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ISO/IEC 17025:2017 Lab Management System Effectiveness Verification by Using Quantitative Approach

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Abstract

Introduction: ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories" (ISO, 2017) is focused on both management and technical requirement of laboratories. Its accreditation is mandatory is many countries due to its regulatory requirement. From last 2-3 years, accreditation of ISO/IEC 17025 becomes obligatory in some sectors of Pakistan (pesticides, electricity transmission etc.).

Methods: In this research work; validity of the ISO/IEC 17025 standard is verified by conducting Interlab Comparison (ILC) between 26 testing and calibration laboratories of 5 different sectors. Comparison of ISO/IEC 17025 accredited labs performance is done with labs that are non-accredited or on implementing phase of accreditation. One-way ANOVA analysis of labs Z-values are conducted among 40 parameters of 26 labs.

Results: Study results show, there is a significant difference between accredited and non-accredited labs. Furthermore, one sample t-test is conducted to find out the accuracy of accredited labs; as per research findings all labs results are with in limit but accredited labs have high accuracy as compare to implementing phase or non-accredited labs.

Keywords: ISO 17025 Effectiveness, Comparison of Accredited and non-accredited labs, ISO 17025 Accreditation & Accuracy.

Introduction

Laboratories play key roles in quality control & assurance activities of material testing and performance by conducting verification of raw material or finished products. If raw material is not verified properly; it may cause of non-conforming product irrespective of your operation effectiveness. Similarly, if final products are not verified, it will lead to customer dis-satisfaction. In both cases, society is the effected of such non-conformance. As per market research conducted on drugs sample in developing countries; around 13.6% of drugs found substandard or falsified due to which these countries are suffered $10 billion to $200 billion financial loss [1]. According to Federal Road Safety Corps (FRSC) report; 772 out of 9000 reported road side accidents in 2015 due to sub-standard or expired tyres [2]. As per news agency, around 24 motor bike riders lost their life due to sub-standard helmets in Karachi, because it could not protect them from serious head injuries [3].

ISO/IEC 17025 deal with the "General requirements for the competence of testing and calibration laboratories" [4].

ISO/IEC 17025 "General requirements for competency of testing and calibration laboratories" targets lab personnel, test method, equipment, material & environment in order to improve the quality of test results [4]. Accreditation is an independent confirmation that labs operations with in define scope are acceptable by ILAC signatory countries [5] as accredited lab get benefit from Mutual Reorganization Agreement (MRA) [6]. ISO/IEC 17025 accreditation has direct effect on company performance.

Laboratory management system ISO/IEC 17025:2017 is comprehensive standard as compared to ISO 9001. Basically, ISO 9001 is the mother of all management standards as it deals with management side only but ISO/IEC 17025 deals with management as well as operational aspects of laboratory. ISO 9001:2015 is the sub-set of ISO/IEC 17025:2017; as in clause 8 of ISO/IEC 17025 latest version; there are two options. Option A is to implement all mandatory requirements of ISO 9001:2015 and in option B, if company is already certified ISO 9001:2015 then it can integrate with it.

There are some difficulties faced by lab during ISO/IEC 17025 standard implementation. Some of the difficulties that are noted during implementation of this standard are following:

a. Lack of Management Commitment

b. High turnover of lab staff and lack of availability of specified job descriptions [7].

c. Lack of availability of material/ reagents that is used in testing activities

d. High cost testing or calibration activities due to usage of standards, CRM etc.

e. Equipment maintenance especially in developing countries where service staff of companies are not present. If any equipment is out of order then company service staff is called from abroad that is time and resource consuming [8].

f. Difficulty in participation of quality assurance program as in developing countries; as some labs are pioneers in its sector so they don't find out lab for ILC activity.

According to José Barradas; equipment management and evaluation of measurement uncertainty are the major problem in ISO/IEC 17025 [9] both of these requirements are the mandatory part of ISO/IEC 17025 standard accreditation. In equipment management, requirements related to equipment whether it is calibration, preventive or corrective maintenance, correction factors, equipment manuals and technical guidelines all need to be addressed. In uncertainty calculation; knowledge of statistical techniques is required and further factors related to type A and type B uncertainty need to be calculated for final combine uncertainty [10].

As per research, accredited lab staffs have a sound knowledge of management system and their technical skills are also improved [11]. Clause 6.2 of ISO/IEC

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17025:2017 standard requirement; competency of lab staff is the combination of qualification, education, trainings, skills, technical knowledge and experience. To increase the competency of lab staff; trainings are the easiest way because education, qualification and experience are time bounded. Training plans are developed to increase the technical and managerial skills of staff. On-job and off job trainings are two basic types of training. Training that is placed on working premises is known as on-job training, conducted for better understanding of specific task or technical skill. It has positive effect on manager's creativity and economical. Whereas trainings that take placed out of premises in known as off job training better for multi experience learning and knowledge sharing. [12] Study results show that training has effect on employee's competence [13].

Methodology

In order to analyze the effectiveness of ISO/IEC 17025 in term of z-value, Inter Lab Comparison has been conducted between labs. This interlab comparison has been conducted by one of the competent consultancy firm working in this field from last 20 years. For this comparison, a team based on technical personnel including statistical expert has been developed who conducted ILC from 2017 to mid-2019. On the basis of z-value, results of all labs have been analyzed. There were total 26 labs from the following sectors which have participated in ILC:

1. Calibration Labs (4)

2. Electrical Testing Labs (6)

3. Material Testing Labs (Destructive and Non-Destructive) (3)

4. Livestock Labs (3)

5. Chemical Testing Labs (10)

For analysis purpose labs are categorized into 3 types:

• Labs had faced 3rd party final audit and clear objections highlighted in it. For such labs **"Faced 3rd Party Audit" (A)** is used

• Labs that are on implementing stage and implemented some requirements of ISO/IEC 17025 standard. For such lab **"Implementing Phase" (I)** is used

• Labs working with normal routine not started implementation of ISO/IEC 17025 standard. **"No implementation Started" (N)**

Hypothesis Testing

After conducting and closing 3rd party audit findings; Consensus, Inter Lab Comparison/ Proficiency Testing has been conducted by sending test samples and results of these test sample have been evaluated by calculating Z-Value using ISO/IEC 17043:2010. But before analysis; normality test of labs data has been conducted.

$$z = \frac{x - X}{\sigma}$$

According to this standard if,

Z ≤ |2| Satisfactory performance and generate no signal

|2| < Z < |3| Questionable performance and generates a warning signal

Z ≥ |3| Un-Satisfactory performance and generates on action signal

It must be noted here that it does not matter while calculating Z-Score, whether the final result is in Negative (-ve) or Positive (+ve). These characteristics are ignored. It just shows direction either above or below the mean.

During this study, following one sample t-test hypothesis are tested for effectiveness purpose:

μo=Lab following ISO/IEC 17025 requirements & completed audit cycle having ILC/PT results Z ≥|2|

μ/ = Lab following ISO/IEC 17025 requirements & completed audit cycle having ILC/PT results Z <|2|

Detail of these labs and parameters include in this research work is given in **(Table 1)**. While conduction of inter lab comparison; confidentiality and impartiality was ensured. Confidentiality was ensured by blind coding of samples and not sharing the results of other labs.

Table 1: has the detail of labs parameters, for which z-values have been calculated.

Sector	Parameters for ILC	No.
Calibration **(CB)**	Gas Volume 20% **(V_{20})**	**4**
	Gas Volume 80% **(V_{80})**	
	Gas Volume 100% **(V_{100})**	
	Electronic Volume Corrector (EVC) Pressure 20 Psi **(P_{20})**	
	Electronic Volume Corrector (EVC) Pressure 40 Psi **(P_{40})**	
	Electronic Volume Corrector (EVC) Pressure 60 Psi **(P_{60})**	
	Electronic Volume Corrector (EVC) Pressure 80 Psi **(P_{80})**	
	Temperature Calibration 60 F **(T_{60})**	
	Temperature Calibration 80 F **(T_{80})**	
	Temperature Calibration 120 F **(T_{120})**	
Electrical Testing **(E)**	HV Winding Resistance Test **(R_H)**	**3**
	LV Winding Resistance Test **(R_H)**	
	Transformer Turn Ratio Test **(R_H)**	
	No Load Test (Iron Losses) **(L_i)**	
	Load Losses Test (Copper Losses) **(L_c)**	
Electrical Testing **(E)**	Test of Accuracy due to variation of current (KWH) 10% **(V_c)**	**3**
	Test of Accuracy due to variation of current (KWH) 25% **(V_c)**	
	Test of Accuracy due to variation of current (KWH) 50% **(V_c)**	
	Test of Accuracy due to variation of current (KWH) 100% **(V_c)**	
	Test of Accuracy due to variation of current (KWH) max **(V_c)**	
	Test of Accuracy due to variation of frequency (% Error For KWH) 5% at PF 1 **(V_f)**	
	Test of Accuracy due to variation of frequency (% Error For KWH) 100% at PF 1 **(V_f)**	
	Test of Accuracy due to variation of frequency (% Error For KWH) Imax at PF 1 **(V_f)**	
	Test of Accuracy due to variation of frequency (% Error For KWH) 10% at PF 0.5 **(V_f)**	
	Test of Accuracy due to variation of frequency (% Error For KWH) 100% at PF 0.5 **(V_f)**	
	Test of Accuracy due to variation of frequency (% Error For KWH) Imax at PF 0.5 **(V_f)**	
Material Testing **(M)**	Tensile Strength (**T_S**)	**3**
	Elongation @ Break (**E_L**)	
	Hardness (**H_D**)	
	Specific Gravity (**S_G**)	
	Rheometer Testing (Scotching time)	
	Rheometer Testing (Curing time)	
Livestock **(L)**	Sperm Concentration (Millions per ml) (**S_c**)	**3**
	Post Thaw Motility % (**P_M**)	
Chemical Testing Labs **(C)**	Active Concentration of Acetamiprid (**A_C**)	**10**
	Density of Acetamiprid (**A_D**)	
	pH at 1% in distilled water of Acetamiprid (**A_P**)	
	Active Concentration of Lambda-Cyhalothrin (**L_C**)	
	Density of Lambda-Cyhalothrin (**L_D**)	
	pH at 1% in distilled water of Lambda-Cyhalothrin (**L_P**)	

In preparing results of ILC/consensus; impartiality was ensured by involving 3rd person (Sector experts) who had prepared all these results and he had no concerned and link with participated labs.

Number of labs are mentioned in **(Table 2)**. Out of 26 labs; 4 calibration labs in which 1 is at A, 2 is at I & 1 is at N phase. Similarly, 3 material testing labs, 6 electrical labs (3 transformers & 3-meter testing), 3 livestock labs and 10 chemical testing labs. In table 2; 2nd column from left side PM (Parameters) of each lab is given in front of it. Z-values are conducted using formula mention in section 3.1. One worker perform test at least 3 times. Replicates of each test parameters are conducted and to minimize error analysis average values are used for this study.

Results Analysis

For conducting ANOVA analysis to find out the significant difference between Lab A, I & N; Z-value results in **(Table 3)** in which there are parameters given in right most column and in front of these parameters z-values of labs are given. Labs who have not provided results its respective cells are empty.

Before analyzing z-value results; normality test on readings are conducted in order to strengthen the study. As Z-value is unitless and it is absolute so normality test is conducted. P-value results of normality test of Lab I, A & N are 0.213, 0.155 & 0.063 respectively. All values are greater than 0.05 so it's mean that data is normal and ready for further analysis. Detail of Lab I, A & N are given in **(Figures 1-3)**.

One-way ANOVA: Lab (A), Lab (I) & Lab (N)

As data is normal so one way ANOVA test is conducted on Z-Values of

Table 2: Total Test Conducted by Labs.

Lab	PM	No. of labs	A	I	N	No. Test	No. of Analyst	Total
Calibration (1-4)	10	4	1	2	1	8	3	960
Material (1-3)	6	3	1	1	1	3	1	54
Electrical (1-3)	5	3	1	1	1	3	1	45
Electrical (4-6)	11	3	1	1	1	3	1	99
Livestock (1-3)	2	3	2		1	10	3	180
Chemical (1-10)	6	10	3	3	4	3	1	180
							Grand Total	1518

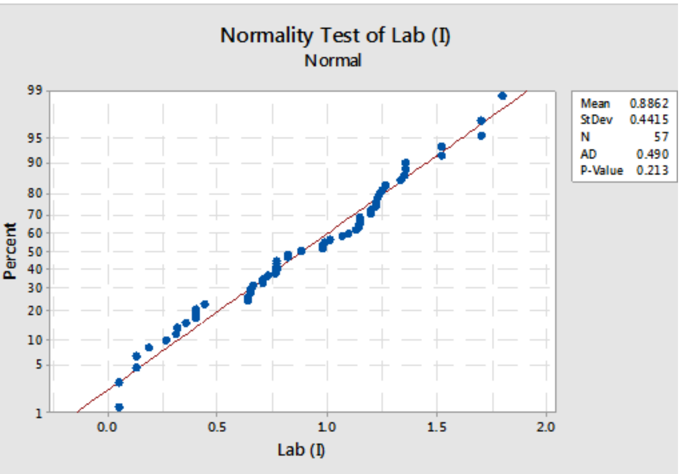

Figure 1: Normality Test of Lab I.

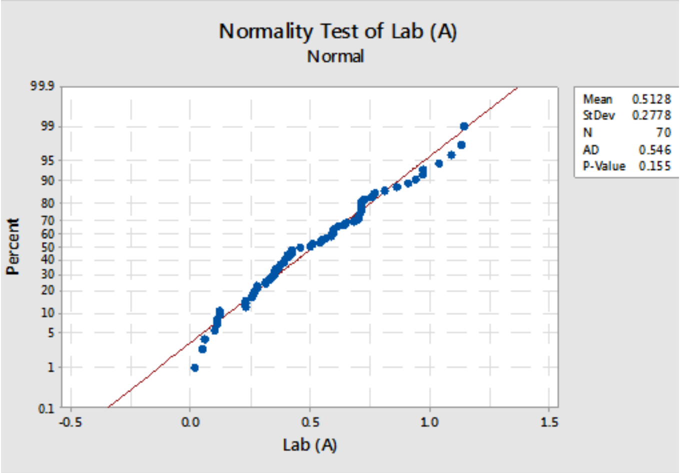

Figure 2: Normality Test of Lab A.

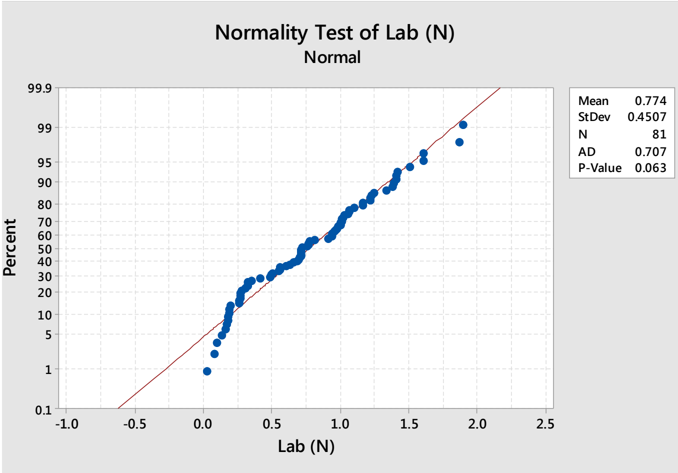

Figure 3: Normality Test of Lab N.

testing labs (A, I, N) using Minitab version 17 to find out whether there is any significant difference between the results of Labs A, I & N. Results of ANOVA is given below in **(Fable 4)**.

Interpretation

P value is less than 0.05 so results are significant and our null hypothesis is rejected at least mean of 1 lab is different. As per results of Post hoc Tukey Test results of Lab (N) and Lab (I) significantly different from Lab (A).

Results of lab A is closed to zero (0.4190, 0.6067) or true value, so on the basis of this we can say results of Lab A is more accurate as compare to

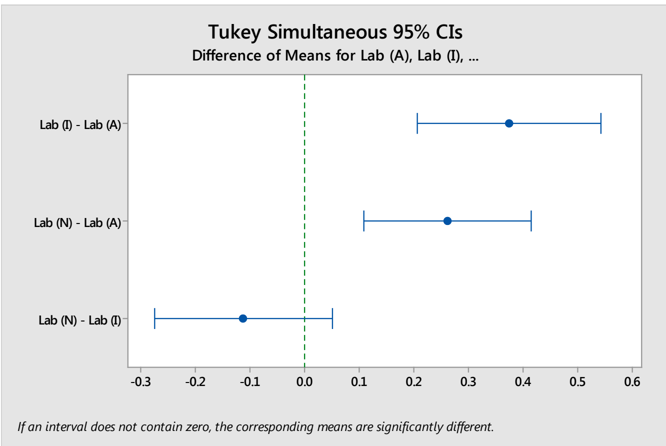

Figure 4: Turkey Simultaneous 95% CIs of All Labs.

Table 3: (A, I, N) Labs Z-Value.

Absolute Z-Value Table of Labs				
Lab (A)	**Lab (I)**	**Lab (N)**	**Parameter (Table 1)**	**Type of Lab**
0.65	0.36	0.1	V_{20}	Calibration Labs
0.60	0.05	0.49	V_{80}	
0.68	0.64	0.2	V_{100}	
0.11	0.82	0.18	P_{20}	
0.10	1.52	0.17	P_{40}	
0.12	0.88	0.19	P_{60}	
0.60	0.66	0.33	P_{80}	
1.09	0.64	0.26	T_{60}	
0.76	0.82	0.33	T_{80}	
	1.52	1.03	T_{120}	
	0.31		T_{60}	
	0.73		T_{80}	
	0.99		T_{120}	
0.11	1.01	0.91	L_i	Electrical (Transformer) Testing Labs
0.23	1.24	1.00	L_i	
0.42	1.14	0.72	L_C	
0.35	1.13	0.78	L_C	
0.59	1.15	0.56	V/T	
0.59	1.15	0.56	V/T	
0.60	1.15	0.55	V/T	
0.71		0.71	R_H	
0.71		0.71	R_H	
0.71		0.71	R_H	
0.39	1.34	0.98	V_c	Electrical (Meter) Testing Labs
0.26	1.22	1.07	V_c	
	0.27	1.22	V_c	
	0.40	1.07	V_c	
0.34	1.36	1.02	V_c	
0.35	1.36	1.00	V_f	
0.64	0.77	1.41	V_f	
0.06	1.25	1.25	V_f	
	1.10	1.10	V_f	
	0.98	0.98	V_f	
	1.22	1.22	V_f	
1.04	1.20	0.31	V_f	
0.71	1.35	1.41	V_f	
0.42	0.71	0.96	V_f	
	1.20	1.38	V_f	
0.94	0.44	0.26	V_f	
	1.07		V_f	
	0.32	0.97	T_S	Material Testing Labs
	0.76	0.61	E_L	
1.13	1.26	0.13	H_D	
	0.71	1.41	S_G	
	1.22	1.22	S_G	
0.55		0.27	S_c	Livestock Labs
0.23		0.08	P_M	
0.12	0.05	1.51	A_C	Pesticides Labs
0.91	0.19	0.27	A_C	
0.05	0.98	0.76	A_C	
		1.39	A_C	
0.77	0.77	0.77	A_D	
0.70	0.77	0.77	A_D	
0.70	0.77	1.34	A_D	
		1.90	A_D	
0.97	0.13	1.61	L_C	
0.86	0.65	0.94	L_C	
0.02	1.70	1.01	L_C	
		0.71	L_C	
0.97	0.13	1.61	L_P	
0.28	0.65	0.94	L_P	
0.33	1.70	1.01	L_P	
		0.71	L_P	
1.14	0.40	1.87	L_D	
	0.40	0.33	L_D	
	1.80	0.70	L_D	
		0.94	L_D	

Table 4: One Way ANOVA of All Labs.

Null hypothesis			All means are equal		
Alternative hypothesis			At least one mean is different		
Significance level			α = 0.05		
Equal variances were assumed for the analysis					
Factor Information					
Factor	Levels		Values		
Factor	3		Lab (A), Lab (I), Lab (N)		
Analysis of Variance					
Source	**DF**	**Adj SS**	**Adj MS**	**F-Val.**	**P-Val.**
Factor	2	4.812	2.4062	15.18	0.000
Error	205	32.492	0.1585		
Total	207	37.305			
Factor	**N**	**Mean**	**StDev**	**95% CI**	
Lab (A)	70	0.5128	0.2778	0.4190, 0.6067	
Lab (I)	57	0.8862	0.4415	0.7822, 0.990	
Lab (N)	81	0.7740	0.4507	0.6868, 0.8612	
Pooled StDev = 0.398118					

Table 5: Tukey Pairwise Comparisons of Transformer Labs.

Factor	N	Mean	Grouping
C-Lab (A)	70	0.5128	B
C-Lab (I)	57	0.8862	A
C-Lab (N)	81	0.7740	A

other. Furthermore, standard deviation of Lab A is also less than other its mean results are more precise as compare to other labs.

To test hypothesis as mention in 3.1 related to Z value. Lab A data are extracted from table 3 and 1 sample t-test is conducted on it to find out whether z value to greater or less than 2.

Sample T-test

A-types labs that have faced 3rd party audit and close findings, 1 sample t-test analysis results of such labs are given in table 4. These results are calculated using Minitab 17 version.

Hypothesis

μ_o= Lab following ISO/IEC 17025 requirements & completed audit cycle having ILC/PT results Z ≥|2|

Table 6: A-Lab Z-Values

Z-Value of Accredited Lab			
E-Lab (A)	**PM**	**L-Lab (A)**	**PM**
0.11	L_i	0.55	S_C
0.23	L_p	0.27	
0.42	L_C	0.23	P_M
0.35	L_Z	0.08	
0.59	V/T		
0.59	V/T	**CB-Lab (A)**	**PM**
0.60	V/T	0.65	V_{20}
E-Lab 4 (A)	**PM**	0.60	V_{80}
0.71	R_H	0.68	V_{100}
0.71	R_H	0.11	P_{20}
0.71	R_H	0.10	P_{40}
0.39	V_c	0.12	P_{60}
0.27	V_c	0.60	P_{80}
0.00	V_c	1.09	T_{60}
1.34	V_c	0.76	T_{80}
0.34	V_c		
0.35	V_f	**M-Lab (A)**	**PM**
0.64	V_f	0.32	T_S
0.06	V_f	0.76	E_L
1.32	V_f	1.27	H_D
1.37	V_f	0.71	S_G
1.22	V_f	1.22	R_C
1.04	V_f		
0.71	V_f		
0.42	V_{F100H}		
0.94	V_{FXH}		
C-Lab (A)	**C-Lab (A)**	**C-Lab (A)**	**PM**
0.12	0.91	0.05	A_C
0.77	0.77	0.7	A_D
0.02	0.86	0.97	L_C
0.97	0.28	0.33	L_P
		1.14	L_D

Table 7: t-test Results Lab Wise.

Variable	N	Mean	Std. Dev.	SE Mean	95% Upper Bound	T	P
E-Lab 2 (A)	7	0.41	0.19	0.07	0.56	-21.59	**0.0**
E-Lab 4 (A)	20	0.76	0.45	0.10	0.93	-12.39	**0.0**
C-Lab (A)	13	0.61	0.39	0.11	0.80	-12.81	**0.0**
L-Lab (A)	27	0.45	0.16	0.03	0.50	-49.91	**0.0**
M-Lab (A)	4	1.20	0.07	0.03	1.28	-24.65	**0.0**
CB-Lab (A)	9	0.52	0.34	0.11	0.74	-12.91	**0.0**
Lab (A)	55	0.69	0.26	0.04	0.75	-37.1	**0.0**

μ'= Lab following ISO/IEC 17025 requirements & completed audit cycle having ILC/PT results Z <|2|

Interpretation

P value of all labs are less than **0.05** in last column of table 8, so our Null hypothesis

"Lab following ISO/IEC 17025 requirements & completed audit cycle having ILC/PT results Z ≥ |2|"

For all labs null hypothesis is rejected. It's mean that labs have following ISO/IEC 17025 requirements & completed audit cycle having ILC/PT results Z ≤ |2| satisfactory performance and generate no signal ((ISO), 2010) [14-19].

Conclusion

According to study results; labs that have implemented ISO/IEC 17025 standard requirements, its results are more accurate as compare to other labs, if we link accuracy with Z-value (table 5). As Z-value close to zero accuracy of results are increased. Standard deviation of Lab (A) is also low (0.2778) as compare to Lab (I) & Lab (N) Although results of other Labs (I) and (N) are also within range because Z-values are less than 2 but it is less accurate as compare to Lab (A).

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