DOI: 10.7860/JCDR/2024/72466.20399

Original Article

Microbiology Section

# A One-year Cross-sectional Study on Analysis of Financial Losses in Serology Section of Microbiology Laboratory: A Quality Improvement Project

CHAITALI SURESH DABHI[1], AMITA LALITKUMAR DABHI[2], CHIRAG MANOJKUMAR MODI[3]




## ABSTRACT

**Introduction:** Clinical diagnostic laboratories hold a significant place in healthcare as they play an important role in diagnosis, treatment and prevention of disease and draw a substantial hospital budget as well as generate considerable revenue. Profit earned by a diagnostic laboratory is the difference between the income generated from and expenditure incurred by the laboratory in performing laboratory tests. These expenses can be further divided into: i) direct cost-amount related directly to test performance, supplies and labour; and ii) indirect costs apply to items necessary to run laboratory, are not test specific. It has been observed that apart from expenditures mentioned above, there are several financial losses that are not evident in terms of their presence and magnitude are not taken into account by the cost-accounting system.

**Aim:** To identify hidden losses, analyse its magnitude in terms of financial loss and identify the reasons for the same in serology section of Microbiology laboratory.

**Materials and Methods:** This quality improvement, cross-sectional study was conducted at serology section of Microbiology laboratory, Shree Krishna Hospital, Karamsad, Gujarat, India from 1st April 2021 to 31st March 2022 which included all tests/control repeated, tests which are outsourced due to unavailability of test kits or consumables required to run the test, test kits/devices that crosses the expiry date and are discarded unused were included in the study. All calculations were done in Indian National Rupees (INR) with predefined formulas in Microsoft excel sheet involving simple summation and deduction to find out financial loss in particular category. As it was time bound study all the tests fulfilling inclusion criteria were included.

**Results:** Maximum loss was observed in serology section was due to: (i) repeat testing, 55508.9 INR; and (ii) outsourcing of tests due to unavailability of test kits or consumables, 10485 INR. No loss observed due to kit/test device crossed expiry date and are discarded unused.

**Conclusion:** This study will enable the laboratory to plan and implement corrective and preventive actions that are targeted towards reduction of such financial losses and generate more profit at laboratory level.


**Keywords:** Direct and indirect cost, Hidden financial loss, Repeat testing, Total laboratory cost

## INTRODUCTION

In the era of modern medicine, the services of clinical diagnostic laboratories have a considerable influence on medical decision making by healthcare providers in the diagnosis, treatment and prevention of disease [1,2]. The reason behind this dramatic increase in the demand of laboratory services are developments of advanced laboratory equipment like automation, newer diagnostic tests and other extensive advancement in laboratory technologies that provide opportunities for appropriate diagnosis. As a direct impact of this improved service there is an increase in the funds invested in running a diagnostic laboratory [1-3]. In emerging countries like India, where financial resources are limited for laboratory services [3], the main challenge is to maintain or increase the quality of services for optimal patient care while simultaneously lowering cost and maintain position in today's competitive world [1-3]. Cost accounting of a diagnostic laboratory includes financial calculation of: 1) Preanalytical; 2) Analytical; and 3) Postanalytical phases.

Net profit of laboratory is the calculation of total income generated/total laboratory revenue after deducting total laboratory cost [1,3]. This total laboratory cost is further divided in to direct cost and indirect cost: i) direct cost includes amount related directly to test performance, supplies and labour; and ii) indirect costs, also known as 'overheads', apply to items necessary to run laboratory, are not test specific and include expenditures on quality control, maintenance and repairs of equipment, service contracts, equipment lease or rental, continuing professional development activities, utility bills, insurance, taxes, etc., [4]. The net profit is the amount of money made per test that exceeds sum of direct and indirect cost [4]. Studies have been conducted in the past to assess the cost accounting system of laboratories with an intention to identify areas of improvement in the working system, thereby increasing the profit and reducing the losses and suggested adopting an activity based costing rather than traditional accounting method [3,5,6]. As per our knowledge, this may be the first study analysing the hidden financial losses of one section of the laboratory with detailed analysis of reasons of such losses in Gujarat, India. Unlike other studies, authors have tried to identify reasons of monetary losses which can be corrected at laboratory level. This article can be useful as a basic module for other laboratories to make their own system to identify some important, correctable, preventable and hidden financial losses and increase the net profit.

The aim of the study was to identify and evaluate the magnitude of several hidden expenses due to repeat testing, outsourcing of test due to unavailability of test kits or the consumables, expired kits/test device discarded unused, identify reasons of repeat testing by performing a root cause analysis through five whys technique and identifying corrective and preventive actions to address the problem on hand.

Primary objective was to analyse the total financial losses (INR) due to repeat testing, outsourcing of tests performed in house and due

to expiry of unused kits in serology section. Secondary objectives were to identify major reasons of repeat testing of individual test parameter for patient's/control sample and its contributing financial loss and to evaluate magnitude of monetary loss for repeat testing as per: (i) test method performed (Manual vs Automation); (ii) working shifts (routine shift vs emergency shift).

## MATERIALS AND METHODS

This quality improvement project was a cross-sectional study conducted at serology section of Microbiology Laboratory, Shree Krishna Hospital, Karamsad, which is a 900-bed NABH accredited hospital in Gujarat, India and is affiliated with Bhaikaka University. The Microbiology Laboratory is a part of Shantaben Suryakantbhai Desai (VASO) Diagnostic centre. This Diagnostic centre is NABL accredited.

This time bound study was carried out for a period of 12 months from 1st April 2021 to 31st March 2022 after approval by the Institutional Ethics Committee (Registration No: IEC/BU/2021/Ex.09/85/2021, Date:01/04/2021) (Registration No: IEC/BU/2021/Ex.36/424, Date: 23/10/2021). The microbiology division received total of 55,105 test requests during the study period including bacterial and fungal culture, staining and serological tests of which serological tests comprise of 29,510 (53.55%) test requests.

All tests mentioned in [Table/Fig-1], including control tests, received during study period and fulfilling the inclusion criteria mentioned below were taken into consideration.

| S. No. | Name of the test | Method | S. No. | Name of the test | Method |
|---|---|---|---|---|---|
| 1 | Hepatitis B surface antigen | Immunochromatography | 10 | Hepatitis E virus IgM antibody | Immunochromatography |
| 2 | Hepatitis B surface antigen | Enzyme linked fluorescent assay | 11 | Urine pregnancy test | Immunochromatography |
| 3 | Anti-Hepatitis C virus antibody | Enzyme linked fluorescent assay | 12 | Rheumatoid Arthritis (RA) test | Latex agglutination |
| 4 | Anti-Hepatitis C virus antibody | Gold conjugate spot test | 13 | Antinuclear Antibody (ANA) profile | Immunoblot |
| 5 | Rapid Plasma Reagin | Slide flocculation | 14 | Anti HBs antibody test | Enzyme linked fluorescent assay |
| 6 | Widal test | Tube agglutination | 15 | HIV antibody test | Rapid immunoconcentration test |
| 7 | Dengue NS1 antigen | Immunochromatography | 16 | SARS COV2 IgG and IgM antibody test | Enzyme linked fluorescent assay |
| 8 | Dengue IgG and IgM antibody test | Immunochromatography | 17 | Antistreptolysin O (ASO) test | Latex agglutination |
| 9 | Hepatitis A virus IgM antibody | Enzyme linked fluorescent assay | | | |

**[Table/Fig-1]:** Serology tests included in the study.

**Inclusion criteria:**

i. Where a test or control was repeated (without collection of another sample, only test repeated);

ii. Tests which were required to be outsourced due to unavailability of test kits or any of the consumables required to run the test;

iii. All test kits/test devices which crossed the expiry date and were discarded unused.

All tests' procedures undergo quality control testing as per laboratory policy. Following receiving requests for laboratory tests, the samples were collected and transported to the lab, tests were run as per the standard operating procedure for each test, results were interpreted and released.

**Exclusion criteria:** Where test/control repeated as a part of lot verification was not included.

Before initiating data collection, an orientation session regarding the objectives and methodology of the study was conducted for faculties, resident doctors and technicians involved in processing and reporting samples. They were assured that the study performed solely to identify the gaps in the system rather than individuals. A Participant Information Sheet (PIS) was provided to all the staff members for their information. The purpose of the orientation was to encourage the staff members to honestly report the test that was repeated in the serology section, with correct reasons, to the investigator.

**Informed consent process:** The study did not involve any participants. Laboratory staff was involved in reporting the repeat tests to the investigator, was a day-to-day practice for which consent was not required. It was assured that their names shall not be revealed at any time during and after the study and that no punitive actions shall be taken for the losses identified in the study.

**Calculation of loss:**

1. Using the activity based costing adopted by the laboratory, the loss incurred for repeat test was calculated as shown in [Table/Fig-2]

The reasons for the repeat test were identified using '5 Whys' technique and was documented in the data collection form [7]. The most common errors which were reasons for a repeat test, found in the literature search and included were- processing of incorrect test, processing of incorrect sample, failure to reject poor quality sample (clotted, haemolysed or lipemic sample), processing by trainee staff, lack of adherence to standard operating procedure for the test, failure of control sample, processing from expired kit, doubtful result or failure to correlate clinically as decided by faculty of Microbiology, machine breakdown and others (Misplaced device, labelling error, faulty device, failure to interpret results on time). Mohammedsaleh ZM and Mohammedsaleh F and Plebani M mentioned similar reasons for most laboratory errors [8,9]. A result was considered as doubtful in tests such as Immunochromatography techniques where a test band was barely visible making it difficult to interpret or in case of agglutination or flocculation tests where the visibility of clumps or floccules was inconclusive when observed by two or more faculties. Practice of reporting repeat testing by technician on daily basis is the important way to identify, rectify and document common reasons for repeat testing [8].

| Calculation of loss for individual test which is repeated= | Processing cost of the mentioned test (cost of the test device) (a) | Manpower cost (55% of processing cost) (b) | Total direct cost (c)=a+b | Overheads (7% of total direct cost) (d) | Total loss (e)=c+d |
|---|---|---|---|---|---|

**[Table/Fig-2]:** Calculation of loss (INR) incurred for repeating test [4].

2. The loss incurred due to unavailability of test kit or consumables was calculated as the reduction in the amount of profit gained by the institute provided the test was conducted in our lab.

Loss incurred due to unavailability of test kit or consumables=profit gained by the institute if the test was performed in-house minus profit gained by the institute if the test was outsourced [Table/Fig-3] [8,9].

| Test outsourced | Total number of tests outsourced (a) | Profit of single test when test performed inhouse (b) | Total profit if done inhouse c=(a*b) | Profit of single test when the test outsourced (d) | Total profit if done outsourced e=(a*d) | Loss f=c-e |
|---|---|---|---|---|---|---|

**[Table/Fig-3]:** Calculation of outsourced test loss (INR).

The reasons for unavailability of test kit or consumables were not sought for during the present study. Logistic has been provided by outsourced laboratory so it was not calculated for the calculation of loss due to outsourcing.

The purchase cost of the kit/test device was considered as loss incurred due to discarding of kits/devices that were not used within the expiry period.

## STATISTICAL ANALYSIS

All the data collected in Microsoft Excel file as per the above-mentioned formulas for easy calculation and compilation of data for defined study period which is followed by calculation of:

Total loss=Loss due to repeat tests/controls+Loss due to unavailability of test kit/consumables (outsourcing)+Loss due to discarding the expired test kit/device that were discarded unused.

Analysis of repeat tests done in detail by categorising it further into:

(i) Loss incurred due to repeat testing of individual test;

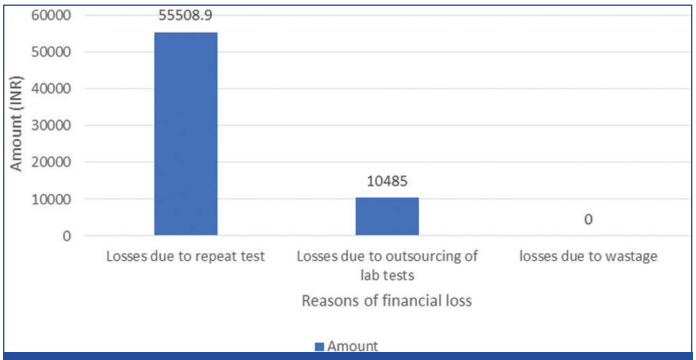
(ii) Reasons of repeat tests and its frequency;

(iii) Frequency and loss due to repeat tests as per the method of processing i.e., manual method and automation method.

(iv) Frequency of repeat tests as per processing in routine working hours and emergency hours.

## RESULTS

After one year of data analysis, the total loss occurred at serology section of Microbiology laboratory, was INR 65,993.9. As mentioned in plan of statistical analysis, this total loss is calculated by simple summation of losses due to repeat tests, outsourced test and expired kit. [Table/Fig-4] describes the distribution of total financial loss incurred in the present study.




**[Table/Fig-4]:** Distribution of financial losses (INR) incurred in the present study.

The major reason for the losses was: (i) repeat testing of a sample or control (INR 55508.9) (84%) followed by; (ii) losses due to outsourcing of the tests due to unavailability of the test kits in the laboratory (INR 10485) (16%). There were no losses incurred due to the expired kits or devices.

Detail analysis of losses due to repeat testing:

[Table/Fig-5] describes the frequency of repeat testing as well as loss incurred due to it for individual serology tests.

| Test | Method | (Automated (A)/Manual (M)) | Number of repeat testings n (%) | Loss (INR) (%) |
|---|---|---|---|---|
| Hepatitis B surface antigen | Immunochromatography | Manual | 12 (4.48) | 204.5 (0.37) |
| Hepatitis B surface antigen | Enzyme linked fluorescent assay | Automated | 45 (16.79) | 5909.07 (10.65) |
| Anti-Hepatitis C virus antibody | Enzyme linked fluorescent assay | Automated | 71 (26.49) | 12421.08 (22.38) |
| Anti-Hepatitis C virus antibody | Gold conjugate spot test | Manual | 15 (5.60) | 1105.92 (1.99) |
| Rapid Plasma Reagin | Slide flocculation | Manual | 29 (10.82) | 1346.66 (2.43) |
| Widal test | Tube agglutination | Manual | 8 (2.9) | 505.84 (0.9) |
| Dengue NS1 antigen | Immunochromatography | Manual | 28 (10.45) | 11145.12 (20.08) |
| Dengue Ig G and Ig M antibody test | Immunochromatography | Manual | 12 (4.48) | 9513.14 (17.14) |
| Hepatitis A virus IgM antibody | Enzyme linked fluorescent assay | Automated | 2 (0.75) | 597.48 (1.07) |
| Hepatitis E virus IgM antibody | Immunochromatography | Manual | 1 (0.37) | 56.17 (0.10) |
| Urine pregnancy test | Immunochromatography | Manual | 6 (2.24) | 127.69 (0.23) |
| RA test | Latex agglutination | Manual | 1 (0.37) | 23.66 (0.04) |
| ANA profile | Immunoblot | Manual | 6 (2.24) | 7031.37 (12.66) |
| Anti HBs antibody test | Enzyme linked fluorescent assay | Automated | 17 (6.34) | 3746.4 (6.75) |
| HIV antibody test | Rapid immunoconcentration test | Manual | 12 (4.48) | 868.74 (1.57) |
| SARS COV2 IgG and IgM antibody test | Enzyme linked fluorescent assay | Automated | 2 (0.75) | 777.8 (1.40) |
| ASO test | Latex agglutination | Manual | 1 (0.37) | 128.26 (0.23) |
| Total loss | | | 268 | **55508.9** |

**[Table/Fig-5]:** Frequency of repeat testing and loss incurred for individual serology test.

Using the formula mentioned in [Table/Fig-2], loss for individual repeat test is calculated. For example, repeat test loss for ASO test, calculated as: Total direct cost of ASO test is 119.87 INR, overheads are 8.39 INR, so total loss if one test of ASO repeated is 128.26 INR. Likewise, loss of all the individual test calculated as per the frequency of the test repeated.

Total 268 repeat testing were done during the study period accounting for loss of 55508.9 INR. Anti-hepatitis C virus antibody test (n=71) and Hepatitis B surface antigen test (n=45) performed by Enzyme linked fluorescent assay (automation) had the highest frequency of repeat testing. Rapid Plasma Reagin test (n=29) by slide flocculation and Dengue NS1 antigen test (n=28) by Immunochromatography were the most common tests undergoing repeat testing among manual methods. Though ANA by immunoblot was repeated less commonly (n=6) but cost of individual test is higher contributing to significant amount of loss INR 7031.37.

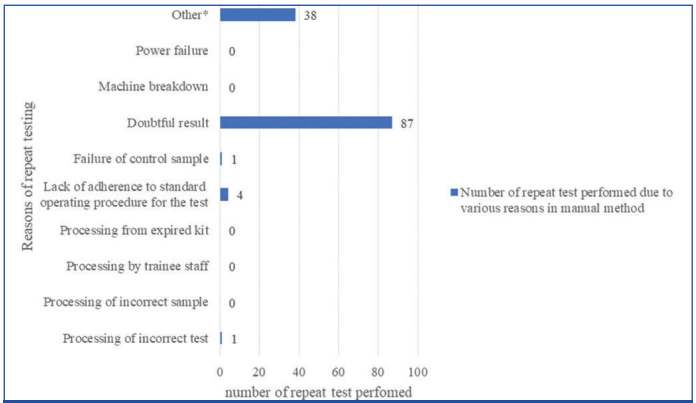
As mentioned in [Table/Fig-6], the most common reason for a repeat testing was a doubtful result (n=102). Out of total 102 doubtful results, (n=87) tests were performed by manual method whereas (n=15) tests were performed by automation method. Machine breakdown (n=57) and power failure (n=24) were the other two major reasons. There was no repeat testing due to: (i) Failure to reject poor quality sample (clotted, haemolysed, lipemic sample); (ii) Processing by trainee staff; (iii) Processing from expired kit.

| Reasons for repeat testing | n (%) |
|---|---|
| Processing of incorrect test | 10 (3.73) |
| Processing of incorrect sample | 7 (2.60) |
| Processing by trainee staff | 0 |
| Processing from expired kit | 0 |
| Failure to reject poor quality sample (clotted, haemolysed, lipemic sample) | 0 |
| Lack of adherence to standard operating procedure for the test | 8 (2.99) |
| Failure of control sample | 10 (3.73) |

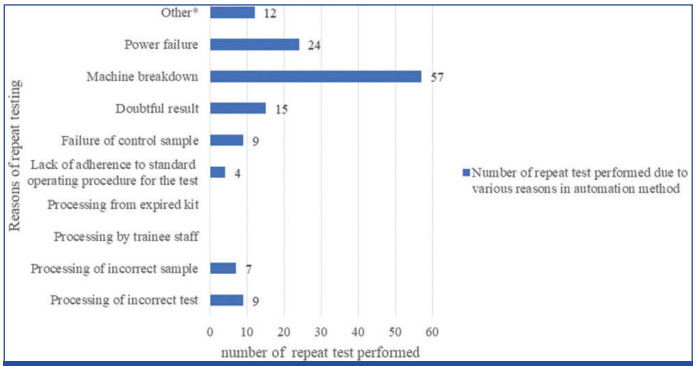
| | |
|---|---|
| Doubtful result | 102 (38.06) |
| Machine breakdown | 57 (21.27) |
| Power failure | 24 (8.96) |
| Other* | 50 (18.66) |
| Total | 268 |

**[Table/Fig-6]:** Reasons for repeat testing and its frequency.
*Misplaced device, labelling error, faulty device, failure to interpret results on time

**Repeat testing in manual methods and automation:** Out of 268 repeat testing, (n=137) (51.1%) repeat testing were done in automation which accounts for loss of 23451.83 INR whereas (n=131) (48.8%) testing was done in manual method which accounts for loss of 32057.07 INR as mentioned and calculated in reference of [Table/Fig-5]. Detail analysis of reasons of repeat testing in manual and automation method shown in [Table/Fig-7,8].




**[Table/Fig-7]:** Number of repeat test performed due to various reasons in manual method.




**[Table/Fig-8]:** Number of repeat test performed due to various reasons in automation method.

**Retesting in emergency hours and routine hours:** In the present study, out of total 268 retesting, n=175 (65.30%) repeat testing weredone in emergency hours whereas n=93 (34.70%) repeat testing were done in routine hours.

The losses due to outsourcing of the tests due to unavailability of the test kits in the laboratory were (INR 10485) (16%) as shown in [Table/Fig-9].

| Test outsourced | Total number of tests outsourced (a) | Profit of single test when test performed inhouse (b) | Total profit if done inhouse c=(a*b) | Profit of single test when the test outsourced (d) | Total profit if done outsourced e=(a*d) | Loss f=c-e |
|---|---|---|---|---|---|---|
| HCV | 233 | 325 | 75725 | 280 | 65240 | 10485 |

**[Table/Fig-9]:** Calculation of outsourced test loss (INR): As per [Table/Fig-3] equation.

## DISCUSSION

Several quality improvement studies have been conducted with an objective to reduce losses happening in a diagnostic laboratory [1,2]. As mentioned by Gujral S et al., each laboratory needs to be do costing exercise as per the requirement to understand the economics involved and to identify and correct insufficiencies [6]. A consistent and unbiased method for estimating loss provides adequate information that will identify key targets for quality improvement [10]. Although the amount of loss (INR 65,993.9) seems to be minute, it only represents a sample area from a huge diagnostic laboratory having several other disciplines. As the major bulk of this loss was due to repeat testing and the most common reason for repeat testing was doubtful results (n=102) out of which n=87 repeat test performed by manual method. Manual methods that include latex agglutination, slide flocculation and immunochromatography, need a better technical skill and are interpreted by visual inspection of the test results. Inadequate knowledge or training, lack of technical skills such pipetting, mixing of sample and reagent, rotation of cards for latex agglutination or slide flocculation, etc., can affect the final result. Lack of adherence to standard operating procedures in such cases directly affects the final results. Unlike automated methods where the results are interpreted by the machine and displayed on the screen or on paper prints, manual methods are dependent to observer's skills and can often have subjectivity when observed by more than one observer. In majority of cases the visualisation of results has to be performed in a stipulated time. An early or late observation may lead to a false positive or false negative result. There was n=50 repeat tests (18.66%) out of 268 were due to other reasons which were also associated with poor technical skills. The high number of doubtful results in the present study highlights the limitations of manual methods as well as need for continual skill assessments of the laboratory staff. Carlson RO et al., mentioned in his study that laboratory staff if not involved in continuous improvement activities leads to major impact on laboratory failure cost [1]. Mohammedsaleh ZM and Mohammedsaleh F mentioned low level of education and training among staff members reflected in a lower level of output in performing laboratory test [8]. Plebani M also signifies the effect of personal training and supervision by expert staff will ultimately have positive impact on outcome of testing [9]. Aggarwal K et al., also suggested repeated training and continuous education programmes can be implemented as a part of corrective-preventive action to reduce errors by technical staff to great extent [11].

Lippi G and Da Rin G, and Al Naam YA et al., mentioned several advantages of automation over manual methods in their articles for improving quality of testing by lowering risk of human errors, more efficient integration of test results compared to manual methods, increasing accuracy and precision of test results [12,13].

In present study, 57 (21.27%) tests out of 268 repeat tests were due to machine breakdown by automated methods. Automated systems are capable of handling several samples at one time but simultaneously breakdown of the machine may suddenly lead to failure of all the test that were being processed at that time. Carlson RO et al., mentioned unplanned equipment downtime as the important hidden factor contributing to laboratory cost [1]. Plebani M in his study mentioned that equipment malfunction leads to 7-13% of errors, which falls under the category of analytical error and preventable by laboratory itself [9]. A periodic preventive maintenance therefore remains the mainstay to prevent such breakdowns and avoid losses. Power failure with lack of back up electrical supply also ends up in losing number of tests, n=24 (8.96%) in this study, that were being processed at that time. Authors recommend a need for better preventive maintenance and an electrical back up plan to avoid such losses in future.

Poor staff scheduling is considered as major hidden factor contributing to internal failure cost by Carlson RO et al., [1]. At our set-up, the number of staff in emergency hours is less compared to routine hours and shares work of different sections of the laboratory. In addition, the constant supervision of senior members of the laboratory, which is there during routine hours, is not present. As a result, the chances or errors during emergency hours increases

as seen in this study n=175 (65.30%) out of 268 repeat tests. Mohammedsaleh ZM and Mohammedsaleh F stated similar findings that, to prevent errors, numbering of staff working in emergency hours should be sufficient enough to avoid work overload [8].

### Limitation(s)

As per literature search, similar types of study designs and methodology were not found. Only few studies based on activity based cost accounting system for laboratories were found in India. Authors tried to align the findings of previous literature as possible as they could.

## CONCLUSION(S)

Such quality improvement project provides an insight of magnitude of hidden financial losses incurred by a diagnostic laboratory and allows one to identify the reasons of losses which may not have been taken into consideration. It reveals need for frequent trainings and continual skill assessment of the laboratory staff. Advancement to newer automation technologies for running tests minimise the risks of human technical errors and subjectivity to evaluate results of tests. This study module can be useful for primary level laboratories to establish their own system to identify such hidden financial losses at laboratory level and increase the net profit.

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**PARTICULARS OF CONTRIBUTORS:**

1. Associate Professor, Department of Microbiology, Pramukhswami Medical College and Shree Krishna Hospital, Bhaikaka University, Karamsad, Anand, Gujarat, India.
2. Ex-Postgraduate Resident, Department of Microbiology, Pramukhswami Medical College and Shree Krishna Hospital, Bhaikaka University, Karamsad, Anand, Gujarat, India.
3. Professor, Department of Microbiology, Pramukhswami Medical College and Shree Krishna Hospital, Bhaikaka University, Karamsad, Anand, Gujarat, India.

**NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:**
Dr. Chaitali Suresh Dabhi,
21, Nilkanth Avenue, Near Sardar Patel Education Campus, Bakrol Vadtal Road, Anand-388315, Gujarat, India.
E-mail: dabhichaitali911@gmail.com



**PLAGIARISM CHECKING METHODS:** [Jain H et al.]

- Plagiarism X-checker: Apr 27, 2024
- Manual Googling: Oct 24, 2024
- iThenticate Software: Oct 26, 2024 (2%)

**ETYMOLOGY:** Author Origin

**EMENDATIONS:** 7

**AUTHOR DECLARATION:**

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? No
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Apr 26, 2024**
Date of Peer Review: **Jul 13, 2024**
Date of Acceptance: **Oct 28, 2024**
Date of Publishing: **Dec 01, 2024**