Innovative Journal of Medical and Health Sciences
Received 5 Mar 2020 | Accepted 1 Apr 2020 | Published Online 13 Apr 2020

DOI: https://doi.org/37149729197
IJMHS 10 (4), 923–929 (2020)

ISSN (O) 2277-4939 | (P) 2589-9341 IF:1.6

ORIGINAL ARTICLE

Evaluation of Validity of New Biochemistry Analyzer ARK Diagnosis FALCON (Mini)

Neelam Gusain[1*] | Anuradha B Patil[2]

[1]Tutor, Department of Biochemistry, Alfalah School Of Medical Science and Research Centre, Haryana, India.

[2]Professor and Head, Department of Biochemistry, KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College, Belagavi, Karnataka, India.

Abstract

Introduction: Medical laboratories provide information and services that contribute to the effective healthcare delivery of the system. Laboratory results permit physicians and different healthcare professionals to make acceptable evidence-based diagnostic or therapeutic decisions for their patients.

Methods: The Clinical Laboratory Standard Institute (CLSI) Guideline was used to determine the efficiency of ARK Diagnosis FALCON mini based on its Precision and Linearity. Glucose and Urea were analyzed, precision was done using three levels of pooled sera twenty sample of each level and for linearity testing done by preparing five different dilutions. The performance of the ARK Diagnosis FALCON mini is compared with manufacture's claim. The results were presented as mean, standard deviation, coefficient of variation (CV %) and correlation coefficient (r) by using SPSS.

Results: For Precision, Calculated CV% of all three levels was within the manufacturer's CV%. The linearity results were also within the allowable range. The performance comparison revealed that the expected value and observed value are comparable, with Correlation coefficients (r) >0.9978 for glucose and urea. Precision and linearity both are within the allowable criteria.

Conclusion: The cross-sectional study conducted to see whether the newly installed analyzer meets the performance criteria. Our results demonstrate that intraassay precision and linearity of the ARK analyzer meets the requirement of laboratory as per the CLSI guidelines. This gives a green signal for installation of the instrument. Maintaining the quality thereafter is another challenge and an ongoing process it should be maintained by internal and external quality control protocol.

Keywords: Validation study, Precision, Linearity, Glucose, Urea, CLSI, CV%.

1 | INTRODUCTION

Medical laboratories provide information and services that contribute to the effective healthcare delivery of the system. Laboratory result enables physicians and other healthcare professionals to make appropriate evidence-based diagnostic or therapeutic decisions for their patients (1). Health care providers expect results that are accurate, obtained in an effective manner, within a suitable time frame and at an acceptable cost. Diagnostic validation may be a formal demand of accreditation standards, including ISO 17025 and ISO 15189, those tests/methods and instruments should be validated before diagnostic use to confirm reliable results for patients, clinicians or referring laboratories and their quality should be maintained throughout its use (2).

The installation of new instruments and methodologies within the clinical laboratory necessitates validation studies (3).

Validation is a concept that has evolved in the United States in 1978 and has expanded through the years to embrace a wide range of activities. Validation is an integral part of current Good Manufacturing Practice (cGMP). The word validation merely means that an assessment of validity or action of proving effectiveness. It is mainly supported by, FDA regulations describing current good manufacturing practice (4).

There are three principles of validation – Instillation qualification (IQ), Operational qualification (OQ) and Performance qualification (PQ). PQ is the process which frequently produces acceptable product under the normal operating condition. There are eleven main principles to the PQ laboratory test validation protocol (5). These are Specificity, Linearity, Accuracy, Precision, Robustness, Range, Limit of detection (LOD), Limit of quantitation (LOQ), Ruggedness, Selectivity and Suitability (6). In our study we tend to evaluate the validation of a new instrument by two important validation parameters Precision and Linearity while others parameters are for method validation.The Precision of an analytical procedure expresses the closeness of agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions (7).

Linearity is the ability to obtain test results, which are directly proportional to the concentration of an analyte in the sample (8)

The ARK Diagnosis FALCON mini fully automated Biochemistry analyzer is a random access, multi-channel and modular-design system with a flexible potential for consolidation designed for laboratories with a high workload. ARK Diagnosis FALCON mini is a fully automated system for various Biochemical test. It has a throughput of up to 200tests/hr. The present study was undertaken to evaluate a new Biochemistry analyzer and see whether it meets the analytical performance criteria based on a validation procedure for precision and linearity by two analyte glucose and urea and compare with manufacturer's claim, which has been studied extensively.

2 | MATERIALS AND METHODS

In our study, we validated ARK analyzer by two validation parameters– Precision and Linearity. We used CLSI EP05-A3 guidelines to assess precision and linearity. By using two biochemistry analytes Glucose and Urea for assessment of validation parameters. Precision verification from 20 pooled sera replicates of urea and glucose

Table 1 Pooled serum sample sufficient to prepare 20 aliquots of 0.5ml of 3 levels, high, normal and low as follows :

TABLE 1: Procedure for preparing aliquots

ALIQUOTS	GLUCOSE LEVEL (mg/dl)	UREA LEVEL (mg/dl)
20	<60(LOW)	<15(LOW)
20	90(NORMAL)	30(NORMAL)
20	>200(HIGH)	>50(HIGH)

Supplementary information The online version of this article (37149729197) contains supplementary material, which is available to authorized users.

Corresponding Author: *Neelam Gusain*
Department of Biochemistry, Alfalah School of Medical Science and Research Centre, Haryana, India
Email: gusainneelam024@gmail.com

2.1 | General procedure for analysis

All the samples were analyzed by using the New Biochemistry fully-automated analyzer ARK DIAGNOSIS FALCON (mini).

2.1.1 | Evaluation of Precision (Intra-assay):

- Collection of 20 high, low and normal concentrations of urea and glucose serum samples
- Glucose and Urea levels were estimated in these samples by kit method in new biochemistry fully automated analyzer
- These samples were pooled and store at -20^{o} C
- 5 samples per day were analyzed so in 4 days 20 samples of high, low and normal concentrations analyzed

2.1.2 | Evaluation of Linerity:

For the linearity testing, we selected an abnormal sample of high concentration and low concentration of Urea and Glucose. Progressively dilute it until it crosses the lower limit of linearity. We prepare different dilution of 1:3, 1:5, 1:10, 1:50 and 1:100.
Urea was estimated by Glutamate Dehydrogenase (GLDH) – Urease method and Glucose by Glucose oxidase - Peroxidase (GOD-POD) method using ARK Diagnosis FALCON mini analyzer. The results were presented as mean, standard deviation, coefficient of variation (CV %) and correlation coefficient (r) by using SPSS.

3 | RESULTS

A cross sectional study was done to evaluate the new biochemistry analyzer for analytical performance by two validation parameters precision and linearity using two analytes glucose and urea. The data obtained from the study was compiled, tabulated and subjected to statistical analysis. The results are presented under the heading of the various parameters considered the study.
The calculated coefficients of variation for normal, low and high urea were close to manufacture's coefficient of variation which was 2.79 and 0.77 for normal and high Urea respectively.Table 2

The calculated coefficient of variation for normal, low and high Glucose were close to manufacture's coefficient of variation which was 0.59 and 0.48 for normal and high Glucose respectively.Table 3

The calculated coefficient of variation for normal, low and high Glucose were close to manufacture's coefficient of variation which was 0.59 and 0.48 for normal and high Glucose respectively. Table 4Table 5Table 6 and Table 7

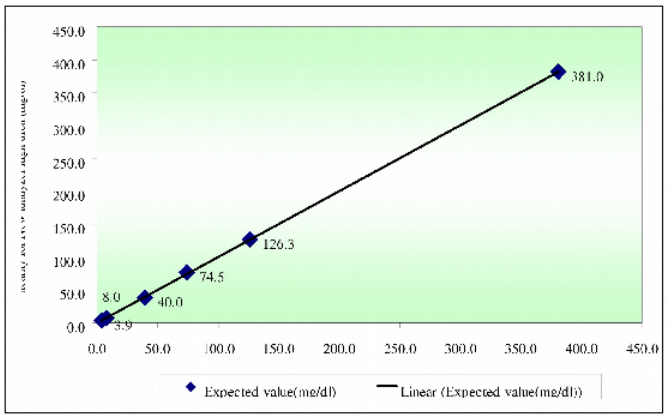

FIGURE 1: Scatterplot of linearity for new analyzer High Urea value (mg/dl). This graph Figure 1shown X and Y have a strong positive linear correlation, r value is exactly +1 indicate a perfect positive fit.

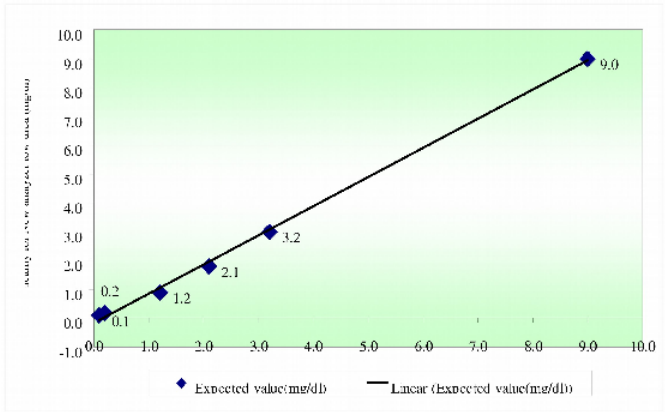

FIGURE 2: Scatter plot of linearity for new analyzer Low Urea value (mg/dl). Figure 2 The corelation co-efficient shows a strong positive linear correlation,which is r=0.9982.

TABLE 2: Comparison of Manufacturer's coefficient of variation with study coefficient ofvariation in normal, high and low urea within-run precision.

Summary	Normal Urea within run	High Urea within run	Low Urea within run
Min	21.0	124.1	8.2
Max	23.4	127.9	8.9
Mean	21.9	125.9	8.4
SD	0.60	0.99	0.22
CV%	2.74	0.78	2.70
Manufacturer's coefficient of variation	**2.79**	**0.77**	

TABLE 3: Comparison of Manufacturer's coefficient of variation with study coefficient ofvariation in normal, high and low glucose within-run precision.

Summery	Normal glucose within run	High glucose within run	Low glucose within run
Min	95.8	265.4	48.2
Max	97.9	269.4	49.6
Mean	96.8	267.3	48.7
SD	0.58	1.38	0.43
CV	0.60	0.51	0.89
Manufacturer's coefficient of variation	**0.59**	**0.48**	

TABLE 4: Linearity Range of High Urea

SERIAL NO.	DILUTION	OBSERVED VALUE	EXPECTED VALUE	RECOVERY(%)
1	Undiluted	381.8	381.8	100
2	1:3	126.3	127.2	99.2
3	1:5	74.5	76.36	97.5
4	1:10	40	38.18	104.7
5	1:50	8	7.63	104.8
6	1:100	3.9	3.81	102.6
Mean recovery percentage				101.4
SD				3.02

4 | DISCUSSION

The clinical laboratory has a central role to give an accurate and acceptable patient result. The installation of a new instrument and methodologies in clinical laboratory require validation studies to ensure that the new instrument will give acceptable standards of performance. Validation aims to establish evidence that provides a high degree of assurance that the machine accomplishes its intended requirements. In our study, we validated new Biochemistry analyzer by two validation parameters– Precision (intraassay) and Linearity. We used CLSI EP05-A3 guidelines to assess precision and linearity.

TABLE 5: Linearity Range of Low Urea

SERIAL NO.	DILUTION	OBSERVED VALUE	EXPECTED VALUE	RECOVERY(%)
1	Undiluted	9	9	100
2	1:3	3.2	3	106
3	1:5	2.1	1.8	116.6
4	1:10	1.2	0.9	133
5	1:50	0.2	0.18	111
6	1:100	0.1	09	111
Mean recovery percentage				112.9
SD				11.3

TABLE 6: Linearity Range of High Glucose

SERIAL NO.	DILUTION	OBSERVED VALUE	EXPECTED VALUE	RECOVERY(%)
1	Undiluted	500	500	100
2	1:3	170.1	166.6	102.1
3	1:5	120.8	100	120.8
4	1:10	46	50	92
5	1:50	11	10	110
6	1:100	4.9	5	98
Mean recovery percentage				103.8
SD				10.1

TABLE 7: Linearity Range of Low Glucose

SERIAL NO.	DILUTION	OBSERVED VALUE	EXPECTED VALUE	RECOVERY(%)
1	Undiluted	40	40	100
2	1:3	14	13.3	105.2
3	1:5	8.5	8	106
4	1:10	4.2	4	105
5	1:50	1	0.8	125
6	1:100	0.5	0.4	112.5
Mean recovery percentage				108.9
SD				8.8

We used two Biochemistry analytes Glucose and Urea for assessment of validation parameters. Precision verification from 20 pooled sera replicates of urea and glucose.Urea (intraassay) gave a co-efficient of variation (CV %) of normal urea-2.74 , high urea- 0.78 and low urea – 2.70 which comparable with manufacturer's CV%- Normal urea-2.79 and high urea- 0.77 which is under acceptable range.Glucose (intraassay) gave a co-efficient of variation (CV %) of normal glucose-0.60, high glucose- 0.51 and low glucose- 0.89 comparable with manufacturer's CV % of normal glucose -0.59 and high glucose-0.48which is close to obtained CV%.

The linearity evaluation was performed according to the CLSI guideline EP6-A. Linearity provides information about the precision of assay results for samples tested at different levels of dilution in the chosen sample diluents. The recovery for the ob-

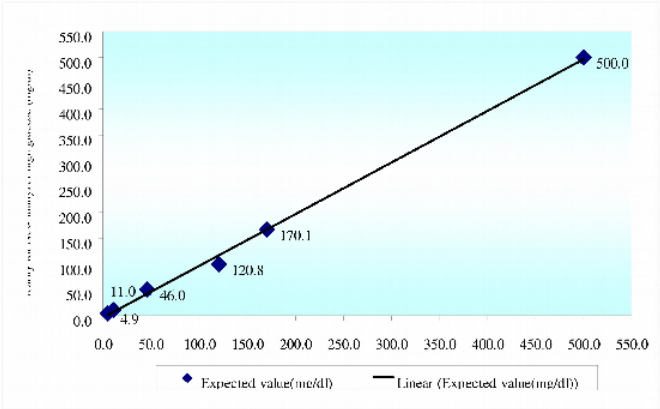

FIGURE 3: Scatter plot of linearity for new analyzer High glucose value (mg/dl). Figure 3 The corelation co-efficient shows a strong positive linear correlation,which is r=0.9978.

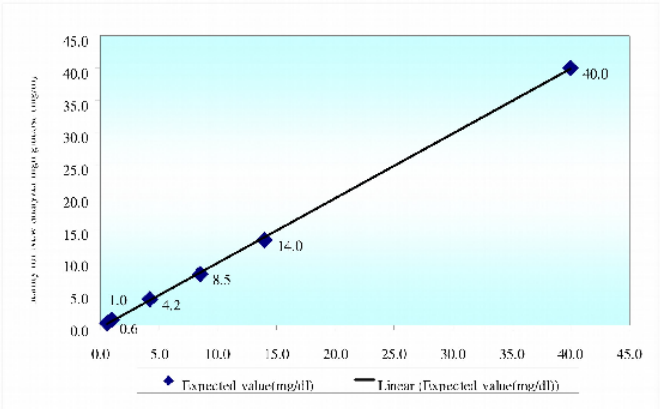

FIGURE 4: Scatter plot of linearity for new analyzer low glucose value (mg/dl). Figure 4 The corelation co-efficient shows a strong positive linear correlation,which is r=0.9998.

served value is identical to recovery obtained for the analyte prepared in standard diluents. The linearity results obtained for urea and glucose are acceptable because there was no significant difference in the performance expected value and the observed value from new analyzer. Recovery too was within an acceptable limit (90-120%), with y= 1.0x-0.027 and r – 1of high urea, y= 0.988x+0.18 and r– 0.99 of low urea, y= 0.997x+3.90 and r– 0.99 of the high glucose and y= 0.995x+0.32 and r- 0.99 of low glucose between expected and observed values.

The ARK Diagnosis FALCON (mini) analyzer performs well with regard to its precision and linearity for glucose and urea.

5 | CONCLUSION

The cross-sectional study conducted to see whether the newly installed analyzer meets the performance criteria. Our results demonstrate that intraassay precision and linearity of the ARK analyzer meets the requirement of laboratory as per CLSI guidelines .This gives a green signal for installation of the instrument. Maintaining the quality there after is another challenge and an ongoing process should be maintained by internal and external quality control protocol.

ORCID

Gusain Neelam https://orcid.org/0000-0002-6960-8431

REFERENCES

1. Abebe N. Analytical Evaluation of the Clinical Chemistry Analyzer AU 480 Beckman Coulter. European Journal of Clinical and Biomedical Sciences. 2016;2(6):59–62.
2. Álvarez SI, Andreu FA. Procedures for validation of diagnostic methods in clinical laboratory accredited by ISO 15189. Modern Approaches to quality control. 2011;.
3. Hartmann AE. Validation Protocol for New Methods or Instruments in the Clinical Laboratory. Oxford University Press (OUP); 1983. Available from: https://dx.doi.org/10.1093/labmed/14.7.411. doi:10.1093/labmed/14.7.411.
4. Ahir KB, Singh KD, Yadav SP, Patel HS, Poyahari CB. Overview of validation and basic concepts of process validation. Sch Acad J Pharm. 2014;3:178–90.
5. Quality System Regulation Process Validation-FDA;.
6. Das B. Validation protocol: first step of a lean-total quality management principle in a new laboratory set-up in a tertiary care hospital in India. Indian Journal of Clinical Biochemistry. 2011;26(3):235–278.

7. Guideline IH. Text on validation of analytical procedures. In: International Conference on Harmonization; 1994. p. 1–5.

8. Moffat AC, Trafford AD, Jee RD, Graham P. Meeting the International Conference on Harmonisation's Guidelines on Validation of Analytical Procedures: Quantification as exemplified by a near-infrared reflectance assay of paracetamol in intact tablets The opinions expressed in the following article are entirely those of the authors and do not necessarily represent the views of either The Royal Society of Chemistry or the Editor of The Analyst. Analyst. 2000;125(7):1341–51.

How to cite this article: Gusain N., Patil A.B. Evaluation of Validity of New Biochemistry Analyzer ARK Diagnosis FALCON (Mini). Innovative Journal of Medical and Health Sciences. 2020;12−17. https://doi.org/37149729197