

**CLINICAL ANALYSIS LABORATORY
COSTANZO MARCELLO S.A.S.**

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CHARTER OF SERVICES

Lazio Region: Decree of the Commissioner ad Acta 6 October 2014, no. U00311

Date:

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Dear Patient, this Service Charter has been prepared to provide you with information on the structure, on the services offered and to make you aware of the principles to which the management is inspired.

The path that is proposed to you must be as efficient as possible. To achieve this goal, it is necessary to establish a discussion with you through which it will be possible to verify the degree of satisfaction of your expectations.

The collaboration that you will offer us in this regard will be precious to us.

- **Efficiency,**
- **quality,**
- **Courtesy**

are the commitments we make to our patients in offering diagnosis and treatment services

Efficiency means good organization and planning of activities, coordination and integration of services, compliance with the agreed times for the execution of services, transparency in relations with the public, constant effort for improvement.

Quality of diagnosis and treatment activities. This is the goal of our doctors who use modern diagnosis and treatment protocols with skill and experience, work in teams integrated with multidisciplinary skills, use the most modern tools and techniques, adapt to national and international guidelines and follow the updating of their respective disciplines.

Courtesy and respect for the patient are priority commitments for all of us, doctors, technicians and administrative staff.

This charter of services has been drawn up with the contribution of the health specialists working in the structure and is subject to revision or integration also deriving from your suggestions.

The Legal Representative

Marcello Costa

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SECTION I - COMPANY PRESENTATION

1.1. PRESENTATION

The Costanzo Marcello s.a.s. Clinical Analysis Laboratory has been active since 1975 and definitively accredited by the Lazio Region with decree U00226 of 09/11/2012.

The principle of accreditation, based on the verification of structural, technological and organizational suitability, represented the starting point of an evolution of the structure that has set as its objective of primary importance the maximum customer satisfaction through the pursuit of increasingly satisfactory levels of quality in terms of courtesy, reliability and availability.

The structure with an area of about 212 m² is located on the ground floor of a building located in Rome in P.le Delle Medaglie d'Oro 20 - 00136.

The set objectives are pursued through the diagnostic services of the **affiliated** Basic Analysis Laboratory

The "Costanzo Marcello s.a.s." Analysis Laboratory has adopted an internal quality management system in reference to the UNI EN ISO 9001:2015 standard in order to manage the minimum requirements for the regional operating authorization and the additional requirements of institutional accreditation.

1.2. STRUCTURE AND SERVICES

The Costanzo Marcello SAS Clinical Analysis Laboratory is configured as a Basic Analysis Laboratory affiliated with the National Health Service.

1.3. BASIC PRINCIPLES

Quality

Our strategy is to make the COSTANZO MARCELLO clinical analysis laboratory a reference laboratory in its catchment area for the offer of clinical analysis services.

The organization's mission is applied in the following standards, which we maintain for our staff and our patients:

Professional performance

A control over the processes that ensures our patients the appropriateness of the result.

Services to the user

To ensure the standards set out in the Service Charter and to improve the performance perceived by users in general.

Technology Resources

Renewal of the instrumentation for a continuous improvement of clinical analyses.

Human Resources

Ensure the continuous maintenance of staff skills through CME training courses to offer a professionally adequate service.

Institutional Recognition

Maintain definitive accreditation within the National Health Service

The Organization develops its commitment to continuous improvement through plans and actions aimed at improving services, processes and performance through the achievement of the objectives listed in the review report.

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This quality policy represents the daily commitment of our entire team to guarantee patients effective, safe and cutting-edge care.

1.4. RIGHTS AND OBLIGATIONS

A) - RIGHTS

- 1) The right to respect for personal dignity and moral, political and religious convictions, guaranteeing:
 - Protection from any pressure – direct or indirect – on the patient's beliefs, as a basic condition for a relationship of trust between the patient and health professionals.
 - Confidentiality in the execution of visits and treatments.
- 2) Right to freedom of choice, guaranteeing:
 - Access to the facility on time
 - Possibility of refusing the diagnostic and therapeutic method.
- 3) Right to quality of care, guaranteeing:
 - Attention to safety in the practice of medicine, in the execution of treatments and in patient care.
 - Quality performance.
 - Updating and application of scientific advances in the medical, diagnostic and therapeutic fields.
 - Possibility for the Doctor to have at his disposal every means necessary in the context of his diagnosis and treatment activity and respect for his professional independence, with the sole limitation of the ethical imperatives inherent in the profession.
 - Activation of the internal process for quality control.
- 4) Right to information, guaranteeing:
 - Adequate information on the characteristics of the health facility, on the benefits and services provided, on the methods of access, on the internal organization.
 - An impartial indication on the possibility of further investigations and treatments that may be available at other facilities.
 - An appropriate and understandable update on diagnoses and therapeutic acts, in order to be able to express an effectively informed consent.
 - The confidentiality of data relating to the person of the patient and his or her medical history.
 - The easy identification of internal staff.
- 5) Right to complain, guaranteeing:
 - The possibility of filing complaints.
 - Precise information on how complaints are submitted.
 - Specific communications regarding the outcome of complaints.
 - The opportunity to express one's opinion on the quality of services.

6) Right to privacy

For the concrete implementation of the legislative principles on respect for Privacy (EU Regulation 2016/679 and subsequent amendments), the patient can, by signing the appropriate forms available at the reception office:

- to provide for the methods of managing their personal data;
- know how to issue and deliver reports.

7) Personal data processing

In application of the regulations in force on the subject, the organization guarantees all users the utmost confidentiality on the personal and health data that it acquires by virtue of obligations deriving from the law.

Such confidentiality is guaranteed:

- through the application of a specific policy document, provided for by EU Regulation 2016/679 as amended;

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- by a punctual and constant monitoring system;
- compliance with the provisions on the subject developed by the Health Directorate, adopting all the measures that may be appropriate to ensure the widest respect for the fundamental rights and freedoms and dignity of the data subjects.

B) -DUTIES:

- Each patient within the facility has the duty to maintain responsible behavior, at all times, respecting and understanding the rights of other patients and with the willingness to collaborate with the medical, nursing, technical staff and with the Health Management;
- It is the duty of every patient to promptly inform health care providers of his or her intention to renounce scheduled health care and services so that waste of time and resources can be avoided;
- The patient is required to respect the environments, equipment and furnishings found within the health facilities, considering them everyone's heritage and therefore also his own;
- In consideration of being part of a community, it is advisable to avoid any behavior that may create disturbing or uncomfortable situations for other patients
- It is necessary to respect the ban on smoking; this is not only due to legal provisions but above all for the respect of one's own health and that of other patients;
- The patient has the right to correct information on the organization of the health facility but it is also his duty to obtain information at the appropriate times and in the appropriate places;

1.5. WHERE WE ARE

The structure "Costanzo Marcello s.a.s." is located in Rome on the ground floor of a building located in P.le delle Medaglie d'Oro 20 in the province of Rome.

It can be reached by car.

By public transport:

- Metro A – Ottaviano stop
- Bus line 913

The structure has no architectural barriers.



OPENING HOURS AND USEFUL NUMBERS:

For information on the services provided, you can contact the facility in the following ways:

Phone: 0635453655

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Email: labmcostanzo@gmail.com

Website: <https://www.analiscinichecostanzo.it>

Opening of the Laboratory to the public

| | | |
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| Withdrawals | Monday to Friday Saturday | from 7.30 a.m. to 10.30 a.m. from 7.30 a.m. to 10.30 a.m. |
| Opening hours | Monday to Friday Saturday | from 7.30 a.m. to 3.00 p.m. from 7.30 a.m. to 1.00 p.m. |
| Report collection | Monday to Friday Saturday | from 12.00 to 15.00 from 12.00 to 13.00 |

SECTION II – SERVICES

2.1. AUTHORISED - ACCREDITED HEALTH SERVICES PROVIDED

CLINICAL ANALYSIS

- Clinical Chemistry
- Hormonal Analysis
- Tumor markers
- Medical Genetics
- Hematology and coagulation
- Immunology
- Virologia

MICROBIOLOGICAL ANALYSIS

Culture, bacteriological and microbiological examinations

- Antibiogram
- Parasitology
- Scotch test
- Research chlamidia, mycoplasma, gardnerella etc.

CYTOLOGICAL ANALYSIS

- PAP TEST
- Seminal fluid
- Fertilità
- Urinary Cytology

The precise list of the services provided and the related costs is available on request and displayed in the facility.

2.2. DATA CONTROLLERS

The following people work within the structure:

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| n. | Surname and Name | Job Title |
|----|--------------------|------------------------------|
| 1 | COSTANZO VALENTINA | ADMINISTRATIVE/ AUXILIARY |
| 2 | FALCETTI DANIELA | ADMINISTRATIVE/ AUXILIARY |
| 3 | PARISI TEODORO | PRE-LIFT DOCTOR |
| 4 | COSTANZO MARCELLO | LEGAL REPRESENTATIVE |
| | MARIA SANTAMARIA | TECHNICAL DIRECTOR |
| 5 | LUCA GIORGI | LABORATORY TECHNICIAN |

The responsibility for the clinical analysis laboratory lies with the technical director but all operators are required to perform the tasks entrusted to them to the best of their ability.

SECTION III – SERVICES

3.1. HEALTH SERVICES

At the Secretariat located at the entrance there is a Reception service available to users to provide all the information required.

Documents to be presented at the time of acceptance:

Doctor's request, valid identification document, ticket exemption card, and health card.

No reservation is required for on-site withdrawals.

To avoid uncomfortable queues, at the time of admission, patients are called to the secretariat counter according to a progressive number, distributed by the special "queue eliminator" machine located in the waiting room.

Home blood collection and home delivery of reports

The laboratory, **by appointment**, provides a service (for a fee) of home sampling and delivery of the answers to the patient's home.

The service is carried out by internal staff of the structure, from Monday to Saturday.

3.2. PAYMENT OF BENEFITS

The dedicated tariff is available at the Secretariat.

Payment for the service takes place at the time of acceptance and can be made, as well as in cash, also by debit or credit card.

3.3. COLLECTION OF REPORTS

The date and time for the collection of the report are communicated to the patient during the acceptance phase, at the same time as the delivery of the personal coupon for the collection of the reports.

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To ensure the confidentiality of personal data, the delivery of the report and the commercial invoice takes place after requesting the patient's personal coupon for the collection of the report or, in the absence of this,

- identity document
- Proxy indicated when signing the consent form for data processing
- signed proxy and document of the authorizing patient.

Sending report by fax or e-mail

The patient has the right to request that his report be sent to his or her e-mail or fax address, as indicated and authorized when signing the consent form for data processing.

A copy of the report can be requested at the acceptance desk. The reports are normally kept for 1 year after the service. The copy of the report is delivered within 3 working days of the request at no additional cost.

3.4. DESCRIPTION OF SERVICES

1. Clinical Analysis

Acceptance

- ❖ Call in progressive order to the acceptance desk
- ❖ Review of the contract and acceptance of benefits
- ❖ Delivery of the receipt of acceptance/proxy/informed consent
- ❖ Delivery of the invoice (for simultaneous payment)
- ❖ Issuing Picking Labels
- ❖ Calling the Customer via the acceptance number
- ❖ Execution of the withdrawal
- ❖ Customer's leave if he does not manifest problems
- ❖ Sorting of samples and biological samples to the analytical area
- ❖ Control and preparation of biological samples and samples
- ❖ Checking results and validating on the computer system
- ❖ Printing and signing of the complete report
- ❖ Delivery of reports
- ❖ Possible provision of the Assistance Service

The report to be delivered to the patient is printed by the secretariat with the help of the computer system and, subsequently, closed in windowed envelopes in accordance with the Privacy Law.

3.5. METHODS OF COLLECTION OF SAMPLES TO BE EXAMINED

Appropriate collection and transport of biological materials for microbiological examination is the essential condition for ensuring the quality of the result. An inappropriate collection and/or sending of a biological sample results in incorrect therapeutic treatment with possible damage to the patient and unnecessary increase in costs.

Venous sampling

In preparation for the collection, fasting of at least 6 hours is required.

Urine test

The sample must be collected before going to the laboratory (check the presence, in the prescription to be delivered at the time of sampling, of the "urine test"), in a sterile container with the patient's name and surname on the adhesive tag.

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It is preferable to collect the first urine of the morning after a wash of the external genitalia. It is sufficient that the container is filled to half its volume, the cap must be properly closed in order to avoid dispersion.

Urine culture

(Not to be performed during antibiotic therapy)

It is carried out on the first urine of the morning (at least 3 hours after the last urination) using a sterile container, after carefully washing the hands and external genitalia with soap and water, eliminating the first jet and collecting the second (unless otherwise specifically requested by doctor).

Urine samples collected in non-sterile or not tightly closed containers are not accepted. In the case of newborns for whom urine collection is required in a special bag, if the sample cannot be delivered at the established times, it is recommended to keep it in the refrigerator until it is transported to the laboratory. Biological samples for crops should be delivered as soon as possible.

24-hour urine collection

It is necessary to have a suitable container that can be purchased in pharmacies.

To successfully run the collection:

1. Discard the first urine of the morning;
2. From this moment on, collect all the urine that will be produced in the next 24 hours, including the first one the following morning.

The container should be kept cool for the entire time of harvesting.

FAECES: chemical, physical and parasitological examination

Collect the stool sample in a clean, dry container;

No dietary restrictions are necessary before harvesting;

Write your name and surname on the sample.

FAECES : monoclonal occult blood research

The test is specific for human hemoglobin and does not require diet.

It is recommended to perform the test on 3 samples collected at intervals of 1-2 days

Detection of occult blood in the stool

The test requires a diet to be carried out in the 3 days prior to the exam, AVOID:

- meat-based foods of any kind, legumes, bananas, meat, chicken or fish broth, eggs.
- drugs based on Fe, Cu, Cr, aspirin, vitamin C.

It is advisable to brush your teeth with extreme caution and not to have the examination if you suffer from bleeding gums. It is recommended to perform the test on 3 samples collected at intervals of 1-2 days.

Feces: culture examination (coproculture)

Collect a small amount of feces (a hazelnut) and place it in a clean container (there are containers equipped with a scoop). The sample must not be contaminated with urine and should be delivered to the laboratory as soon as possible.

Report if antibiotic therapy is in progress.

The container can be purchased at the pharmacy.

Scotch Test

It is considered the method of choice for the search for Pinworms. The sample should be taken in the morning before cleaning and local hygiene.

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To carry out the test, it is necessary to request the necessary material and the sheet with instructions from the secretariat.

Blood Glucose and Insulin after a meal

Unless otherwise prescribed by a doctor, the sample is usually taken 1 or 2 hours after breakfast (cappuccino + croissant) or 2 hours after lunch.

Load test (glycemic and insulinemic curve)

It is preferable to take the sample after fasting for at least 8 hours after signing the informed consent. If the value resulting from the stick is less than 126 mg/dl, the sampling physician performs a first (baseline) sample, after which the patient is made to drink the ready-to-use glucose solution (unless otherwise prescribed by a doctor). The sampling physician carries out, after loading, samples at 30', 60', 90', 120' (unless otherwise prescribed by a doctor).

These tests involve the presence of the patient in the laboratory for a few hours. In these cases, patients are invited to go to the laboratory by 7:45 am.

Creatinina clearance

Go to the laboratory fasting and with a 24-hour urine collection (see 24-hour urine collection).

SECTION IV – PROTECTION MECHANISMS/FORMS/INSTRUMENTS

4.1 INSURANCE PROTECTION

The center is insured for accidents that may occur to patients and visitors within the facility. In the event of an accident, it is necessary to notify the Legal Representative immediately for the consequent obligations;

4.2 PATIENT CARE SERVICE

The patient is always followed in every step of his path by the reception staff.

4.3 PROTECTION OF PERSONAL DATA

Respect for the rights to confidentiality and the correct management of users' sensitive personal data is guaranteed according to current regulations. The information referred to in Legislative Decree 196/2003, GDPR 2016/679 and EU Regulation 679/2016 is provided with a special sign in the waiting room. The authorization for the processing of data must be signed at the time of first acceptance.

In compliance with the aforementioned privacy documents, the reports are delivered directly to the patient or to a person delegated by him/her upon presentation of the coupon issued at the time of collection.

In the case of a request for special tests (HCV, HIV, pregnancy test), the report must be delivered only to the holder of the report or to an authorized person

- with the proxy indicated at the time of signing the authorization to process data,
- with subsequent formal delegation and in possession of the owner's document.

4.4 COMPLAINTS

Patients can report inconveniences, incorrect behavior, useful suggestions for improving services, by contacting the secretariat (who will fill in a non-compliance form) or the Quality Service Manager or by forwarding a written complaint to the Technical Management.

A questionnaire was also prepared to assess patient satisfaction.

A reasoned complaint is considered by the laboratory as a stimulus to improve the quality of performance.

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4.5 PATIENT COURT

In the event of failure by the Facility to fulfil its rights, the patient can turn to the Tribunal for the rights of the Patient.

National Headquarters: Via Flaminia, 53 - 00196 Rome - Tel. 06 367181 - Fax 06 36718333

4.6. QUALITY STANDARDS

| STANDARDS THAT DEFINE THE STRUCTURE IN ITS OVERALL ACTIVITY | | |
|--|--|--|
| AREA UNDER CONSIDERATION | QUALITY FACTOR | QUALITY STANDARDS |
| Access | Ability to provide clear and simple information | Presence of qualified personnel. Presence of adequate signage |
| Removal of architectural barriers | Possibility of allowing disabled access throughout the structure | Removal of all architectural barriers and implementation of facilitated paths. |
| Relations with Users | Easy recognition of staff | All staff are provided with an identification card. |
| Reporting inefficiencies | Possibility of submitting observations and/or complaints | Collectors for observations and/or complaints. |
| User Satisfaction | Level of satisfaction with the services offered | Questionnaire present at reception |
| Respect for privacy | Enforcement of Personal Data Protection Legislation | Informed consent requested for the management of personal data. |
| Correct and clear information | Preventive information | Delivery of information leaflet |