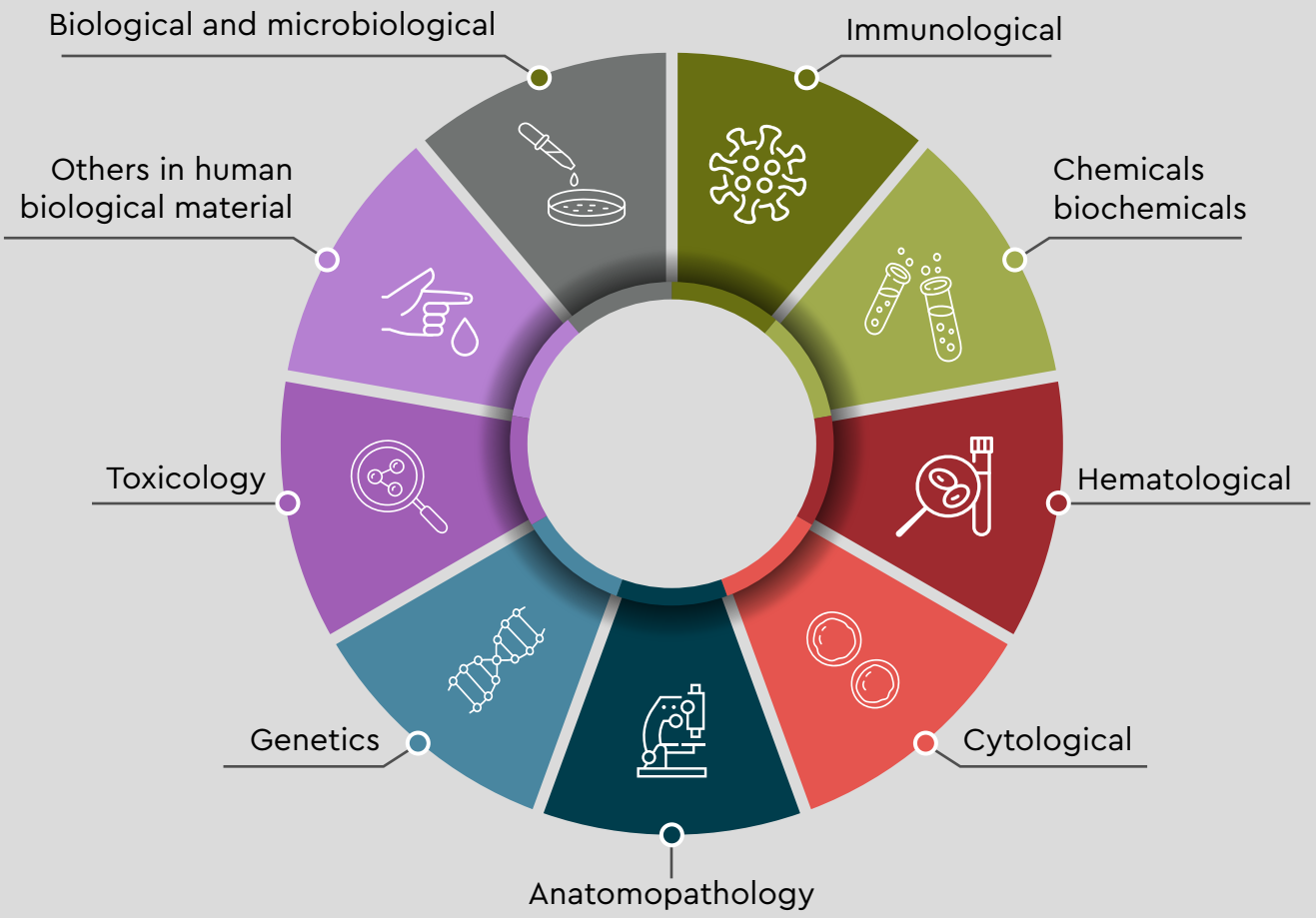
Machado Meyer

NEW REGULATION ON CLINICAL ANALYSIS

MAIN CHANGES

Since August 1, 2023, a new regulation provides for clinical laboratories, pathological anatomy and clinical analysis exams (EAC) - **RDC Anvisa n° 786/2023.**

The new rule **fully replaces** RDC Anvisa No. 302/2005 and includes the following clinical tests/proceedings:



In addition, RDC Anvisa No. 44/2009 was amended to remove the exhaustive list of tests allowed in pharmacies and drugstores, which considerably increases the screening and triage capability of these facilities for overall health assistance.

SERVICE MODALITIES

TYPE I

It encompasses pharmacies and consultations rooms (i.e., specialized care facilities) and allows the performance of EACs by qualified professionals, subject to specific sanitary licensing. In the case of pharmacies, the EAC serves for screening in pharmaceutical assistance actions and sanitary guidance, for example, for monitoring or evaluating the effectiveness of the treatment prescribed to the patient.

Pharmacy test results have no confirmatory purposes.

To perform an EAC that requires an instrument for reading, interpreting, and visualizing results, the Type I Services must contract the supervision of a clinical laboratory (**Type III Service**).

Does not allow (among others): venipuncture and arterial puncture; biological material receipt or forwarding; EAC with its own methodologies *(in-house)* and EAC that uses urine as biological material.

Analytical methodology, reagents or analytical systems developed, produced, and validated for use in its own environment, and can be applied in research or in support of diagnosis and therapeutics.

TYPE II

These are collection stations, that is, services linked to only one clinical laboratory in corporate or contractual terms. Allows the collection and storage of biological samples. It is possible to perform the tests/proceedings allowed **for Type I Services** and face-to-face tests whose performance occurs at the time of collection.

The modality also covers:

Collection, receipt, storage, packaging, processing, and transport of biological material in the pre-analytical phase for execution by clinical laboratory (**Type III Service**).

Service of collection and execution of EAC in itinerant unit, domicile and in-company.

It does not allow the realization of EAC's analytical phase by its own methodologies (*in house*).

TYPE III

These are clinical and pathological anatomy laboratories. It is the most complete type of service, in which it is possible to perform all types of EAC; collection, receipt, storage, packaging and transportation of biological material; sending biological material for EAC by a support laboratory; and EAC collection and execution service in an itinerant unit, home, company and health care facility.

It allows the development and use of its own methodology (*in-house*), including materials of general laboratory use and isolated reagents, which are marketed as manufacturing product's inputs. It is also possible to use other materials labeled internationally such as *Research Use Only* (RUO), Analytic Specific Reagent (ASR) or *Investigational Use Only* (IUO).

It is forbidden to: market, pass on, donate, or deliver for consumption reagents or any products from that operation.

Itinerant EAC Service: A unit that performs EAC-related activities outside of a fixed location but linked to a **Type III Service**.

It is not allowed to provide any kind of assistance with the physical structure in motion. Measurements and checks should be made only after the instrument has been assembled at the stopping place for service. It is also necessary to keep records of attendance.

The Ministry of Health and local health authorities may provide for additional regulations as part of their public health promotion and protection policies.

MANDATORY CLAUSES WHEN CONTRACTING EAC ATIVITIES

Anvisa RDC No. 786/2023 expressly requires the contracting of activities related to the EAC, with the following minimum requirements:

- Obligations, responsibilities and roles of the subjects involved
- Control and qualification criteria for EAC chain steps
- Documentation requests for proving its sanitary regularity
- Conducting audits
- Traceability flows
- Criteria for control and qualification of chain steps
- Log flow for traceability control
- Compliance with all requirements of the analytical, pre-analytical and post-analytical phases

HEALTH INFORMATION SECURITY

It is mandatory to implement an information systems policy, which should establish how to access data and information of patients and service professionals, as well as the control of patient's data release, changes and results of tests (including histories with dates, times, user and place where the registration or change of information occurred).

OTHER REQUIREMENTS

Physical and technological infrastructure, organizational structure, document management, quality actions, training, risk, and waste management, among others.

DEADLINES

EAC services must comply with the new requirements by November 10, 2023.

CONTACT

RENATA ROTHBARTH
Partner
rrothbarth@machadomeyer.com.br
+55 11 3150-7000

LEGAL INTELLIGENCE CENTER
Our insights on issues that impact your business
Access our content: www.machadomeyer.com/legalintelligence