# Description of the quality indicators defined in the National Reference Laboratory in Tuberculosis of CRPHF/Ensp/Fiocruz by means of the process mapping methodology

*Descrição dos indicadores da qualidade definidos pelo Laboratório de Referência Nacional em Tuberculose do CRPHF/Ensp/Fiocruz por meio da metodologia de mapeamento de processos*

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## ABSTRACT

**Introduction:** The National Reference Laboratory (LRN) in Tuberculosis (TB) is a laboratory unit of highly specialized technical excellence that has developed projects involving training in human resources and the enhancement of techniques essential for the diagnosis of TB. Its purpose is the continuous improvement of all laboratory processes and their quality management, with the purpose of collaborating on and strengthening the actions in the network that integrate it in the aid of surveillance and in the fight against TB. **Objectives:** This research aims to describe the quality indicators that were defined through the process mapping methodology, with the objective of promoting and raising the level of quality and reliability of the different laboratory processes performed at LRN in TB. **Method:** For the definition of indicators, process mapping was used which, through flow charts, can establish and determine the most appropriate indicators for LRN in TB. After defining these indicators, they were described with their respective titles, preventive and corrective measures, importance and goals. **Results:** The results of the research suggest that the established indicators are fundamental for the laboratory processes, since they improve quality management. **Conclusion:** Through this study, we seek to encourage and impel the managers involved in the field of TB and in the field of health on the utility and the need to control and measure processes, being able to standardize them with the help of indicators or other quality tools.

**Key words:** indicators of quality in health care; total quality; total quality management; tuberculosis.

## INTRODUCTION

During decades the concept of quality has evolved from simple adequation to standard to adequation to clients' needs, which have become more and more evident over the years[1-3].

Concerning healthcare, in the beginning, the theme quality was relevant for just a small group of physicians enlightened on the subject. Later, in the early 20th century, quality assurance appeared in the United States. It can be considered the first method of ensuring quality in health[4].

Around the years 1970s and the late 1980s, according to the precept that each citizen has the right to have the most adequate service that medicine can offer, the World Health Organization (WHO) took measures designed to develop assurance of quality in health systems[4-8].

In 1998, the Joint Commission on Accreditation of Hospitals, created in 1951 in the United States, became the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), aimed at following and monitoring the quality of provided health services by consultancy, accreditations, certifications or education in this field[6, 9-11].

By means of this practice and the support from WHO, many other countries have built different and new methods to monitor and assess quality in health. As a consequence, at the end of the 1980s, in Latin American countries, concern for quality was started by government incentive. The motivation was the creation of models for hospital accreditation, which were initiated by the Pan American Health Organization (PAHO) and by the Federación Latinoamericana de Hospitales[4, 6, 8, 10, 12, 13].

In Brazil, the concept of quality was disseminated also by the accreditation of health services, which began in 1986, when Colégio Brasileiro de Cirurgiões [the Brazilian College of Surgeons (CBC)] created the Commission of Hospital Assessment. Another meaningful point for the evolution of the concept of quality in health in Brazil was the easy access to information that the users of these services gained, by the creation of the Consumer Defense Code, on September 11, 1990, and Manual dos direitos dos pacientes (the manual of patients' rights), on October 26, 1993[4, 6, 8, 10, 12-16].

In 1991, having as support the creation of the manual of accreditation standards for Latin America, prepared by WHO and PAHO, accreditation programs were run as the first mechanisms proposed for hospital accreditation[6, 8, 10, 12].

Based on the importance of accreditation programs in Brazil, in 1994, the Ministry of Health (MH) developed the Programa de Avaliação e Certificação de Qualidade em Saúde [Program of Evaluation and Certification of Quality in Health (PACQS)]. That program counted on voluntary participation, aimed at encouraging continuous improvement, harmonizing and creating basic criteria common to all hospitals. The program was only launched in 1998 and became the Consortium for Brazilian Accreditation (CBA)[6, 8, 10, 12].

In that same year, the first edition of the Brazilian Manual of Hospital Accreditation was published[14].

In 1999, the National Organization of Accreditation (ONA) was born, a private non-profit institution that has the function of regulating, setting standards, and monitoring the whole accreditation process in Brazil. And as a process resulting from this culture, in 2000, health institutions, such as hospitals, began to be evaluated and accredited by ONA and they could make use of this accreditation to praise their service, ensuring customer loyalty[8-10, 12, 14, 17].

Finally, in 2001, the National Agency of Health Surveillance (Anvisa) officially recognized the Brazilian Accreditation System to integrate even more the National System of Health Surveillance. As a result of this advance, three new accreditation manuals were created: hemotherapy, nephrology and renal replacement therapy

services, and clinical laboratories, which nowadays are in their fourth edition[8-10, 12, 14, 17].

The clinical laboratory can be characterized as a physical structure directed to the conduction of laboratory tests and the practice of laboratory medicine. The aim of these laboratory tests is to help and provide correct diagnosis, as well as to avoid diseases, estimate the period of time of a disease and its prognosis, observe the impact of treatment, and analyze the presence of risk factors of harm to human health. Therefore, the conduction of a test can be traditionally divided in three phases: pre-analytical, analytical and post-analytical[18-22].

With this characteristic, a laboratory test is considered adequate when it is effective, clear, and objective, being available to the population.

The concept of quality in clinical laboratories in Brazil progressed through the same reasoning employed in the several health areas. Within this context, the Sociedade Brasileira de Patologia Clínica/Medicina Laboratorial (SBPC/ML) has been the pioneer in issues about accreditation and laboratory quality[19-21, 23, 24].

In 1994, in its statute, SBPC/ML already characterized the construction and consolidation of standards as objectives for the conduction of countless laboratory tests. And during the 1970s decade, it presented by means of an own publication in the Brazilian Journal of Clinical Pathology a proposal for revising and adapting the practices of the American College of Pathologists (ACP) to the Brazilian reality[8, 23, 24].

In 1976, in Brazil, the National Program of Quality Control (PNCQ) was set up. In 1977, another important hallmark in this scenario was the creation of Control-Lab, designed to create opportunities for clinical laboratories to participate in wider quality control programs. In the same period SBPC/ML and Control-Lab created a program for internal and external quality control, unheard-of in the country, termed Program of Excellence in Medical Laboratories (PELM)[8, 24-26].

In 1998, by means of the already established partnership between Control-Lab and SBPC/ML, the Program of Accreditation of Clinical Laboratories (PALC) was created, which in its turn was revised and up-to-dated in the following years (2004, 2007, and 2010)[8, 18, 24, 27].

In the country, the type of service offered by a clinical laboratory is not subjected to regulation. Thus, laboratories that hinder services in the area of clinical pathology/laboratory medicine may ask for accreditation voluntarily to the General Coordination for Accreditation of Instituto Nacional de Metrologia,

Qualidade e Tecnologia (Cgre/Inmetro), which is the accreditation body of conformity assessment bodies recognized by the Brazilian government.

Due to the great importance given to analytical results released by a clinical laboratory, Brazil has several laboratory networks that require their participants to have internationally recognized management systems, seeking this recognition by government bodies[21].

According to a survey carried out by the Brazilian Institute of Geography and Statistics (IBGE) in 2014, there are approximately 16,650 clinical laboratories in the country, of which 4,917 are public and 11,970 are private. The quality management systems for clinical laboratories intend to provide reliability in results, bringing users closer and closer to these establishments. Nowadays around 70% of results released by clinical laboratories are responsible for the crucial information directly affecting medical decision[8, 21, 28].

Quality indicators are procedures of measurement indispensable for organizations to have success in their processes. A noteworthy and very important particularity in the use of these tools is their simplicity, easy access, along with the low cost, uncomplicated understanding of these methods, which provide their propagation and application in the organizational setting[12, 29].

Indicators also appear in strategic management as forms of representation that contribute to managers' decision taking, being seen as the foundation of this type of management[12, 22, 29, 30].

Consequently, indicators can be defined as follows: graphically represented qualitative or quantitative information, able to show productivity evolution and performance, of processes involved in products and the services that organizations offer regarding efficacy, efficiency, or satisfaction level. Performance indicators, as they are also known, can be associated with a behavior of processes, characterizing the following conditions: cost, profit, production cycle, rework, degree of use of raw material, and conformity of products[12, 22, 29, 30].

The indicators defined and established at an institution must be clearly and objectively described, being composed of: a title, a comparative referential, a numeric value (mathematical relationship), its importance, goals, and preventive and corrective measures – that will be able to demonstrate success or failure of a specific process. The goals are the aims or objectives to be met and they are the key agents of the enterprise management process[12, 22, 29, 30].

In order to create an efficient indicator, it is advisable to follow some parameters, which are the basis of the implementation method used in organizations, so that indicators show their actual applicability and safety. They are: selectivity, extent, simplicity, clarity, traceability, specificity and stability, accessibility, accuracy and low cost[9, 12, 22, 29-31].

Indicators are seen as quality parameters, in which performance and behavior of a process are classified as satisfactory when they are within the established limits. They are considered items of measurement of an operation, activity, or process, essential for guidance of policies of action and planning that integrate programs of several areas[8, 12, 22].

Some efforts have been made to standardize indicators in the health field. In Brazil, the Information Technology Department of the Unified Health System (Datasus), organ of the MH, makes available in its site some indicators that can be used in this scenario. Another means that offers basis in questions on health indicators is the publication of basic indicators of health in Brazil: concepts and applications, of the Inter-Agency Network for Health Information (Ripsa), also of the MH, in partnership with PAHO[12].

Different studies have been carried out lately due to the importance of indicators in this field. Those studies use benchmarking practices and describe the indicators that are usually more employed in clinical laboratories, for example, enabling other laboratories to use these indicators to control their processes seeking continuous improvement[8, 22].

As a consequence of those studies, new versions of the JCAHO accreditation manuals and the PALC norm have already brought in their requisites for the use of indicators in laboratory management, allowing for these laboratory indicators to be responsible for providing an evaluation of efficacy and efficiency of these several phases that make a laboratory test. More recently, a Program of Laboratory Indicators was devised, through the partnership of Control-Lab and SBPC/ML, which provides clinical laboratories the means to measure, compare and standardize their activities and processes with the indicators established by Control-Lab[22].

Tuberculosis (TB) is considered one of the most ancient diseases of mankind. Its causing agent is the Koch bacillus, which was so named in honor of the scientist that described it. Robert Koch identified, in 1882, a slow-growth bacterium that caused the disease: the *Mycobacterium tuberculosis*. Today we know other five species that are listed as causing TB, forming a complex termed *M. tuberculosis*[32-34] complex (MTBC).

To this date, TB is considered a very difficult and crucial problem for public health in Brazil and the world. The WHO estimates that around eight to nine million new cases of TB

occur per year; approximately three million of these cases die because of the disease. In Brazil the occurrence of 70 thousand cases is estimated per year, so it is one of the 22 countries given priority by WHO that concentrate 80% of the world TB burden. Rio de Janeiro is the state that displays the highest incidence rates (73.8 cases per 100 thousand inhabitants) and mortality (5.4 deaths per 100 thousand inhabitants) in the country, which presents 21 municipalities of priority for TB control due to other epidemiological characteristics, mainly concentrated in the metropolitan region of the state[32-35].

On that account, in 1993, WHO publicly stated that TB is a world emergency and started recommending the adoption of the strategy Directly Observed Therapy Short Course (DOTS) as a global response to control the infirmity[32-35].

Due to the continuing problem, along with the high rates of treatment dropouts, and with low percentage of cure and detection of cases, in 1988 the Tuberculosis Control National Program (PNCT) was launched in Brazil. That program incorporated some innovations such as coverage expansion, supervised treatment (recommended by the new DOTS strategy), and a new form of resource transfer to municipalities, which is provided in the form of bonus[32-35].

In that same period of the 1990 decade, Brazil went through a process of change in the health public system. Those alterations came from the creation of the Brazilian Unified Health System (SUS). That is how the National System of Public Health Laboratories (Sislab) was born[32-35].

Sislab was defined by Ordinance 2031 from 2004 of MH as a group of laboratories networks that were planned according to a disease or program, hierarchically according to the complexity degree of activities related to health surveillance. The laboratory networks comprise epidemiological surveillance, environmental surveillance, sanitary surveillance, and attention to health. Thus their subnetworks are defined as: collaborating centers (CC), national reference laboratories (LRN), regional reference laboratories (LRR), state reference laboratories (LRE), municipal reference laboratories (LRM), local laboratories (LL), and frontier laboratories (LF)[36].

Within this classification, LRN are laboratory units that have as competencies to perform high-complexity procedures that complement diagnosis and the analytical quality of the whole network, besides technically coordinating the laboratory surveillance network, assisting the national manager in the monitoring, normalization, standardization, and in the evaluation of laboratory activities, among other responsibilities[36]. In the case of TB, the LRN in TB is inserted in the Centro de Referência Professor Hélio Fraga (CRPHF), a departmental unit of Escola Nacional de Saúde Pública Sergio Arouca (Ensp) of Fundação Oswaldo Cruz (Fiocruz), in the city of Rio de Janeiro, Brazil.

The LRN in TB has as part of its attributions the conduction of tests such as bacilloscopy, culture (bacterial isolation), identification of mycobacteria of MTBC and mycobacteria not belonging to that complex [non-tuberculous mycobacteria (NTM)], and traditional and automated sensitivity tests to antimicrobials, besides methods of molecular biology that contribute to identification of tuberculous and non-tuberculous mycobacterial species, and in the detection of mutations that confirm resistance to antimicrobials. In 2006, the LRN in TB went through reforms using the international standard of biosecurity. With the implementation of this concept, a decisive step was taken to follow a new model for the public health laboratory network, which has as its cornerstone the concern with observation of norms of human security, environmental, and of quality systems in their greater focus[22, 36].

Therefore, to meet the norms established by the MH and society demands, the LRN opened in 2006 the level 3 laboratory of biosecurity with new facilities, according to international biosecurity standards for work with TB[22, 36, 37].

It is worthy stressing that this laboratory already has a system of quality management implemented and accredited by the Coordenação Geral de Laboratórios [General Coordination of Laboratories (CGLAB)]/Secretaria de Vigilância Nacional [Secretariat of National Surveillance (SVS)] of MH, according to ABNT NBR ISO/IEC 17025 norm. Since 2008, the LRN in TB began migration of its system to the ABNT NBR NM ISO 15189 norm, specific for laboratories that manipulate and carry out tests with biological samples. Nowadays the laboratory has implemented in its quality management system (QMS) the ABNT NBR NM ISO 15189 norm, but, in spite of this, there are no indicators of quality defined for the technical activities of the laboratory[22, 36].

It is important that at a LRN, quality indicators are well defined, as these are laboratory units of technical excellence, highly specialized in their areas and fundamental for strategies of public health in the country, as previously mentioned[22, 36].

In this context, the definition and the description of quality indicators stand out as an important tool for measurement and analysis of the different technical activities, supporting, thus, the establishment of improvement and decision taking by the respective managers[22, 33, 34, 35, 37].

For this reason, this study reports a project of standardization of indicators, according to ABNT NBR NM ISO 15189 norm, which recommends implementation, monitoring, and systematic evaluation of laboratory processes. This standardization of quality

indicators results from the description of these indicators, and, in its turn, the description of these indicators happens by their definition, using the process mapping methodology to define the most adequate ones to be used in the main processes carried out at the LRN in TB, aiming to assess performance, efficiency, and efficacy of these tests, ensuring reliability in the results released by the laboratory.

Given the hierarchical strategic public health importance of LRN in TB, it is vital that quality indicators are defined and described to meet the requirements of the technical norm implemented there, besides providing the monitoring of technical processes aimed at continuous improvement.

## OBJECTIVES

• Map the processes involved in the tests by means of process mapping methods;

• define quality indicators for the major processes carried out at the LRN in TB;

• describe indicators: name them, define the importance of each one, establish goals and recommend corrective and/or preventive measures for their potential deviations.

## METHOD

The methods used in this study were divided into steps, in which some tools were employed to reach these objectives. They are:

• profile of the enterprise;

• process mapping;

• indicators definition and description.

The profile and the presentation of the enterprise used in this study were based on the definition model of enterprise profile employed in the excellence criteria of the National Quality Prize. That profile encompasses the description of some pieces of information responsible for creating the image of an enterprise profile. They are: composition of a society or identification of supporting or founder members; society – main communities with which the organization keeps relationships; QMS; purpose and size; clients and market; main facilities; workforce; suppliers and inputs; operational system/computerized system; products and processes[29, 38].

Information items to build up the enterprise profile of LRN in TB were obtained from the following documents:

• internal documents: Manual of Tuberculosis Bacteriology; Laboratory Quality Manual of Tuberculosis Bacteriology; Management Procedure 13 – plan for residues of health services of Sislab; Management Procedure 14 – risk classification;

• external documents: Ordinance no. 15 of the National Health Foundation (Funasa), reissued by SVS on September 23, 2004, with no. 2031; Ordinance no. 70, from 2004, MH, SVS; Ordinance no. 97, from 2008, MH, SVS.

The analysis of process mapping began with a list of steps/questions described in a way to reveal the activities involved in that process. That proposal was formulated specifically for this study, based on Villela's[38] proposal. The questions are:

1) what is the objective of this process?

2) what are the inputs?

3) what are the outputs?

4) which resources are used in terms of work, equipment, materials, budget, and time?

After answering those questions, **Figure 1** was developed, which presents process mapping. As results of these tables' descriptions, flow charts were prepared for each process.

| Macroprocess: | | Objective: | |
|---|---|---|---|
| Description of the process: | | | |
| Subprocesses: | | Responsible: | |
| Description of the subprocesses: | | | |
| Activities | Objectives | Documents | Actors ○ ● |

FIGURE 1 – *Process mapping*

*Macroprocesses: the main clinical assays of LRN were characterized; objective: the purpose of each clinical assay was reported; process description: the groups of activities connected with each macroprocess were portrayed; subprocesses and description of subprocesses: all the steps were described that are directly linked to each process and that support the macroprocess; responsible: the responsible ones for each subprocess were listed; activities and objectives: all activities and specific objectives were detailed that occur in processes and subprocesses, which produce a particular result; documents: all the documents were described that are used in the respective activities; actors: were represented by the LRN sectors and divided into two classes: committed actors – sectors directly committed to the activities and the macroprocess; involved actors – sectors that help some activities and the macroprocess.*

*LRN: National Reference Laboratory; ●: committed actor; ○: involved actor.*

### Definition and description of indicators

At this moment of methodology, a survey was carried out of information based on the view and strategy of the institution, using process mapping and its flow charts, able to identify critical points and chose quality indicators, in agreement with its goals, which would be able to act efficiently and effectively on processes relevant to the laboratory.

The information and data obtained during the study are presented in the topic "Results", under tables and figures to better clarify them.

## RESULTS

The information to build up the enterprise profile were divided in topics, and, then, they were put together to come up with the laboratory profile design. **Figure 2** presented the description of the information responsible for characterizing the profile of LRN in TB.

Subsequently, we had the description of information responsible for detailing the processes mapping of LRN in TB, expressed in flow charts for each process:

• **Figure 3** presented and elucidated the macroprocess of sample management;

• **Figure 4** presented and elucidated the macroprocess of bacilloscopy;

• **Figure 5** presented and elucidated the macroprocess of cell culture assay;

• **Figure 6** presented and elucidated the macroprocess of the assay identification of MTBC and NTM species;

• **Figure 7** presented and elucidated the macroprocess of sensitivity test assay;

• **Figure 8** presented and elucidated the macroprocess of new methodology assay.
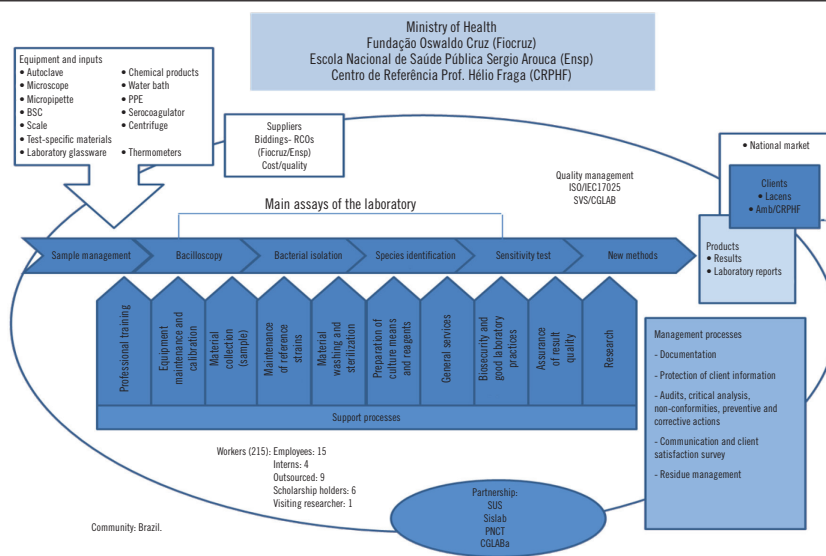


FIGURE 2 – *Enterprise profile*

*PPE: personal protection equipment; BSC: biological safety cabinet; SVS: Secretaria de Vigilância Nacional; Lacens: Laboratórios Centrais de Saúde Pública; RCO: mandatory insurance of civil responsibility; SUS: Unified Health System; Sislab: National System of Public Health Laboratories; PNCT: Tuberculosis Control National Program; CGLAB: Coordenação Geral de Laboratórios.*
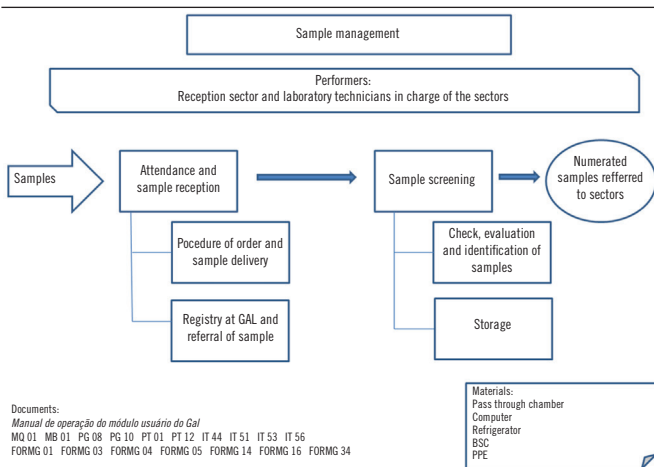


FIGURE 3 – *Flow chart of sample management*

*GAL: Gerenciador de Ambiente Laboratorial; BSC: biological safety cabinet; PPE: personal protection equipment.*
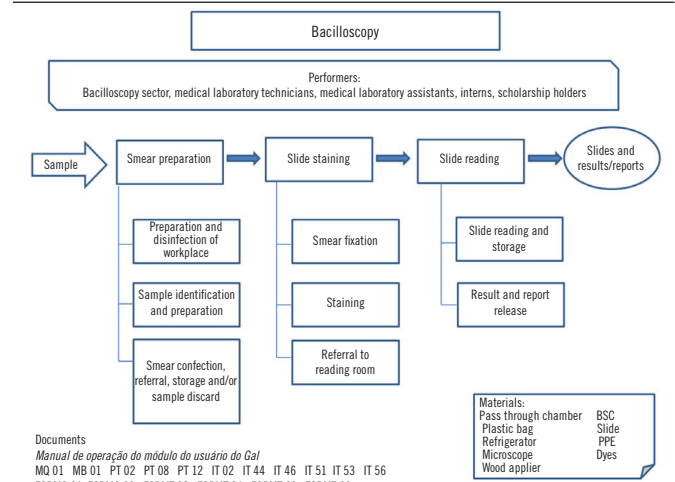


FIGURE 4 – *Flow chart of bacilloscopy assay*

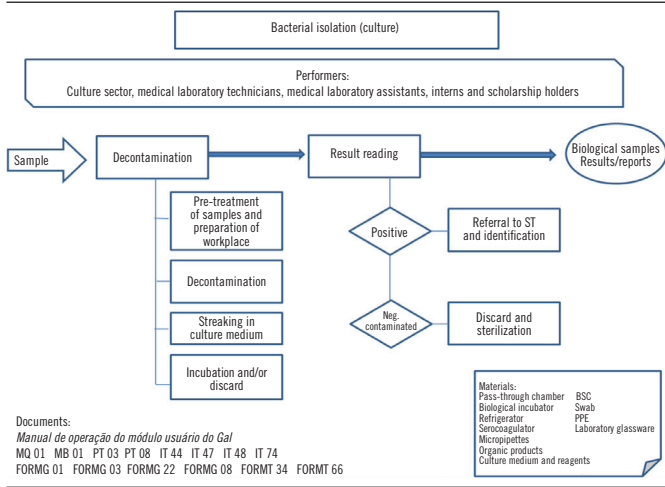*BSC: biological safety cabinet; PPE: personal protection equipment.*

**FIGURE 5** – *Flow chart of bacterial isolation (culture) assay*

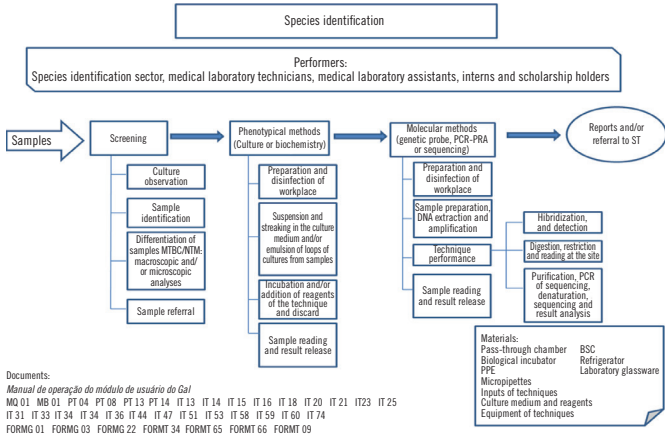*ST: sensitivity test; BSC: biological safety cabinet; PPE: personal protection equipment.*



**FIGURE 6** – *Flow chart of MTB and NTM species identification assay*

*PCR-PRA: polymerase chain reaction-pattern restriction analysis; ST: sensitivity test; BSC: biological safety cabinet; PPE: personal protection equipment; MTBC: M. tuberculosis complex; NTM: non-tuberculous mycobacteria.*
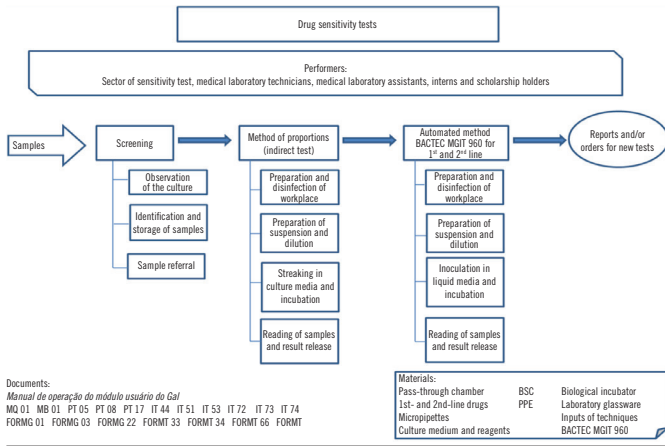


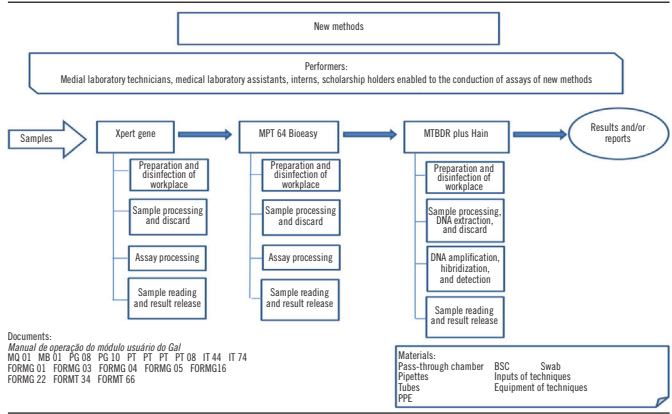**FIGURE 7** – *Flow chart of the sensitivity test assay*



**FIGURE 8** – *Flow chart of new methodologies*

*BSC: biological safety cabinet; PPE: personal protection equipment.*

According to flow charts of the processes of LRN in TB obtained by process mapping, the indicators defined were divided into two groups: indicators relevant to all processes and indicators of efficacy of time of result release. Thus, **Table 1** described the indicators that were relevant to all processes, and **Table 2**, the indicators that were related to time efficacy of result release.

## DISCUSSION

TB also persists as an obstacle for world public health, mainly in Brazil. Over the decades, the development of operations in TB, the improvement of essential techniques that have been developed and the researches in this field allowed for an improvement in the disease diagnosis, besides supplying the specific knowledge for this scope[29, 34].

Thus, public health programs developed specially for TB control intend, in the beginning, to interrupt the disease transmission chain. This means that the faster the diagnosis is, the earlier the specific treatment will be initiated. To this end, it is important that all processes intrinsic to disease diagnosis are well controlled and analyzed, mainly laboratory diagnoses which are the mainstay of medical decisions. Thus, the aim is to cancel any factor, error or flaw that can cause risk in these activities that are responsible for generating diagnostic results. As a consequence, the use of quality indicators is an example of tool that can aid the experience of quality management[8].

For the current study, indicators were recommended based on characteristics such as: effectiveness – that is about promoting the expected results; equity – that indicates their impartiality; and efficiency – that expresses the indicator capacity to reach its defined goals. The definition of indicators is adapted to the

TABLE 1 – Definition and description of indicators relevant to all processes

| Name of indicator and numerical value | Importance | Corrective and/or preventive measures | Goal |
|---|---|---|---|
| **Percentage of non-conforming samples** | | | |
| Total number of non-conforming samples in the last 30 days/total number of samples received at the same period of 30 days × 100 | This indicator measures the percentage of non-conforming samples in relation to the total of samples received at the same period. It is a quality indicator, linked to strategic and operational levels of the laboratory | <u>Preventive</u><br>Standardize labels; use coolers with thermometer and description of material exit time from place of origin; promote continuous education about good collection, storage, packaging, and transport of samples<br><br><u>Corrective</u><br>Inform the place of origin and require clarifying or shipping of another sample; register occurrence and the actions taken in each situation | 10%-20% |
| **Percentage of errors in sample register** | | | |
| Total number of errors in sample register in the last 30 days/total number of sample registers in the same period of 30 days × 100 | This indicator measures the amount of errors in the register of samples in relation to the total number of registers made in the same period. It is a quality indicator, linked to strategic and operational levels of the laboratory | <u>Preventive</u><br>Promote activities of continuous education about processes and subprocesses directly and indirectly related to this indicator<br><br><u>Corrective</u><br>Standardize and computerize request; inform about place of origin and ask for clarifying or shipping of a new sample; register the occurrence and the actions taken in each situation | 10%-15% |
| **Percentage of samples with the aspect of saliva** | | | |
| Total number of samples with inadequate volume or aspect of saliva in the last 30 days/total number of samples with entrance in the same period of 30 days × 100 | This indicator measures the percentage of samples with physical aspect not recommended in relation to the total of samples for the conduction of assays. It is a quality indicator linked to strategic and operational levels of the laboratory | <u>Preventive</u><br>Adequately guide the patient in the collection of samples; promote activities of continuous education about the processes and subprocesses directly and indirectly related to this indicator<br><br><u>Corrective</u><br>Order a new sample | 10%-20% |
| **Percentages of contaminated samples** | | | |
| Total number of contaminated samples in the last 30 days/total number of samples in the same period of 30 days × 100 | This indicator measures the amount of contaminated samples in relation to the amount of samples that did not have signs of contamination in the same period. It is a quality indicator, linked to strategic and operational levels of the laboratory | <u>Preventive</u><br>Promote activities of continuous education about the processes and subprocesses directly and indirectly related to this indicator<br><br><u>Corrective</u><br>Correct the routine flow of laboratory work; reorganize the system of sample transportation; use more energetic techniques of decontamination; discard reagents | 3%-5% |
| **Percentage of agreement of obtained results of internal control used in the techniques with their defined parameters** | | | |
| Total number of internal control in line with their defined parameters used in the last 30 days/total number of internal controls used in the same period of 30 days × 100 | This indicator measures the percentage of positive and negative controls used in the techniques that are in line with their parameters previously defined in relation to the total of used controls. It is a quality indicator, linked to strategic and operational levels of the laboratory | <u>Preventive</u><br>Promote the plan of reading strains of MTBC and NTM as monthly control; use strains in each battery of assays of species identification and sensitivity tests; perform a monthly plan of streaking reference strains; promote activities of continuous education about the processes and subprocesses directly and indirectly related to this indicator<br><br><u>Corrective</u><br>Make use of new controls and discard controls with alterations | ≥ 95% |
| **Percentage of repeated tests** | | | |
| Total number of repeated tests in the last 30 days/total number of tests carried out in the same period × 100 | This indicator measures the amount of tests repeated because of a flaw in the technique or in the sample in relation to the total of performed tests. It is a quality and productivity indicator, linked to strategic, operational and managerial levels of the laboratory | <u>Preventive</u><br>Stipulate the maximum number of samples to be analyzed at the same time; verify reagent validity; use new positive and negative controls; streak samples in newer culture media; promote activities of continuous education about processes and subprocesses directly and indirectly related to this indicator; define rate of inconclusive tests; offer a policy of mensuration of false-positive, false-negative and inconclusive results | 10%-15% |

| Percentage of conformities in the filling of temperature forms | | | |
|---|---|---|---|
| Total number of filled fields in the last 30 days/total number of existing fields in the forms in the same period of 30 days × 100 | This indicator measures the amount of notes taken in relation to the amount of notes that must be taken in temperature forms. It is a quality indicator, linked to strategic and operational levels of the laboratory | Preventive<br>Standardize the verification of temperature check with highest and lowest; correctly fill the temperature control form, and, when the temperature is out of the safety range, warn the quality manager so that all correct measures be taken (maintenance, disclosure of non-conformities, etc.); promote continuous education about the processes and subprocesses directly and indirectly linked to this indicator | 85% |
| Percentages of conformities in proficiency tests | | | |
| Total number of concordant slides 365 days/total number of reread slides in the same period of 365 days × 100 | This indicator measures the amount of concordant rereadings in relation to the total number of reread samples. It is an indicator of quality and productivity, linked to strategic, managerial, and operational levels of the laboratory | Preventive<br>Promote activities of continuous education about the processes and subprocesses directly and indirectly related to this indicator; perform correctly and adequately the techniques used in the assay, always following the guidance of existing procedures and instructions | 80%-90% |

*MTBC:* M. tuberculosis *complex; NTM: non-tuberculous mycobacteria.*

TABLE 2 – Definition and description of efficacy indicators of result release time

| Name of indicator and numerical value | Importance | Corrective and/or preventive measures | Goal |
|---|---|---|---|
| Percentage of bacilloscopy results released within 24 h after sample reception | | | |
| Total number of results released within 24 h in the last 30 days × 100/total number of bacilloscopy results released in the same period of 30 days | This indicator measures the amount of bacilloscopy results released within 24 h after sample reception in relation to the amount of results released per month. It is an indicator of productivity and exit, linked to managerial and operational levels of the laboratory | Preventive<br>Conduct the bacilloscopy assay no longer than 4 h after sample registry; plan bacilloscopy assay: a) creation of a plan of verification of biosafety cabinet work; b) creation of a checklist of inputs and materials that will be used in the bacilloscopy assay; c) creation of a monthly plan for preparation of solutions and reagents; d) creation of a plan of instructions for the use of microscope; promote activities of continuous education about processes and subprocesses directly and indirectly related to this indicator<br><br>Corrective<br>Identify in which moment delay is occurring: slide preparation, reading, result registration, report typing, and report release; reorganize workflow | 85%-95% |
| Percentage of culture results released within 30 and/or 60 days | | | |
| Total number of tests with results released within 30 and 60 days in the last 30 days/total number of exams carried out in the same period of 30 days × 100 | This indicator measures the amount of results released within 30 and 60 days in relation to all results released in the same period. It is an indicator of productivity and exit, linked to managerial and operational levels of the laboratory | Preventive<br>Plan the culture assay: a) creation of a plan for verification of biosafety cabinet working; b) creation of a checklist of inputs and materials that will be used in the culture assay; c) creation of a monthly plan for preparation of solutions, reagents, and culture media; promote activities of continuous education about the processes and subprocesses directly and indirectly related to this indicator<br><br>Corrective<br>Identify which moment delay is occurring: culture readings, result registration, typing of reports and shipping of reports; reorganize workflow | 85%-95% |
| Percentage results of identification species assays released within 30 days | | | |
| Total number of tests with results released within 30 days in the last 30 days/total number of tests carried out in the same period of 30 days × 100 | This indicator measures the amount of results of species identification released within 30 days in relation to all results released in the same period. It is an indicator of productivity and exit, linked to managerial and operational levels of the laboratory | Preventive<br>Plan the species identification assay: a) creation of a plan for verification of biosafety cabinet work; b) creation of a checklist of inputs and materials that will be used in the culture assay; c) creation of a monthly plan for preparation of solutions, reagents, and culture media; verify if from the moment positivity was detected in the culture, identification tests were ordered up to result release; promote activities of continuous education about the processes and subprocesses directly and indirectly relate to this indicator<br><br>Corrective<br>Identify in which moment delay is occurring: culture growth, culture reading, failure in molecular methods, problems with equipment, inputs, result registration, typing of reports and shipping of reports; reorganize workflow | 85%-95% |

| Percentage of results of sensitivity test assays released within 30 days | | |
|---|---|---|
| Total number of tests with results released within 30 days in the last 30 days/total number of tests carried out in the same period of 30 days × 100 | This indicator measures the amount of results of sensitivity tests released within 30 days in relation to all results released in the same period. It is an indicator of productivity and exit, linked to managerial and operational levels of the laboratory | Preventive<br>Plan the assay of sensitivity test: a) creation of a plan for verification of biosafety cabinet work; b) creation of a checklist of inputs and materials that will be used in the culture assay; c) creation of a monthly plan for preparation of solutions, reagents, and culture media; promote activities of continuous education about the processes and subprocesses directly and indirectly related to this indicator<br><br>Corrective<br>Identify in which moment delay is occurring: culture growth, culture readings, failures in the methods, problems with equipment, inputs, result registration, typing and shipping of reports; reorganize workflow    85%-95% |

| Percentage of assay results of Xpert gene released within 24 h after sample reception | | |
|---|---|---|
| Total number of results released within 24 h in the last 30 days/total number of results released in the same period of 30 days × 100 | This indicator measures the amount of results of assays of Xpert gene released within 24 h after sample reception in relation to the amount of results released per month | Preventive<br>Plan the assay of Xpert gene: a) creation of a plan for verification of biosafety cabinet work; b) creation of a checklist of inputs and materials that will be used in the assay; c) creation of an instruction plan to use the device specific of the technique; promote activities of continuous education about the processes and subprocesses directly and indirectly related to this indicator<br><br>Corrective<br>Identify in which moment delay is occurring: failures in the method, problems with devices, inputs, result registration, typing and shipping of reports; reorganize workflow    85%-95% |

organization complexity and size, as well as its mission and objectives[8]. Hence the importance of detailing the enterprise profile so that in the first moment we can understand its actual category and its processes, with a systematic evaluation of processes being done next by means of process mapping and construction of flow charts, which help managers understand and clarify critical points of each process that must be monitored so that there are no mistakes, flaws or non-conformities, what always promotes the continuous improvement of laboratory quality as a whole[8].

Indicators help in standardization and definition of quality specifications for the different processes and assays. However, there is still not a consensus on the best indicators to be used in laboratories. For this reason, in a first moment, indicators were defined that can help quality management at the present moment, what does not avoid that later, by means of new critical points, internal audits, among others, define new indicators, and some that nowadays are implemented become obsolete[22].

Many barriers remain to build indicators in the health care field, mainly in clinical laboratories specialized in specific diseases, as it is the case of LRN in TB. One of the greatest barriers is the lack of information necessary to calculate indicators and the reliability of these data, which cannot be disregarded. However, calculating these indicators, even with all the difficulties, is fundamental to help in the enhancement of information quality. And the adoption

of a system of measurement management in the health sector is a determining factor for the success of the institutions that hinder services in this area[22].

When well administrated, indicators, both in the health area as in the other areas, are considered primary tools for the management of services and processes, having as main objective improving quality management. Thus, total quality management (TQM) does not mean only diagnostic control in the health area or production control in the other areas. TQM and the use of quality indicators encompass a management strategy that seeks efficiency and efficacy of the most diverse organizations, regardless of their size, activity, or acting field, being public or private. The processes that are part of this management context are responsible for the continuous enhancement of these enterprises, guiding them to higher levels of quality and competitiveness, using methodologies mainly supported in the management of these processes as an essential factor to measure and transform their form of managing[17, 22].

This study is aimed at encouraging and impelling managers involved in the health field about the usefulness and the necessity of controlling and measuring processes, being able to standardize them with the aid of indicators or other quality tools. For the future, we hope these activities will be disseminated so as to become a routine practice in this activity field.

## CONCLUSION

This work is in line with what is described by literature concerning indicators. The results observed here confirm the importance of applying quality indicators as profitable and relevant quality tools in the context of clinical laboratories, especially in the TB scope. Based on the future monitoring of these indicators, corrective and preventive measures can be implemented to fit processes, of which the most considerable are continuous education and training of professionals.

## RESUMO

*Introdução: O Laboratório de Referência Nacional (LRN) em Tuberculose (TB) é uma unidade laboratorial de excelência técnica altamente especializada que tem desenvolvido projetos envolvendo a capacitação de recursos humanos e o aprimoramento de técnicas fundamentais para o diagnóstico da TB. Seu propósito é a melhoria contínua de todos os processos laboratoriais e a sua gestão da qualidade, com o intuito de colaborar e fortalecer as ações na rede que o integram no auxílio à vigilância e no combate da TB. Objetivos: Esta pesquisa tem a finalidade de descrever os indicadores da qualidade que foram definidos por meio do método de mapeamento de processos, com o objetivo de promover e elevar o nível da qualidade e da confiabilidade dos diferentes processos laboratoriais realizados no LRN em TB. Método: Para a definição dos indicadores, foi utilizado o mapeamento de processos que, por meio de fluxogramas, pode estabelecer e determinar os indicadores mais adequados para o LRN em TB. Após a definição desses indicadores, eles foram descritos com seus respectivos títulos, medidas preventivas e corretivas, importância e metas. Resultados: Os resultados da pesquisa sugerem que os indicadores estabelecidos são fundamentais para os processos do laboratório, visto que melhoram a gestão da qualidade. Conclusão: Por intermédio deste estudo, buscamos incentivar e impulsionar os gestores envolvidos no campo da TB e no campo da saúde sobre a utilidade e a necessidade de controlar e medir os processos, podendo padronizá-los com a ajuda dos indicadores ou outras ferramentas da qualidade.*

*Unitermos: indicadores de qualidade em assistência à saúde; qualidade total; gestão de qualidade total; tuberculose.*

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