

Evaluating the accuracy and precision of glucose measurement results in some government medical laboratories in eastern Libya

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Abstract:

In a clinical laboratory, quality control is essential for verifying test results are reliable and have appropriate levels of precision and accuracy. It is well recognized that laboratory analysis influences over 70% of medical decisions made regarding patient care. An internal quality control procedure verifies that the test produces consistently reliable results on a daily basis.

Objective of this study to evaluate how implementing internal quality control affected test result accuracy and precision in the clinical labs in east Libya.

Material and methods: The control serum is lyophilized serum containing component concentrations suitable for clinical laboratory quality control and known concentrations for each laboratory analysis. Test, like a glucose test, to evaluate the pipettes, reagents, or lab equipment. The test findings are then compared using the known concentration of control sera in accordance with the internal quality control system. Levey and Jennings Chart and Westgard Rules.

Stabilized control sera with established concentrations (both normal and pathological) were employed in the laboratories of ten government hospitals in east Libya, which received every day one aliquot container sample of control sera normal and one aliquot container of pathological for fifteen days. The total number of samples was 300 (150 normal and 150 pathological) for the investigation in order to assess precision and accuracy. Additionally, questionnaires were used to evaluate internal quality control procedures.

Keywords: Laboratory Quality Control, Levey and Jennings Chart, Westgard Rules, East Libya.

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تقييم مدى دقة وصحة نتائج قياس الجلوكوز في بعض المختبرات الطبية الحكومية بشرق ليبيا

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الملخص

في المختبرات السريرية، تعد مراقبة الجودة أمرًا ضروريًا للتحقق من أن نتائج الاختبار موثوقة ولها مستويات مناسبة من الدقة والصحة. ومن المعروف أن التحليل المختبري يؤثر على أكثر من 70% من القرارات الطبية المتخذة فيما يتعلق برعاية المرضى. يتحقق إجراء مراقبة الجودة الداخلي من أن الاختبار ينتج نتائج موثوقة باستمرار على أساس يومي. الهدف من هذه الدراسة هو تقييم مدى تأثير تطبيق مراقبة الجودة الداخلية على دقة نتائج الاختبار وإحكامها في المختبرات السريرية في شرق ليبيا.

المواد والطرق: مصل التحكم هو مصل مجفف بالتجميد يحتوي على تراكيز مكونات مناسبة لمراقبة الجودة في المختبرات السريرية والتركيزات المعروفة لكل تحليل مختبري. مثل اختبار الجلوكوز، لتقييم الماصات أو الكواشف أو معدات المختبر. ثم تتم مقارنة نتائج الاختبار باستخدام التركيز المعروف لأمصال المراقبة وفقًا لنظام مراقبة الجودة الداخلي. مخطط ليفي وجينينغز وقواعد ويستغارد.

تم استخدام أمصال المراقبة المستقرة ذات التركيزات المحددة (سواء الطبيعية أو المرضية) في مختبرات عشرة مستشفيات حكومية في شرق ليبيا، والتي كانت تستقبل كل يوم عينة واحدة من الأمصال التحكم العادية واحدة من الأمصال المرضية لمدة خمسة عشر يومًا. وكان العدد الإجمالي للعينات 300 (150 طبيعية و150 مرضية) للتحقيق من أجل تقييم الدقة والصحة. بالإضافة إلى ذلك، تم استخدام الاستبيانات لتقييم إجراءات مراقبة الجودة الداخلية.

الكلمات المفتاحية: مراقبة جودة المختبرات، مخطط ليفي وجينينغز، قواعد وستغارد، شرق ليبيا.

Introduction

The provision of high-quality medical laboratory services is essential to improving the diagnostic value and saving lives. This is because disease control and prevention are predicated on the detection of disease. [1] As a result, the way laboratory services are provided varies depending on the nation. The World Health Assembly asked the World Health Organization (WHO) to create a program for diagnosis at primary health care institutions in poor nations in 1979 as a solution to this difficulty Labs must adhere to the set standards for quality control of test procedures; this includes meeting any manufacturer's criteria as well as the minimum necessary quality control [2].

For the purpose of disease monitoring and diagnosis, high-quality laboratory services are a crucial component of health care delivery. However, because many developing nations are unaware of the importance of laboratory services, these facilities suffer from a lack of funding, inadequate management, inefficient operations,[3] inadequate quality control systems, a lack of quality assurance procedures, inadequate training, and low employee enthusiasm. [4,5] For health laboratories, achieving, maintaining, and enhancing accuracy, timeliness, and dependability are significant difficulties. As doctors rely more and more on clinical chemistry testing to provide accurate diagnoses, clinical chemistry laboratories are becoming more and more important in the medical field. As a result, the quality of clinical chemistry labs cannot be compromised, particularly in the modern world when the development of advanced gear and analytical techniques has made laboratory testing incredibly straightforward. If such quality standards are upheld by any laboratory, they will not only immediately help patients but also provide a significant boost to the laboratory. [4] Ensuring the traceability of analytical data is a common requirement for all laboratories; this can only be accomplished with effective internal quality control and external quality evaluation procedures. [5] Therefore, it should come as no surprise that the International Standards Organization (ISO) has mandated that all laboratories providing testing services adhere to IQC and EQA. [4,5]

Internal quality control, or IQC, was first employed by the World Health Organization (WHO) in 1981. It was described as "a set of procedures for continuously assessing laboratory work and the emergent results." IQC, or identification of precision and accuracy, is the process of internally verifying that a test produces consistent results every day. "The laboratory shall design IQC systems that verify the attainment of the intended quality of results," according to ISO15189. Periodically practicing IQC is recommended for both routine analytical runs and—most importantly—whenever new equipment or methods are to be evaluated or employed. Calibration, control and reference material measurements, within-run precision measurements, control chart use, and the interpretation of simple statistics are examples of basic IQC procedures. [6,7]

The utilize of factual apparatuses gives a visual implies to get it quality control information so that opportune activity can be taken when methods issues are detected. [8]

In the 1990s, there was a widespread belief that research institutions should focus more on pre- and post-analytical quality because analytical quality was not an issue.[9] Westgard calls this notion a fallacy that has never been verified and contends that analytical quality control is the first step in effectively managing and monitoring mistakes across the entire clinical laboratory testing process. [10]

When combined, IQC and EQA offer a way to guarantee the consistency and accuracy of data and are essential instruments in the lab. EQA is a valuable addition, when it comes to IQC, many laboratories are given the same materials and asked to submit their findings to a coordinating center. The results are then compared to ascertain each laboratory's level of accuracy. Furthermore, EQA offers ongoing training and instruction for laboratories. To the greatest extent feasible, EQA ought to

encompass the full suite of tests as well as the examination procedure, from sample receipt, preparation, and analysis to reporting and interpretation. [11]

Internal laboratory comparison, or EQA, is a useful indicator of laboratory performance and offers the ideal platform for laboratory monitoring. EQA, also known as internal laboratory comparison, offers the ideal platform for laboratory monitoring and serves as a reliable indicator of the effectiveness, competency, and proficiency of a laboratory. In order to achieve a between-laboratory and between-methods agreement, further objectives of EQA include identifying internal laboratory discrepancies and evaluating a reference material's suitability for use in a test or procedure. One or more of the four types of EQA studies—method evaluation, competence, certification, and proficiency testing studies—may be used, depending on the size of the EQA scheme and the specific goals selected.[12]

In an effort to raise laboratory standards throughout Africa, the World Health Organization's Regional Office for Africa (WHO AFRO) implemented a step-by-step accreditation process in 2008.

Limited quality assurance and control protocols are one of the issues African clinical chemistry laboratories face, according to a very recent publication by the WHO's African Health Monitor (2010). The publication even suggested creating a "National Public Health Reference Laboratory" as a solution. We have seen inadequate quality control procedures in our labs since there was very little IQC and very little EQA. [13] The current study focuses on evaluating the use and implementation of internal quality control in laboratories by used known concentration control sera.

Westgard Rules

Are multirule QC rules to help analyze whether or not an analytical run is in control or out-of-control. To determine whether an analytical run is in control or out of control, multirule quality control employs a combination of decision criteria, or control rules. [14] Six distinct control criteria are used by the well-known Westgard multirule QC technique to determine whether an analytical run is acceptable. [15] A single criterion or set of control limits, on the other hand, is used in a single-rule QC approach. [16] An example of this would be a Levey-Jennings chart with control limits set as the mean plus or minus

two standard deviations (2s) or the mean plus or minus threes. [17] "Westgard rules" are appropriate when two separate control materials are measured one or two times per material, as is the case in many chemistry applications. [18] Generally, they are employed with two or four control measurements each run. [19] A few substitute control guidelines are more suitable when three control materials are analyzed, which is common for applications in haematology, coagulation, and immunoassays. [20]

In Westgard rules, certain control rules or decision criteria are abbreviated with a short hand notation. For example, 1_{2s} is used to indicate that one control measurement exceeds the 2-stander limit. [14] Table 1 Shows the common Westgard rules with figurs: [14, 15, 16].

	Table 1. Common Westgard rules.					
Rule	Criteria	Figure				
1 _{3s}	When a single control measurement is greater than the mean plus 3s or the mean minus 3s control limit, a run is rejected	+3s +2s +1s Mean -1s -2s -3s 1 2 3 4 5 6 7 8 9 10				
1 _{2s}	When the control limits are set as the mean plus/minus 2s, this rule serves as a warning rule, causing the subsequent rejection rules to carefully examine the control data	+3s +2s +1s Mean -1s -2s -3s -1 2 3 4 5 6 7 8 9 10				
2 _{2s}	When two consecutive control measures surpass the same mean plus 2s or the same mean minus 2s control limit, the 2 _{2s} reject is triggered	+3s +2s +1s Mean -1s -2s -3s 1 2 3 4 5 6 7 8 9 10				

Table 1: Common Westgard rules.

4s	Reject a group if one control measurement surpasses the mean plus two standard deviations and another surpasses the mean minus two standard deviations.	+3s +2s +1s -1s -2s -3s -1 2 3 4 5 6 7 8 9 10
4 _{1s}	Reject when 4 consecutive control measurements exceed the same mean plus 1s or the same mean minus 1s control limit.	+3s +2s +1s Mean -1s -2s -3s 1 2 3 4 5 6 7 8 9 10
10x ,8x	Reject when 10 or 8 consecutive control measurements fall on one side of the mean.	+35 +25 +15 Mean -15 -25 -35 1 2 3 4 5 6 7 8 9 10

Material and methods

Between January and March of 2024, ten hospitals in east Libya's medical laboratories hosted a cross-sectional laboratory investigation that was descriptive in nature. A questionnaire was used to gather data, and it contained personal information, internal quality control information, and multiple control sera. Lyophilized serum of known concentration was prepared and then split into two aliquot containers, one labeled "Normal" (containing 84.7 mg/dl of glucose target value) and the other labeled "Pathological" (274 mg/dl of glucose target value). The samples were then sent to labs for glucose analysis. For a period of fifteen days, one aliquot container sample of normal control sera and one aliquot container sample of pathological sera were sent daily to the ten medical laboratories that were part of this investigation. The total quantity of samples was 300 sample (150 Normal, 150 Pathological).

Levey & Jenning chart, Westgard Rules, and internal quality control procedures are followed when comparing the test results in the laboratory to the known concentrations (glucose=84.7 mg/dl & 274 mg/dl) of control sera.[21] The control serum is a lyophilized serum that has component concentrations appropriate for clinical laboratory quality control. These concentrations are known for each analysis in a clinical laboratory test, such as a glucose test to assess the pipettes, reagents, and equipment used in the lab. To keep an eye on the clinical laboratory's test capability as well as the precision and accuracy of the measurement system, multiple control sera are employed.

Preparation of multi-control sera

The vial containing the multicontrol sera was taken out of the freezer and allowed to come to room temperature by Choose Wood LC. Make sure the lyophilized material is at the bottom of the vial by gently tapping the vertically positioned vial. After that, the rubber and screw cap was carefully removed to prevent any lyophilizate loss. Reconstituted by carefully and precisely adding 5.0 ml of distilled or deionized water to the vial's side. After that, gently replace the rubber stopper, and allow it to stand at room temperature for half an hour. made certain that the lyophilizate's constituent parts had all dissolved. Foam formation is prevented. Pour the necessary amount into the sample cup, then do the QC test you asked for or have it examined similarly to the same way as patient samples. [22]

Storage and stability: If the control is kept in an unopened vial at 2–8°C and shielded from light, it remains stable until the date specified on the label. When the note is in use, please store the control tightly capped after reconstitution. The control should not be re-frozen once it has thawed to room temperature. [22]

Assay value: The value sheet contains a list of the control assay values (the goal value and range) that were established using the routine method and the Mindray standard transfer procedure. The range was computed as the target value (±3**SD**) standard deviations, and the target value was

acquired from the Mindray measurement system. The control settings are unique for various chemical analyzer models and lot numbers. [22,23]

Interpretation of quality control: The control result needs to fall within the specified range as stated on the manufacturer's control value sheet. The measurement system needs to be examined, and any necessary remedial action needs to be put into place, if the control result is outside of the acceptable range.

Statistical analysis: Internal quality control data as well as personal information were gathered through the use of a questionnaire. Microsoft Excel 2010 (Redmond, USA) for Windows and the statistical software for social sciences (SPSS) version 25 were used for the analysis. We computed the mean, standard deviation, and coefficient of variation.

Results and discussion:

In this study, two levels of control sera—Normal and Pathological—lyophilized serum with known concentration. Aliquot containers were used to separate the prepared sera. Assigned the labels "Normal" (containing glucose goal value of 84.7 mg/dl) and "Pathological" (247 mg/dl). The study's populations consisted of ten laboratories.

For fifteen days, the medical laboratory in east Libya receives a daily delivery of control sera to be evaluated for the sole parameter glucose (mg/dl) run as a sample. In order to evaluate the pipettes, reagents, and instruments which are used in clinical laboratory tests, the control sera include components at concentrations suitable for clinical laboratory quality control, with known quantities for each analyte in clinical laboratory testing.

Table 2 demonstrated that head managers required further training in quality control (60%) and that they must be knowledgeable about evaluating technicians and staff members inside the laboratory (60%) as not all of the laboratories chosen for this study had assessment techniques.

Regretfully, however, 80% of these labs displayed poor application of a quality handbook.

Eighty percent of laboratories did not have an internal quality control program, according to the results, and no one was in responsibility of internal quality.

Only 20% of laboratories had standard operating procedures for some tests, and only 20% of laboratories inspected the internal quality control sample at least once a month, indicating that not all laboratory tests had SOPs. The study conducted by Neumaier et al. (2000) [24], & Younis OY, et al. (2019) [26] yielded similar results to this issue, with 80% of the participants not using a control chart.

Most of the laboratories (40%) were poor applying to quality for calibration of automatic pipette upon purchase and (80%) of laboratories do not recalibration of pipettes after a period of operation and this agree with Neumaier et al. (2000) [24], Afrifa (2012) [25] & Younis OY, et al. (2019) [26] and finding showed all of the laboratories in this study are spectrophotometers used.

Variables	Yes	No
Are there training courses in quality control?	40%	60%
Does the laboratory have an administrative structure?	40%	60%
Is there a system in place at the laboratory to assess worker performance?	40%	60%
Is there a book on quality control in the lab?	20%	80%
Is there an internal quality control program?	20%	80%
Is an internal auditing team in place?	40%	60%
Do all tests conducted in the laboratory adhere to SOPs?	20%	80%
Before any examination, is the internal quality control sample examined every day?	20%	80%
Exists an internal quality control table, or control chart?	20%	80%
Exist written policies or procedures regarding the acquisition of lab solutions?	0%	100%
Exists a mechanism to manage the supply of chemicals and lab solutions?	0%	100%
Is the instrument calibrated when you buy?	0%	100%
When a "automatic pipette" is purchased, is it calibrated?	40%	60%
After some use, does the automatic pipette require recalibration?	20%	80%
Type of instruments used in laboratories :spectrophotometer	100%	0%

Table2: Data analysis for laboratory managers.

Table 3 revealed that four laboratories (lab4 to lab7) had mean & \pm SD lower than the target (had mean \pm SD = 84.7 \pm 8.5). Additionally, it was demonstrated that the same four laboratories had lower pathological control sera means (mean \pm SD=274 \pm 27) and that lab 10 had a mean \pm SD higher than the target.

The CLIA-88 proficiency testing requirements for acceptable performance for glucose have established 10% as the medically permissible tolerance. The parameters that showed a significant variance in the sigma (SD) values for the two QC levels have to be assessed cautiously. Reevaluating the process is necessary.[27] Based on this low (CV% of 5% or less generally good technique performance, whereas CVs of 10% and greater show unsatisfactory performance), the CV% in all laboratories is evaluated.[28]

Coefficients of variation (CV%) for most of the glucose from the laboratories were above10%. Except one laboratory in normal control (lab1) and in pathological control sera three laboratories (lab1, lab 9 & lab 10) were below 10%. This means finding all laboratories generally bad method performance.[28]

		Normal	Control	Ē	Pathological Control			
Lab No	Mean	SD	Target Mean	CV%	Mean	SD	Target Mean	CV%
Lab 1	87.67	7.97		9.09	255.13	19.60		7.68
Lab 2	91.11	11.63		12.77	259.87	35.40		13.62
Lab 3	85.80	11.11		12.95	296.80	78.99		26.61
Lab 4	75	8.91		11.88	232.73	30.79		13.23
Lab 5	59.60	20.37		34.18	222.67	32.01		14.09
Lab 6	59.63	20.73		34.59	220.67	31.10		14.09
Lab 7	74.27	7.50	84.7 + 8.5	10.09	241.93	38.28	274+27	15.82
Lab 8	81.47	14.72	00.0	18.07	293.77	18.17		6.18
Lab 9	84.22	17.63	-	20.93	260.67	26.53		10.18
Lab 10	84.33	14.24		16.88	308.67	28.14		9.12

Table 3: The SD and CV% for both normal and pathological	control sera were determined using
laboratory values.	

Every laboratory had a systematic error, as Table 4 demonstrates. If the test value is less than the real value, it is indicated by the sign. Concurring to the Levey and Jenning chart of quality control, the laboratory results were considered exact in case the distinction between each reading and the other did not surpass \pm 2SD. Accuracy is typically reported as a percent difference. This fact clarified that, while the results for the two laboratories testing normal control sera (labs 5 and 6) were accurate within \pm 2SD; this could be because the pipettes were handled improperly or the calibration was not done correctly. [25]

As a result, the more precise the results are, the smaller the difference between the values. This fact suggests that some laboratories were not precise, such as (lab 2, lab 5 & lab 6 for normal control sera) and (lab 3, lab 5m, lab 6, lab 8, & lab 10 for pathological control sera). This could be because of poor instrument maintenance, which affects the final result. Therefore, laboratory equipment used in clinical chemistry analysis frequently contributes to maintaining good accuracy and precision.

It is to be expected that there can be issues with the precision and accuracy of the measurements made in these laboratories. [30] (see Figure 1 A&B).

	Normal	Control	Pathological Control		
Lab No	Accuracy %	Precision	Accuracy %	Precision	
Lab 1	4	3	-7	-19	
Lab 2	8	6	-5	-14	
Lab 3	1	1	8	23	
Lab 4	-11	-10	-15	-41	
Lab 5	-30	-25	-19	-51	
Lab 6	-30	-25	-19	-53	
Lab 7	-12	-10	-12	-32	
Lab 8	-4	-3	7	20	
Lab 9	-1	0	-5	-13	
Lab 10	0	0	13	35	

Table 4: The Accuracy and precision for both Normal and pathological control sera.









Figure 2 A & B (N and P) shows the results of Laboratory 1 in measuring the control samples at the normal level and the pathological level. Evaluation of the Westgard rules showed acceptance of these results.



Figure 2(A): Glucose test results for lab 1 (normal control sera).



Figure 2 (B): Glucose test results for lab 1 (pathological control sera).

Figure 3(A)& (B) showed the Glucose results of lab 2 which in days 11 of normal control sera and in day 6 of pathological control sera exceeded ±2SD (Rule:1/2s) warning rule, Patient results are acceptable.



Figure 3A: Glucose test results for lab 2 (normal control sera).



Figure 3 (B): Glucose test results for lab 2 (pathological control sera).

Figure 4 A& B (N and P) shows the results of Laboratory 3 in measuring the control samples at the normal level and the pathological level. Evaluation of the Westgard rules showed acceptance of these results.



Figure 4 A: Glucose test results for lab 3 (normal control sera).



Figure 4 (B): Glucose test results for lab 3 (pathological control sera).

Figure 5 A (N) shows the results glucose control sera of Laboratory 4 at the normal, which showed accurate and precision results, but the Glucose results of pathological sera (Fig 5 B) in days 4 exceeded ±2SD (Rule:1/2s) warning rule, Patient results are acceptable.



Figure 5 (A): Glucose test results for lab 4 (normal control sera).



Figure 5B: Glucose test results for lab 4 (pathological control sera).

Figure 6 (A) (N), showed 4 consecutive results from day 1 to the day 4; day 8 and day 11, 12 and 14 which exceeded ±3SD this is a "rejection rule,". Also Fig 5 B(P) show exceeds control sera results - 3SD, which is sensitive to efficient errors. Quiet results are not satisfactory and ought to be reanalyzed after remedial activity has illuminated the issue. The taking after likely causes inappropriate procedure when dealing with the quality control, dishonorable capacity temperature redress of the quality control results and lacking support of the instrument.



Figure 6A: Glucose test results for lab 5 (normal control sera).



Figure 6B: Glucose test results for lab 5 (pathological control sera).

Figure 7 A (N), showed Day 3, 7, 8 and9 exceeded \pm 3SD this is a "rejection rule," which is touchy to systematic mistakes. Quiet comes about are not worthy and ought to be re-analyzed after remedial activity has illuminated the issue. The taking after plausible causes inappropriate procedure when dealing with the quality control, inappropriate capacity temperature rectification of the quality control comes about and lacking upkeep of the instrument.



Figure 7A: Glucose test results for lab 6 (normal control sera).

Figure 7 B(P) appeared days 2, 4, 8 and 14 surpassed \pm 2SD, control comes about has surpassed the set-up mean +/- 2SD range. This is often a "warning rule," which does not show an "out-of-control" condition, but is expected to start to assist testing Understanding comes about are worthy, no remedial activity is required.



Figure 7B: Glucose test results for lab 6 (pathological control sera).

Figure 8 A (N) shows that the control sera on day 15 exceeded the permissible limit of +2 SD (rule 12, warning rule), and It is necessary to know why the error occurred. The results must be accepted and this function series must not be rejected (running).



Figure 8 A: Glucose test results for lab 7 (normal control sera).

Figure 8 B(P) appeared day 9 and10,12 and 13 two tests come about surpass the mean with a 3standard deviation. This is often a "rejection rule," which is delicate to irregular mistake. The analyzer is "out-of-control." Quiet comes about are not satisfactory and ought to be re-analyzed after remedial activity has illuminated the issue. Too appeared day 13 surpassed -3SD rejection run the show.



Figure 8 B: Glucose test results for lab 7 (pathological control sera).

Figure 9 A (N) shows the reason of rejected the run, which the control sera on day 4 and 10 exceeded the limit of ± 3 SD. (1 3s Rule) This rule states that: If one of the levels of the two controls used is outside the limits of ± 3 SD. This rule indicates the presence of a random error. It indicates the beginning of a large systematic error. In this case, it rejects the run (Rejection Run) and performs a corrective action. At the same time, Figure 9 B (P) shows the acceptance of pathological control sera results of laboratory No. 8.



Figure 9 A: Glucose test results for lab 8 (normal control sera).



Figure 9 B: Glucose test results for lab 8 (pathological control sera).

Figure 10 A (N) shows the rejection of the results of the control samples for the following reasons: the presence of the control samples for days 6, 11, and 15 outside the control (+3SD). The second reason is the presence of the control point 6 at (-3SD), and the presence of the next point at (+2SD) (the difference in two SD successive values that exceed 4. Figure 10 B (P) shows the acceptance of the results of pathological control sera.



Figure 10A: Glucose test results for lab 9 (normal control sera).



Figure 10 B: Glucose test results for lab 9 (pathological control sera).

Figure 11 A(N) shows the presence of the control samples for day 1 outside the control (+3SD). Figure 11 B (P) shows the acceptance of the results.



Figure 11 A: Glucose test results for lab 10 (normal control sera).



Figure 11 B: Glucose test results for lab 10 (pathological control sera).

Conclusion:

Using known concentrations of control sera, the application and practice of internal quality control in laboratories was evaluated and assessed. Internal quality control can be used in clinical laboratories to improve test results' reliability and precision, which could lead to better diagnosis and treatment as well as improved public health in underdeveloped nations. Additional research ought to be carried out in the field of study, and all Libyan laboratories must employ control sera, control charts, and SOPs. And follow up on quality because the study revealed that there is a significant weakness in the accuracy and validity of the results.

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