comes after a lot of quality assured and quality controlled steps and processes. Several of such steps are pre-analytical processing, collection, demographic, volume etc, with intra-analytical steps of instrument accuracy, precision, chemicals, and mechanics; and most importantly, the operator or analysist. Clinical laboratory at tertiary care hospitals works 24/7 in 2 or 3 shifts spanning upto 12 or 8 hours each, respectively. Keeping precision at par all the times, in every shift is a difficult task that lab supervisors, QA personnel, consultants and pathologist have to face 24/7. Even with today's very efficient and proficient technology of ECL, MEIA, ELSIA and modern total lab automated and integrated instrumentation, deviation in accuracy, precision, reproducibility is rampant and if not controlled or remain unchecked, cause or induce systemic errors in analysis and reporting. In last one decade, strong emphasis was given to introduce precision, accuracy, standardization and reproducibility amongst labs, within different section of labs under one roof or even in a single specialty such as clinical biochemistry, to provide quality assured and timely reports to patients and clinicians. Present study describe comparative performance and precision evaluation of

thyroid hormones, T3, T4, FT3, FT4 on electro-chemi luminesce ECL Cobas e411(Roche Diagnostics, Basil) during two different shifts, morning and evening.

Materials and Methods

All procedures and protocols for analysis and comparative determination via regression correlation R2 was done as per methods described earlier [1]. Twenty five samples were selected from normal adults of either gender aged 27 yrs-45 yrs., without indication of any thyroid disease nor on any type of medications. Cobas e411 immunoassay analyzer, that uses electro-chemi luminesce (ECL) technology was used to analyzed Thyroid hormones, Tri-iodothyronine T3, tetra-iodothyronine T4 and Free T3 (FT3) and Free T4 (FT4). Samples were collected in serum activator tubes (Red Top), serum removed and stored at -20^{O}C, until analyzed. Samples were run in duplicates in morning shift and in evening shift in one go using two different set/pair of technologist. Mean was used to plot regression analysis. Results are expressed as R2 and percent precision amongst two different shifts.

Results

Results are summarized in Fig 1 to 4. Data depicted excellent precision and accuracy of performance amongst staff, working in two different shifts (morning and evening). Similar set of samples were analyzed by both groups and given precision of 98.22% for T3, 95.41% for T4, 94.81% for FT3 and 97.01% for FT4. Y-intercept and R2 regression correlation data is as follows; T3 = y = 1.172x - 0.1596, R^2 = 0.9822 (Fig 1), T4 = y = 0.8693x + 1.0312, R^2 = 0.9541 (Fig 2), FT3 = y = 0.9275x + 0.1555 R^2 = 0.9481 (Fig 3) and y = 1.2043x - 0.2559 R^2 = 0.9701 (Fig 4).

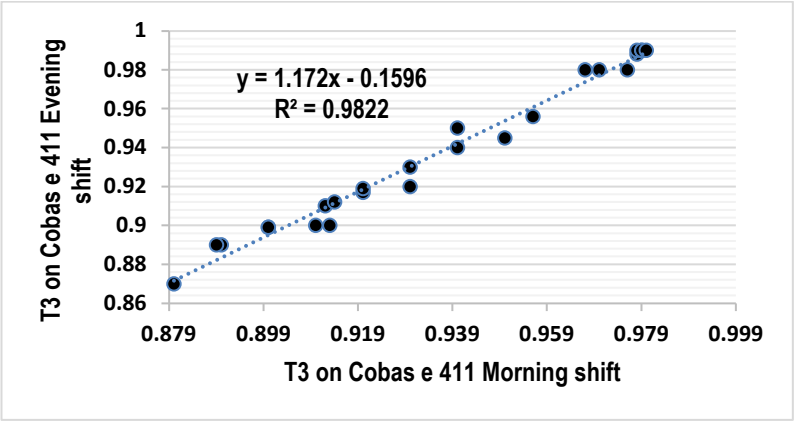

Figure 1: Comparative precision analysis of T3 on two ECL Cobas e 411 analyzers in two different shifts

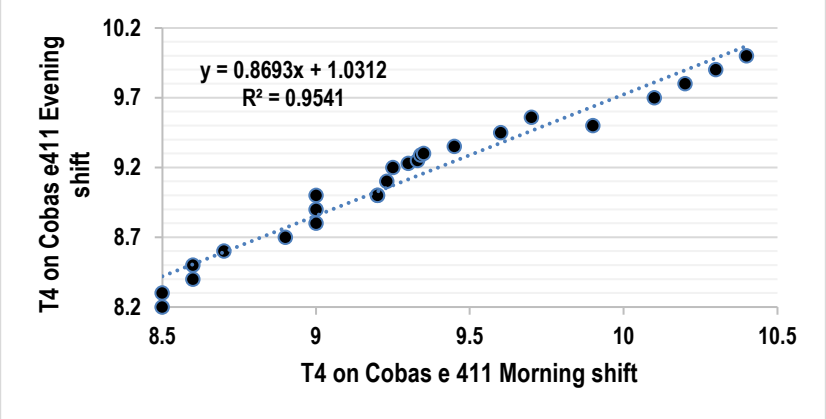

Figure 2: Comparative Precision analysis of T4 on two ECL Cobas e 411 analyzers in two different shifts

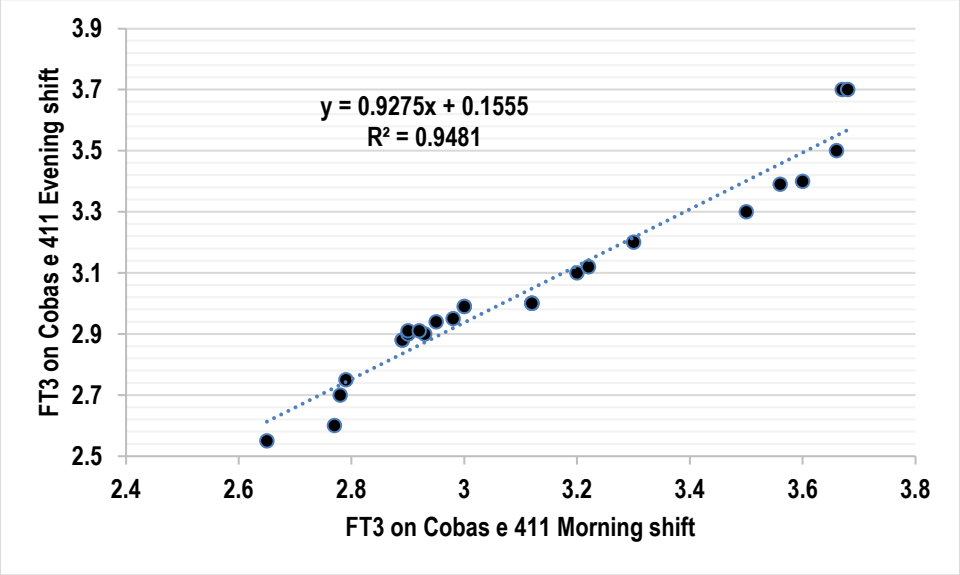

Figure 3: Comparative precision analysis of FT3 on two ECL Cobas e 411 analyzers in two different shifts

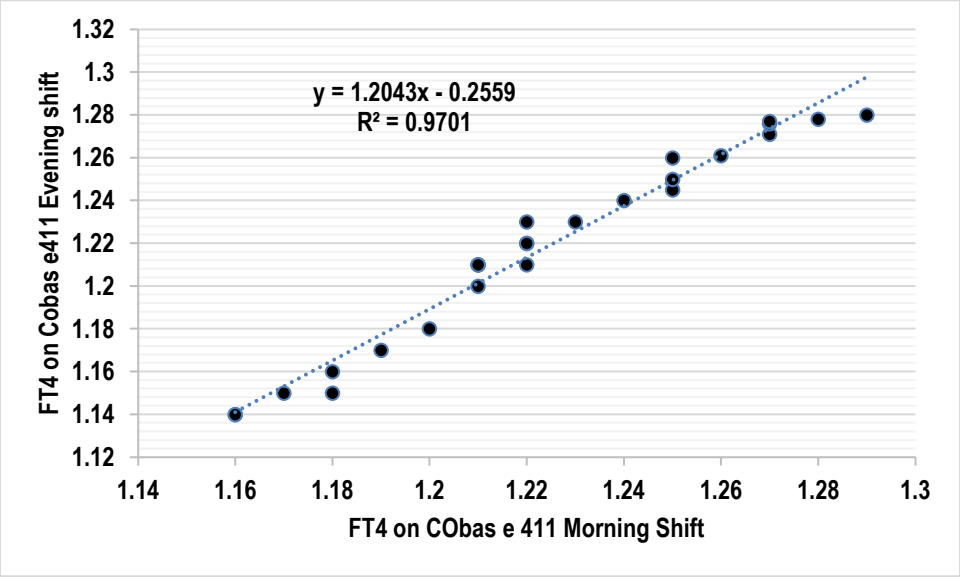

Figure 4: Comparative precision analysis of FT4 on two ECL Cobas e411 analyzers in two different shifts

Discussion

Comparative performance evaluation and assessment of staff competencies is as important as having an accurate, standardized, technologically advanced instrument. Clinical Laboratory Standard Institute (CLSI) strong advocates having strategies for competency assessment of staff and written guidelines as how to go about it. Some salient features are [2]; 1)-Observing staff performing routine patients tests, 2)-Observation as how accurate the staff record and report the results, 3)-Ability of staff to read, understand and review intermediary results or data sheets, quality control and proficiency records, including periodic preventive maintenance record, 4)-Direct observation regarding staff performing instrument functions and its daily maintenance, 5)-assessing the analytical performance of staff by giving them to analyze random samples, blind testing samples, and/or external proficiency testing such as College of American Pathologist (CAP) surveys and lastly 6)-Evaluating problem solving skills.

Shift wise work is essential in a clinical laboratory which services a tertiary care hospital. Shifts usually divided either into 12 hrs or 8 hrs. For later group, shifts are morning, evening and night. In recent years, like other routine chemistry, certain hormone analysis also became significant for patients timely diagnosis, of which thyroid hormone profile is one of it [1]. Clinical laboratories has a significant and critical role is patient care since eons. It provides data, reports that helps clinicians in diagnosing the disease, facilitate treatments, assess follow-ups and progress of treatments. Thus quality of lab reports became a substantial component to provide what has been pledged to patients and clinicians. Seventy percent of all diagnosis is now dependent on a clinical laboratory report [3]. Instruments, kits, methods, technology, staff, all these components are now essential and work in harmony to have a quality assured lab services. Therefore, attention now been given not only to quality control measures but also how to assess implemented quality method, instrumentations, techniques and trained staff using international clinical laboratory standards. Our present study demonstrate excellent precision of thyroid hormone analysis in two different shifts, demonstrating accuracy of performance amongst staff, working in two different shifts (morning and evening). Similar set of samples were analyzed by both groups and given precision of 98.22% for T3, 95.41% for T4, 94.81% for FT3 and 97.01% for FT4.

Conclusion

Thyroid hormone assays are now mandatory requirement for infants and for those patients suffering from thyroid diseases and getting a laboratory reports of such clinical significance is essentially finalized by a lot of quality assured and quality controlled steps and processes. Present study describes comparative performance and precision evaluation of thyroid hormones, T3, T4, FT3, FT4 on electro-chemi luminesce ECL Cobas e411(Roche Diagnostics, Basil) by two different shifts, morning and evening and given precision of 95.41% to 98.22% for T3, T4, FT3 and FT4. This shows that the staff, whether in different shifts are well trained, skilled with understanding of instrumentation, quality assurance and standardized protocols.

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