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ACCURACY OF STANDARDS IN CHOLESTROL DIAGNOSTIC KITS

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ABSTRACT: The percentage error observed in the claimed standard concentration of cholesterol 200 mg/dl for kits A to D is found to be 0.6, 12.3, 8.96 and 3.76 respectively. As per the guidelines of CLIA [8] allowable error is ±10% for cholesterol estimation. Similarly as per the NCEP [9] guidelines ± 9 % error is allowable. Therefore, it is noted that kit A is the best kit with an error of just 0.6% followed by kit D which showed an error of 3.76%. Kit C is the third best kit which had an error of 9%. However, kit B failed to meet the CLIA and NCEP requirements as it exhibited an error as high as 12.3%. This highlights that artificial standards provided by the kit manufacturers with reagents cannot be relied upon as a calibrator system, since at the very beginning of calibration the system would fail, as observed in case of kit B in this experiment.

INTRODUCTION: A standard solution provides a known value for calibration of testing procedure and represents purity, truth and correctness [1]. The standard solutions are prepared artificially for use on photometric determinations as a reference solution to determine the concentration of the specimens to be tested.

The determination of accuracy of standard solution ensures the absence of systematic error of calibration.

MATERIALS AND METHODS: For serum cholesterol assay the diagnostic kits commonly available are evaluated in the present work.

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For serum cholesterol assay the diagnostic kits commonly available are evaluated in the present work. Use of single standard calibration methodology is always advised to verify the accuracy and reproducibility of standards after calibrating the test with biological calibrator and verifying them with quality control material. The artificial standard of cholesterol provided in the kit has higher stability than the biological material (calibrator and quality control material), but their reliability is higher than artificial standards.

Expiry date mentioned on the standard solution container is also the expiry date of the entire diagnostic kit. A properly reconstituted biological quality control material is more dependable because of its consensus mean derived from thousands of the laboratories. However, there are

two drawbacks attached with too much dependability on biological material used for ensuring calibration of a method. First of all, the calibrators are derived from consensus mean of thousands of laboratory using particular instruments (which are mostly high tech machines not used in small scale clinical laboratory) along with particular set of reagents, which may not be available with every laboratory using them.

Secondly, since it has biological matrix, its stability is for shorter duration. It is because of these shortcomings that the dependability on artificial standard solution used in cholesterol assay becomes important. Therefore, in majority of clinical setups in India, the cholesterol solution is used as calibrator, which is verified by the manufacturer on semi-auto analyzer while using same reagent as its users. The quality of this calibrator can be verified on quality control material, which has acceptable range instead of a target.

RESULTS: The observations were read between 20-45 minutes of incubation interval at 37 ^{o} C. Traceability to accuracy of a method will depend upon traceability of the calibrator used. Therefore, it is important that laboratories should use a reagent kits as such to maintain traceability.

In this study the calibration is applied once in the beginning of the calibration procedure and the same is verified with the result of two level quality control solutions with each batch of assay [2]. The verification of the internally done quality control parameters is done against the external quality assessment programs under the proficiency testing programs [3, 4]. Under such conditions, when entire system including instruments, human factor, preservation and reagents are verified for its reportability [5], the standards of all four reagent kits under study were assayed to assure their reliability.

Performance characteristics of a given reagent kit are only valid if this kit is used as per recommended, by the manufacturer. A manufacturer cannot take responsibility for the performance characteristics outcome, when there is modification in the application procedure of a reagent kit, by the laboratory. For kits used as recommended, an implementation validation is sufficient. This validation is well described in clinical laboratory improvement amendments [6], requirements; calibration. However, in this study the manufacturer's protocol was not modified. Against the calibrator the standards were analyzed to determine their accuracy. The replication of assay was done ten times for each standard solution from the four diagnostic kits under this study. The standard cholesterol solution containing 200mg/dl was provided by the manufacturer was evaluated here for its accuracy.

RESULT AND DISCUSSION: The experiment is done by repeating the assay ten times for each kits standard for a period of five days, while assaying twice a day at different times. Several different analytical runs on different days should be included to minimize any systematic errors that might occur in a single run and a minimum of five days is recommended [7].

The mean concentration of standards in mg/dl is as follows, Kit A to Kit D 198.5, 224.5, 217.9, 192.5 respectively (**table 1**). The mean concentration for each assayed standard solution is very close to its designated 200mg/dl. Moreover, the mean variance was within 16.8, 47.28, 28.73 and 20.1. The mean SD was within 4.1, 6.876, 5.36 and 4.48 respectively. The L. J. charts for all the kits from A –D are drawn (**Chart I to IV**). Standard cholesterol solution containing 200mg/dl provided by the manufacturer was evaluated.

The percentage error observed for kits A to D is found to be 0.6, 12.3, 8.96 and 3.76 respectively. As per the guidelines of CLIA [8] allowable error is ±10% for cholesterol estimation. Similarly as per the NCEP [9] guidelines ± 9 % error is allowable. Therefore, this is noted that kit A is the best kit with an error of just 0.6% followed by kit D which showed an error of 3.76%. Kit C is the third best kit which had an error of 9%.

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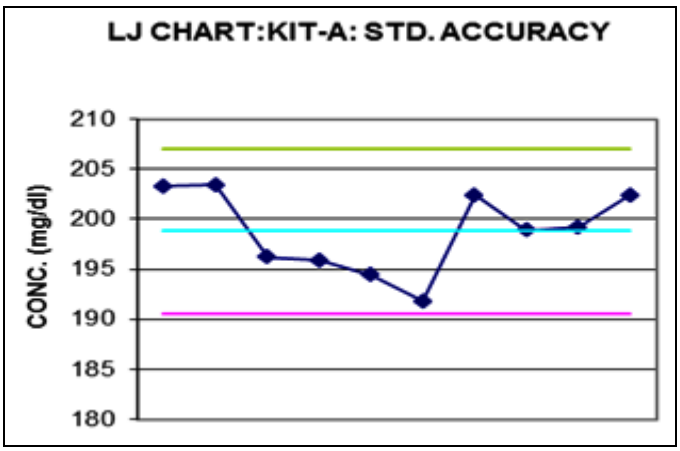
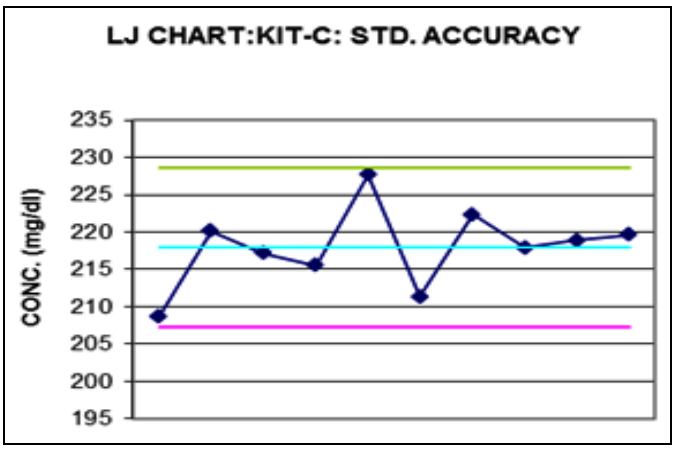
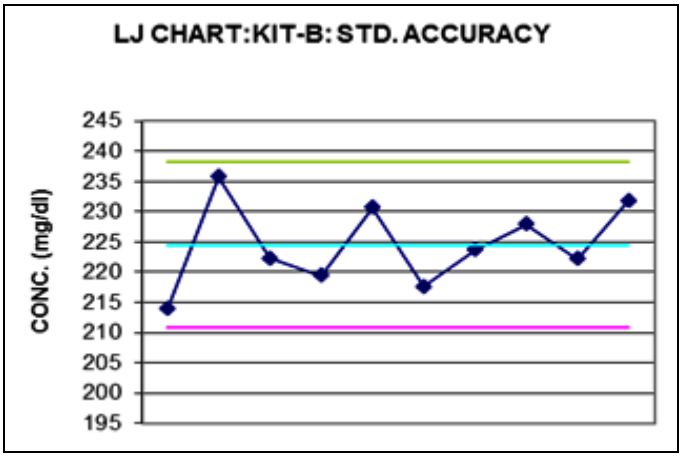


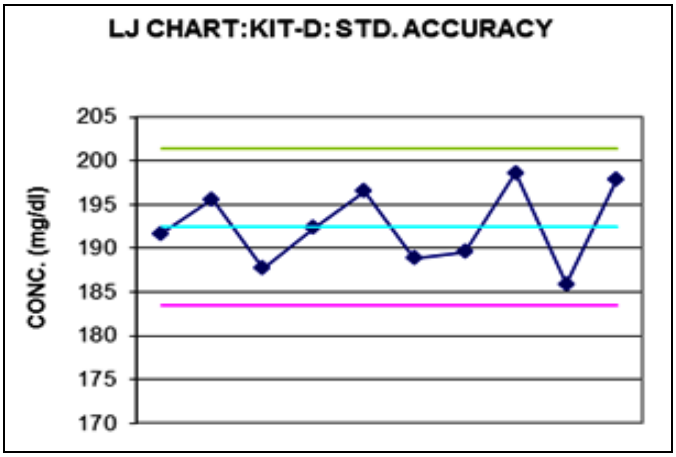
LJ CHART: KIT A: STD ACCURACY: CHART I



LJ CHART: KIT C: STD ACCURACY: CHART III



LJ CHART: KIT B: STD ACCURACY: CHART II



LJ CHART: KIT D: STD ACCURACY: CHART IV

TABLE 1: ACCURACY CHART

S. NO.	KIT-A	KIT-B	KIT-C	KIT-D
1	203	213.9	208.7	192
2	203	235.7	220.1	196
3	196	222.3	217.2	188
4	196	219.4	215.5	192
5	194	230.7	227.7	197
6	192	217.6	211.3	189
7	202	223.7	222.3	190
8	199	227.9	217.9	199
9	199	222.2	218.9	186
10	202	231.8	219.6	198
MEAN	198.8	224.5	217.9	192.5
Std Dev	4.1	6.876	5.36	4.48
VAR	16.8	47.28	28.73	20.1
% Error	0.6	12.3	8.96	3.77

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