J Bras Patol Med Lab. 2020; 56: 1-10.

10.5935/1676-2444.20200039

Nonconformities in clinical laboratories in Macapá, Amapá, Brazil, based on the RDC no. 302/2005/Anvisa

Não conformidades em laboratórios clínicos de Macapá, Amapá, Brasil, com base na RDC nº 302/2005/Anvisa

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ABSTRACT

Introduction: Clinical analysis laboratories are health care facilities that provide resources for outpatient and/or emergency diagnoses; they are regulated in Brazil by the Resolution of the Collegiate Board of Directors (RDC) no. 302, of October 13, 2005, of the Brazilian National Agency of Sanitary Surveillance (Anvisa). **Objective:** The aim of this study was to perform a normative evaluation in clinical analysis laboratories, based on RDC no. 302, of October 13, 2005. **Material and method:** This is a cross-sectional and descriptive study. Twelve clinical laboratories participated in the study. The data were obtained through a structured questionnaire and answered by the technical leaders of the participating laboratories, in the municipality of Macapá, Amapá, Brazil. **Results:** The average nonconformity found among the participants was 9.64%, which allowed an overall evaluation among them as satisfactory, in relation to the minimum requirements demanded by the standardization recommended by Anvisa. When the participants were analyzed individually, there was a variation from 4.82% to 21.69% of the nonconformities index. Other studies agree with the results, however there is disagreement in a research carried out in Porto Alegre, Rio Grande do Sul, Brazil, possibly due to the fact that the laboratories present in this study do not have a quality management system in their processes. **Conclusion:** Laboratories 2, 3, 4, 6, 9, 11, and 12 were rated as satisfactory. Laboratories 1, 5, 7, 8 and 10 were rated as partially satisfactory. No laboratories were rated as unsatisfactory.

Key words: clinical analysis laboratory; evaluation studies as a subject; legislation as a subject.

RESUMO

Introdução: *Os laboratórios de análises clínicas são estabelecimentos de saúde que oferecem recursos aos diagnósticos ambulatoriais e/ou emergenciais; são regulamentados no Brasil pela Resolução da Diretoria Colegiada (RDC) nº 302, de 13 de outubro de 2005, da Agência Nacional de Vigilância Sanitária (Anvisa).* ***Objetivo:*** *Este trabalho teve como objetivo realizar uma avaliação normativa em laboratórios de análises clínicas, tendo como base a RDC nº 302, de 13 de outubro de 2005.* ***Material e método:*** *Estudo transversal e descritivo, com a participação de 12 laboratórios clínicos. Os dados foram obtidos por meio de questionário estruturado respondido pelos responsáveis técnicos dos laboratórios participantes, no município de Macapá, Amapá, Brasil.* ***Resultados:*** *A média de não conformidade encontrada entre os participantes foi de 9,64%, o que permitiu uma avaliação geral entre eles como satisfatórios, em relação aos requisitos mínimos exigidos pela normatização preconizada pela Anvisa. Quando os participantes foram avaliados individualmente, houve variação de 4,82% a 21,69% no índice de não conformidades. Outros estudos apresentam resultados concordantes; contudo, há discordância em uma pesquisa realizada em Porto Alegre, Rio Grande do Sul, Brasil, possivelmente pelo fato de os laboratórios presentes neste estudo não terem um sistema de gestão de qualidade nos seus processos.* ***Conclusão:*** *Os laboratórios 2, 3, 4, 6, 9, 11 e 12 foram avaliados como satisfatórios; os laboratórios 1, 5, 7, 8 e 10, como parcialmente satisfatórios. Nenhum laboratório foi avaliado como insatisfatório.*

Unitermos: *laboratório de análises clínicas; estudos de avaliação como assunto; legislação como assunto.*

First submission on 07/12/19; last submission on 07/16/19; accepted for publication on 12/26/19; published on 05/18/20

RESUMEN

Introducción: *Los laboratorios clínicos son establecimientos de salud que ofrecen recursos para diagnósticos ambulatorios y/o de emergencia; son regulados en Brasil por la resolución del Directorio Colegiado (RDC) nº 302, de 13 de octubre de 2005, de la Agencia Nacional de Vigilancia Sanitaria (Anvisa).* ***Objetivo:*** *Este trabajo tuvo como objetivo efectuar una evaluación normativa en laboratorios clínicos, teniendo como base la RDC nº 302, de 13 de octubre de 2005.* ***Material y método:*** *Estudio transversal y descriptivo, con la participación de 12 laboratorios clínicos. Los datos se obtuvieron mediante cuestionario estructurado contestado por los responsables técnicos de los laboratorios participantes, en el municipio de Macapá, Amapá, Brasil.* ***Resultados:*** *La media de no conformidades entre los participantes fue de 9,64%, lo que permitió una evaluación general entre ellos como satisfactorios, con respecto a los requisitos mínimos exigidos por la Anvisa. Cuando los participantes fueron evaluados individualmente, hubo variación de 4,82% hasta 21,69% en el índice de no conformidades. Otros estudios presentaron resultados concordantes; sin embargo, hay desacuerdo en una investigación realizada en Porto Alegre, Rio Grande do Sul, Brasil, posiblemente porque los laboratorios participantes en ese estudio no tienen un sistema de gestión de calidad en sus procesos.* ***Conclusión:*** *Los laboratorios 2, 3, 4, 6, 9, 11 y 12 fueron evaluados como satisfactorios; los laboratorios 1, 5, 7, 8 y 10, como parcialmente satisfactorios. Ningún laboratorio fue evaluado como insatisfactorio.*

Palabras clave: *laboratorio de análisis clínico; estudios de evaluación como asunto; legislación como asunto.*

INTRODUCTION

Clinical analysis laboratories (CAL) are health facilities of great responsibility and health impact, which provide outpatient and/or emergency diagnostic services[1]. The process of laboratory testing is divided into three phases: pre-analytical, analytical and post-analytical. Each of these presents with specific procedures, from the initial phase, upon the request of test ordering, until the report issuing, and consequent therapeutic approach by other health professionals. A laboratory error can be characterized when there are problems or interfering factors in at least one of these three phases of the laboratory testing process[2].

The Brazilian National Health Surveillance Agency [Agência Nacional de Vigilância Sanitária (Anvisa)] regulates the operation of clinical laboratories through the Resolution of the Collegiate Board [Resolução da Diretoria Colegiada (RDC)] no. 302, of October 13, 2005 (RDC 302/2005/Anvisa)[3], defining several requirements for the operation of clinical laboratories and collection points (**Figure**). According to this RDC, laboratories must ensure the reliability of the services provided, through the implementation of all the items contained therein, thus guaranteeing the total quality of clinical laboratories[3-5].

Laboratory nonconformity is a failure to comply with one or more regulations specified by the policies and procedures that regulate the CAL. When detecting a nonconformity occurrence, it must be corrected and the potential for recurrence, eliminated[6]. To guarantee the quality of the laboratory diagnostic process, it is recommended to carry out preventive and investigative procedures

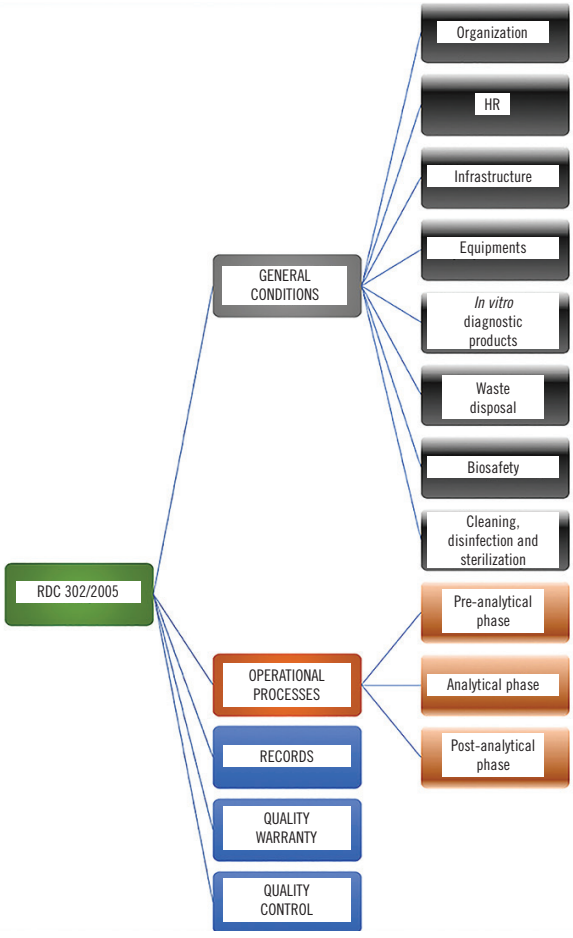

FIGURE – *Items comprising the RDC 302/2005/Anvisa*

RDC: Resolution of the Collegiate Board of Directors; Anvisa: Brazilian National Health Surveillance Agency; HR: human resources.

for nonconformities, seeking to increase safety and improve processes, in addition to reducing the risk of diagnostic errors[5].

CAL can conduct internal audits to assess whether their processes are compliant with different legal regulations[7]. However, when concluded, the audit results of the processes are not disclosed for access in the literature, and there is a scarcity of studies on laboratory quality control, mainly at the national level. Additionally, similar research with a normative assessment approach or normative-based assessment research is lacking in the literature, despite the importance of evaluating these health facilities that are directly related to diagnostic support for patients' therapeutic approaches. This work aimed to carry out an evaluation of the laboratories in Macapá, Amapá, Brazil, for the items provided in the RDC 302/2005/Anvisa.

METHODOLOGY

A cross-sectional and descriptive study, with the participation of 12 clinical laboratories, public and private, from spontaneous sampling in the municipality of Macapá, from January to May 2017 was carried out. This study complied with the ethical considerations set out in resolution 466/2012 of the Brazilian National Health Council and was submitted to the Research Ethics Committee (REC) of the Universidade Federal do Amapá (UNIFAP) with approval number 2.073.522 and Certificate of Presentation for Ethical Appraisal [Certificado de Apresentação para Apreciação Ética (CAAE)] number 48528315.0.0000.0003.

The regulation used to carry out the normative evaluation was the RDC no. 302, of October13, 2005[3], which provides for the technical regulation for the operation of clinical laboratories. Data were collected using a structured questionnaire. To validate the data collection instrument, Delphi Technique was used[8]. The questionnaire was applied and completed by the technician responsible for the laboratory, featuring a research instrument by participating institutions.

Items 5 to 9 of the RDC 302/2005/Anvisa Annex address the minimum requirements for the operation of clinical analysis laboratories, including their sub-items, which were used as process variables to rate qualitative scores as: satisfactory, partially satisfactory or unsatisfactory. As a scoring system, the instrument was based on meeting, by relative frequency, the different processes represented by items 5 to 9 present in the RDC 302/2005/Anvisa, including their respective sub-items, with the following dimension: satisfactory – when 0% to 10% of nonconformities are detected; partially satisfactory – 11% to 30% nonconformities; and unsatisfactory – when there was 31% or more nonconformities. For the construction of this scale, values of 100% were considered for each relative frequency analysis[9, 10].

As a criterion for sampling inclusion, the participating laboratories had to carry out laboratory tests and be duly registered with the regional class councils of Biomedicine and Pharmacy, located in the municipality of Macapá (**Table 1**). The laboratories that refused the invitation did not participate in this research. To preserve the identity of participants, the laboratories were identified with Arabic numerals, in decreasing order, as laboratory 1, laboratory 2, laboratory 3, according to this nomenclature standard until laboratory 12.

TABLE 1 – Number of participating laboratories approved for normative evaluation of this study

Professional councils	Registered	Approved
CRBM	16	9 (56.25%)
CRF	10	3 (30%)
Total	26	12 (42.16%)

Source: Author data, 2017.
CRBM: Conselho Regional de Biomedicina (Biomedicine Regional Council); CRF: Conselho Regional de Farmácia (Regional Pharmacy Council).

RESULTS

General conditions

Organization, human resources and infrastructure

In relation to the item Organization, laboratory 4 reported that does not implement the process control system required in sub item 5.1.4, which refers to the implementation and quality assurance; laboratory 1, regarding sub item 5.1.7, does not establishes a document structure of hierarchical organizational chart. Both presented 12.5% of nonconformities with the RDC 302/2005/Anvisa; in this item, they were rated as partially satisfactory.

Regarding item 5.2.2, which provides holding training and permanent education records for employees, laboratories 3 and 5 declared that they do not hold it, characterizing 25% nonconformities. Regarding conducting admission medical examinations, referred to in item 5.2.4, laboratory 1 does not perform them. This nonconformity violates what is advocated by the Brazilian Ministry of Labor, which requires an Occupational Health Control Program [Programa de Controle Médico de Saúde Ocupacional (PCMSO)].

Therefore, the laboratories 1, 3 and 5 were evaluated as partially satisfactory, as they presented 25% of nonconformities rates. The Infrastructure item was composed of only one normative requirement, which led to laboratory 1 to 100% nonconformities, obtaining unsatisfactory evaluation.

Laboratory equipment and instruments

The component requirements of this sub-item include: the requirement for laboratories to use equipment corresponding to the size of their service demands; written instruction on equipment procedures and techniques, which can be replaced by manufacturers' manuals provided if they are in Portuguese; the performance of preventive and corrective maintenance of this equipment with evidence registration; and the calibration and maintenance of measuring equipment. All participating laboratories showed conformity with these requirements.

Regarding sub-item 5.4.1d of the RDC 302/2005/Anvisa, which refers to the maintenance of measuring equipment, laboratories 4 and 11 presented 14.28% of nonconformities in relation to their execution, and were evaluated as partially satisfactory.

In vitro *diagnostic products*

This sub-item, consisting of seven normative items, depicts the conditions related to the use of inputs and reagents, whether for exams or for uses in good laboratory practices, such as the use of 70% alcohol to disinfect the countertops, 0.9% sodium chloride for biological samples dilution or preparation of reagents, among others. In these matters, Anvisa establishes criteria that enable practices to reduce the risks inherent to handling of chemical and biological products.

Regarding sub item 5.5.1, referring to product acquisition records for *in vitro* diagnostics, nonconformity was found in laboratories 1 and 8. For sub item 5.5.3, which deals with label identification of reagents or inputs, nonconformity was found in laboratories 1, 4, 6, 7, 9, and 10, which resulted in 28.57% of nonconformities to laboratory 1 and 14.29% of nonconformities to laboratories 4, 6, 7, 8, 9, and 10. Therefore, they were evaluated as partially satisfactory for these requirements.

Waste disposal, biosafety and cleaning, disinfection and sterilization

This normative item provides for conformity with the requirements of the resolution RDC no. 306, of December 7, 2014, which addresses the technical regulation on health service waste management. The individual components of this regulation were not analyzed, but rather, whether or not the participant used the required guidelines regarding the management of their respective health service waste. Laboratories 8 and 11 reported that they do not have a Health Service Solid Waste Management Plan [Plano de Gerenciamento de Resíduos Sólidos de Saúde (PGRSS)], thus violating this normative item. This sub-item is composed of only one normative requirement; laboratories 8 and 11 were rated as unsatisfactory.

Regarding the aspects of biosafety, the normative sub-item 5.7.2, which addresses the technical responsible for the clinical laboratory for recording the level of biosafety of the environments or areas, based on the procedures performed, equipment, and microorganisms involved, adopting compatible safety measures, nonconformities were detected regarding the compliance by laboratories 5, 7, 9, 10, and 12. These represented 50% nonconformities; they were rated as unsatisfactory. All participating laboratories did not present nonconformities in sub items 5.8.1 and 5.8.2, referring to cleaning, disinfection and sterilization.

Operational processes

Pre-analytical phase

Sub-item 6.1 refers to the requirements demanded in the phase of conducting exams named pre-analytic phase. Nonconformities were not found among the participating laboratories in sub-items 6.1.1, 6.1.2, 6.1.4, 6.1.7.1, 6.1.11 and 6.1.12 (**Table 2**).

From the reported nonconformities, laboratories 5, 7, 8, and 11 were rated as satisfactory, and laboratories 1, 4, 9, and 10, as partially satisfactory.

Analytical phase

Evaluating all the items comprising the analytical phase, laboratories 1, 2, 3, 7, 8, 9, 10, and 12 presented nonconformities ranging from 4.76%% to 23.81% (**Table 3**). In view of the reported nonconformities, laboratories 2, 3, 7, and 9 were rated as satisfactory, and laboratories 1, 8, 10, and 11, as partially satisfactory.

Post-analytical phase

Regarding sub item 6.3.7, which deals with the serological diagnostic analysis reports of anti-human immunodeficiency virus (anti-HIV) antibodies to be in agreement with what is recommended by the Brazilian Ministry of Health, laboratory 3 is not in conformity. Regarding sub item 6.3.8.1, which addresses the way in which the rectification of reports occurs, laboratories 3 and 10 presented nonconformities. Assessing all items comprising the post-analytical phase, laboratories 3 and 10 presented nonconformities ranging from 11.11% to 22.11% and were rated as partially satisfactory.

TABLE 2 – Presentation of the percentage of nonconformities and nonconforming sub-items referring to the pre-analytical phase

Normative item	Participating laboratories												Average
	1	2	3	4	5	6	7	8	9	10	11	12	(SD)
Percentage of nonconformities of the 15 requirements items related to the sub-item Pre-analytical phase	20	0	0	20	6.66	0	6.66	6.66	13.33	20	6.66	0	8.33 (8.1)
6.1.1 (Written and/or verbal instructions to patients)	X							X	X	X	X		
6.1.2.1 (Identification of inpatients by medical records)				X									
6.1.4 (Patient Registration)							X			X			
6.1.7.1 (Traceability on who collected the sample)	X			X					X	X			
6.1.11 (Sample transport under biosafety conditions)					X								
6.1.12 (Sample transport outsourcing contract)	X			X									
Evaluation	PS	S	S	PS	S	S	S	S	PS	PS	S	S	S

Source: Author data, 2017.

SD: standard deviation; X: nonconforming item; S: satisfactory (0%-10% nonconformities); PS: partially satisfactory (11%-30% nonconformities).

TABLE 3 – Presentation of the percentage of nonconformities and nonconforming sub-items referring to the analytical phase

Normative item	Participating laboratories												Average
	1	2	3	4	5	6	7	8	9	10	11	12	(SD)
Percentage of nonconformities of the 21 requirements items referring to the Analytical Phase sub-item	23.81	9.52	9.52	0	0	0	4.76	14.28	4.76	14.28	19.04	0	8.33 (8.15)
6.2.5.1 (Critical result)	X												
6.2.6 (CQI monitoring)							X			X	X		
6.2.7 (Water purity)	X	X						X	X	X	X		
6.2.11 (Anti-HIV antibodies)			X										
6.2.12 (Compulsory notification)	X									X	X		
6.2.14 (Responsible for POCTs)			X										
6.2.15 (List of POCTs)	X	X						X					
6.2.15.1 (POCTs registration)								X					
6.2.15.4 (POCTs registration and training)	X										X		
Evaluation	PS	S	S	S	S	S	S	PS	S	PS	PS	S	S

Source: Author data, 2017.

SD: standard deviation; CQI: continuous quality improvement; HIV: human immunodeficiency virus; POCT: point of care test; X: nonconforming item; S: satisfactory (0%-10% nonconformities); PS: partially satisfactory (11%-30% nonconformities).

Records

All laboratories reported conformity regarding the records, thus guaranteeing the recovery and availability of their critical records, in order to allow traceability of the released report. In addition, they also claim that changes made to critical records contain date, name or legible signature of the person responsible for the change, preserving the original data. Regarding this item, all participants were rated as satisfactory.

Quality Assurance

According to the RDC 302/2005/Anvisa, item 8.1 deals with the clinical laboratory to ensure the reliability of the laboratory services provided, through, at least, internal and external quality control (proficiency tests). It consists of only one evaluative item. Only laboratory 10 reported that does not include this item; it was rated as unsatisfactory for presenting nonconformity in one item.

Quality control

This item deals, in general, with decision making for nonconformities actions related to the use of quality control and, if they are detected, on the implementation of correction or contingency measures when facing suggestions of detected errors in the analytical processes of the laboratory. Evaluating all the sub-items comprising the Quality Control item, laboratories 1, 2, 4, 6, 7, 8, 10, 11, and 12 obtained nonconformities that ranged from 9.09% to 45.45% (**Table 4**). Laboratories 2 and 6 were rated as satisfactory; laboratories 1, 4, 7, 11, and 12, as partially satisfactory; and laboratories 8 and 10, as unsatisfactory.

Conformity and nonconformity items

In the RDC 302/2005/Anvisa, items 5 to 9 of Annex I, lists all the basic requirements for the operation of clinical analysis laboratories in Brazil, whether public or private. These items consist of 83 sub-items of requirements for operating these institutions.

Regarding the evaluation score, the results of relative frequency were considered satisfactory when the questionnaires were answered and presented 0% to 10% of nonconformities; partially satisfactory, when presenting 11% to 30% of nonconformities; and unsatisfactory, when presenting 31% or more of nonconformities. From evaluative items 5 to 9, there was a predominance of information on conformities, as shown in **Table 5**.

TABLE 4 – Presentation of the percentage of nonconformities and nonconforming sub-items referring to quality control

Normative item	Participating laboratories												Average (SD)
	1	2	3	4	5	6	7	8	9	10	11	12	
Percentage of nonconformities of the 11 requirements items related to the item Quality control	27.27	9.09	0	27.27	0	9.09	27.27	45.45	0	36.36	18.18	18.18	18.18 (15.01)
9.1 (CQI/EQC)								X		X		X	
9.2.3 (Control rejection)		X		X			X	X		X	X		
9.3.1 (Proficiency testing)	X			X			X	X					
9.3.1.1 (EQC alternative)	X			X			X	X		X		X	
9.3.4 (Registro de não conformidades de EQC)	X					X		X		X	X		
Evaluation	PS	S	S	PS	S	S	PS	U	S	U	PS	PS	PS

Source: Author data, 2017.

SD: standard deviation; CQI continuous quality improvement; EQC: external quality control; X: nonconforming item; S: satisfactory (0%-10% nonconformities); PS: partially satisfactory (11%-30% nonconformities); U: unsatisfactory (31%-100% nonconformities).

TABLE 5 – List of nonconformities found referring to items 5 to 9 of Annex I, of RDC 302/2005/Anvisa

Quantitativo de Itens Normativo da RDC/302	Participating laboratories												Average (SD)
	1	2	3	4	5	6	7	8	9	10	11	12	
Conforming items	65	78	79	75	73	79	73	72	78	69	77	79	75 (4.49)
Nonconforming items	18	5	4	8	10	4	10	11	5	14	6	4	8 (4.49)
Percentage of nonconforming items out of the 83 items basic requirements for laboratory operation	21.69	6.03	4.82	9.64	12.05	4.82	12.05	13.26	6.03	16.87	7.23	4.82	9.94 (4.15)
Evaluation	PS	S	S	S	PS	S	PS	PS	S	PS	S	S	S

Source: Author data, 2017.

RDC: Resolução da Diretoria Colegiada (Collegiate Board Resolution); Anvisa: Brazilian National Health Surveillance Agency; SD: standard deviation; X: nonconforming item; S: satisfactory (0%-10% nonconformities); PS: partially satisfactory (11%-30% nonconformities).

The average of nonconformities found among the participants was 9.64%, which allowed a general assessment among them to be satisfactory, in relation to the minimum requirements demanded by the standardization recommended by Anvisa. When the participants were analyzed individually, there was a variation from 4.82% to 21.69% of nonconformities.

In this context, laboratories 2, 3, 4, 6, 9, 11, and 12 presented 6.03%, 4.82%, 9.64, 4.82%, 6.03%, 7.23%, and 4.82%, respectively, of nonconformities, with general normative evaluation as satisfactory. In contrast, laboratories 1, 5, 7, 8, and 10 were evaluated as partially satisfactory, as they presented nonconformities rates of 21.69%, 12.05%, 12.05%, 13.26%, and 16.87%, respectively.

DISCUSSION

The results referring to the laboratories that hold a sanitary permit and a technician responsible corroborate the study by Gonçalves Machado (2016)[11], carried out in the region of Patos de Minas, Minas Gerais, Brazil, which sought to analyze the effectiveness of the Health Surveillance actions regarding conformity with items of the RDC 302/2005/Anvisa. However, in eight years of health inspection (2006 to 2013), there was a variation from conformity levels regarding health establishments referring to holding or not the health permit license for operating their respective health intervention functions.

According to Chaves (2010)[12], quality management includes the actions used to produce, manage and control quality assurance, constituting the determination of a policy and quality objectives, using indicators and targets in a clinical analysis laboratory, in performing laboratory tests. In this scenario, laboratory 1 does not establish a hierarchical organizational chart, and this nonconformity may imply failure to achieve goals in the laboratory's quality management system[13].

The lack of records and training may enable the analysts and technicians involved in the process of carrying out laboratory tests to not to perform the clinical correlations with the results due, which can provide the non-detection of errors present in discrepancies or incoherent data. However, this scenario may be minimized with training and qualification of the laboratory's technical team[14, 15].

The presence of nonconformities found on laboratory equipment and instruments can contribute to errors in the analysis. A good example are pipettes and glassware not calibrated that can dispense aliquots above or below the adjusted volume for reconstituting lyophilized commercial control samples (samples from a plasma or serum pool that undergo a dehydration process to conserve blood metabolites) in blood samples, reagents, supplies, among others. Thus, the execution of diagnostic techniques can be easily diverted to falsely negative or positive results, compromising the values of analytes present in the results of released results and, subsequently, the appropriate medical therapeutic conduct[16, 17].

According to Najat (2017)[18], the lack of monitoring reagents and inputs increases the possibility of using these materials after the expiration date. Thus, it can contribute to the deviation of the result and even errors in diagnostic dosage or the presence of discrepancies between the results and the patient's clinical status, unnecessarily, causing a possible request for another sample collection to confirm results.

Nonconformities on biosafety provide contradictory information on whether or not to perform a PGRSS. As it is a minimum criterion for obtaining the environmental permit to start the activities and the operation of the establishment in question in this study, the question arises whether, at the time of obtaining the environmental permit, the required items to obtain it were properly checked. Therefore, it can be inferred that, in practice, there is still nonconformities with the current regulation[19, 20].

The nonconformities on which the technician responsible for the clinical laboratory to document the level of biosafety of the environments or areas, based on the procedures performed, equipment and microorganisms involved, adopting compatible safety measures, corroborate the study by Lima and Barreira Filho (2016)[21], carried out in a public laboratory in Capistano, Ceará, Brazil[22].

In contrast, Lima and Barreira Filho found a lack of instructions on cleaning, disinfection and sterilization in a public laboratory in Ceará, which disagrees with the results obtained in the present study, which found no nonconformities regarding this sub item. Possibly, there is a lack of conformity with the regulations in public laboratories due to the need for investment in professional qualification in human resources, including health managers. The authors also argue that the inspection of conformity with this regulatory regulation is the responsibility of health surveillance, which should not favor or fail to inspect irregularities in the public service.

The pre-analytical phase corresponds to the indication of the exam, prescription of the request, communication of instructions for preparing the patient, evaluation of the laboratory client in relation to the conditions that precede the collection of the biological material, sample collection procedures, storage, conditioning, preservation, and transport of the biological sample until the moment of examination is carried out in the analytical

phase. Therefore, it consists of all the procedures that precede the performance of laboratory tests, whether inside or outside the laboratory, as in collection points[22, 23]. The nonconformities data in this phase obtained in the present study are in agreement with those by Lima and Barreira Filho (2016)[21]. The study by Coriolano, Silva and Lamounier (2016)[24] reports that most laboratory errors are associated with the lack of collection instructions and the inappropriate samples preparation; such errors increase the need to another biological sample collection[25].

The handling of samples from their origin in the collection is related to pre-analytical errors. Therefore, monitoring who performed the collection is a way to standardize traceability and implement quality in exam processing. Studies demonstrate that the pre-analytical phase is the one in which the highest frequency of errors occurs, which are mainly associated with manual tasks, human resource turnover, negligence, lack of training and adherence to good laboratory practices[26-28].

According to Silva (2014)[1], the analytical phase corresponds to the beginning of the validation of the analytical system through internal quality control and ends when the execution of the analytical process generates a result. Regarding the processes of this phase, the communication of critical results may be relevant to clinical decisions, patient safety and operational efficiency, since they represent potentially life-threatening situations and require rapid and timely evaluation by doctors[4, 7, 17].

According to Bonamigo and Fabiano Campos Soares (2011)[29], the underreporting of a compulsory notification disease is an irregularity that harms the Brazilian health system, and can generate substantial damages as the knowledge about them and their problems are subsidizing for the promotion of control actions and the development and maintenance of public health policies.

The post-analytical phase consists of the steps performed after the examination, which includes calculations and consistency of results, release of reports, storage of patient samples, transmission and storage of results and technical advice. In addition, the therapeutic conduct that the patient may receive through the contribution and the results obtained is also associated with this phase[27, 29].

Regarding the reliability of the laboratory services provided, through at least internal quality control and external quality control, only laboratory 10 reported that it does not practice them. In the first analysis, discrepancies of results can be observed in the responses to the questionnaire used as a data collection instrument in this research, since laboratories 7 and 11 responded that they do not monitor the analytical phase (internal and external quality control) – item 6.2.6 –, while, based on item 8.1, they claim that they ensure the reliability of their results with the use of internal and external control.

To monitor the performance of internal control, the results of the controls need to be plotted on a control chart and compared to the acceptable limits of the biological variation coefficient for each analyte. Among the control monitoring tools most used in the internal quality control routine, the Levey-Jennings chart stands out, using the Westgard rules. Therefore, internal quality control assessments undergo daily, weekly and monthly assessments. These rules help to monitor analytical runs and identify possible systematic or random errors, which makes it possible to identify the source of the problem[29-33].

Regarding the performance of external control by the clinical laboratory, some laboratory analytes may not be covered by proficiency testing programs; however, there is alternatives possibility, such as interlaboratory control among laboratories[29,34]. Feres *et al*. (2016)[26] found positive and negative results in relation to the evaluation of laboratory indicators in a university laboratory. Indicators can be used as instruments for the quantitative representation of processes, they are important assessment tools to provide data for quality planning, improvement interventions, and support for the development of preventive or corrective actions. The mentioned study did not demonstrate whether there was a predominance of conformity or nonconformities.

On the other hand, Wislocki (2011)[35], in a study carried out at the Clinical Analysis Laboratory at the Hospital de Clínicas de Porto Alegre, found a level of laboratory nonconformities that ranged from 0.22% to 0.67%, confronting the results found in the present study. These different results may have occurred because the laboratories that presented these nonconformities in Macapá reported that they do not implement or perform quality management in their processes.

This research had limitations regarding the number of participants in the city of Macapá due to the use of spontaneous sampling. In addition, the use of questionnaires can infer answers with doubtful value when not confronted with an observational analysis in search of evidence to prove the answers provided. At the time of this work, there was no accredited laboratory in the city. Finally, there is a limitation in the literature on publications that address the subject, both in evaluative research and in normative evaluation based on the items of that standard above-mentioned. This scarcity may have influenced the discussion of the results, but it did not compromise the conclusion of this study.

CONCLUSION

The evaluation carried out in this study is based solely on the normative items provided in the RDC 302/2005/Anvisa, exempting the researcher's subjectivity on the evaluation process. Further studies that seek evaluations involving health issues are needed to assess whether there has been a change after the intervention carried out by this study and in other participants that integrate another analysis. According to the RDC 302/2005/Anvisa, laboratories 2, 3, 4, 6, 9, 11, and 12 were rated as satisfactory; laboratories 1, 5, 7, 8, and 10, as partially satisfactory. No laboratory was rated as unsatisfactory. Most laboratories complied with current regulations; however, reported nonconformities need to be addressed by their respective managers for a proposed correction.

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