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Abdalla Eltoum Ali
Department of Clinical Chemistry.
Faculty of Medical Laboratory Sciences.
Alzaiem Alazhari University. Khartoum, Sudan
Email: Abouali20@yahoo.com

QR Code for Mobile users

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Assessment Criteria for Accreditation of Government Hospitals' Laboratories in Sudan according to the international standards. Khartoum State – Sudan.

Abdalla Eltoum Ali*[1], Mohammed Ahmed I Holi[2], Mohammed M. Osman[3], Salah Abdelgader Elmahadi [4]

[1].Department of Clinical Chemistry. Faculty of Medical Laboratory Sciences. Alzaiem Alazhari University. Khartoum, Sudan

[2].Department of Microbiology. Faculty of Medical Laboratory Sciences. Alzaiem Alazhari University. Khartoum, Sudan

[3]. Department of Pathology, Faculty of Medicine, University of Khartoum, Sudan

[4]. Department of Clinical Chemistry , Faculty of Medical Laboratory Sciences, The National Ribat University, Sudan.

Abstract

Introduction: The international standard Clinical Pathology Accreditation UK , WHO-AFRO accreditation and ISO 15189 Medical laboratories -Particular requirements for quality and competence are the basis for this accreditation. These requirements not only require a management system and manual in the medical laboratory but also require that the laboratory be found competent to perform specific medical tests or types of tests.

Objective: The study aimed to assessment Governmental Hospitals' Laboratories situation and their performance according to international standards scale.

Methods: The present study designed descriptive Series of case studies in thirty eight Government Hospitals' Laboratories located in Khartoum state, the intervention application of Continuous Quality Improvement techniques to assess laboratories processes; total Quality Systems standards into laboratories were measured by Checklist contain standards elements and score of each element was conducted according to their importance of international standards. The quality control in this study was carried out for 15 tests, used control sera.

Results:-Results availability of international standards for total quality management implementation in the laboratories is between 36% -86% the mean 65%, the safe laboratory design and organization 77.5%, laboratory organization 48.5%, document and management system 45.5%, quality of Personnel management 55.5%.

The observed errors of laboratories in the preanalytical phase of testing were 60% and 37% in analytical phase, only 3% errors was reported in the post-analytical phase, continual improvement for laboratories auditing 26% . The quality control program 67% had internal quality control, 33% had national quality control, and the acceptability of quality control results for all laboratories was 72%, total absolute error 55.56%, inaccuracy (variation) 11.5%, imprecision CV 25.1%.

Conclusion: This study showed significant correlation between adoption of international standards and improved of accuracy and reliability on medical laboratories tests.

Keywords: Quality Management System, Quality control, ISO/IEC 17025, ISO 15189, CPA.

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INTRODUCTION

Quality management is defined as the part of the overall management function that determines and implements quality policy, It was gradually that by doing the right things from the beginning, i.e. relevantly, timely, and effectively from economic point of view, would satisfy the needs set and stated by the many stakeholders of medical laboratories. [1,2].

The importance of quality in the functioning of health care laboratories in developing countries has been universally recognized. Laboratories practicing the principles of quality assurance generate relevant, reliable and cost-effective results.[3]

Every laboratory takes great pains to ensure that the methods in use continue to produce reliable result, a reliable and quality laboratory service is achieved and sustained not just by implementing quality control of laboratory tests.[4]

Total quality management those areas of laboratory practice that most influence how laboratory service functions and uses its resources to provide a quality and relevant service.[5]

Throughout the 1980s and the 1990s, much attention has been paid to principles of quality management associated with organizational structures, responsibilities, procedures, processes, and resources.[6]

So quality assurance system, which is management system, designed to give the maximum confidence and represent all the activities under taken to predict and prevent poor quality.[7]

Quality assurance system in laboratory diagnostic services involves all measures that can be taken to improve the efficiency and effectiveness of the service and thus enhance the trust in the laboratory result.[8]

It means service, which gives people what they need, as well as what they want and does so low cost. [9]

The quality control and quality assessments represent part of quality assurance, which aim at predicting and preventing problems. Quality assurance utilizes quality control and the methods of the quality management cycle to assure the quality of a service.[8]

The increasing role of national and international standardizing bodies is stressed as well as implementation of rules of "good laboratory practice". Objectively established quality goals for all services are highly needed in order to provide a rationale for the efforts dedicated to quality improvements. Quality goals for many clinical chemistry and haematology investigations are now available.[10] Accreditation has verified that procedures and results are technically valid, that laboratory staff is competent, and confirms that the laboratory conforms to a quality management system.

Within the UK there are two laboratory accreditation bodies, operating in complementary fields, the United Kingdom Accreditation Service [UKAS] and Clinical Pathology Accreditation (UK) Ltd [CPA]. [11,12]

Most clinical laboratories in the UK have now had several years experience of accreditation. [11]

WHO has consistently advocated implementation and assessment of quality in health laboratories. In order to provide technical assistance to member States to strengthen their quality systems and establish an accreditation mechanism, an intercountry workshop was organized in Thailand, Fifteen countries participants attended the workshop. It was facilitated by experts from the Bureau of Laboratory Quality Standards. [13]

The World Health Organization Regional Office for Africa (WHO AFRO) established a stepwise approach, using a 0- to 5-star scale, to the recognition of evolving fulfilment of the ISO 15189 standard rather than pass-fail grading. WHO AFRO's accreditation process is not intended to replace established ISO 15189 accreditation schemes, but rather to provide an interim pathway to the realization of international laboratory standards. Laboratories that demonstrate outstanding performance in the WHO-AFRO process will be strongly encouraged to enroll in an established ISO 15189 accreditation scheme.[14]

Thailand has developed and successfully implemented such a model, where national standards for health laboratories have been developed and initially applied on a voluntary basis. Once the national standards have been implemented, laboratories are in a better position to meet the requirements of international standards. Thailand adopted this approach with a high degree of success. [15]

The accreditation program of clinical laboratories based on ISO 15189 has been introduced in many countries, except for those in USA where all clinical laboratories must be required to follow the federal law, CLIA'88. It will certainly help the accredited clinical laboratories improve their quality and competence, In Japan started the accreditation program for clinical laboratories, based on ISO 15189:2003.[16]

This standard has commonly been employed as an accreditation tool for clinical laboratory in Europe and Australia.[17]

Ongoing evaluation and improvement processes are essential to ensure that the service provided by the laboratory meets the needs and requirements of users, Internal audit of quality management system provides evidence to demonstrate that the quality management system has been effectively established, implemented and maintained and Internal audit of pre examination, examination and post examination processes is

required to ensure that they are being conducted according to agreed procedures. Calibration and Internal quality control helps to ensure that the examinations are being correctly performed.[16, 18]

EQAS is a schematic external assessment plays an important role in the quality management system, especially in health laboratories, and is a very specific and specialized part of the monitoring process. [16,18]

MATERIAL & METHODS

The basic requirement for total quality management were evaluated in thirty eight governmental laboratories located in Khartoum State- Sudan ,the study was designed as analytical and descriptive study to evaluating governmental hospitals laboratories situation and laboratories performance on quality Indicators with international standards scale , the evaluation by questionnaire are covering the managerial and technical requirements standards is adopted or not adopted in laboratory (YES or NO) theses include the following :-

Organization and management: system (Quality policy, plans, Quality manual, Document control, Control of process & quality records and Control of clinical material).

Personnel:(Professional direction ,Personnel management ,Staff orientation and induction, Job descriptions and contract ,Staff records ,Staff annual joint review ,Staff training and education)

Premises & environment: (Premises and environment, Facilities for staff, Facilities for patients, Facilities for storage, Health and safety and safe laboratory design)

Equipment and materials: (Management of equipment, reagents, calibration and quality control material)

Pre- examination processes: (Information for users and patients, Request form Specimen collection and handling, Specimen transportation, Specimen reception, Referral to other laboratories)

Examination processes: (Selection and validation of examination procedures, Examination procedures, assuring the quality of examinations

Post examination processes: (Reporting results, the report, error calculation, Transcription errors, result report in wrong unit, Clinical advice & interpretation).

Evaluation & quality assurance: Evaluation and improvement processes (External and Internal audit of quality management system, External Internal audit of examination processes, External quality assessment).

World Health Organization (WHO) Regional Office for Africa (AFRO) accreditation scheme: showing the stepwise recognition of laboratory performance. Based on the percentage score, laboratories are assigned an accreditation level, based on 1 to 5 stars. Laboratories International standards or CAP and ISO 15189 accreditation, but to serve that receive a 5-star rating are strongly encouraged to transition to an internationally established accreditation scheme. Laboratories will be recognized on a 0- to 5-star ascending scale according to international standards ISO15189. Laboratories that fail to achieve at least 55% on assessment will not be awarded a star ranking ,1-star rate between 55% to 64% , 2 - star 65% to 74% , 3- star 75% to 84% and 4- star 85% to 94%. Laboratories that achieve 95% or more will receive a 5-star rating laboratories that receive a 5-star rating are strongly encouraged to transition to an internationally established accreditation scheme.

Quality control :The quality control assessment in this study we gave two samples to each laboratories normal and abnormal quality control sera for measuring 15 clinical chemistry tests routine investigation and the major testes required these tests are: glucose, urea, creatinine, Sodium, potassium, calcium,, phosphate, uric acid, cholesterol. Triglyceride, albumin, bilirubin, alkaline phosphatase, Alanine aminotransferase (ALAT) and Aspartate aminotransferase (ASAT) were chosen for this purpose being most common tests in clinical laboratories.

Ethical clearance:

Approval was obtained from The Health Laboratories Administration – Ministry of Health Khartoum State and the director of the laboratories.

Data analysis: The data was analyzed by SPSS software and formulated into figures and tables used the Microsoft Excel computer program.

Collected data was quantified by zero score for no standards adopted in laboratories and 1 score for yes available standards adopted in laboratories according to international standards. The quality control results analysed by statistical quality control (Inaccuracy, total error, total absolute error).

% Variation:

(Mean- Expected volume) / Expected Volume X 100 (Measure of accuracy).

Relative error (RE %): Relative error (RE %) (Inaccuracy %): Relation between the absolute error and the mean value in percentage.

Precision: Is the reproducibility of a method, or the degree of variation to be expected when a sample is analyzed repeatedly by a given method.

%CV= (SD/ Mean) X 100 (measure of precision).

Absolute error (A.E): Difference between estimated value and the mean Value (CL. target mean). Total Absolute Error% AFTER the total error %calculated to all parameters as mentioned above. The sum of total error to all parameter without +- sign, divided by the number of parameter calculated Is the average of total error without +- sign

Total Error %

Total error %(measurement error) (the maximum permissible (error) is the sum of random error (cv) and the systematic error (AE %). MPE (%) = 1.65CV + SE (%) were SE% is the AE% (Affected by the sign of the AE %)

Results

Thirty eight governmental laboratories located in Khartoum State presented in this study the results of assessment the current situation of the laboratories in table (1) the Premises & Environment of Lab's.

Standards scale required	Management System	Premises & Environment of Lab's.	Quality of Personnel management	Safety for Lab's Staffs	Quality Assurance	Total Quality Management
Available	52%	71 %	55.5%	66%	77%	65%
Not available	48%	29%	45.5%	34%	23%	35%
Notice	Quality Planning = 17% , Document control =45%		Staff training &education =24%	Vaccination of staff =16%	Patient Identification = 8%	

Table (1): The standard of TQM Adopted in 38 Hospital Laboratories according to International Laboratory Standards

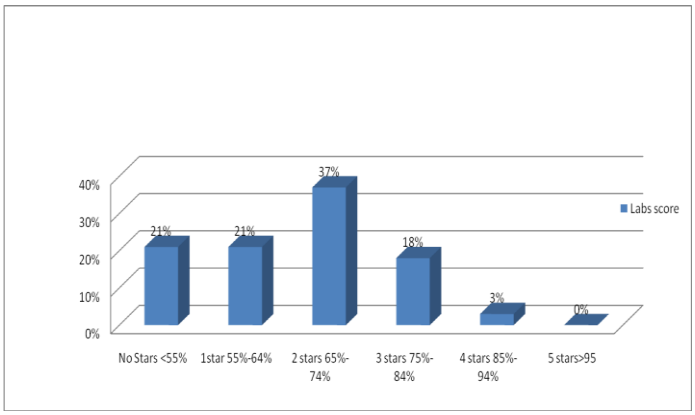

Figure (1): The distribution of the 38 laboratories according the WHO –AFRO step-Wise laboratory accreditation process.

Laboratory organization & safe laboratory design: some laboratory lack facilities of the patient reception, 6 = 17% of the laboratories have quality policy and quality planning, 16% of laboratories staff have vaccination and most lack of continues training education.

the World Health Organization Regional Office for Africa (WHO AFRO) established a stepwise approach, using a 0- to 5-star scale, to the recognition of evolving fulfilment of the ISO 15189 standard in Figure (1) most of labs have 2 stars =37% of labs no laboratory have 5 tars .

Quality improvement processes : most of the laboratories have internal quality control, all laboratories have no international quality control, Laboratories Audit system 2= 5% of the laboratories have national audit and no laboratories have international audit figure (3).

Quality assurance : the 60% 0f the errors in pre analytical steps, in analytical phase most of the laboratories don't use quality control material in every batch ,in post analytical phase the errors occurs are few = 3 % of the errors, the most errors occurs in the laboratories is pre- analytical as shows in figure (2).

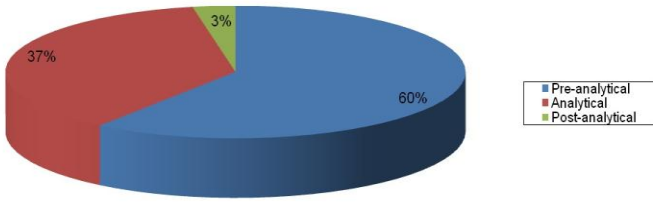

Figure (2) Errors in medical Laboratories

Quality control results: In this study most of instrument is manual few automation = 5% used in laboratories participate in this study results of quality control , used normal control sera (average) test results CV(imprecision) 28.9% , Variation (inaccuracy) 10.4 % and total absolute errors 57.5% table (2). And the average results used pathological control sera results CV (imprecision)22% , Variation (inaccuracy) 12.7 % and total absolute errors 53.6% table (3), finally the quality control results of all enzymes are poor results due to lack of staff training.

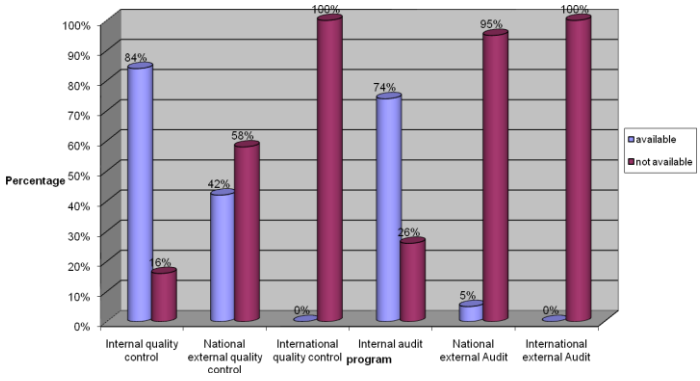

Figure (3): Quality improvement processes adoption in all Laboratories

	Tests	Target Value	Mean	SD	CV% (Imprecision)	Variation % (Inaccuracy)	Total Error %	Total Absolute Error%
1	Glucose	117 mg/dl	115 mg/dl	22	19.1%	1.71%	33.35%	
2	Urea	42 mg/dl	57 mg/dl	10.8	18.9	35.7%	57.48%	
3	Creatinine	1.35 mg/dl	1.3 mg/dl	0.385	29.6%	3.7%	52.64%	
4	Sodium	144 mmol/L	141 mmol/L	6.15	4.36%	2.1%	9.29%	
5	Potassium	4.7 mmol/L	4.7 mmol/L	0.78	16.6%	0.0%	16.59%	
6	Calcium	9.63 mg/dl	8.7 mg/dl	0.19	2.18%	9.7%	13.89%	
7	Phosphate	5.3mg/dl	5.2 mg/dl	0.57	11%	1.9%	20.07%	
8	Uric acid	5.0 mg/dl	4.5 mg/dl	1.25	27.8%	10%	46.98%	
9	Cholesterol	168 mg/dl	160 mg/dl	33	20.6%	4.8%	39.03%	
10	Triglyceride	153 mg/dl	152 mg/dl	32.6	21.4%	0.65%	54.44%	
11	Albumin	3.32 gm/dl	3.5 gm/dl	0.48	13.7%	5.4%	28.30%	
12	Bilirubin	1.0 mg/dl	1.2 mg/dl	0.41	34.2%	20%	73.03%	
13	Alk. Ph	194 UI/L	179 IU/L	88	49.1%	7.7%	89.38%	
14	AST	38.3 UI/L	30 UI/L	22.66	75.5%	21.7%	(152.2)%	
15	ALT	36.8 UI/L	25.6 UI/L	20.6	80.4%	30.4%	(176.4) %	
	Average	-	-		28.29%	10.4%	-	**57.53%**

Table:(2) Laboratories Quality control results of used normal control sera

	Tests	Target Value	Mean	SD	CV % (Imprecision)	Variation % (Inaccuracy)	Total Error %	Total Absolute Error%
1	Glucose	249 mg/dl	233 mg/dl	36	15.5%	6.4%	32.43%	
2	Urea	145 mg/dl	134 mg/dl	25	18.6%	7.6%	38.89%	
3	Creatinine	3.7 mg/dl	4.3 mg/dl	1.05	24.6%	16.2%	54.45%	
4	Sodium	153 mmol/L	148 mmol/L	7.6	5.1%	3.3%	11.78%	
5	Potassium	7.3 mmol/L	6.4 mmol/L	0.74	11.65%	12.3%	33.28%	
6	Calcium	15.6 mg/dl	13.1 mg/dl	1.82	13.9%	16%	42.01%	
7	Phosphate	9.5 mg/dl	8.6 mg/dl	1.15	13.4%	9.5%	32.57%	
8	Uric acid	11.2 mg/dl	11.3 mg/dl	2.26	20.1%	0.9%	33.1%	
9	Cholesterol	266 mg/dl	252 mg/dl	31.3	12.4%	5.3%	26.01%	
10	Triglyceride	235 mg/dl	239 mg/dl	43.2	18.1%	1.7%	31.53%	
11	Albumin	4.71gm/dl	4.7 gm/dl	0.5	10.6%	0.2%	17.7%	
12	Bilirubin	4.6 mg/dl	4.8 mg/dl	1.09	22.7%	4.3%	41.61%	
13	Alk. Ph	407 UI/L	312 UI/L	129	41.34%	23.3%	98.6%	
14	AST	174 UI/L	101 UI/L	51.3	50.8%	42.0%	(156)%	
15	ALT	123 UI/L	72 UI/L	36.6	50.8%	41.5%	(154.6)%	
	Average	-	-	-	22%	12.7%	-	**53.6%**

Table: (3) laboratories Quality control results used Pathological control sera

DISCUSSION

Sudan does not have a national laboratory accreditation body for medical laboratories only Khartoum state give license certificate for provide sectors on local laboratories standards the importance of developing minimal national quality standards for health laboratories, which should be mandatorily followed by all laboratories becomes very important Achieving international standards could then follow on an optional and voluntary basis see table(1) most of laboratories in this study lack for implantation of TMQ.

ISO15189 will be an important template for assessing and recognizing the competence of medical laboratories in their technical capacity and the effective quality management of a professional service and its staff--with or without the aim of accreditation. [19, 20]

Previous study revealed in Malaysia the establishment of a National Accreditation Standard for medical testing laboratories based on ISO 15189, and the passing of the Pathology Laboratory Act in Parliament in mid-2007. The Pathology Laboratory Act 2007 seeks to ensure that the pathology laboratory is accountable to the public, meets required standards of practice, participates in Quality Assurance programmes, is run by qualified staff, complies with safety requirements and is subject to continuous audit. [21]

The establishment of a formalized system to improve public medical laboratories throughout the WHO-AFRO Laboratory Accreditation Program A " step-wise" approach to quality improvement in Africa, Laboratories that demonstrate outstanding performance in the WHO-AFRO process will be

strongly encouraged to enrol in an established SO 15189 accreditation scheme[14], most of the laboratories in this study below than three stars according the WHO-AFRO Laboratory Accreditation Program A " step-wise" .

Previous study shown the more recent surveys on errors in laboratory medicine conclude that in the delivery of laboratory testing, mistakes occur more frequently before (pre-analytical) and after (post-analytical) the test has been performed, preanalytic performance indicators has not been universally defined A suitable approach is to develop a systsem based on representative preanalytic performance measures and on criteria for specimen acceptability In our experience, implementation of a systematic error-tracking system in daily practice has provided meaningful information on the local preanalytical processes more susceptible to errors, providing an ideal foundation for efficient feedback and enabling evaluation of specific responsibilities. [22,23,24]

Other study revealed in the preanalytical phase of clinical chemistry analyses, many sources may contribute to the uncertainty of the result. [25]

Laboratory errors occur in the preanalytical phase of testing. In view of the paucity of studies examining preanalytical errors, we evaluated our laboratory request forms for the frequency and impact of incomplete data. [26]

Also other study showed most errors are due to pre-analytical factors (46-68.2% of total errors), while a high error rate (18.5-47% of total errors) has also been found in the post-analytical phase. [27]

Different study showed the rates of analytical errors in clinical laboratories, and currently available evidence demonstrates that the pre- and post-analytical steps of the total testing process are more error-prone than the analytical phase. [28]

I disagree the study showed 41% were observed in the preanalytical phase of testing, 55% in the post analytical phase, and only 4% in the analytical phase [29], the distribution of errors throughout the laboratory working process: most occurred in the pre- or post analytical phases, whereas a minority (13–32% according to the studies occurred in the analytical portion.[30,31]

In this study I agree that most of errors is pre-analytical errors .[32,33] see figure(2) .

Although increased automation, advanced analytical techniques and sophisticated information technology have greatly improved the performance and quality in medical laboratory testing, several studies show that significant amounts of errors occur. [34,35]

No quality system will continue to be maintained or to develop without regular testing by the use of audit techniques. It has been stated that "You get what you inspect not what you expect!". As work becomes more demanding it gets more difficult to keep track of all activities within the laboratory External or internal quality audit helps prevent a drop in good laboratory practice and through regular review, provides a better understanding of the day to day problems which occur in the laboratory and participated laboratories in this study need to be I established and improvement the system of audit see basis in figure(3) .

The external quality assessment (EQA)' has been recommended by WHO consultative meeting in 1980.,In Thailand EQA newsletters, and yearly summer-time seminar and training prove to be the essential education tools promoting both laboratory quality and standard intensively. [36]

The participation in EQA scheme has gained in importance with publication of laboratory accreditation standard ISO/ICE 17026 and ISO 15189 according to ISO/IC.E 17025 article 5.9, ISO 15189 states in 5.6.4 laboratories are required to ensure the quality of their results by interlaboratory comparison or Proficiency test programs. [37, 38, 39]

The findings of the study in Lebanon and particularly the improvement in laboratory performance observed during the study period, highlight the importance of establishing the Lebanese External Quality Assessment Scheme, and justify further efforts to expand and strengthen this scheme. [40]

External quality control EQC programmes are organised on a regional, national or international level and are concerned with the comparability of test results, EQC is a retrospective evaluation of quality, in this study most of laboratories had regional and internal quality control but not had national or external quality control see figure(3)

The results of quality control in this study found many variation the best laboratories results are cholesterol, albumin, sodium, triglyceride, phosphate, potassium, glucose, uric acid the acceptable results more than 70% for both control sera for 3 SD see table (2,3)

Imprecision and inaccuracy are performance characteristics, not quality requirements. Performance certainly contributes to quality, but they are not the same thing. A given level of analytical quality can be achieved by different combinations of imprecision and inaccuracy, in this study many factors affect the measuring plasma enzymes and also the lack of training staff these increase the non acceptable laboratories results , the assessment of all laboratories results increase the imprecision CV=25.4% ,and inaccuracy =11.5% and the total absolute error 55.56% and acceptability of the results 72% see table(2,3)

In the developing world there is rarely sufficient infrastructure to maintain long-term operation of modern clinical laboratory instruments. Limited access

to service technicians, shortages of skilled personnel, lack of user groups or professional societies for consultation, and lack of funds for reagents and maintenance all contribute to poor long-term sustainability ,Further complicating the establishment of reliable services can be the use of analyzers from multiple manufacturers, which may potentially lead to unharmonized. (42,43,44,45,46)

CONCLUSION

The evaluating hospital laboratories performance on Quality Indicators With international standards scale In this study we conclude that :

The total quality management is slowly gaining popularity in laboratories study , most of laboratories lack to establishment the continues quality improvement programs such as quality audit, external quality control, management of reagents, calibration and quality control material, there is significant different between the implementation the total quality management in laboratory and to obtain reliable and accurate results.

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