

COLLEGIATE BOARD RESOLUTION No. 978 OF 6 JUNE 2025

Provides for the operation of Services that perform activities related to Clinical Analysis Tests (CAT).

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, items III and IV, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VI, Paragraph 1 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 4 June 2025, and I, Acting Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Article 1. This Resolution establishes the technical and health requirements for the operation of Services that perform activities related to Clinical Analysis Tests.

Section II

Scope

Article 2. This Resolution applies to all Services that perform activities related to Clinical Analysis Tests, whether public or private.

Article 3. Clinical Analysis Tests include, but are not limited to, biological, microbiological, immunological, chemical, biochemical, immunohematological, hematological, cytological, cytopathological, anatomopathological, genetic, molecular biology, cellular biology, mycology, parasitology, toxicology, urinalysis, or other tests on biological material of human origin.

Article 4. This Resolution does not apply to the marketing of *in vitro* diagnostic products classified as self-testing devices granted marketing authorization by Anvisa.

Sole paragraph. The use of *in vitro* diagnostic products classified as self-testing devices must comply with the provisions of this regulation when performed by higher-level professionals legally qualified to perform their professional duties.

Section III

Definitions

Article 5. For the purposes of this Resolution, the following definitions are adopted:

I – licensing permit: a document, or equivalent, issued by the competent state, municipal, or Federal District health agency, authorizing the operation of establishments performing activities under health surveillance;

II – analyte: a substance or set of substances of interest intended to be identified or quantified;

III – legally valid signature: physical or digital signature, qualified or advanced, in accordance with Law No. 14,063 of 23 September 2020;

IV – calibration: a set of operations under specified conditions, which establishes the correspondence between the values indicated by a measuring device and a reference material, for the purpose of standardizing or adjusting equipment or procedures;

V – Distribution Center (DC): a support establishment for the Service that performs CAT, authorized by the competent health surveillance agency, capable of carrying out activities associated with the storage, packaging, and transportation of biological material;

VI – batch certificate: a document that identifies and certifies the approval of a batch of *in vitro* diagnostic product, evaluated by a batch-by-batch Certification Program;

VII – isolated office: a healthcare facility, authorized by the competent health surveillance agency, which performs specialized healthcare activities under the technical responsibility of a legally qualified higher-level healthcare professional;

VIII – contract: a written instrument that defines the legal transaction entered into between the contracting parties, stipulating the obligations and rights of each party;

IX – Quality Control (QC): a form of monitoring through the analysis of control samples, in order to monitor the results to determine the precision and accuracy of the analytical process using internal quality control (IQC) and external quality control (EQC);

X – External Quality Control (EQC): determination of the accuracy and performance of CAT analytical process, carried out through inter-laboratory comparisons conducted by a Proficiency Testing Provider, also known as Proficiency Testing Programs;

XI – Internal Quality Control (IQC): a procedure conducted in conjunction with the biological material testing to assess the accuracy of the analytical system and whether it is operating within pre-defined tolerance limits;

XII – analytical run: a period of CAT execution, defined by a pre-established time or a specific number of patient samples, provided that repeatability conditions are maintained. These conditions include variables previously defined by the Service performing the CAT, such as preventive and corrective maintenance, reagent or calibrator batch changes, equipment initialization or restart, among others that may impact the consistency of results;

XIII – notification holder or marketing authorization holder: a legal entity, public or private, manufacturer or importer, responsible for the *in vitro* diagnostic product in Brazil, holding the marketing authorization for the *in vitro* diagnostic product, issued by Anvisa;

XIV – primary packaging: packaging that is in direct contact with the biological material to be transported, constituting a container, wrapper, or any other form of protection, removable or

not, intended to bottle, maintain, contain, cover, or package the biological material to be transported, also called internal packaging;

XV – Healthcare Establishment (HE): is the delimited physical space, fixed or mobile, where human healthcare actions are performed under technical responsibility;

XVI – equipment: instrument or apparatus developed by the manufacturer for use as an *in vitro* diagnostic product;

XVII – measuring equipment: *in vitro* diagnostic product used to perform measurements, alone or in conjunction with other complementary measuring equipment. Also known as a measuring instrument;

XVIII – Clinical Analysis Test (CAT): operational process, consisting of the pre-analytical, analytical, and post-analytical phases of the Services that perform activities related to CAT, whose objective is to determine the value or characteristics of a biological sample. Also known as clinical analysis testings or assays;

XIX – analytical phase: set of processes, with a specific description, used to perform analyses according to a specific method;

XX – post-analytical phase: phase that begins after obtaining valid analysis results and ends with the issuance of the report and communication arrangements for interpretation by the requester;

XXI – pre-analytical phase: phase that begins with the request for analysis, continues with the acquisition of the biological material, and ends with the initiation of the analysis itself;

XXII – written instructions: all written forms of documentation of activities performed and information on the execution of procedures, such as standards, protocols, and standard operating procedures, which may be provided in printed or digital form;

XXIII – clinical laboratory: a healthcare facility that performs activities related to clinical analysis tests, including the pre-analytical, analytical, and post-analytical phases. Activities performed exclusively by the anatomical pathology laboratory are excluded from this definition;

XXV – anatomical pathology laboratory: a healthcare facility that performs activities related to anatomopathological diagnostic procedures, including the pre-analytical, analytical, and post-analytical phases;

XXV – support laboratory: a Type III Service, authorized by the competent health surveillance agency, that performs analyses on biological material sent by another Type III Service;

XXVI – batch: identification of a product obtained in a manufacturing cycle characterized by its homogeneity;

XXVII – biological material or biological sample: tissue or fluid from the human body, such as excrement, bodily fluids, cells, tissues, organs, or other fluids of human origin or isolated from them;

XXVIII – primary biological material: tissue or fluid from the human body, such as excrement, bodily fluids, cells, tissues, organs, or other fluids of human origin or isolated from them that have not undergone alterations in their natural state or that have not been subjected to activities aimed at preparing them for analysis, such as centrifugation, filtration, cooling, and heating;

XXIX – in-house methodology: analytical methodology, reagents, or devices developed, produced, and validated by the Type III Service for use in its environment, which may be applied in research or to support diagnosis and therapy;

XXX – patient: person from whom the biological material is collected to be submitted to the CAT;

XXXI – collection point: Healthcare Establishment classified as a Type II Service, linked, corporately or contractually, to only one Type III Service;

XXXII – operational processes: all activities related to the performance of CATs, divided into pre-analytical, analytical, and post-analytical phases;

XXXIII – *in vitro* diagnostic product: reagents, calibrators, standards, controls, sample collectors, materials, and equipment, used individually or in combination, with intended use determined by the manufacturer, for *in vitro* analysis of biological material derived from the human body, exclusively or primarily to provide information for diagnostic, monitoring, screening, or to determine compatibility with potential blood, tissue, and organ recipients. Also known as an *in vitro* diagnostic medical device;

XXXIV – single-use *in vitro* diagnostic product: an *in vitro* diagnostic product that is used for a single patient during a procedure and then discarded and cannot be reused;

XXXV – legally qualified professional: a professional with higher education registered with the respective Professional Council, with their competencies assigned by law;

XXXVI – batch-by-batch certification program: a program conducted by a proficiency testing provider, contracted by the notification or marketing authorization holders, aimed at the individual evaluation and certification of each batch of an *in vitro* diagnostic product, analyzed by a laboratory accredited by standards NBR ISO/IEC 17025 or NBR ISO 15189;

XXXVII – quality control provider: a term given to the group of establishments responsible for conducting IQC and EQC programs, as well as for producing control samples for IQC and EQC;

XXXVIII – proficiency testing provider: an establishment accredited according to standard ISO/IEC 17043 responsible for conducting proficiency testing programs;

XXXIX – traceability: the ability to retrieve the history, application, or location of the product under consideration through registered identification;

XL – validation report: a document in which the validation procedures, records, results, and evaluation are consolidated and summarized;

XLI – Legal Representative (LR): an individual vested with legal powers to perform acts on behalf of the legal entity or establishment;

XLII – Technical Representative (TR): a legally qualified professional who assumes technical responsibility before the Health Surveillance Agency for the service that performs activities related to the CAT;

XLIII – mobile CAT service: a Healthcare Facility that performs activities related to Clinical Analysis Tests (CAT) outside its fixed headquarters or the Type III Service associated with it. This type of service is characterized by carrying out its activities sporadically or seasonally, being carried out outside the establishment, limited to specific and temporary interventions, and intended for a specific population in a specific environment, such as homes, businesses, and establishments.

Therefore, CAT-related activities cannot be carried out continuously and regularly, thus not being characterized as a fixed establishment;

XLIV – technical personnel supervisor: a legally qualified professional who supervises technical personnel in person during the period of operation of the Service performing activities related to the CAT;

XLV – validation: a process established by documented evidence that proves that a specific activity complies with predetermined specifications and meets quality requirements.

CHAPTER II

SERVICES

Section I

Classification

Article 6. The Services that perform activities related to Clinical Analysis Tests are comprised of the Service that performs CAT and the Distribution Center.

Article 7. For the purposes of this Resolution, the Service that performs CAT is classified as:

I – Type I Service (TIS);

II – Type II Service (TIIS);

III – Type III Service (TIIS); and

IV – Mobile CAT Service.

Section II

Type I Service

Subsection I

Classification

Article 8. The classification of the Isolated Office and the Pharmacy as Type I Service is permitted, provided that the technical requirements provided for in this regulation are met.

Subsection II

Classification Rules

Article 9. Only Healthcare Facilities that meet the requirements established in this Resolution for this service are classified as Type I Service.

Article 10. The mandatory requirements for classifying a Healthcare Facility as a Type I Service are:

I – perform CAT exclusively on biological material obtained by capillary puncture, nasopharyngeal, and/or oropharyngeal swab collection;

II – perform all stages of all operational processes related to the CAT in the facility itself (on-site), including the IQC and EQC;

III – do not safekeep, store, or transport biological material (own or third party's), except for IQC and EQC material;

IV – do not perform in-house methodology; and

V – use only equipment that does not require the use of reagent water produced on-site.

Article 11. The CAT performed in a Type I Service must be performed exclusively by a legally qualified professional.

Article 12. Isolated offices are only permitted to perform CAT for the purpose of integrating healthcare and subject to the qualifications of the professional performing it.

Subsection III

Infrastructure

Article 13. Type I Service must be equipped with at least the following mandatory items:

I – patient reception area sized according to demand and separate from the CAT collection and execution room;

II – cleaning material storage;

III – public restroom; and

IV – CAT collection and execution room.

Paragraph 1. The cleaning material storage area may be located in the restroom space.

Paragraph 2. The items in items I, II, and III of the caption of this article may be shared with other service units.

Article 14. The CAT collection and execution room must be equipped with at least the following mandatory items:

I – sink;

II – countertop;

III – table;

IV – collection chair;

V – if there is an *in vitro* diagnostic product that requires temperature-controlled storage and IQC and EQC materials, exclusive refrigeration equipment must be used for storage and

preservation, with at least temperature measurements taken, recording the maximum, minimum, and instantaneous temperatures, and in accordance with the instructions for use;

VI – area for storage of equipment and materials; and

VII – container for disposal of sharps and waste.

Paragraph 1. Sharing of refrigeration equipment is permitted only for medications that do not require dedicated refrigeration equipment.

Paragraph 2. Sharing the CAT collection and execution room is permitted for the provision of healthcare by a legally qualified professional, subject to the cumulative health and infrastructure requirements for all activities performed there.

Article 15. In an isolated public or private office classified as a Type I Service, the collection and execution room may be the same space as the consulting room, provided the requirements established in this Resolution are met.

Article 16. The CAT collection and execution room in a Type I Service must have natural ventilation or an air conditioning system.

Article 17. The lighting in the CAT collection and execution room must be designed so as not to interfere with the assessment of the CAT and the patient's skin color.

Article 18. The isolated office classified as a Type I Service must have a procedure area related to the CAT.

Section III

Type II Service

Subsection I

Classification

Article 19. The Collection Point is classified as a Type II Service.

Article 20. The Isolated Clinic may be classified as a Type II Service, provided it meets the requirements provided for in this Resolution.

Subsection II

Classification Rules

Article 21. Only Healthcare Facilities that meet the requirements established in this Resolution are classified as Type II Services.

Article 22. The mandatory requirements for classifying a Healthcare Facility as a Type II Service are:

I – perform CAT only on biological material obtained by capillary puncture, nasopharyngeal, and/or oropharyngeal swab collection;

II – when performing CAT, all steps of all phases of the operational process related to the CAT must be performed in-house, including the IQC and EQC;

III – not to perform in-house methodology; and

IV – use only equipment that does not require the use of reagent water produced in-house.

Article 23. The collection of other biological materials in addition to those mentioned in Article 22, Item I, of this Resolution, is permitted exclusively for the pre-analytical phase of Type III Service.

Paragraph 1. The collection of biological materials referred to in the caption of this article may only be performed by a qualified professional;

Paragraph 2. The collection of venous and arterial blood is authorized only at Collection Points;

Paragraph 3. Type II Service is permitted to transcribe the report issued by Type III Service, provided that the reliability of the data and traceability of the service responsible for the analytical stage are guaranteed; and

Paragraph 4. Type II Service is permitted to perform in-person CAT, which must occur at the time of collection.

Article 24. Type II Service is only permitted to collect, store, package, process, and transport biological material as part of the pre-analytical phase for the execution of the CAT in Type III Service.

Article 25. Type II Service is prohibited from receiving biological material sent by another Service that performs activities related to the CAT.

Sole paragraph. The receipt of biological material sent by the Mobile CAT Service to the Collection Point is an exception to the provisions of the caption of this article.

Article 26. The safekeeping and storage of IQC and EQC material is permitted, in accordance with the manufacturer's instructions.

Subsection III

Infrastructure

Article 27. The Type II Service must be equipped with at least the following mandatory items:

I – reception area sized according to demand and separate from the CAT collection and execution room;

II – cleaning material storage;

III – public restroom;

IV – eating area;

V – employee locker room/restroom;

VI – patient snack area;

VII – CAT collection and execution room; and

VIII – patient restroom attached to the CAT collection and execution room, which must also be accessible to Persons with Disabilities (PWD).

Paragraph 1. The items referred to in items I through V may be shared with other service units.

Paragraph 2. Type II Services located within shopping centers may share common areas of these establishments designated for restrooms, cleaning material storage, and storage for employee belongings.

Article 28. The CAT collection and execution room must contain at least the following mandatory items:

I – stretcher;

II – area for receiving, sorting, and temporary storage of biological material;

III – sink;

IV – countertop;

V – table;

VI – chair with arm for collection;

VII – in the case of *in vitro* diagnostic products and IQC and EQC materials that require temperature-controlled storage, dedicated refrigeration equipment must be used for storage and preservation, with at least temperature measurements performed, recording the maximum, minimum, and instant temperatures, and in accordance with the instructions for use;

VIII – dedicated refrigeration equipment for the storage and preservation of biological material, with at least temperature measurements performed, recording the maximum, minimum, and instant temperatures;

IX – area for shipping transport containers;

X – area for storing equipment and materials; and

XI – container for disposal of sharps and waste.

Sole paragraph. Sharing the item referred to in Item VIII is permitted only with medications that do not require dedicated refrigeration equipment.

Article 29. The CAT collection and execution room in Type II Services must have an air conditioning system.

Article 30. Type II Services may be equipped with a collection box, as provided for in Collegiate Board Resolution – RDC No. 50 of 21 February 2002 and its updates.

Article 31. The lighting in the CAT collection and execution room must be designed so as not to interfere with the assessment of the CAT and the patient's skin color.

Article 32. An isolated office classified as a Type II Service must have a dedicated procedure area for carrying out CAT-related activities.

Sole paragraph. In an Isolated Office classified as a Type II Service, the collection and execution room may be the same space as the consulting room, provided the requirements provided for in this article are met.

Section IV

Type III Service

Subsection I

Classification

Article 33. The clinical laboratory and the anatomical pathology laboratory are classified as Type III Services, provided they meet the technical requirements provided for in this regulation.

Subsection II

Classification Rules

Article 34. Only healthcare facilities that meet the requirements established in this Resolution are classified as Type III Services.

Article 35. Type III Services are allowed to perform:

I – all CAT;

II – all activities related to the phases of the operational process; and

III – the submission of biological material for CAT by a Support Laboratory.

Article 36. Type III Services may use Support Laboratories to perform their CAT.

Article 37. Type III Services must formalize the provision of services as a Support Laboratory through contracts, in accordance with this Resolution.

Article 38. Type III Services must annually evaluate the quality of the services provided by the Support Laboratory, considering:

I – proof of the Support Laboratory's regularity with the local health authority; and

II – proof of the analytical quality of the contracted tests through the results obtained through participation in Proficiency Testing Programs.

Article 39. Type III Services are allowed to contract with a Support Laboratory located outside of Brazilian territory.

Paragraph 1. The contracted Support Laboratory must be registered with the competent health authority of the country where it is located.

Paragraph 2. A copy of the original document proving the establishment's regularity with the competent health authority of the country where it is located must be available to the Brazilian health authority, accompanied by a sworn translation into Portuguese.

Subsection III

Infrastructure

Article 40. The physical infrastructure of Type III Services must meet the requirements of Collegiate Board Resolution – RDC No. 50 of 21 February 2002 and its updates.

Article 41. The CAT collection and execution room in Type III Services must have an air conditioning system.

Article 42. The lighting in the CAT collection and execution room must be designed so as not to interfere with the assessment of the CAT and the patient's skin color.

Section V

Mobile CAT Service

Article 43. Only Type III Services may maintain a Mobile CAT Service, whether in-house or contracted.

Article 44. The contracted Mobile CAT Service must have a permanent headquarters with a licensing permit or equivalent, issued by the local health agency, expressly indicating the activities performed.

Sole paragraph. The Mobile CAT Service may have its permanent headquarters at the Type III Service that maintains it.

Article 45. The Mobile CAT Service must be registered with the competent health authority of the location where its activities are carried out.

Article 46. The Mobile CAT Service must have a legally qualified professional as Technical Manager.

Sole paragraph. In the event of the Technical Manager's absence, the Mobile CAT Service must have a legally qualified professional to replace him/her.

Article 47. The Mobile CAT Service is prohibited from performing the CAT while the physical structure is in motion.

Sole paragraph. The performance of the CAT is permitted on means of transportation used in urgent and emergency situations.

Article 48. The Mobile CAT Service must perform measurements and inspections after assembling the equipment at the service stop, maintaining records to attest to compliance with the design and performance characteristics declared by the manufacturer, as well as the requirements of this Resolution and other applicable regulations.

Article 49. The Mobile CAT Service must follow the other requirements for the Service that performs CAT defined in this Resolution.

Article 50. The Mobile CAT Service may only collect and transport biological material for the Type III Service associated with it.

Sole paragraph. A Type III Service is permitted to contract a Mobile CAT Service for the collection of biological material to be sent to its associated Collection Point.

Article 51. The Mobile CAT Service may only perform CAT if it meets the following mandatory requirements:

I – perform CAT exclusively on biological material obtained by capillary puncture, nasopharyngeal, and/or oropharyngeal (swab) collection;

II – not to perform in-house methodology; and

III – use only equipment that does not require the use of reagent water produced in the service.

Paragraph 1. The Mobile CAT Service is permitted to collect biological materials other than those provided for in the caption, Item I, of this article, provided it is performed by a qualified professional and only within the scope of the pre-analytical phase, for the execution of the analytical phase of the CAT at the Type III Service associated with it.

Paragraph 2. The Mobile CAT Service is only permitted to collect, store, package, process, and transport biological material as part of the pre-analytical phase for the execution of the CAT in the Type III Service.

Paragraph 3. The Mobile CAT Service is not permitted to transcribe the report released by the Type III Service.

Paragraph 4. The Mobile CAT Service is permitted to perform an in-person CAT, which must occur at the time of collection.

Paragraph 5. The location where the activities of collection and execution of CAT will be carried out must have, at a minimum, facilities that guarantee privacy and personalized service.

Article 52. The collection and execution of CAT in the Mobile CAT service must be performed by a trained professional.

Article 53. The Mobile CAT Service must perform the IQC and EQC, as established in this Resolution.

Sole paragraph. The Mobile CAT Service may perform the IQC and EQC, as determined by the Type III Service that maintains it.

CHAPTER III

GENERAL CONDITIONS

Section I

General and Specific Conditions

Article 54. Only Healthcare Facilities may be classified as Services that perform CAT.

Article 55. Only Healthcare Facilities that meet the requirements established in this Resolution will be permitted to perform CAT-related activities.

Article 56. The classification rules established in this Resolution must be applied to classify Healthcare Facilities.

Article 57. Classification of Healthcare Facilities as a Service that performs CAT is the sole responsibility of the local health surveillance agency.

Article 58. Provided that the technical requirements set forth in this regulation are met, Healthcare Facilities, as part of the public administration, may be classified as services that perform CAT.

Article 59. The Collection Point that performs only the pre-analytical phase is classified as a Type II Service and must follow the provisions of this regulation pertaining to the activities performed.

Article 60. The CAT performed by the pharmacy authorized as a Type I Service is for screening purposes, without confirmatory purposes, with a view to integrating pharmaceutical assistance, healthcare, and health guidance actions in accordance with Law No. 13,021 of 8 August 2014 and Collegiate Board Resolution – RDC No. 44 of 17 August 2009, and its updates.

Paragraph 1. The result of the CAT performed by the pharmacy must support information regarding the user's health status and risk situations, as well as allow for monitoring or evaluation of the effectiveness of the treatment prescribed by a legally qualified professional.

Paragraph 2. The record of the CAT result performed at the pharmacy must be included in the Pharmaceutical Service Declaration.

Article 61. The Collection Center may only forward biological material to the Type III Service with which it has a relationship.

Article 62. The Collection Center must be linked, either corporately or contractually, to only one Type III Service.

Article 63. Type I Services must have a licensing permit or equivalent document issued by the local health authority, indicating the activities related to the CAT, as well as the activities of a pharmacy or isolated office.

Article 64. The Service that performs the activities related to the CAT must implement actions to promote patient safety and improve the quality of the service provided.

Article 65. Isolated Offices classified as Type II services are permitted to perform CAT using microscopy.

Article 66. CAT results that indicate suspected Compulsorily Notifiable Disease must be reported in accordance with GM/MS Consolidation Ordinance No. 4 of 28 September 2017, and its updates, and GM/MS Ordinance No. 420 of 2 March 2022, and its updates.

Article 67. Services that perform CATs for Compulsorily Notifiable Diseases (CND) must follow the diagnostic guidelines set forth in the respective ordinances approved by the Ministry of Health.

Section II

Organization of Healthcare Facilities within the Public Administration

Article 68. Healthcare Facilities within the public administration classified as Type II Services are exempt from the requirement to have an employee locker room/restroom, a patient snack area,

and a patient restroom attached to the CAT collection and execution room, which must also be accessible to Persons with Disabilities (PWD).

Article 69. For Healthcare Facilities within the public administration classified as Type I Services, CATs may be performed on any primary biological material.

Article 70. For Healthcare Facilities within the public administration classified as Type II Services, CATs may be received, stored, packaged, processed, and transported during the pre-analytical phase for CATs to be performed at another Type II Service or Type III Service within the public administration.

Article 71. For Healthcare Facilities within the public administration classified as Type II Services, CATs may be performed using any biological material, provided they are used in single-use equipment or by microscopy methodology in the service itself (on-site) with the aim of supporting health care.

Article 72. The mobile CAT is permitted to collect and transport any biological material during the pre-analytical phase for the execution of the CAT in a Healthcare Facility that is part of the public administration and is classified as a Type II or Type III Service.

Sole paragraph. Within the scope of public policies for health promotion and protection, and disease prevention and control, the Mobile CAT Service must be linked to a fixed Healthcare Facility.

Section III

Organization of the Service that Performs Activities Related to Clinical Analysis Tests

Article 73. The Healthcare Facility classified as a Service that performs activities related to Clinical Analysis Tests must have a licensing permit or equivalent document, issued by the local health authority, indicating the activities related to the CAT.

Article 74. The Healthcare Facility classified as a Service that performs activities related to CAT must be registered in the Brazilian Registry of Health Establishments (CNES, in Portuguese).

Article 75. The Healthcare Facility classified as a Service that performs activities related to CAT must have a legally qualified professional as Technical Manager.

Sole paragraph. In the event of the Technical Manager's absence, the Service performing CAT-related activities must have a legally qualified professional to replace him/her.

Article 76. The Service that performs activities related to Clinical Analysis Tests (CAT) must have a documented organizational structure.

Article 77. The Service performing CAT-related activities is responsible for establishing a data and information access policy, whether computerized or not, necessary to provide the service and to ensure the protection of patient information in accordance with Law No. 13,709 of 14 August 2018, the General Data Protection Law (LGPD, in Portuguese), or any other legal regulation that may amend or replace it.

Article 78. The Service performing CAT-related activities must evaluate the quality of its products or services in the event of suspected quality deviations.

Sole paragraph. All records must be accessible and specified in written instructions.

CHAPTER IV

RELATIONSHIPS

Section I

Contracting

Article 79. The contracting of activities related to the CAT must establish the responsibilities of the parties involved and the control and qualification criteria.

Article 80. For suppliers of inputs and service providers of activities not related to the CAT, a written contract is not required. Only invoices and equivalent documents will be acceptable as proof of the legal transaction between the parties.

Sole paragraph. When applicable, the parties must request documents that prove compliance with health requirements and other regulatory requirements by the other party.

Article 81. The parties must ensure that all products, materials, and knowledge delivered to them are suitable for their intended purpose.

Article 82. The obligations, responsibilities, and functions of the parties must be set forth in a written contract, with a view to verifying compliance with the provisions of this Resolution.

Sole paragraph. The contract must provide for at least:

I – express authorization for the parties to conduct audits to verify compliance with this Resolution;

II – traceability control;

III – compliance with all requirements of the analytical, pre-analytical, and post-analytical phases of this Resolution, where applicable;

IV – the obligation for the parties to communicate quality deviations and identified risks to each other in a timely manner so that corrective measures can be implemented;

V – the obligation for the parties to provide all necessary information to the other party to ensure safe and risk-reduced operations;

VI – the obligation for the parties to comply with the requirements set forth in this Resolution, in order to guarantee the safety, quality, and reliability of test results.

Article 83. The Legal Representative of the Service performing CAT-related activities is responsible for ensuring compliance with the obligations set forth in the contract for the establishment for which they are responsible.

CHAPTER V

QUALITY MANAGEMENT

Section I

Quality Assurance Program (QAP)

Article 84. The Service performing CAT-related activities must implement the Quality Assurance Program (QAP).

Article 85. The Service performing CAT-related activities must ensure that the execution of the activities corresponds to the intended purpose, adopting all necessary safety, quality, and effectiveness requirements.

Sole paragraph. Compliance with the provisions of the caption of this article is the responsibility of the Legal Representative and the Technical Representative of the Service performing CAT-related activities.

Article 86. The Service performing CAT-related activities must implement a QAP, which includes, at least:

- I – technology management;
- II – management of inherent risks;
- III – document management;
- IV – personnel management and ongoing professional education;
- V – Operational Process management; and
- VI – Quality Control Management (QCM).

Article 87. Quality Control Management (QCM) must be documented, and its effectiveness must be monitored by the Technical Manager through performance indicators.

Sole paragraph. The Service performing CAT must compare the results of its performance indicators using software and, when unavailable, using updated bibliographical references.

Section II

Technology Management

Article 88. All products subject to health surveillance used by the Service performing CAT-related activities must be registered with Anvisa.

Sole paragraph. The Service performing CAT-related activities must ensure that the products and equipment are used exclusively for their intended purposes, in compliance with applicable regulations and in accordance with the manufacturers' instructions for use.

Article 89. The Service performing CAT-related activities must manage its technologies, maintaining, but not limited to, the conditions of selection, acquisition, transportation, receipt, storage, distribution, installation, calibration, operation or use, disposal, and traceability.

Article 90. The Service performing CAT-related activities must monitor the performance and safety of products under health surveillance and service provision, as well as adopt strategies to

identify and report incidents, adverse events, and technical complaints, investigate these occurrences, and adopt measures to prevent their recurrence.

Paragraph 1. Reports of adverse events and technical complaints associated with products under health surveillance or healthcare must be made by the services through the Health Surveillance Notification System (Notivisa, in Portuguese), or any system that replaces it.

Paragraph 2. The Service performing CAT-related activities must collaborate in the operationalization of field actions involving equipment acquired for use in its activities.

Article 91. The Service performing CAT-related activities must establish, implement, and maintain criteria to ensure the quality of the CAT.

Article 92. The Service performing CAT-related activities must perform and maintain records of preventive and corrective maintenance on the equipment, in accordance with the instructions for use.

Sole paragraph. In the absence of a definition by the equipment manufacturer regarding the frequency of preventive maintenance, it must be performed at least annually.

Article 93. The Service performing CAT must maintain records of equipment measurements and inspections.

Article 94. Each Service performing CAT must establish and maintain documented procedures for calibrating its equipment, including guidelines specified by the manufacturer.

Paragraph 1. Equipment calibration must be performed at least as frequently as recommended by the manufacturer.

Paragraph 2. In the absence of manufacturer recommendations, calibration must be performed at least once a year.

Article 95. The Service performing CAT-related activities must ensure effective means for storing *in vitro* diagnostic products and biological material, ensuring their preservation, effectiveness, and safety, even in the event of a power outage.

Article 96. Equipment that requires temperature control must have at least temperature measurements performed, recording the maximum, minimum, and instantaneous temperatures.

Sole paragraph. For continuously operating equipment, recording must be performed to monitor equipment operation throughout the process requiring temperature control.

Article 97. The Distribution Center must use dedicated refrigeration equipment, recording the maximum, minimum, and instantaneous temperatures, for the storage of biological material requiring temperature control.

Subsection I

***In Vitro* Diagnostic Products, Reagents, and Supplies**

Article 98. The Service performing CAT-related activities must have equipment appropriate to the complexity of the service and necessary to meet its needs.

Article 99. The Service performing CAT-related activities must maintain written instructions in Portuguese for the equipment, which may be replaced or supplemented by manufacturer's manuals.

Article 100. The Service performing CAT-related activities must record the receipt of *in vitro* diagnostic products, reagents, and supplies.

Sole paragraph. Records of *in vitro* diagnostic products received must include data such as the batch number, compliance with shipping conditions, date of receipt, and other information necessary to ensure traceability and quality.

Article 101. Reagents and inputs fractionated or prepared by the Service performing CAT and used by it must be identified with a label containing:

I – name of the reagent or input;

II – concentration or specification;

III – batch number, when applicable;

IV – date of preparation;

V – name of the person responsible for fractionation or preparation;

VI – expiration date;

VII – storage conditions; and

VIII – information regarding potential risks.

Paragraph 1. The sale of reagents and inputs fractionated or prepared by the Service performing CAT is prohibited.

Paragraph 2. The receipt and shipment of reagents and quality control materials fractionated by other Services performing activities related to CAT are prohibited.

Article 102. The use of reagents, inputs, and products for *in vitro* diagnostics, as well as their preservation and storage conditions, must comply with the manufacturer's recommendations for use. Revalidation after expiration is not permitted.

Article 103. The Service performing CAT is permitted to perform analytical tests to ensure the quality of the supplies and products used in the Service's operational processes.

Article 104. The storage area must be equipped with appropriate equipment for temperature and humidity control, in accordance with the manufacturer's instructions.

Subsection II

Information System

Article 105. The Service performing CAT must define a policy of responsibilities to establish:

I – systematic access to data and information of patients and service professionals;

II – control of access to the entry and modification of patient data and test results, including records with the date, time, user, and location where the information was entered or modified;

III – a systematic process for releasing test results and patient reports, whether automatic or manual;

IV – information privacy and confidentiality policy; and

V – a defined and documented system for protection against unauthorized access.

Article 106. The Service performing CAT-related activities must evaluate and verify the system or software before its implementation and document it, including information regarding availability, reliability, data integrity, and the responsibilities of institutions and users.

Subsection III

Management of Inherent Risks

Article 107. The Service performing CAT-related activities must define and implement measures for the constant improvement of risk management inherent to the technologies used.

Article 108. The Service performing CAT-related activities must organize, structure, and implement actions for the continuous improvement of work processes.

Sole paragraph. Continuous improvement of work processes must include at least ongoing planning, execution, evaluation, and intervention in the structure, processes, and results of the CAT.

Article 109. Risk management must include, at least:

I – identification, analysis, evaluation, treatment, monitoring, and communication of risks;

II – identification of possible equipment failures and human errors that could result in healthcare-related incidents and the promotion of necessary preventive measures;

III – documented investigation determining the causes of possible equipment failures, identified human errors, or noncompliance with current regulations, their consequences, and the necessary preventive and corrective actions; and

IV – implementation of preventive and corrective actions identified during the investigations.

Article 110. The Service performing CAT-related activities must maintain and make available to all employees written biosafety instructions, covering at least the following items:

I – written instructions on biological, chemical, physical, occupational, and environmental safety, according to the procedures performed, equipment, and microorganisms involved, adopting compatible safety measures;

II – instructions for use of personal protective equipment (PPE) and collective protective equipment (CPE);

III – procedures in case of accidents; and

IV – handling and transportation of biological material, when applicable.

Subsection IV

Waste Management

Article 111. The Service performing CAT-related activities must implement the Healthcare Waste Management Plan (PGRSS, in Portuguese) meeting the requirements of Collegiate Board Resolution – RDC No. 222 of 28 March 2018 and its updates, as well as Collegiate Board Resolution – RDC No. 661 of 30 March 2022 and its updates.

Article 112. The Service performing CAT-related activities must have written instructions for cleaning, disinfecting, and sterilizing surfaces, facilities, equipment, articles, and materials.

Sole paragraph. The sanitation of the areas must be ensured to guarantee the safety of patients and professionals.

Article 113. The cleaning of the area where the CAT is performed must be recorded daily, at the beginning and end of business hours.

Paragraph 1. All areas related to the performance of CAT must be clean before all services.

Paragraph 2. After each activity, the need for a new cleaning procedure must be verified.

Article 114. Sanitizers and products used in cleaning and disinfection processes must be registered with Anvisa and used according to the manufacturer's specifications.

Section III

Document Management

Article 115. All documentation and records covered by this Resolution must be maintained and archived for at least 5 (five) years.

Article 116. Changes made to records must include the date, name, or legally valid signature of the person responsible for the change, preserving the original data.

Sole paragraph. All documents that comprise the Quality Assurance Program must be in Portuguese.

Article 117. The Service that performs CAT must keep the following documents updated and available in physical or electronic format:

I – Basic Architectural Design approved by the competent health authority;

II – list and records of all procedures performed;

III – inventory of products subject to health surveillance;

IV – list of names of all staff, their duties, qualifications, and workloads;

V – records demonstrating the implementation of the Continuing Education and Quality Assurance Programs; and

VI – records of results from the Proficiency Testing and Internal Quality Control programs.

Article 118. The Service performing CAT-related activities must provide documents proving its health compliance, whenever requested by the competent health authority.

Article 119. The Service performing CAT-related activities must provide, at the test sites, documented procedures guiding its activities, including:

- I – systematic recording and release of results;
- II – procedures for potentially critical results; and
- III – systematic review of results and release of reports by a legally qualified professional.

Section IV

Personnel Management and Continuing Education of Professionals

Article 120. The Service performing CAT-related activities must have teams sized according to its demand profile.

Article 121. Within the scope of public policies for health promotion and protection, and disease prevention and control, the Ministry of Health and the State, Municipal, and Federal District Health Secretariats may use the services of a qualified professional to collect and perform CAT, and shall be responsible for the necessary training and capacitation to ensure that the activities related to CAT are carried out in accordance with this Resolution.

Article 122. The Service performing CAT-related activities must have a legally qualified professional supervising the technical personnel, on-site, during its operating hours.

Paragraph 1. The supervisor of the technical personnel may be the Technical Manager.

Paragraph 2. The Service performing CAT-related activities may have one or more supervisors of the technical personnel.

Paragraph 3. In the event of the technical personnel supervisor's absence, the Service performing the CAT-related activities must have a legally qualified professional replace him/her.

Article 123. The Service performing CAT-related activities must maintain records of the training and qualifications of its professionals, compatible with the functions performed.

Article 124. The Service performing CAT-related activities must implement a Continuing Education Program for its entire team.

Article 125. The Continuing Education Program must include:

- I – initial and periodic training and capacitation, with a minimum frequency of once a year;
- II – theoretical and practical training and capacitation based on risk management, whenever new processes, techniques, or technologies are implemented, or before new personnel join the processes; and
- III – evaluation methodology to demonstrate the effectiveness of training and capacitation activities.

Article 126. Periodic training and capacitation must cover at least the following topics:

- I – written instructions;
- II – patient safety;

III – management of risks inherent to the technologies used; and

IV – Quality Assurance Program.

Article 127. Training and capacitation must be recorded, including the date, time, workload, content taught, and the name and professional qualifications of the instructor and the workers involved.

CHAPTER VI

OPERATIONAL PROCESSES

Section I

Pre-analytical Phase

Subsection I

Traceability of Biological Material

Article 128. The Service performing CAT-related activities must ensure and demonstrate the traceability of all activities related to biological material in the pre-analytical, analytical, and post-analytical phases.

Article 129. The report released by the Service performing the CAT must contain the name and CNES registration number of the establishment(s) responsible for the analytical phase of each CAT performed.

Sole paragraph. The identification of biological material, when performing tests at the time of collection and with immediate delivery of the report to the patient, may be simplified by including the patient's full name and age or date of birth, provided that traceability between the biological material and the patient is possible, in order to guarantee the safety of the patient and their biological material.

Article 130. When using proprietary methodology, the Type III Service must ensure the traceability of all inputs, reagents, and other components used in the analysis.

Article 131. The Service performing CAT-related activities must ensure the retrieval and availability of all information related to the CAT.

Article 132. The Service performing the CAT must:

I – provide the patient or guardian with instructions (physical, digital, or verbal) in accessible language, guiding the preparation and collection of biological material, with the goal of ensuring the patient's understanding;

II – request the patient to provide a valid photo ID to prove their identification for registration;

III – provide written, available, and updated instructions for all pre-analytical activities; and

IV – provide means that allow traceability of the entire pre-analytical phase.

Paragraph 1. For patients receiving emergency care or undergoing hospitalization, proof of identification data may also be obtained from their medical records.

Paragraph 2. The professional responsible for collecting biological material for anatomopathological examinations must verify the patient's identity and the correct characterization of the material to be examined.

Paragraph 3. Within the scope of public policies for health promotion and protection and disease prevention and control, in the absence of a valid photo ID, proof of patient identification for registration may be provided as established in current Ministry of Health regulations.

Article 133. The Service performing CAT-related activities and collecting the biological material is responsible for patient registration.

Article 134. Patient registration must include the following information:

I – patient identification number;

II – patient full name;

III – social name, when applicable;

IV – date of birth;

V – biological sex;

VI – mother's name;

VII – patient's telephone number or address; and

VIII – name and contact information of the guardian, in the case of a minor or incapacitated person.

Article 135. The Service performing CAT-related activities and collecting the biological material is responsible for registering the CAT.

Article 136. The CAT registration must include the following information:

I – name of the applicant;

II – date and time of the service;

III – time of collection of the biological material, when applicable;

IV – name and CNES registration number of the unit responsible for collecting the biological material;

V – tests requested and type of biological material;

VI – additional information;

VII – name of the professional who performed the registration;

VIII – name of the professional who collected the biological material, when applicable;

IX – name of the professional who validated receipt of the biological material, when applicable;

X – expected date for delivery of the report, when applicable;

XI – indication of urgency, when applicable; and

XII – additional patient information relevant to the CAT, such as the use of medication and vitamins, and health conditions.

Article 137. The Service performing the CAT must provide the patient or their guardian with proof of healthcare containing:

I – registration number;

II – patient's name;

III – date of healthcare;

IV – expected date of report delivery;

V – list of requested tests; and

VI – contact information for the Service performing CAT-related activities.

Sole paragraph. Proof of healthcare may be waived in cases of CAT performed at the time of collection, upon delivery of the report to the patient or their guardian.

Article 138. Biological material must be identified at the time of collection or upon receipt by the Service performing EAC-related activities.

Paragraph 1. The identification of the biological material must contain at least:

I – patient's name;

II – date of birth or age;

III – type of biological material; and

IV – patient identification number.

Paragraph 2. The date and time of collection must be traceable by the Service performing the CAT.

Article 139. The Service performing the CAT must define criteria for acceptance, rejection, identification, and performance of CAT on biological material.

Subsection II

Transportation of Biological Material

Article 140. All senders, carriers, recipients, and others involved in the transportation of human biological material, without prejudice to the provisions of other current regulations specific to each material and mode of transportation, must transport the biological material in accordance with the requirements of Collegiate Board Resolution – RDC No. 504 of 27 May 2021 and its updates.

Article 141. The Service performing CAT-related activities is responsible for sending the biological material for laboratory testing to national and international Support Laboratories.

Article 142. The import and export of biological material must be conducted in accordance with Collegiate Board Resolution – RDC No. 81 of 6 December 2008 and its updates, and with Health Ministry Ordinance No. 472 of 9 March 2009 and its updates.

Article 143. All transported biological material must contain, in its tertiary packaging, at least the information specified in Collegiate Board Resolution – RDC No. 504 of 27 May 2021 and its updates.

Subsection III

Distribution Center

Article 144. The Service performing CAT-related activities may maintain its own Distribution Center or a contracted one to carry out activities related to the storage, packaging, and transportation of biological material.

Article 145. The Distribution Center is prohibited from receiving biological material from the Mobile CAT Service.

Article 146. The Distribution Center must have a legally qualified professional as Technical Manager, in accordance with the rules of the respective Professional Council.

Article 147. The Distribution Center must verify and record the applicable transportation and storage conditions, including special requirements for temperature, humidity, or exposure to light, expiration date, quantities received, and cargo integrity.

Article 148. The Distribution Center is not permitted to:

- I. violate the primary packaging of biological material; and
- II. perform activities related to the analytical and post-analytical phases.

Article 149. The Distribution Center must hold a licensing permit or equivalent document issued by the competent health agency, expressly indicating the activities performed.

Article 150. The Distribution Center must have a documented organizational structure.

Article 151. The Distribution Center must be equipped with at least the following mandatory items:

I – a room for receiving, sorting, and temporary storage of biological material, with a minimum area of 3.0 m², containing at least:

- a) countertop;
- b) sink;

II – employee changing rooms/restrooms;

III – purging;

IV – cleaning material storage;

V – container for disposal of sharps and waste;

VI – area for storage of equipment and materials; and

VII – area for receiving and shipping transport containers.

Sole paragraph. Monitoring of controlled temperature and humidity must be recorded.

Article 152. The Distribution Center is prohibited from carrying out activities not associated with the storage, packaging, and transportation of biological material.

Article 153. The Distribution Center must perform a quality assessment of a product or service in the event of suspected quality deviations.

Sole paragraph. All records must be accessible and specified in written instructions.

Section II

Analytical Phase

Article 154. The Service performing CAT must:

I – have written, available, and updated instructions for all analytical processes, and the manufacturer's instructions for use may be used;

II – provide means that allow traceability of the entire analytical phase;

III – define risk limits, critical values, or alert values for tests with results that require immediate decision-making, and define a communication flow to the responsible healthcare professional or the patient when an immediate decision is required;

IV – define, when applicable, the purity level of the reagent water used in tests and quality controls; and

V – implement the necessary assessments and tests to ensure compliance with the purity level of the reagent water.

Article 155. The analytical process must be referenced in the manufacturer's instructions for use, in bibliographic references, or in scientifically valid research conducted by the Service performing CAT.

Article 156. The Service that performs antimicrobial susceptibility testing and phenotypic detection of resistance mechanisms must follow Health Ministry Ordinance No. 64 of 11 December 2018 and its updates, and use reference cultures listed in the documents of the Brazilian Committee on Antimicrobial Susceptibility Testing (BrCAST).

Subsection I

In-House Methodology

Article 157. Only Type III Services may develop and use their own methodology.

Article 158. Type III Services that use their own methodology must document it, including at least the following:

I – description of the process steps;

II – traceability of all products and inputs used;

III – specification and approval system for inputs, reagents, and equipment;

IV – validation system for steps and procedures, volume of reagents, types of biological material, materials required, method of interpreting results; and

V – determination of the sensitivity and specificity of the methodologies.

Sole paragraph. Type III Service may use, as a component of the CAT procedure using its own methodology, general laboratory materials and isolated reagents marketed as inputs for product development, as well as others labeled internationally as Research Use Only (RUO), Analytic Specific Reagent (ASR), or Investigational Use Only (IUO).

Article 159. Type III Services must specify in the report which results were obtained using their own methodology.

Article 160. Type III Services are prohibited from selling, passing on, donating, or delivering reagents or any product derived from their own methodology for consumption.

Sole paragraph. The provisions of the caption of this article do not apply to the provision of reagents and materials for use in the pre-analytical phase by the associated Type II Service.

Article 161. Type III Services may pass on or transfer scientific knowledge resulting from the development of their own methodology.

Article 162. All activities related to the operational phases of implementing their own methodology must occur within the service that developed it.

Article 163. The suitability of their own methodology for its intended use must be demonstrated through scientific justification and the operational conditions of the Type III Service, through a validation study, national guidelines or standards.

Paragraph 1. The provisions of the caption of this article exclude basic compendial general methods such as pH measurement, among others.

Paragraph 2. Instructions for use of products labeled as Research Use Only (RUO), Analytic Specific Reagent (ASR), or Investigational Use Only (IUO) are not accepted as the sole basis for validation.

Article 164. The Type III Service must prepare a validation report describing the procedures, materials required and used, analytical parameters, acceptance criteria, and results, with sufficient detail to allow for their reproduction and, when applicable, statistical evaluation.

Section III

Post-Analytical Phase

Article 165. The Service performing CATs must have written instructions for releasing results and legally valid signatures of reports, covering routine, on-call, urgent, and emergency situations.

Sole paragraph. The Service performing CATs must define the communication flow to the patient and the physician or healthcare professional responsible for the patient when an immediate decision is required.

Article 166. The report must be legible, without transcription errors, written in Portuguese, dated, and signed by a legally qualified higher-level professional.

Article 167. The report must contain at least the following:

I – name of the Service performing the CAT responsible for the analysis, with its respective CNES number;

II – address and contact telephone number of the Service performing the CAT responsible for the analysis;

III – name and registration number of the Technical Manager with the respective professional association;

IV – name and registration number with the respective professional association of the legally qualified professional who signs the examination report;

V – name and identification number of the patient;

VI – age or date of birth;

VII – date of collection of the biological material;

VIII – name of the examination, type of biological material, and analytical method;

IX – examination result and unit of measurement;

X – reference values, technical limitations of the methodology, and data for interpretation;

XI – specification of the proprietary methodology used, when applicable;

XII – when biological material with restrictions is accepted, this condition must be included in the report;

XIII – date of issue of the report; and

XIV – legally valid signature.

Sole paragraph. In cases where the Support Laboratory is located outside Brazilian territory, information regarding the National Registry of Healthcare Establishments (CNES) is not required in the report.

Article 168. Type III Services that choose to transcribe reports issued by the Support Laboratory must ensure their accuracy.

Sole paragraph. The person responsible for releasing the report may add interpretive comments to the Support Laboratory's text, considering the patient's condition and the overall context of the tests.

Article 169. The report must include the name of the Support Laboratory that performed the test.

Article 170. If any correction is necessary to any information contained in a previously issued report, this must be made in a new report clearly stating the correction made.

Sole paragraph. In the event of significant changes after the report has already been delivered or made available, Type II and Type III Services must ensure that the patient or their guardian is

contacted to inform them of the fact and record the name of the contact and the date of such communication.

CHAPTER VII

QUALITY CONTROL MANAGEMENT (QCM)

Article 171. The Service performing CAT must ensure the reliability of the CAT through QCM.

Article 172. QCM consists of, at a minimum, Internal Quality Control (IQC) and External Quality Control (EQC).

Article 173. IQC and EQC must be performed exclusively at the Service performing the CAT (on-site), and their performance outside the establishment is prohibited.

Article 174. The Service performing CAT must maintain records of Quality Controls, as well as written instructions for their implementation.

Article 175. The service performing CAT must have QCM applied to all CATs performed.

Article 176. QCM must be documented, including:

I – a list of all tests performed;

II – the method of control and frequency of use;

III – limits and acceptability criteria for control results;

IV – evaluation and recording of control results; and

V – External Quality Control (ECQ) performance report for all tests performed by the Service performing CAT that uses commercial control samples, issued by the Proficiency Testing Provider at least annually.

Section I

Internal Quality Control (ICQ)

Article 177. Every Service performing CAT must participate in ICQ programs.

Article 178. Participation in ICQ programs must be individual for each Service performing CAT.

Article 179. The Service performing CAT must perform ICQ on all equipment in use.

Article 180. The Service performing CAT must perform ICQ for all analytes performed, including:

I – monitoring the analytical phase by analyzing the control sample, recording the result obtained and analyzing the data;

II – definition of acceptance and rejection criteria for results by analyte type and according to the methodology used;

III – approval or rejection of analyses after evaluation of control sample results;

IV – recording of inadequacies, investigation of causes, and actions taken for rejected control sample results; and

V – criteria for evaluating control sample results.

Article 181. For ICQ, the Service performing CAT must use commercial control samples or control samples provided by Quality Control Providers registered with Anvisa.

Article 182. When commercial control samples or control samples provided by a Quality Control Provider are not available, the Service performing CAT must adopt alternative methods of assessing the accuracy of the analytical system described in the scientific literature.

Sole paragraph. The control sample must be analyzed in the same manner as the patient's sample.

Article 183. For CATs performed with single-use *in vitro* diagnostic products, the ICQ must be performed, at a minimum, at each batch change, at each shipment, and in accordance with the manufacturer's instructions.

Paragraph 1. If the single-use *in vitro* diagnostic product uses measuring equipment to perform the CAT, the ICQ must be performed at each preventive maintenance and corrective maintenance.

Paragraph 2. For CATs that require *in vitro* diagnostic products not covered by the caption of this article, the ICQ must be performed, at a minimum, at each analytical run, in accordance with the manufacturer's instructions, at each preventive maintenance and at each corrective maintenance.

Article 184. The frequency of ICQ performance at each batch change may be reduced according to technically established criteria and provided that:

I – it ensures compliance with the ICQ objective;

II – it provides initial training on test implementation by the supplier, the evidence of which must be maintained at the Service;

III – certificates approved by batch-by-batch certification programs must be available. These certificates must be conducted by laboratories accredited by NBR ISO/IEC 17025 or NBR ISO 15189 and contracted by the marketing authorization holders.

Sole paragraph. The certificate provided by batch-by-batch certification programs must be maintained by the Service performing CAT-related activities and be available to the competent health authority.

Section II

External Quality Control (ECQ)

Article 185. Every Service performing CAT must participate in ECQ programs.

Article 186. Participation in ECQ programs must be individual for each Service performing CAT.

Article 187. The Service performing CAT must perform ECQ on all equipment in use.

Article 188. The Service performing CAT must perform ECQ for all analytes analyzed.

Article 189. The Service performing CAT must verify, at least annually, the availability of proficiency testing for these tests with Quality Control Providers.

Sole paragraph. For tests not covered by ECQ Programs, the Service performing CAT must adopt alternative methods of assessing the accuracy of the analytical system described in scientific literature.

Article 190. Only Type III Services may donate biological material to a Proficiency Testing Provider.

CHAPTER VIII

FINAL AND TRANSITIONAL PROVISIONS

Article 191. The Services covered by this regulation have a period of 90 (ninety) days to comply with the terms of this Resolution, starting from the date of its publication.

Sole paragraph. The items related to the physical infrastructure of the Service that performs CAT must be met when renovations or expansions are carried out on existing services, new construction is carried out, or facilities not previously intended for health services are adapted, or those that have undergone a change in the use of one or more of their areas.

Article 192. Failure to comply with the provisions of this Resolution constitutes a health violation, under Law No. 6,437 of 20 August 1977, without prejudice to applicable civil, administrative, and criminal liabilities.

Article 193. Collegiate Board Resolution – RDC No. 786 of 5 May 2023, published in the Federal Official Gazette No. 88 of 10 May 2023, Section 1, page 161, is hereby revoked.

Article 194. This Resolution shall come into effect on the date of its publication.

RÔMISON RODRIGUES MOTA

Acting Director-President