ORIGINAL RESEARCH PAPER

Medical Biochemistry

A STUDY OF VALIDATION OF A NEW BIOCHEMISTRY AUTOANALYZER IN A TERTIARY HEALTHCARE CENTRE

KEY WORDS: Validation, Quality Control, Automation, Autoanalyzer, Biochemistry, Blood tests, EQAS, Westgard.

Prof. (Dr.) Chinmoy Biswas Prof. & HOD, Dept. of Biochemistry, Agartala Govt. Medical College, Agartala.

Dr. Supratim Acharjee* Junior Resident (Academic), Dept. of Biochemistry, Agartala Govt. Medical College, Agartala. *Corresponding Author

Dr. Chayanika Biswas Junior Resident (Academic), Dept. of Community Medicine, Seth GS Medical College, Mumbai.

ABSTRACT

Evidence-based medicine is basically a positivistic, biomedical perspective. Its focus is on offering clinicians the best available evidence about the most adequate treatment for their patients. In the Era of Evidence based Medicine, the Diagnosis & Treatment protocol is largely dependent on the Diagnostic Tests of which a lions part is Biochemical Tests. Due to Automation many companies are coming up with new machines everyday. There lies the importance of Validity of an instrument. Authors planned this study in order to provide the Quality assured biochemical testing by validating the new autoanalyzer by comparing the results with an existing EQAS proven autoanalyzer. Comparative analysis chart of test results obtained by both the instruments were drawn, Comparative analysis was done, Statistical Linear Regression plot & Bland Altman plot were also drawn. 22 Unacceptable values & 18 Acceptable values out of 40 run in BIORAD Control Target Values of 10 Tested Parameters in case of Tested Analyzer. While all 40 are Acceptable values out of 40 run in BIORAD Control Target Values in case of Existing Analyzer obtained. ALT, T. Bilirubin, AST, Creatinine, Triglycerides Showing Negative bias. Glucose Showing Positive bias. Total Protein, Albumin not showing good correlation. ALP Showing High Constant error.

INTRODUCTION

Modern medical care is influenced by Two paradigms: 'evidence-based medicine' & 'patient-centered medicine'. Evidence-based medicine is a rather young concept that entered the scientific literature in the early 1990s. It has basically a positivistic, biomedical perspective. Its focus is on offering clinicians the best available evidence about the most adequate treatment for their patients, considering medicine merely as a cognitive-rational enterprise. Evidence-based medicine owes its rapidly growing popularity to its image of providing the ideal integration of individual clinical expertise and external scientific evidence, offering clinicians the best available evidence about the most adequate treatment for their patients. [1] In the Era of Evidence based Medicine, the Diagnosis & Treatment protocol is largely dependent on the Diagnostic Tests of which a lions part is Biochemical Tests. Due to advancement of Technology, the procedure of testing is shifting toward automation. Due to Automation many companies are coming up with new machines everyday. In Tripura also we can see many laboratories which are opening very often. There lies the importance of Validity of an instrument. Validity is the extent to which the interpretations of the results of a test are warranted, which depends on the particular use the test is intended to serve. [2] Both Internal & External validation maintains this work. External validation is usually done through EQAS (External Quality Assessment Scheme). EQAS helps the laboratories assess their accuracy as well as bias of their results and stability of methods over a longer period of time. [3] Authors planned this study in order to provide the Quality assured biochemical testing by validating the results of serum parameters tested by the new autoanalyzer (here-to-fore referred as 'X') by comparing the results with an existing EQAS proven externally validated autoanalyzer (here-to-fore referred as 'Y'). [4]

Objective

To validate the results of serum parameters tested by the new Fully Automated Biochemical autoanalyzer as per existing Westgard norms.

Methodology

In order to validate the reports by this instrument ('X'), authors conducted a series of test drills from 23rd May to 26th May, 2023 in AGMC Biochemistry Service Lab in GBP Hospital. In this period several parameters were tested as mentioned below in 'X' Full auto Biochemical Analyzer in comparison with the presently running Full Auto Biochemical Analyzer ('Y') of Service Lab AGMC whose Quality Control is maintained both Internally & Externally (EQAS). Tests were done from same samples during the drill in both the instruments respectively & proper documentation done of the findings obtained on four (04) consecutive days. We checked for Blood Glucose, Sr. Creatinine, Total Cholesterol, Triglyceride, Total Bilirubin, AST/SGOT (Aspartate Transaminase), ALT/SGPT (Alanine Transaminase), ALP(Alkaline Phosphatase), Total Protein, Albumin, Uric Acid levels from Patient's serum as well as BIORAD controls. Accordingly Comparative analysis chart of the test results obtained by both the instruments were drawn, Comparative analysis with Internationally accepted Acceptance Limits for Proficiency Testing by Clinical Laboratory Improvement Amendments (CLIA) 2024 was done, Statistical Linear Regression plot & Bland Altman plot were also drawn for drawing inference for each of the tested parameters.

During Four (04) Days of the drills i.e. 23rd to 26th May, 2023, tests were done from the same samples of patient's serum in both the instruments respectively. On the 4th Day of the drill, i.e. on 26/05/23, BIORAD Controls [5] were also run as samples Twice (Two separate runs) & tested in both the machines respectively whose reports & Comparative Data are placed at Table no. 1.

Regression analysis plots & Bland Altman plots are placed at Fig. no. 1 to 5.

RESULTS

1. West Guard / CLIA rules numerical interpretation: (Table No. 01)

Measured Data findings run on 26th May, 2023 in the Two Machines i.e. X & Y in comparison with Control Target Values as per 2024 CLIA Proposed Acceptance Limits for Proficiency Testing [5] shows Unacceptable values of X's reports in the case of BIORAD Control Values [6] in Albumin level 1 (both Runs),

Albumin level 2(both Runs), Creatinine level 1(both Runs), Creatinine level 2(both Runs), ALT level 1(both Runs), ALT level 2(both Runs), Total Bilirubin level 1(both Runs), Total Bilirubin level 2(both Runs),Total Cholesterol level 1(2nd Run), Total Cholesterol level 2(both Runs), Triglyceride level 1 (both Runs),AST level 2 (2nd Run).

While it shows Acceptable values of X's reports in the case of Total Cholesterol level 1 (1st Run), Triglyceride level 2 (both Runs), AST level 1(both Runs), AST level 2 (1st Run), ALP level 1(both Runs), ALP level 2(both Runs), Glucose level 1(both Runs), Glucose level 2(both Runs),Total Protein level 1(both Runs),Total Protein level 2(both Runs).

i.e 22 Unacceptable values & 18 Acceptable values out of 40 run in BIORAD Control Target Values of 10 Tested Parameters in case of X Analyzer.

While all 40 are Acceptable values out of 40 run in BIORAD Control Target Values of 10 Tested Parameters in case of Y Analyzer of Biochemistry Department at AGMC & GBPH.

Comparative data of Two Analyzers for BIORAD control values placed in Table No. 1.

Table No. 1 Findings In 2 Machines In Comparison With Biorad Controls [6] As Per 2024 Clia Proposed Acceptance Limits [5] :

BIORAD	TV (Target Value of BIORAD Control) [6]	2024 CLIA Proposed Acceptance Limits for Proficiency Testing [5]	Report of Y (Reference lab)	Whether Acceptable or Not	Report of X (Tested Analyzer)	Whether Acceptable or Not
Albumin 1	3.94	TV ± 8%	3.80	Yes	4.38	No
			3.80	Yes	4.45	No
Albumin 2	2.68	TV ± 8%	2.60	Yes	3.43	No
			2.60	Yes	3.40	No
Creatinine 1	1.8	TV ± 0.2 mg/dL or ± 10% (greater)	1.85	Yes	2.77	No
			1.85	Yes	2.84	No
Creatinine 2	5.39	TV ± 0.2 mg/dL or ± 10% (greater)	5.63	Yes	5.95	No
			5.63	Yes	5.96	No
ALT 1	26.3	TV ± 15% or ± 6 U/L (greater)	28	Yes	35.01	No
			28	Yes	36.93	No
ALT 2	94.6	TV ± 15% or ± 6 U/L (greater)	107	Yes	126.62	No
			107	Yes	131.42	No
T. Bil 1	1.01	TV ± 20% or 0.4 mg/dL (greater)	1.07	Yes	1.58	No
			1.07	Yes	1.61	No
T. Bil 2	4.48	TV ± 20% or 0.4 mg/dL (greater)	4.8	Yes	5.93	No
			4.8	Yes	5.84	No
Chol. 1	258	TV ± 10%	246	Yes	279.34	Yes
			246	Yes	296.85	No
Chol. 2	99.4	TV ± 10%	97	Yes	114.48	No
			97	Yes	113.2	No
TG 1	198	TV ± 15%	199	Yes	228.77	No
			199	Yes	233.79	No
TG 2	84.6	TV ± 15%	91	Yes	93.78	Yes
			91	Yes	89.43	Yes
AST 1	44.7	TV ± 15% or ± 6 U/L (greater)	44	Yes	44.73	Yes
			44	Yes	49.18	Yes
AST 2	205	TV ± 15% or ± 6 U/L (greater)	216	Yes	233.17	Yes
			216	Yes	239.45	No
ALP 1	128	TV ± 20%	136	Yes	111.12	Yes
			136	Yes	116.15	Yes
ALP 2	522	TV ± 20%	569	Yes	461.92	Yes
			569	Yes	484.97	Yes
Glucose 1	89.1	TV ± 6 mg/dL or ± 8% (greater)	95	Yes	92.73	Yes
			95	Yes	95.78	Yes
Glucose 2	285	TV ± 6 mg/dL or ± 8% (greater)	304	Yes	298.5	Yes
			304	Yes	305.3	Yes
Total Protein 1	6.89	TV ± 8%	7.40	Yes	6.64	Yes
			7.40	Yes	6.77	Yes
Total Protein 2	4.78	TV ± 8%	5.0	Yes	4.72	Yes
			5.0	Yes	4.75	Yes

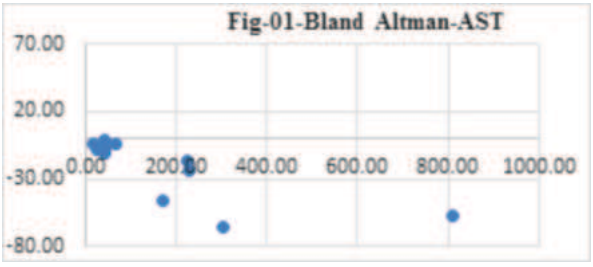
It is also Observed that the measured values of X showing significant difference from the measured values of Y in all the parameters run during the drill in case of samples other than BIORAD controls which are shown in Fig. No. 01 to 05. Hence Statistical analysis was undertaken.

Statistical Interpretation: (Fig. No. 01 to 05)
Linear regression plot analysis was done for analysing & understanding the relationship between the measured values obtained from X & Y. (Fig. No. 4 & 5)

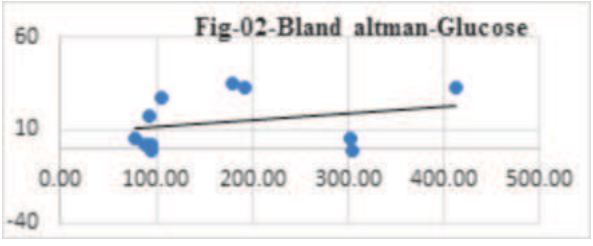
Bland Altman plot analysis was done for assessing the agreement between the measured values obtained from X & Y to provide insight into the magnitude & direction of the differences between the measurements. (Fig. No. 1, 2 & 3)

The Data shows significant difference lies between values of most of the parameters reported from X & Y in statistical interpretation too as follows:

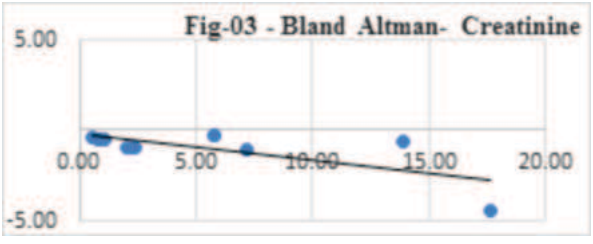
a) ALT (SGPT), T. Bilirubin & AST (SGOT): In Bland Altman plot we get to see there is considerable bias in both the parameters as the cloud of parameters are not equally distributed on two sides of the 0 line. Showing Negative bias. (Fig. No. 01)



b) Glucose: Showing Positive bias (Fig. No. 02)

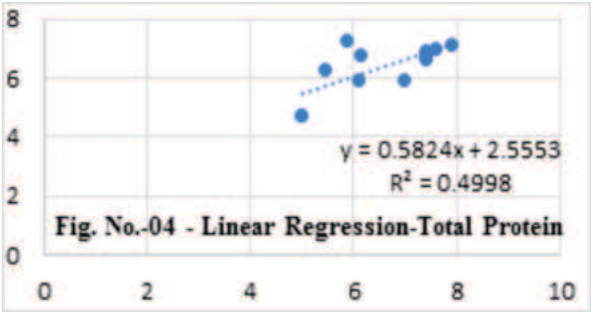


c) Creatinine: Showing Negative bias. (Fig. No. 03)



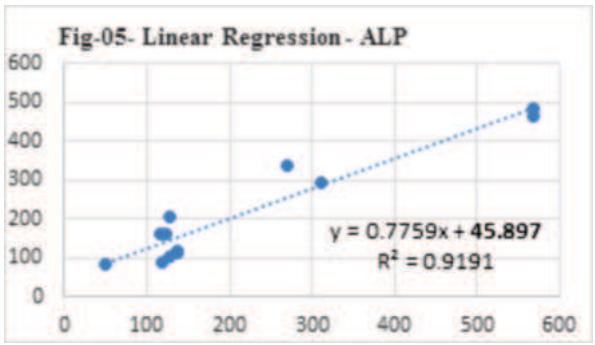
d) Triglycerides: Showing Negative bias.

e) Total Protein: Linear regression is not showing good correlation. (Fig. No. 04)



f) Albumin: Linear regression is not showing good correlation. Albumin showing Negative bias.

g) ALP (Alkaline Phosphatase): Showing High Constant error. (Fig. No. 05)



h) Total Cholesterol: Showing Negative bias.

i) Uric Acid: Number of points inadequate to infer but showing Positive bias.

CONCLUSION

As these days Treatment is based on Diagnosis, so to provide accurate diagnosis we need to maintain the Quality of the Diagnostic Tests. Providing test results of patient's sample parameters based on Quality control testing is the only way to provide quality healthcare to the people. So, for the betterment of the healthcare only the quality controlled validated results of the instruments should be provided to the patients for proper diagnostic assessment to limit the damages due to faulty blood reports. Authors tried to provide the complete analysis of the validation process of the results obtained by the new Biochemistry autoanalyzer in the above study & hoping that their work will aid in improving healthcare facility in their region & also aid in various biochemical laboratories & lab personnels in maintaining & providing quality controlled repots to the people.

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