

SERVICE CHARTER 2023

REVISION MATRIX

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PART ONE

1.1 Introduction: What is the Service Charter?

The current legislation, with particular reference to the Prime Ministerial Decree of 19 May 1995 (Official Gazette No. 125 suppl. ord, No. 65 of 31.05.95) establishes that health facilities must have a "Service Charter".

This represents the pact between the "health facility" and the citizen, in which it is declared how much the structure is able to achieve / offer together with what is required to be respected in the provision of the presentation.

In fact, it is a guide that, by collecting data and news essential to users who want to be informed of the services, contributes to improving more and more the relationship with the users themselves.

The Service Charter of the LAB Analysis Laboratory. RODIO DR. PASQUALE S.R.L., in addition to the more general information, contains an in-depth description of all the services and assistance offered, the places where to improve the relationship between user and structure.

The Service Charter can therefore be considered as the "contract" between the

Laboratory and the patients.



1.2 Presentation of the -

The LAB analysis laboratory. RODIO DR. PASQUALE S.R.L. provides laboratory analysis services as a Basic General with specialized sectors of: clinical chemistry, microbiology, hematology, seroimmunology and toxicology.

The LAB Laboratory. RODIO DR. PASQUALE S.R.L. is adequately equipped to meet the needs of traditional medicine and, over time, has expanded with new equipment and systems adapted to the evolution and transformation that clinical chemistry underwent over the years.

The traditional clinical study of the patient, based on accurate anamnesis and physical examination, is integrated and enriched by a series of analytical investigations, so that the clinic and laboratory diagnostics are integrated for the realization of that common goal constituted by the correct interpretation of the pathological processes that the doctor must diagnose and treat.

The enormous development of science in recent times and in particular the
creation of sophisticated equipment with high sensitivity and specificity, open
new horizons to medicine for understanding the etiopathogenesis of numerous
morbid processes and allow laboratory investigations with the following,
documented, advantages:
□ Greater depth and completeness of knowledge and therefore more
advanced diagnostic possibilities;
$\hfill\square$ Rapidity of study procedures of the patient with earlier and more timely
diagnosis;
□ Possibility to identify the preclinical stages of certain diseases;
$\hfill \square$ Diagnostic deepening with the establishment of etiological and pathogenetic
therapies instead of traditional symptomatic treatments.

However, the clinician cannot use laboratory data and therefore make logical decisions if the data are not reliable: every laboratory test must therefore be brought

and maintained to a high standard of reliability. This standard is achieved and maintained with that practice called "quality control".

The implementation of a complete quality assurance system of the results is the foundation of the operation of our laboratory. It is divided into various components such as the organization of work, the evaluation of the efficiency of the methods, internal quality control, interlaboratory quality control, the clinical evaluation of the reliability of the data.

This quality safety system is consistently added to our usual operating methods, thus completing that very special act that is the laboratory examination.

1.3 Purpose

The LAB laboratory. RODIO DR. PASQUALE S.R.L. is managed by professionals who aim to carry out their role and their activity thanks to the continuous construction of a relationship between doctor and user that must be satisfied mainly in terms of humanity and then excel in technical-health quality, transparency and effectiveness.

1.1 Basic principles

Equality: The LAB laboratory. RODIO DR. PASQUALE S.R.L. in dealing with patients does not make any discrimination on grounds concerning sex, race, language, religion, political ideas, socio-economic and psycho-physical conditions.

Efficiency and effectiveness: The laboratory is constantly committed to:
☐ Improve objective and impartial information on the services provided;
☐ Implement programs for the computerization of diagnoses;
Respect confidentiality towards third parties;
☐ Give more and more consideration to any complaints;
$\hfill \square$ Inform and train the operating staff on the principles of reception in order to improve
the overall quality of the service;
□ Communicate to the staff the importance of meeting the requirements of the client
(Patient) and that these obligations are taken into account in the control of the
orocesses;
□ Identify any staff training needs promptly and promptly;

\square Adapt the structure of the laboratory to the new analytical methodologies and new
technological instruments in the necessary time;
 Ensure continued efforts to prevent problems and shortcomings;
$\ \square$ Ensure the continuous improvement of the service provided to the Customer also
through the examination of implicit and explicit requests of users.

Impartiality and regularity: Provide services according to criteria of objectivity and



regularity; guarantee through its staff the regularity and continuity of the service in compliance with the principles and rules established by the laws and contractual provisions on the subject.



The mission of the LAB laboratory. RODIO DR. PASQUALE S.R.L. is achieved by guaranteeing respect for the 14 fundamental rights enshrined in the "National Protocol of the Health Service":

RIGHT TO TIME, through the rationalization of the production process but without neglecting the "right examination time".

RIGHT TO INFORMATION, through the public relations office, through a clear, detailed, professional and punctual interview with users.

RIGHT TO SAFETY, ensuring the patient the commitment of materials, procedures, equipment inspired by the concept of maximum safety and constantly monitored in the preservation of quality requirements.

RIGHT TO PROTECTION, guaranteeing continuity of care by adapting to the personal needs of the patient, especially if in particular conditions of suffering, the elderly, the disabled, non-self-sufficient subjects, terminally ill patients, children, etc.

RIGHT TO CERTAINTY, providing the right news and certain information.

RIGHT TO TRUST, guaranteeing everyone that every medical act is to protect health.

RIGHT TO QUALITY, through the implementation of quality improvement paths, detecting the quality of the services provided and the satisfaction of the Users, activating, if necessary, all forms of collaboration between the various public and private bodies.

RIGHT TO DIFFERENCE, guaranteeing different treatments that take into account the different needs and with particular attention to the removal of architectural barriers,

avoiding conflict situations, inconveniences, also through the rationalization of services.

RIGHT TO NORMALITY, ensuring respect for the characteristics and personal habits of patients.

RIGHT TO THE FAMILY, involving the family in assisting the sick, creating a climate of collaboration with family members in the exclusive interest of the patient.

RIGHT TO DECISION, through correct information, which allows an "informed consent" to diagnostic procedures.

RIGHT TO PARTICIPATION, encouraging the participation of volunteers, non-profit activities and ensuring the participation of Users.

RIGHT TO THE FUTURE, giving dignity and hope to the life and health expectations of the patient, whatever his clinical conditions, even if terminal.

RIGHT TO REDRESS WRONGS, through the establishment of a complaints desk and continuously detecting the satisfaction index of Users.



1.5 Quality of service

The LAB analysis laboratory. RODIO DR. PASQUALE S.R.L. has started, following the change of the new corporate structure, the certification process of its quality system

pursuant to the UNI EN ISO 9001: 2015 standard: this implies that all resources, both human and technical-organizational, and economic are committed to maintaining a relationship with users and the environment based on improving the quality of the services provided and towards satisfying the implicit and explicit needs and expectations of users.

The Management, with a view to the path taken, has identified and formalized in its quality system the organizational and decision-making structure so that it is possible:

Ensure the achievement of "service requirements";

Ensure the satisfaction of "customer requirements";

Ensure compliance with the Quality Policy, the Internal Regulations and the Charter of Services;

Ensure the achievement of the objectives set in the short and long term;

Operate in such a way as to achieve a "continuous improvement" of services, processes and customer satisfaction.

These objectives are achieved through meetings, courses, working groups aimed at:

Promote the actions necessary to prevent the occurrence of non-conformities on service, process and Quality System;

Identify and record any problem related to the service, the process and the Quality System;

Analyze the data and the various recordings:

Analysis of process and/or service non-conformities and the implementation of the action necessary for its resolution;

Customer return data;

Customer complaints;

The results of customer satisfaction surveys;

The results of internal audits, carried out periodically;

The corrective actions taken and their results.

Demonstrate the ability to regularly provide services that meet customer (patient) and applicable mandatory requirements;

Briefly describe the company functions and their tasks and responsibilities;

Illustrate the procedures and requirements of the System to serve as a reference to the "insiders" and inspectors in charge of internal / external audits and evaluation inspections;

Ensure compliance with the Quality Policy, the Internal Regulations and the Charter of Services;

Ensure customer satisfaction (patients) through the effective application of the system, in particular through:

- the detection of non-conformities and unwanted events;
- analysis of the causes of non-conformities;
- the application of the consequent corrective actions.

Be a vehicle of involvement, from the definition of the System to the maintenance of compliance between specified requirements and results, up to the constant improvement of all quality parameters;

Ensure safety and quality;

Ensure:

- The responsibilities of operators;
- Respect for privacy (pursuant to Legislative Decree no. 196/03 and subsequent updates with GDPR 679/16 EU and Legislative Decree no. 101/18), information, equality, rules and equal treatment for all;
- The continuity of the service, extending as much as possible the hours of activity, avoiding delays in the execution of examinations and in the delivery of reports.

PART TWO

2.1 Information about the structure

The LAB analysis laboratory. RODIO DR. PASQUALE S.R.L. has an agreement with the S.S.N. and is authorized with the Regional Code.

The medical and parametric staff is the one required by current legislation and can maintain with the laboratory an employment relationship, full-time or part-time, or self-employment of coordinated and continuous professional collaboration.

2.2 Location and access to the structure

The registered office of the LAB. RODIO DR. PASQUALE S.R.L., located in Petilia Policastro (KR) in Via Tributi, is the headquarters where the administrative headquarters, the sampling center and the centralized clinical analysis laboratory are located.

2.3 Type of services offered

The field of activity of the LAB laboratory. RODIO DR. PASQUALE S.R.L. provides laboratory analysis services as a basic general with specialized sectors of: clinical chemistry, microbiology, hematology, seroimmunology and toxicology.



The LAB. RODIO DR. PASQUALE S.R.L. performs types of clinical analysis in the following sectors:

- CLINICAL BIOCHEMISTRY
- -TOXICOLOGY
- -HEMATOLOGY
- -COAGULATION
- -MICROBIOLOGY
- Seroimmunology

The services provided by the laboratory are subsidized by the SNS, but users who wish to use the services of the laboratory and do not benefit from the aforementioned subsidies can do so under the solvency regime.



2.4 Timetables

Opening hours:

Morning from Monday to Friday 7.45-13.30;

Afternoon from 15.00 to 16.00

Public relations:

Reference Dr. Franceschina Carvelli

from Monday to Friday from 8.00 to 12.00.

Pick-up times:

Monday to Saturday 7.45-10.30 am

Reporting collection time:

Monday to Friday 10.30-12.00

Complaint:

In order to be able to promptly solve the problems encountered, please communicate any inefficiencies within 3 days

Report delivery time:

During the acceptance phase, the delivery times of the reports will be indicated depending on the type of determination made.

2.5 Provision of the service in case of emergencies and unforeseen events

To better meet the needs of customers the LAB. RODIO DR. PASQUALE S.R.L. carries
out assistance activities both in the phase prior to the provision of the service, and
in the subsequent phase.

For clinical or technical questions, the laboratory staff is available for any clarification or advice during opening hours.

Outside opening hours, in case of need, please send an E-Mai: labanalisirodio@libero.it / info@laboratorioanalisirodio.it

In case of closure of the Laboratory, for holiday shifts, in order to guarantee the provision and continuity of the service in case of EMERGENCIES, the references of other connected structures will be posted "Outside the door" and published on the "website".

2.6 Company organization chart

ORGANIGRAMMA - ORGANIZATIONAL CHART

The Analysis Laboratory is a structure authorized for health activities, in compliance with current legislation. The staff of the laboratory is structured as shown in the figure below.

The health personnel is identified by highly qualified skills and continuous updating. There are several professional figures operating within the laboratory and are coordinated by the Laboratory Director.

2.7 Ancillary services

In the structure of the LAB. RODIO DR. PASQUALE S.R.L. there is no public telephone station, but each user is given the opportunity to use the telephones in the reception room; In the structure there is signs indicating the areas where the various sectors of the laboratory are located (waiting room, sampling room, etc.).

Within the Laboratory, a safety management system is created and managed, in relation to the legal requirements in force. In particular, the laboratory is equipped with all safety authorizations and constantly monitors the level of risk within it, ensuring that it is kept at the lowest possible levels.

2.8 Quality standards

The provision of services that the laboratory LAB. RODIO DR. PASQUALE S.R.L. offers can be done by implementing the choice between:

- benefits under the convention scheme;
- benefits under the solvency regime.

In both cases, the services provided meet quality standards, including:

the systematic detection by the Management of waiting times during collection and reporting;

the establishment of a customer satisfaction questionnaire with which to monitor the level of quality perceived by the user regarding the services offered, in order to identify any problems and their priorities;

simplification of internal administrative procedures;

the technological updating of the laboratory and its internal sectors;

information, to the operating staff, on the principles of reception in order to improve the overall quality of the service.

To further guarantee the quality of the service, the Laboratory has prepared a series of internal procedures with which to define, implement and control all operational activities.

In fact, it is guaranteed:

the periodic control and updating on regulations and technical-scientific instructions that may change over time;

the review activity by management to evaluate the implementation of the quality system;

periodic control of laboratory instrumentation in order to always guarantee maximum efficiency of the instruments and correctness of the analytical results obtained. In addition to providing internal control and calibration of the instrumentation service, the laboratory participates in a national system of self-control of laboratories (EQA)



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and internal self-control systems (CQI) in order to guarantee the maximum quality of the services provided;)

Analyses that are not carried out directly by the LAB. RODIO DR. PASQUALE S.R.L. are entrusted, subject to the patient's authorization, to the highly specialized laboratory:



PARTE TERZA



Sick guardianship rights (User)

3.1 Right to respect

The LAB analysis laboratory. RODIO DR. PASQUALE S.R.L. is committed to developing a positive collaboration with the patient and with the associations for the protection of patients' rights.

The User welcomed into a private health institution enjoys the rights that establish and characterize his relationship with the institution itself. Each user has the right: respect for personal dignity and its moral, political and religious convictions;

confidentiality in the execution of the requested services, in full respect of modesty and personal intimacy; a correct and courteous professional treatment by the staff who are required to address the User, asking him with his name and surname, as well as with the pronominal particle "You";

human environmental conditions, compliance with scheduled and publicly defined schedules, waiting times appropriate to normal work activities;

right to privacy in the delivery of results and reports in relation to the reference standards in force.

3.2 Right to freedom of choice

Each User has the right:

the freedom of choice of the institution, with the sole limitation linked to technical equipment or medical specializations;

access, as soon as possible, to quality services whatever the social, ideological,

economic and age status of the patient;

objective and impartial information on the offer of services;

3.3Right to quality of care

Each User has the right:

services of a quality appropriate to the condition of the patient, in the best possible material conditions;

the benefit of advances in medicine and technology in the diagnostic and therapeutic fields;

basic and specialist professional training of medical and paramedical personnel, also supported by appropriate updating activities;

the progressive activation of an internal quality evaluation and control process;

the availability of the necessary means to the doctor who assumes responsibility for diagnosis and treatment, within the framework of his professional independence, with the sole limitation of ethical imperatives.

3.4 Right to information

Each User has the right to information:

adequate on the characteristics of the health structure, the benefits and services provided by it, the internal organization;

impartial on the possibility of further investigations and treatments, possibly available in other facilities:

objective and appropriate on diagnosis and therapeutic acts, in order to be able to express an effectively informed consent;

correct on the strict respect of the confidentiality of data relating to your person and your illness;

correct on the conditions of provision of the service, on the costs for any additional services.

3.5 Right to complain – U.R.P.

Each User has the right:

to see any complaints taken into consideration;

to receive precise information on how to submit complaints: office, persons competent to receive them, times, location for the mailbox for forwarding observations, if any; to know within a certain period of time the outcome of any complaint presented;

to express its opinion on the quality of the services and assistance received, also through the compilation of specific "customer satisfaction tests".

Each user can report their COMPLAINTS within 3 days, using the appropriate forms of the "Internal Reports", and depositing it in the appropriate box at the entrance of the company.

In order to make the things he hears more understandable to the user, the following is a list of the most frequently used industry terminology:

Laboratory diagnostics: to provide, through the service to the patient, information obtained with chemical, physical and biological methods on tissues or liquids of human nature or on materials related to human pathology for the purpose of prevention, diagnosis and monitoring of therapy.

Service charter: it is the pact between the health facility and the citizen, in which it is declared what the structure is able to achieve and that it is required to respect in the provision of the service.

Test: A technical operation that consists of determining one or more characteristics of a given product, process or other service according to specified procedures.

Test method: Technical procedure specified to perform a priva.

Test report: Document presenting the results of a test and other information relating to it.

Test laboratory: Laboratory that performs the tests.

Laboratory comparison tests: Organize, perform and evaluate tests carried out by two or more laboratories on the same products or materials, according to predetermined conditions.

Proficiency tests (of a laboratory): Determination of the level of performance of a laboratory by means of comparison tests between laboratories.

Accreditation (of a laboratory): Formal recognition of the suitability of a laboratory to carry out specific tests or certain types of tests.

Accreditation system (of laboratories): Systems with their own procedural and management rules to carry out the accreditation of laboratories.

Accreditation body (of laboratories): Body that directs and administers an accreditation system and grants accreditation.

Accredited laboratory: Testing laboratory to which accreditation has been granted.

Accreditation criteria (of a laboratory): Set of requirements prescribed by an accreditation body, which must be met by the laboratory to obtain accreditation.

Evaluation of a laboratory: Examination of a testing laboratory to assess whether it meets the necessary requirements to obtain accreditation.

Technical specification: Document describing the technical requirements that products, processes or services must meet (UNI CEI EN 45020).

First Line Samples: Primary Samples, i.e. of better precision in the possession of the Laboratory.

Recognized Methods of Analysis (Official Methods): They are published in regulatory bulletins both at Community level.

Reference methods: They are evaluated by trade organizations and international

bodies such as ISO, AOAC, IDF, EEC, etc

Routine methods: Evaluated as the reference methods but differ from them by lower accuracy and greater "scope of analysis".

Internal methods: These are test methods developed by the laboratory and for which it is necessary to keep all the documentation: the bibliographic sources, the records relating to the experimental part and everything that led to the formulation of the method.

Reference materials: Reference material (MR) means a material for which one or more properties are sufficiently well defined to be used for the calibration of an apparatus, for the evaluation of a measurement method or for the assignment of numerical values to certain real parameters of the materials. Reference materials may be in gaseous, liquid or solid form, prepared and certified in batches or individually.

Certified reference materials: Certified reference material (MRC) means a material for which one or more property values are certified by a technically sound procedure accompanied by a certificate issued by a certification body, sufficiently well defined to be used for the calibration of an apparatus, for the evaluation of a measurement method or for the assignment of numerical values to certain real parameters of the Materials.