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Research Article

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Quality Control for Uroculture in Clinical Analysis Laboratories in The Alto Vale Do Rio Do Peixe in The State of Santa Catarina

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Abstract

Quality Control (QC) and Good Laboratory Practice regulate the organization, performance and conditions under which tests are performed, registered and released, how biological materials are conserved and disposed of, and results archived. Mostly, the pre-analytical, analytical and post-analytical phases are included in QC. The clinical analysis laboratory is divided into sectors, and in the microbiology sector, the urine culture test known as another standard for diagnosing urinary tract infections (UTI) is carried out, which constitute one of the most constant clinical conditions among human infections, covering several syndromes, recognized by the presence of microorganisms in the urinary tract and because they are often followed by an acute and symptomatic inflammatory response. Observing the importance of quality control in the microbiology sector, this study aimed to evaluate QC practices related to urine samples and urine culture in clinical analysis laboratories in the Alto Vale do Rio do Peixe region in the state of Santa Catarina. Data were obtained through open and closed questions made available to the laboratories via Google forms. Fifteen laboratories were evaluated, of which 11 reported fulfilling 73.4% of the activities within good laboratory practices. Of the laboratories that have collection points, 2 carry out 40% of the practices consistently. According to the results and bibliographical research, it was found that the insertion of Quality Control guarantees a safe health service, and may reduce unnecessary medical prescription, and may even reduce costs to laboratories.

Keywords:

Urinalysis. Urine culture. Quality control.

Introduction

Routine urine examination is essential for the diagnosis of urinary tract diseases, being considered the third most routine analysis performed by clinical analysis laboratories. Furthermore, through the analyses, important data are obtained about the functioning of the urinary system, inflammatory pathologies and infections. Routine urinalysis has three different phases: chemical examination, physical examination, and microscopic examination.

In microscopy, the analysis of urinary sediments is carried out, based on abnormal findings, the test known as Uroculture is then carried out, considered the gold standard for the diagnosis of urinary tract infections, and the patient's antimicrobial therapy will be defined exactly, after antibiogram results, after urine culture [1].

To guarantee reliable results for these and other exams, quality control is usually carried out through some classes of analyses or measurements, and its vital advantages are estimated through the optimization of all processing, methodization of procedures, reduction of time and waste, increasing the degree of confidence in quality, among others. During the operation of a laboratory test, some conditions are necessary to satisfy the requirements of the customers and guarantee the correct conclusion of the results. For this reason, the quality control of clinical laboratories is of such significance, as in addition to increasing safety, it brings credibility to the laboratory, thus contributing to the waiver of safe reports [2,3].

With regard to the quality of the results and phases of the clinical laboratory, it is crucial to define standards and processes to avoid, detect and track errors that may occur from the time the order is placed until the report is delivered. Discerning these flaws is paramount for accepting corrective and preventive actions as a duty of quality control [4].

The QC of laboratory tests has three phases: pre-analytical, which corresponds to guidelines for patient preparation, recognition, collection, handling and storage of the biological sample; analytical that is the operation of the exams and the interpretation of the results, in which the methods applied, preliminary to being part of everyday life, are noted in relation to the sample, test period, accuracy, transparency, perception, particularity, linearity, balance of reagents , assuring the reliability of the results and finally e; the post-analytical that originates with the quantitative and/or qualitative result collected after the analyses and concluded with the delivery of the report [5].

The correct analysis of the uroculture requires a lot of patient preparation and optimal sampling. Although there are guidelines for collecting urine specimens for microbiological examination, patients are often unaware of the importance of an adequate preanalytical method for collecting urine specimens. Furthermore, these factors are generally not directly under supervision by the laboratory.

Laboratory staff, the clinician, and patients need to be educated in specimen collection procedures, and laboratory staff should encourage proper preanalytical procedures. In case of improper urine collection procedure, the collection must be repeated [6,7].

It is significant that the professionals who make up this stage understand that this moment must occur, with care and attention, as it is essential for a quality exam. The present work aims to identify and analyze aspects inherent to QC practices in samples collected for the urine culture test in the microbiology sector in clinical analysis laboratories in the Alto Vale do Rio do Peixe region, Santa Catarina.

Methodological Delimitations

Sample

The present study is an exploratory and descriptive research, where data will be collected about the quality control in urine culture adopted by clinical analysis laboratories, located in the Alto Vale do Rio do Peixe region. To this end, 15 clinical analysis laboratories were included in this study, which had or did not have collection points, which had a microbiology sector and carried out the urine culture examination on their premises, and which had an active registration in the CNES (National Register of Health Establishments), excluding those that did not meet these requirements.

Data Collect

For data collection, a questionnaire was used, pre-validated by peers, containing twenty-six questions, two open and twenty-four closed, based on RDC 302/2005 and on the manual of good clinical practices of the Brazilian Society of Clinical Analysis (SBAC). The questionnaire, which is valid from July to October 2021, was prepared using the Google forms tool and sent to the laboratories through the e-mail address that appeared on the website of each one to be answered by the technicians responsible for the laboratories or responsible by the microbiology sector. When there was no response by e-mail, a telephone call was made contacting the technician in charge of the laboratory to participate in the research.

The information obtained through graphics and texts, provided by the Google Forms tool, were transcribed in the form of texts and reported in the form of descriptive statistics throughout the work.

Ethical Aspects

Data collection was carried out after approval by the Ethics Committee for Research with Human Beings – CEP under number CAAE 50832021.0.0000.8146 and opinion number 4.943.866.

Results and Discussion

The Alto Vale do Rio do Peixe Region has 37 clinical analysis laboratories registered with the CNES and, of these, only 24 are in operation, which represents 64.86% of the registered laboratories. Of the total active laboratories, it was possible to contact 21 (87.5%) units, and of these, 3 did not have a microbiology sector and one was a veterinary clinical analysis laboratory and two did not participate in the research, for unknown reasons, obtaining 15 (71.42%) responding units.

The laboratory reception is the place of first contact with the patient, the receptionist being one of those responsible for starting the pre-analytical phase of quality control, who must receive and transmit clear guidelines using assertive communication with the patient. When asked if the receptionist received some type of training to provide guidance for the collection of urine and culture, 93.3% (n=14) of the responding units said yes and, in relation to their ability to communicate with the patient, 73.3% of the units considered the skill as good, 13.3% very good and 13.3% regular.

They know that there are several ways of transmitting a message to the interlocutor, therefore, when asked about how the orientation for the collection of urine for culture is done, 60% of the responding units reported that this is done only verbally, while 40% reported doing and verbal and printed form.

The guidelines given by the receptionists are essential, as there is a direct influence on the quality of the sample, since there are questions that aim to clarify pre-analytical conditions related to age, gender variation, practice of physical activity, fasting, body position in case of bedridden patients, diet, among others. Such information may influence the analysis results, depending on the patient's condition and, in specific cases, it may be necessary to advise on suspending medications (by written medical order) or physical activity, in addition to providing specific information on the collection and storage of biological material [8].

Ideally, instructions should be provided orally and in writing, accompanied by illustrations whenever possible, to ensure uniformity of the collection procedure [9].

Every sample has its origin and the final destination is the result of the test for which it is intended. The units were asked about how and when the sample received by the patient was identified, so 57.1% of the responding units reported that the identification was made immediately upon receipt of the sample, while 35.7% reported that it was done after issuing the label, however, without the presence of the patient, while 7.1% of the responding units report that the identification was made in the collection room, along with the other samples.

Regarding how this identification was made, 93.3% reported that it was done with a label issued by the system, with a bar code or identification number, while 6.7% reported using a manual label on tape or a blank label.

According to the Manual of Good Practices for Collection, Conditioning and Transport of Biological Samples prepared by LACEN/SC (2019) [10], the effective way to identify the sample is from self-adhesive labels, placed so that the sample can be viewed, and must contain the following data: bar code number generated by the system, patient's full name and municipality.

The lack of identification or doing it incorrectly is one of the most routine and serious errors that occur in the day to day of laboratory operations, such an occurrence can cause major inconvenience, such as disorganization and even

analysis and delivery of wrong results. The sample identification phase is considered pre-analytical and must be performed in the first contact with the patient, obtaining all the necessary information. It must be done with care, as it has such relevance for all subsequent processes [11].

Of the responding laboratories, 33.3% (n=5) had collection points. Then, these units were asked about the time taken to transport the samples to the main laboratory, 60% answered that after transporting the urine for culture, the time for processing the sample was 2 hours, while for the other 40% the time was 4 pm. All units claimed to pack the material in a thermal container with temperature control ranging from 13 to 23º for 60% of the laboratories that had collection points and from 2 to 8º C for the remaining 40%. The temperature was controlled with an external digital thermometer and temperature control sheets for 40% of the laboratories that had collection points, while the other 60% did not perform temperature control.

In general, the proposed time for transporting the urine sample is 2 hours, stored at 20º 25ºC, and can be up to 4 hours when it is stored between 2 to 8ºC. By exceeding this time, the sample may undergo numerous changes ranging from its appearance to its biochemical and microscopic components, depending on the conditions of the environmental factors involved, altering the reliability of the analytical stage of the quality control system [12,13].

According to item 6.1.10 of RDC nº 302/2005, the biological material must be taken to the laboratory properly housed in an isothermal, hygienic, impermeable container that certifies its balance from collection to the examination operation. The transport box must also contain the biological risk symbol, with the heading "Specimens for Diagnosis", the name of the clinical laboratory for which it is intended and with the temperature marker affixed to the outside of the box [12,14].

RDC nº504/202 states that there must be a "transport validation process", with a properly trained and skilled team which provides for guaranteeing the conservation of the biological material, any alteration observed in the transport, must be registered and documented by the technical supervisor who receives the samples [15].

In cases of collection units, outside the headquarters laboratories, bacteriostatic substances or preservatives, such as boric acid and L-cysteine, can be used in urine samples in order to obtain consistent results with the analysis. When questioned, 20% of the units use boric acid to preserve the samples placed at the collection point for later transport, while 80% do not use any type of preservative.

In addition to cooling the sample, the use of chemical preservatives is another conservation method, the most relevant preservative for urine culture is boric acid, which maintains the pH at approximately 6.0 in addition to acting as a bacteriostatic substance. This element favours sample culture, reducing possible chances of false-positive cultures (STRASINGER; DI LORENZO, 2009; EUROPEAN URINALYSIS GROUP, 2000) [9,13]. Inappropriate conservation or the impracticality of refrigeration in the standard time, significantly transposes the number of bacteria in the sample [16].

According to the National Quality Control Program PNCQ (2019) [17], when a sample is intended for urine culture, it must be transported at room temperature within 1 hour and before cooling or preservative within 12 hours.

Bacterial growth is an exponential event in biological samples, and samples must be cultured as soon as possible when they are received by laboratories. The sample processing time from its arrival at the laboratory until sowing is 4h for 64.3% of the responding units, 2h for 14.3% and 21.4% answered that this time reaches 8h, while 60% of the unit's report that the samples are kept under refrigeration until processing and 40% say they do not store the sample.

The Brazilian Society of Clinical Pathology (SBPC), suggests the need for samples to be delivered quickly to the laboratory, and should be processed within a maximum period of up to 2 hours to obtain reliable results.

For bacterial growth, a culture medium rich in biochemical compounds essential for bacterial metabolism is necessary, in which Gram-positive and negative microorganisms must develop. Regarding the culture medium used by the laboratories participating in the study, 93.3% said they used CLED Agar (*Cystine Lactose Electrolyte Deficient*), while 6.7% use MacConkey agar, 93.3% use a commercial sterile loop, while the others use flamed platinum loop, cooling it in the culture medium.

The technique is an important element in the isolation of colonies, being a good sowing crucial in the time of release of the exam. When questioned about the type of sowing used for urine culture, being able to choose more than one technique from those available in the questionnaire (exhaustion, isolation, repeating and carpet), 60% of the responding units reported using the technique of exhaustion, 6.7% isolation, 33, 3% repeat, in addition, 60% of the responding units sow the sample in a biological safety hood, 100% store the plates in an oven at 36ºC±1ºC, 60% consider the cutoff point for positivity of the samples >10^5 CFU/ mL , while that 40% consider the cutoff point for urine culture positivity >10^4 CFU/ mL , and 60% of the responding units use the biological safety hood to sow urine samples for culture and the reading of the samples is performed by the Biomedical or Generalist pharmacist responsible for 100% of the responding units.

There is no standardization of methods applied to all microbiology laboratories for the processing of uroculture, however, each laboratory must have the Standard Operating Procedure (SOP), which is easily accessible for consultation. In order to isolate and quantify the constant microorganisms in urine samples, the Agar Cled medium is effective in distinguishing Gram-positive, Gram-negative bacteria and yeasts [18].

Urinary samples can be inoculated by different inoculation methods and must be incubated at 36ºC±1ºC Kass index. Unless calibrated pipettes are used, colony counts are approximations only and can be changed up to one hundred

times. Due to the various practical advantages, the use of sterile, calibrated and disposable or automated loops of 1 and 10μL for inoculation of urinary specimens is suggested [19,20,21].

According to Prado (2008) [22], in order to correctly perform the cooling of the platinum loop, it must be done previously on the inner wall of the test tube or on the lid of the Petri dish. However, the biochemist must define the best and most guaranteed cooling technique, as the literature also points out the technique of cooling in the culture medium in a portion without bacterial growth.

Regarding the cutoff point, the standards established in the literature state that the number of Colony Forming Units/ml (CFU/ml), considering urinary tract infections, is positive above 10^4 and 10^5 CFU/ml [23].

The literature recommends the use of a barrier for the execution of processes that include infectious agents, with the purpose of protecting the collaborator and the sample from probable contamination, which indicates a critical point for the collaborator's health, since all biological material is considered highly infectious. According to the norm of recommendations, the biological safety cabinet is indispensable in the microbiological analysis laboratory [12].

Every clinical laboratory must adopt criteria that must be followed for acceptance or rejection of samples. In this study, the main rejection criterion indicated by the technicians in charge was a sample brought to the laboratory with the maximum time exceeded and contaminated samples, with an average rejection rate per month of 0.25% of the total number of samples received.

For the Brazilian Society of Clinical Pathology (SBPC) (2015) [23], every microbiological analysis laboratory needs to establish parameters for sample rejection. In cases where the processing and analysis of the sample collected or brought inappropriately must be described in the report in the form of an observation about such conditions that may have interfered in the quality of the result obtained.

The post-analytical phase of quality control involves the release of the report and its inherent aspects. 7% are the biomedical or generalist pharmacists themselves who type up the reports. Regarding the checking of reports in 33.3% of the units there is a double check, while the others do not carry out this process.

According to the National Health Surveillance Agency (ANVISA) (2010) [24], it is up to the microbiologist to compose a brilliant and pragmatic report, enabling communication with the clinical staff, openly, such as by telephone or even in person, or encouraging them to seek the laboratory to reason cases or cooperate in meetings, among other actions [25] determine that the report needs to be legible, without transcription corrections, document in Portuguese, dated and duly signed by a competent professional with a legally qualified higher education level.

Conclusion

Observing the researched laboratories, it was verified that 11 laboratories carry out 73.4% of the activities within the good laboratory practices, of the laboratories that have collection points, 2 carry out, 40% of the practices in a coherent way.

In view of the above, the importance of QC practices for laboratories is observed, when using quality control practices, a laboratory is able to find and correct flaws in the analytical processes, before potentially incorrect patient results are released, it is of It is extremely important to maintain quality control in order to obtain reliable, fast and safe results, this helps the physician in deciding on the appropriate therapy for the patient.

Standard procedures must be implemented and improved, including in this improvement a program involving training in the transport of biological material for uroculture, patient orientation and awareness and diligence of each professional and managers. Thus, quality control in the clinical microbiological analysis laboratory plays an essential role, from patient guidance to the dispensing of results, and it is important that these laboratories provide services that enhance the perspectives of their customers. In this way, the insertion of Quality Control guarantees a safe health service, and may become a useful tool in guiding corrective parameters

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