**Research Article** www.ijcps.com

**International Journal of**
**Chemical and Pharmaceutical Sciences**
2015, Mar., Vol. 6 (1)

ISSN: 0976-9390
IJCPS

# Comparative study on analytical precision of iron profile on conventional Hitachi 912 and modular Cobas 6000 c501 systems

**[1,2] Junaid Mahmood Alam, [2] Jawaid Altaf Baig, [1] Sheikh Matinuddin and [3] Maqsood Ali Ansari.**

[1] Department of Biochemistry lab services and Chemical Pathology, Karachi, Pakistan.

[2] Department of Biochemistry, Liaquat National Hospital and Medical College-Karachi, Pakistan.

[3] Department of Genetics, University of Karachi, Karachi, Pakistan.

*****Corresponding Author:** E-Mail: dr_jmalam@hotmail.com

Received: 14 Mar 2015, Revised and Accepted: 17 Mar 2015

**ABSTRACT**

Inevitably, clinical laboratories are considered a backbone of diagnosis, treatments and management. The present study describes the comparative analysis of analytical precision of iron profile (iron, total iron binding capacity 'TIBC", Ferritin) on two instruments, the stand-alone conventional Hitachi 912 chemistry analyzer and modular Cobas 6000 c501 system. All standard protocols and procedures were followed for present study with a total of 150 patients (Male = 75, female = 75). For instrumental precision, data originating from our conventional chemistry analyzer instrument (Hitachi 912, Roche Diagnostics), regarding iron, TIBC and ferritin were compared on another instrument, the modular Cobas 6000 c501 (Roche-Diagnostics). The iron profile components were analyzed according to standard methods as per manufacturer advices. Comparative analysis of all three parameters manifested considerably significant correlation regarding instrument to instrument precision and accuracy, which is clearly depicted by more than 90% $R^2$ in all three parametric regression viz in males: Iron; $R^2$ = 0.985), Ferritin; 0.979 and in females: Iron ; $R^2$ = 0.937, TIBC; $R^2$ = 0.987, Ferritin; $R^2$ = 0.987. The analytical data showed appreciable regression $R^2$ correlation of 0.94 to 0.987 depicting efficiency of analytical testing, compatibility and precisions of all three parameters, iron, TIBC and ferritin on both instruments.

**Keywords:** Iron profile, Cobas 600 c501, Precision; Turnaround time (TAT).

## 1. INTRODUCTION

Inevitably, clinical laboratories are considered a backbone of diagnosis, treatments and management. In recent years, advancement in technologies, analytical principles and more sophisticated combo-modular system also facilitated and boosted the role of clinical laboratories in health care system. More importantly, in a tertiary care setup, when at any given time, more than 500 to 700 in-house patients needed 24/7 care, inclusive of efficient turn around time (TAT) testing service from clinical lab, it is imperative to have updated analytical instruments and diagnostic techniques to ensure proficient, quality assured and wide range of services to its customers. However the success of medium-level and tertiary care clinical laboratories in providing superior and improved services 24/7, also placed the laboratories under pressure to do more and thus further enhance their technologies and diagnostic care [1-4]. In this regard, procuring better, more efficient, analytically advanced and user-friendly instruments is now became a principle, in other words, performance index (PI) for considering a clinical laboratory worthy of referring too [5,6].

The present study describes the comparative analysis of analytical precision of iron profile (iron, total iron binding capacity 'TIBC", Ferritin) on two instruments, the stand-alone conventional Hitachi 912 chemistry analyzer and modular Cobas 6000 c501 system. The study is the part of on going research by our group [2,3] to ensure and provide better, more efficient, advanced-technology proven testing services, 24/7 to our patients.

## 2. MATERIALS AND METHODS

All standard protocols and procedures were followed for present study as described earlier [2,3]. A total of 150 patients (Male = 75, female = 75) were included in the study. In each gender class, patients were also segregated according to age groups from I to V, where I = 8-15 years, II = 16-25 years, III = 26-40 years, IV = 41-60 years and V = 61-75 years. To ensure that the analytical data originating from our conventional chemistry analyzer instrument (Hitachi 912, Roche Diagnostics), regarding iron, TIBC and ferritin were corresponding to designated age groups and condition, all three parameters were compared with age groups, inclusive of normal and abnormal data. When satisfactory correlation was noted and confirmed, which was considered as $R^2$ greater than 0.90 or 90% correlated, only then samples/data were analytically compared on another instrument, the modular Cobas 6000 c501 (Roche-Diagnostics). The iron profile components were analyzed according to standard methods as per manufacturer advices. Ferritin was analyzed by Particle-enhanced immuno-turbidimetric assay Gen4 [7], iron by colorimetric assay [8] and TIBC by improved-direct colorimetric method [9]. The normal reference ranges for iron is 1-3 years; F = 25-101 μg/dl, M = 29-91 μg/dl; Adults, F = 37-145 μg/dl, M = 59-158 μg/dl; TIBC infants; 100-400 μg/dl, adults = 250-425 μg/dl and Ferritin, Children (3 m to 16 yrs) = 20-200 ng/ml, adults; F = 15-150 ng/ml, M = 30-400 ng/ml. Statistical analysis was done by SPSS 13 and data were considered significant when $P < 0.05$.

## 3. RESULTS

The results are summarized in figure 1 to 12. Comparative analysis of Iron, TIBC and Ferritin was conducted, primarily to assess the precision of data that has been generated by Hitachi 912, on Cobas 6000 c501 modular system and vice versa. It was noted the comparative analysis of all three parameters manifested considerably significant correlation regarding instrument to instrument precision and accuracy, which is clearly depicted by more than 90% $R^2$ in all three parametric regression viz in males: Iron; $y = 1.024\ x + 0.061$ $R^2 = 0.977$ (Figure 1), TIBC; $y = 1.025\ x + -7.541$ $R^2 = 0.985$ (Figure 2), Ferritin; $y = 1.007\ x + 1.983$ $R^2 = 0.979$ (Figure 3), whereas in females: Iron ; $y = 0.931\ x + 3.988$ $R^2 = 0.937$ (Figure 4), TIBC; $y = 0.982\ x + 5.674$ $R^2 = 0.987$ (Figure 5), Ferritin; $y = 1.010\ x + 0.552$ $R^2 = 0.987$ (Figure 6). The mean value of all three parameters in males; Iron = 61.26 ± 2.42 μg/dl; TIBC = 341.73 ± 12.40 μg/dl and Ferritin = 150.49 ± 10.20 ng/ml, respectively and females; Iron = 61.96 ± 4.10 μg/dl, TIBC = 342.90 ± 12.40 μg/dl and ferritin 152.10 ± 8.90 ng/ml, respectively. Similarly, all three parameters were also assessed according to classified age group and noted to be linearly correlated to each other. Here also, the regression correlation of iron, TIBC and ferritin depicted appreciable $R^2$ in the range of 0.94 to 0.95 in males and 0.94 to 0.96 in female population. Age group wise regression analyses resulted in data as Males: Iron; $y = 1.558\ x + 2.062$ $R^2 = 0.952$ (Figure 7), TIBC; $y = 6.085\ x + 110.5$ $R^2$ 0.947 (Figure 8), ferritin; $y = 5.223\ x - 48.01$ $R^2 = 0.952$ (Figure 9) and females: Iron; $y = 1.588\ x + 1.918$ $R^2 = 0.964$ (Figure 10), TIBC; $y = 6.316\ x + 102.9$ $R^2 = 0.956$ (Figure 11), Ferritin = $y = 5.312\ x -49.76$ $R^2$ 0.942 (Figure 12).

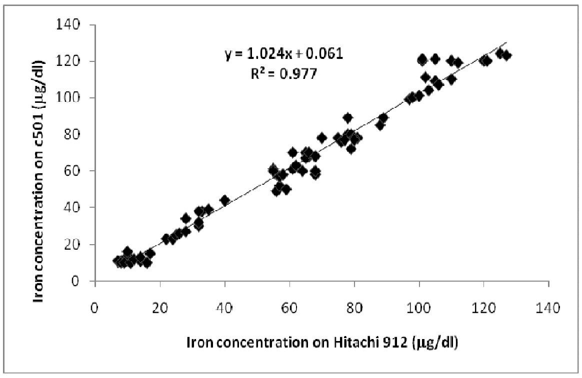


**Figure - 1: Comparative analysis of Iron levels of male patients (n = 75) on 912 and c501.**

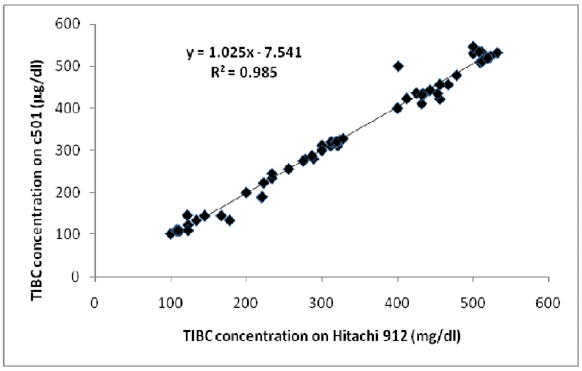


**Figure - 2: Comparative analysis of TIBC concentrations of male patients (n = 75) on 912 and c501.**

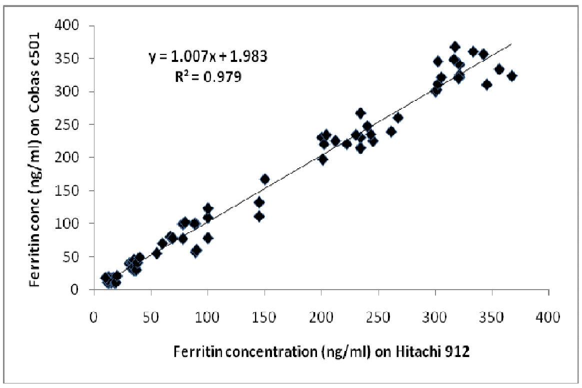


**Figure - 3: Comparative analysis of Ferritin levels in male patients (n = 75) on 912 and c501.**

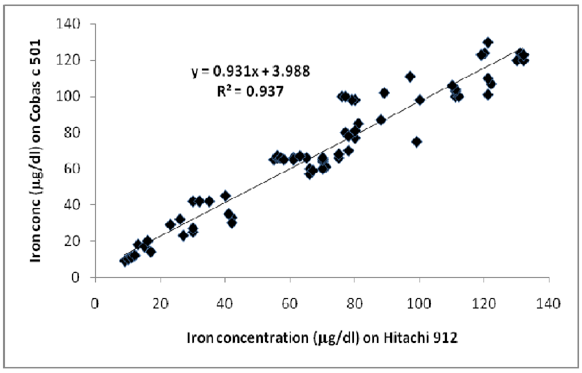


**Figure - 4: Comparative analysis of Iron in Female patients (n = 75) on 912 and c501.**

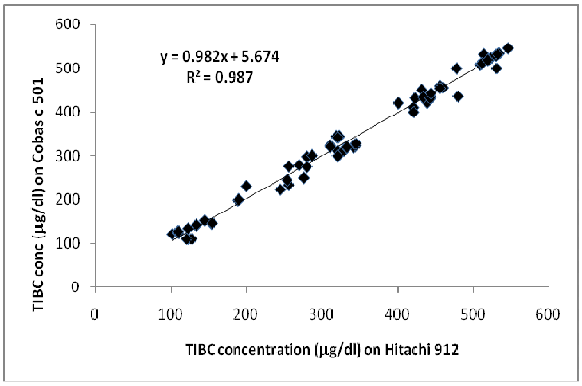


**Figure - 5: Comparative analysis of TIBC in female patients (n = 75) on 912 and c501.**

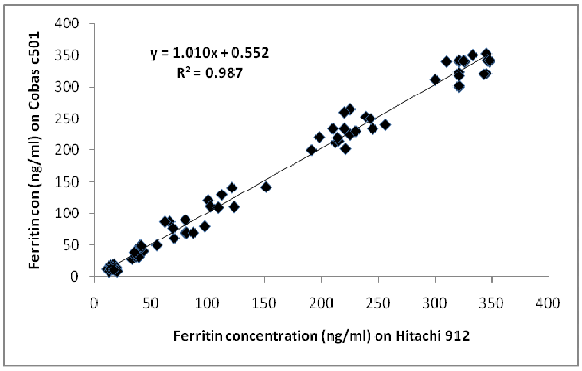


**Figure - 6: Comparative analysis of Ferritin level in female patients (n = 75) on 912 and c501.**

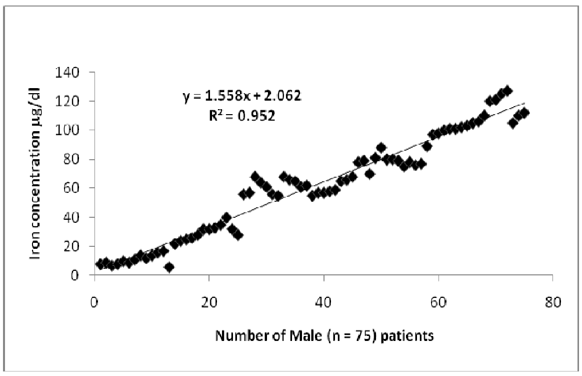


**Figure - 7: Analysis of Iron concentration with patients groups.**

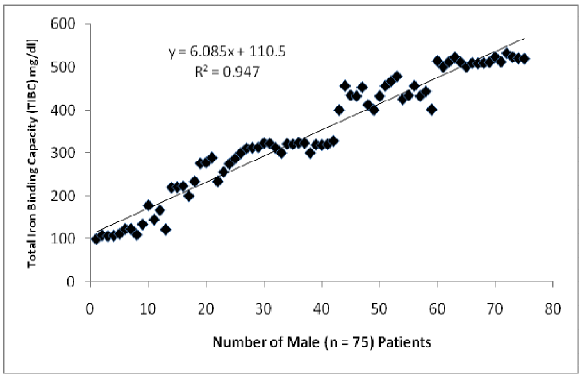


**Figure - 8: Analysis of TIBC with male patient's groups.**

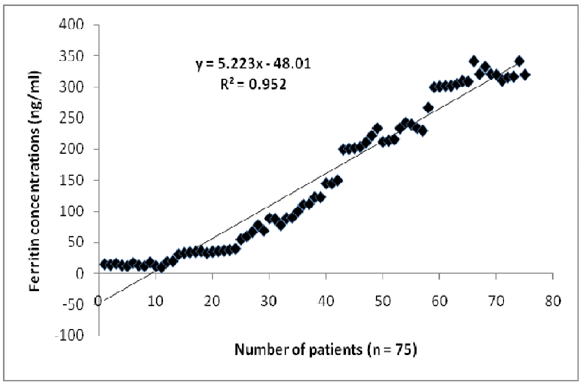


**Figure - 9: Analysis of Ferritin concentration in male (n = 75) patients groups.**

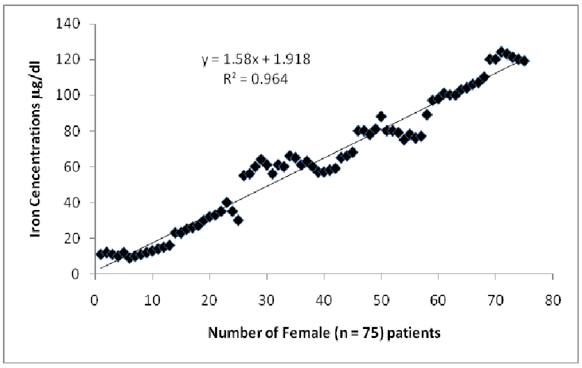


**Figure - 10: Analysis of Iron with female patient's groups.**

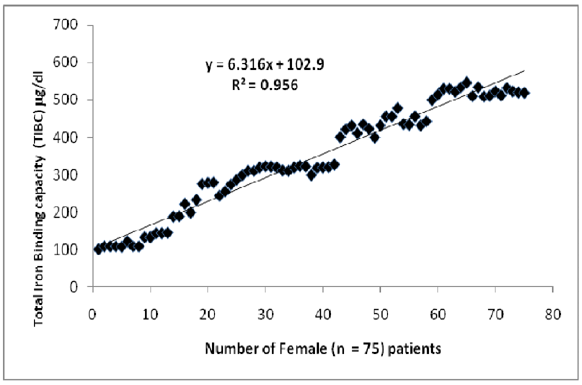


**Figure - 11: Comparative analysis of TIBC with female patient's groups.**

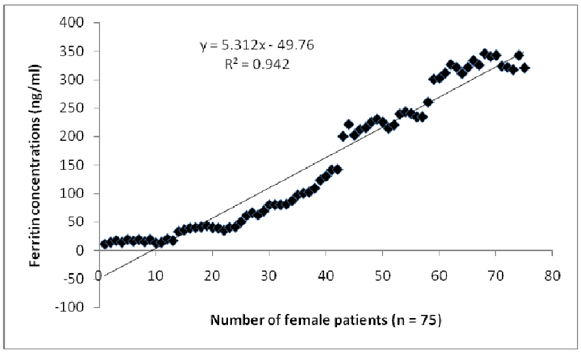


**Figure - 12: Analysis of Ferritin concentration in female patients (n = 75) groups.**

## 4. Discussion

In a routine practice in clinical laboratories, samples needed to be tested simultaneously on several instruments through aliquot preparations, to get a complete profile of patients. Similarly, if a single instrument can generate most of the requested profile of a patient, it still needs to organize its inefficiency, linear analytical steps, different reagents and individual maintenance schedules [1,4,5,10,11]. Procurement of modular system, that can generate maximum number of clinical chemistry profile of a patient within limited time frame, meant both better TAT and efficient delivery, is now been followed, both in developed and developing countries, including Pakistan [2,3]. In recent past, our department also procured Cobas 6000 modular system c 501+e601, including stand-alone Cobas e411, to enhance our productivity and efficiency, regarding existing profile volume and TAT. More recently, two of our comparative studies regarding endocrine profile and routine chemistry on two different instruments, the conventional Hitachi 912 and modular Cobas c501, e601 systems, resulted in greater than 90% coefficient relation and regression $R^2$ of > 0.90 [2,3]. The presented research also showed considerable significant linear regression of iron profile output ranging from 0.94 to 0.98, depicting instrument to instrument precision of 94% to 98%. Regarding iron profile, inclusive of iron, TIBC and ferritin, it is an important combo-parameter to assess iron deficiencies, as well as several hematological disorders.

Establishing a precision balance among various instruments, both conventional and modular, in our tertiary care clinical biochemistry laboratory, which caters around 700 samples/patients 24/7, is an advantage for efficient TAT and better, quality assured results. This facilitates the timely diagnosis of patients, and also provides a definite data to ensure medication and further treatments. Previous studies on instrument comparison and assessment of analytical precision regarding Cobas analyzer, reported correlation coefficient of > 0.975 [12] and 0.946 to 0.999 when comparative studies were carried out on Roche E170 modular immunoassay analyzers using Immuno-plus, anemia controls and human pooled sera [13]. Past and recent developments in clinical biochemistry and laboratory medicine also promoted and facilitated the transition of clinical laboratory from traditional conventional instrument to modular system [14], in addition to efforts for integrating the automated analyzers via centralized hospital laboratories, for efficient turn around time and better through-put [15].

## 5. CONCLUSION

The present study described the comparative analysis of analytical precision of iron profile on two instruments, conventional Hitachi 912 and modular Cobas 6000 c501. The results showed appreciable regression $R^2$ correlation of 0.94 to 0.987 depicting efficiency of analytical testing, compatibility and precisions of all three parameters, iron, TIBC and ferritin.

## 6. REFERENCES

1. Mocarelli P, Horowitz GL, Gerthoux PM, Cecere R, Imdahl R, Ruinemans-Koerts J, Luthe H, Calatayud SP, Salve ML, Kunst A, McGovern M, Ng K and Stockman W. Increasing efficiency and quality by consolidation of clinical chemistry and immunochemistry with modular system SWA. **J of Automated Methods and Management in Chemistry**, 2008; 2008: 211-224.
2. Alam JM, Sherwani SK, Hussain A, Matinuddin S, Kausar R, Ahmed A and Ansari MA. Comparative assessment of analytical performance of conventional chemistry analyzer and modular Cobas 6000 system using Routine Chemistry parameters**. Middle-East Journal of Scientific Research,** 2014; 21(8): 1283-1287
3. Alam JM, Sherwani SK, Islam Z, Kausar R, Naureen S and Sultana I. Performance evaluation of thyroid hormones and thyroid stimulating hormones (TSH) assays by conventional and modular electro-chemi Luminescence (ECL) systems. **World Journal of Medical Sciences,** 2014; 11(3): 315-319.
4. Horowitz GI, Zaman Z, Blanckaert NJC, Chan DW, DuBois JA, Golaz O, Mensi N, Keller F, Stolz H, Kinger K, Marocchi A, Precipe L, McLawhon RW, Nilsen OL, Oellerich M, Luthe H, Orsonneau JL, Richeuz G, Recio F, Roldan E, Rymo L, Wicktorsson AC, Welch SL, Wieland H, Grawitz AB, Mitsumaki H, McGovern M, Ng K and Stockman W. Modular analytics: A new

approach to automaton in the clinical laboratory. **Journal of Automated Methods and Management in Chemistry,** 2005; 2005: 8-25.

5. Seaberg RS, Stallone RO and Statland BE. The role of total laboratory automation in a consolidated laboratory network. **Clin Chem.,** 2000; 46: 751-756
6. Mira A and Lehman C. Workflow analysis an international tool: cost reduction while retaining personnel. **Clin Lab Manage Rev.,** 1999; 13(2): 75-80.
7. Dubois S, McGovern M and Ehrhardt V. Eisenstoffwechsel-Diagnostik mit Boehringer Mannheim/Hitachi-Analysen systemen: Ferritin, Transferrin und Eisen. **GIT Labor-Medizin.,** 1988; 9: 468-471.
8. Tiez NW, Rinker AD and Morrison SR. When is a serum iron really a serum iron?, A follow up study on the status of iron measurements in serum. **Clin Chem.**, 1996; 42: 109-111.
9. Ceriotti F and Ceriotti G. Improved direct specific determination of serum iron and total iron binding capacity. **Clin Chem.,** 1980; 26: 327-331.
10. NCCLS evaluation protocols, national Committee for Clinical Laboratory Standards, Villanova, PA USA 1992.
11. Fraser CG, Peterson PH, Ricos C, Haeckel R. **Criteria for imprecision, In: Evaluation Methods in Laboratory Medicine,** Haeckel R, Ed, VCH, Weinheim, Germany 1993; 87-99.
12. Van Gammeren AJ, van Gool N, de Groot MJ and Cobbaert CM. Analytical performance evaluation of the Cobas 6000 analyzer-special emphasis on trueness verification. **Clin Chem Lab Med.,** 2008; 46: 863-871.
13. Wan B, Augustin R, Chan MK, Leblond J, Verjee Z and Adeli K. Analytical performance and workflow evaluation of the Roche E170 modular immunoassay analyzer in a pediatric setting. **Clin Biochem.,** 2005; 38: 262-271.
14. Zima T. Trends in the clinical biochemistry and laboratory diagnostics. **Cas Lek Cesk.,** 2006; 145(7): 522-525