



# SERVICE CHARTER

Revision number 20 of January 8, 2025

**BIOGENET SRL**

**MEDICAL AND FORENSIC GENETICS LABORATORY**

Verified by:

Quality Management Manager

**BIOGENET**  
LABORATORIO DI GENETICA MEDICA  
E FORENSE  
DIRETTORE TECNICO  
Dott.ssa Elena Falcone

Approved by:

**BIOGENET SRL**  
Amministratore Unico  
Dott.ssa ALESSIA BAULEO

*We are pleased to present to you our "Service Charter."*

*This tool, thanks to your kind and valuable participation, allows us to improve the quality of the services we offer. The aim of our activity is to provide you with a qualified service through the competence, professionalism, and humanity of our staff.*

*The work of all our personnel enabled us to obtain, in July 2004, certification from a third-party body accredited by ACCREDIA, according to the UNI EN ISO 9001 standard (Certificate No.: 11403/04/S).*

*In thanking you for your active collaboration, please consider our staff at your disposal for any information and needs not illustrated in the Service Charter.*

The management and staff

## 1 PREMISE

The Healthcare Services Charter is an instrument to protect the right to health, allowing the Citizen/User to have effective control over the services provided and their quality. All the staff of the BIOGENET Laboratory of Medical and Forensic Genetics are committed to the quality of the Service, with the aim of ensuring the reliability of the provided service, as well as courteous assistance that is always attentive to the needs of the user at all stages of the established relationship.

The Service Charter outlines the quality standards related to the factors of:

### **Assistance, Information, Reception, and Courtesy.**

Assistance, information, reception, and courtesy are the most significant elements for users to assess the formal quality of the service. The BIOGENET Laboratory of Medical and Forensic Genetics is, indeed, aware that listening to the user, providing explanations in comprehensible language, and treating them with kindness, politeness, and respect are essential actions to offer a good service.

### **Reliability, Timeliness, Transparency, and Flexibility.**

Reliability, timeliness, transparency, and flexibility are the most significant elements for evaluating the substantial quality of the service and represent a commitment for BIOGENET S.r.l. to improve performance in terms of correctness and punctuality, as well as to ensure transparency of its activities by making this Service Charter available to users upon request. It is noted that, in the event of unforeseen organizational and/or technological issues (e.g., power outages), appointments will be immediately rescheduled.

The information contained in this publication complies with the D.P.C.M. of May 19, 1995, General Reference Framework of the "Charter of Public Health Services," the DPCM of January 27, 1994, "Principles on the Provision of Public Services," Decree Law No. 502 of December 30, 1992 (Article 14 "Participation and Protection of Citizens' Rights"), and the "National Protocol on the Health Service for the New Citizens' Rights Charters" (1995).

## 2 PRESENTATION OF THE STRUCTURE

### 2.1 STAFF

BIOGENET is a specialized laboratory in Medical and Forensic Genetics, authorized to operate by regional decree DR no. 131845 of 11/12/2001; phone: +39 0984 846425; email: info@biogenet.it; website: www.biogenet.it.

Biogenet obtained regional accreditation (DDG no. 9756 of June 1, 2009) as a Specialized Laboratory in Medical Genetics. On June 24, 2009, it entered into an agreement with the ASP of Cosenza, renewed annually, and since that date has been providing analyses under agreement with the Italian National Health Service (SSN). Subsequently, it obtained authorization to relocate its headquarters with DCA no. 176/2018. Accreditation was finally renewed for a three-year period with Regional Decree No. 403 of December 17, 2024.

BIOGENET establishes a direct relationship with users, who, in addition to patients, include physicians and analytical laboratories for whom it can perform analyses as a service for their patients. Lawyers and courts are also users of BIOGENET for forensic genetic analyses.

The professional figures employed by the structure for the execution of analyses are:

- **Elena Falcone**, Biologist, PhD in Biochemistry and Molecular Biology, Lecturer in Cytogenetics, Technical and Scientific Director of the Laboratory.
- **Alessia Bauleo**, Biologist, Specialist in Medical Genetics, Company Administrator and Laboratory Analyst – Cytogenetics and Cytogenomics Unit.
- **Vincenza Pace**, Biologist, PhD in Molecular Biopathology, Specialist in Clinical Pathology, Researcher and Laboratory Analyst – Cytogenetics and Cytogenomics Unit.
- **Rossella Brando**, Biologist, Specialist in Clinical Pathology, Laboratory Analyst – Molecular Genetics Unit.
- **Laura De Stefano**, Biologist, Laboratory Analyst – Molecular Genetics Unit.
- **Rosalbina Apa**, Biologist, PhD, Specialist in Genetics, Laboratory Analyst – Cytogenetics and Cytogenomics Unit.
- **Maria Grazia Muoio**, Biologist, PhD in Life Science and Technology, Researcher and Laboratory Analyst – Molecular Genetics Unit.
- **Giada Cuconato**, Biologist, PhD in Translational Medicine, Researcher and Laboratory Analyst – Molecular Genetics Unit.

BIOGENET was established with the aim of creating a structure capable of offering users specialized analyses, such as genetic ones, in a region notoriously lacking in this sector.

The Laboratory employs cutting-edge diagnostic techniques recognized by the International Scientific

Community.

To ensure the constant improvement of professionalism, the members of the BIOGENET Staff are enrolled in the main national scientific societies in the sector (S.I.G.U. Italian Society of Human Genetics) and constantly participate in Continuing Education Courses, Conferences, and Workshops.

All personnel entering the structure are selected based on the specific competencies required, their qualifications, developed work experiences, and the attitudes demonstrated during the selection process. For newly employed staff, an adequate period of mentorship with senior experts is provided.

## **2.2 WORKER SAFETY AND HEALTH**

The Management considers the pursuit of safety and the protection of workers in the workplace as a primary objective of company activities. Therefore, it is committed to ensuring that all current regulatory requirements and obligations are implemented and adhered to by all personnel. In particular, the Laboratory operates in compliance with the provisions of the Consolidated Act on worker safety and health in the workplace (Legislative Decree 81/08 and subsequent amendments). In this regard, the Laboratory has developed a risk assessment document that ensures the protection of workers and compliance with regulatory requirement.

### **3 PRINCIPLES AND FUNDAMENTAL RIGHTS**

#### **EQUALITY**

BIOGENET does not discriminate against patients based on gender, race, language, religion, political beliefs, socio-economic status, or psycho-physical conditions.

#### **EFFICIENCY AND EFFECTIVENESS**

BIOGENET is constantly committed to Improving objective and impartial information about the services provided; Implementing programs for the digitization of diagnoses; Respecting confidentiality towards third parties; Giving increasing consideration to any complaints; Informing and training staff on the principles of reception to improve the overall quality of the service; Communicating to staff the importance of meeting customer (Patient) requirements and ensuring these obligations are considered in process control; Identifying training needs of staff promptly and adequately; Adjusting the laboratory structure to new analytical methodologies and technological instruments in a timely manner; Ensuring a constant commitment to the prevention of problems and deficiencies; Guaranteeing continuous improvement of the service provided to the Customer, also through the examination of implicit and explicit user requests.

#### **IMPARTIALITY AND REGULARITY**

Providing services according to criteria of objectivity and regularity; ensuring through its staff the regularity and continuity of the service in compliance with the principles and norms established by laws and contractual provisions.

BIOGENET's activities ensure compliance with the 14 fundamental rights enshrined in the "National Health Service Protocol".

**RIGHT TO TIME** by rationalizing the production process without neglecting the "appropriate examination time".

**RIGHT TO INFORMATION** through the public relations office, ensuring clear, detailed, professional, and timely communication with users.

**RIGHT TO SAFETY** ensuring patients the use of materials, procedures, and equipment inspired by the concept of maximum safety and constantly monitored to maintain quality standards.

**RIGHT TO PROTECTION** guaranteeing continuous care tailored to the Patient's personal needs, especially in cases of suffering, elderly, disabled, non-self-sufficient individuals, terminally ill patients, children, etc. **RIGHT TO CERTAINTY** providing accurate and reliable information.

**RIGHT TO TRUST**, ensuring that all medical acts are in the interest of health protection.

**RIGHT TO QUALITY**, through the implementation of quality improvement paths, assessing the quality of services provided and user satisfaction, and activating, if necessary, all forms of collaboration between various public and private entities.

**RIGHT TO DIFFERENCE**, guaranteeing different treatments that consider varying needs, with particular attention to removing architectural barriers, avoiding conflicts, and discomforts, also through the rationalization of services.

**RIGHT TO NORMALITY** respecting the personal characteristics and habits of patients.

**RIGHT TO FAMILY** involving the family in patient care, creating a collaborative environment with family members in the Patient's best interest.

**RIGHT TO DECISION** through correct information, allowing for "informed consent" to diagnostic procedures.

**RIGHT TO PARTICIPATION** promoting the participation of volunteers, non-profit activities, and ensuring User participation.

**RIGHT TO THE FUTURE** giving dignity and hope to the patient's life and health expectations, regardless of their clinical conditions, even if terminal.

**RIGHT TO REDRESS** through the establishment of a complaint office and continuously monitoring User satisfaction levels.

To ensure the protection of these rights and to fully earn the trust and satisfaction of the user, BIOGENET pays particular attention to the following aspects:

**Care of Tangible Aspects:** the appearance of infrastructure, staff, and communication tools.

**Reliability:** the ability to provide the service reliably and accurately.

**Responsiveness:** the ability to assist customers/users and promptly deliver the service.

**Attitudes:** courtesy, kindness, respect, consideration, and cordiality of the staff.

**Safety:** absence of dangers, risks, and doubts.

**Accessibility** and Ease of Contact.

**Communication:** informing users through understandable language and demonstrating listening skills.

**Understanding** the Customer/User: the willingness to get to know the customers/users and their needs.

#### 4 SERVICES OFFERED AND WORKING HOURS

The Biogenet Laboratory guarantees users genetic services under the conventional agreement with the National Health Service (NHS), based on and within the limits of the contractual terms stipulated with the Cosenza Health Authority. The Laboratory also offers non-conventional services at private professional rates.

Services Provided (Attached is a complete list of tests with prescription methods, costs for private services, and response times):

Every genetic test is preceded by specific Counselling	
<b>Prenatal Diagnosis</b>	<ol style="list-style-type: none"> <li>1. QF-PCR on abortive material</li> <li>2. Non-Invasive Prenatal Testing* (NIPT)</li> </ol>

Every genetic test is preceded by specific Counselling	
<b>Postnatal Diagnosis</b>	<ol style="list-style-type: none"> <li>1. Karyotype analysis on peripheral blood</li> <li>2. Cystic fibrosis gene analysis</li> <li>3. Microdeletion Y analysis</li> <li>4. Hereditary thrombophilia (Factor II gene, gene Factor V gene, MTHFR, PAI-1)</li> <li>5. Genetic predisposition test for Celiac Disease</li> <li>6. Genetic Lactose intolerance test</li> <li>7. HLA-B27 gene analysis</li> <li>8. DYPD gene analysis</li> </ol>

	9. UTG1A1 gene analysis 10. FRAXA gene analysis 11. JAK2 gene analysis 12. CALR gene analysis 13. MPL gene analysis 14. BCR-ABL gene analysis 15. SHOX gene analysis 16. MS-MLPA Prader-Willi Syndrome 17. Cardiomyopathies NGS panel 18. Cardiac arrhythmias NGS panel 19. ASD NGS panel 20. Neurodevelopmental Disorder NGS panel 21. Epilepsy NGS panel; 22. NGS Panels realised for specific diagnostic query; 23. Familiar mutation analysis; 24. CGH-Array in Neurodevelopmental Diseases. 25. Analysis of mutation in parents of a child positive for rearrangement 26. NGS for FC gene 27. BRCA1 BRCA2 genes in NGS
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**Forensic Genetics**

1. Paternity testing on peripheral blood and saliva
2. sibling/kinship testing on peripheral blood and saliva

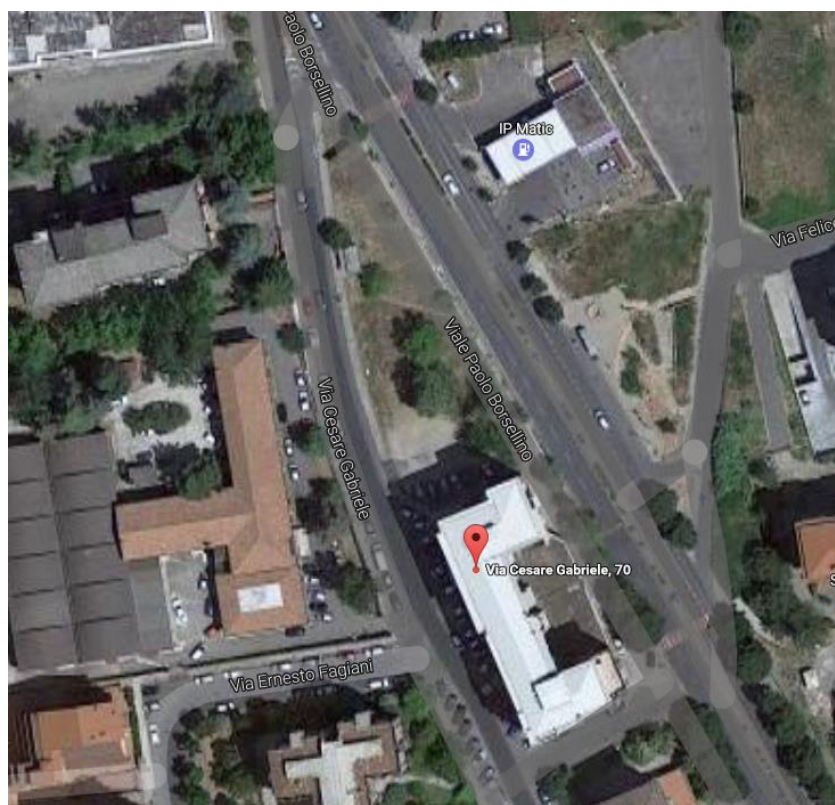
\* Exam administered as a service  
 Genetic Counselling about the report  
 Written Genetic Counselling II Level, Cost not included in the service

**WORKING HOURS**

**Monday - Friday: 8:30 - 14:00; 15:00 - 17:00**

**Saturday: 8:30 - 11:00.**

Biogenet laboratory is in street Cesare Gabriele n. 78, in Cosenza. It can be reached by bus or car.



**INFORMATION FOR THE EXECUTION OF TESTS IN AGREEMENT WITH THE NATIONAL HEALTH SERVICE**

**Documents Required for Services Under Agreement:**

- Referral (red or electronic prescription from the National Health Service)
- Health insurance card or tax code.

The SSR prescription must be correctly completed in all fields. Note: the tax code must always be present and must correspond to that indicated on the health insurance card. Each prescription can include a maximum of 8 services. For genetic tests, it is necessary to indicate the correct description and number of the services requested on the prescription. Since this depends on the methods used by Biogenet Laboratory and the mutations being investigated, so Biogenet has prepared a list of the services to be indicated on the prescription for each type of genetic test provided by the facility.

**Ticket costs € 45,00 + € 1,00 Prescription fee**

**Subject that they don't have to pay ticket**

Income-based exemption:

*Indicated on the prescription in the appropriate box.*

Exemption for Disease:

*Indicated on the prescription in the appropriate box.*

Exemption for pregnancy:

*Indicated on the prescription in the appropriate box (code M50)*

Exemption for preconception period (applied for Karyotype analysis on peripheral blood)

*Indicated on the prescription in the appropriate box (code M00)*

Exemption for suspected rare disease diagnosis

*Indicated on the prescription in the appropriate box (code R99)*

Exemption for protected categories:

- *Indicated on the prescription in the appropriate box.*

## **INFORMATION FOR PRIVATE TESTING**

**Genetic tests can also be provided privately. The fee schedule for these tests is available at the reception desk.**  
*For any exceptions not covered above, please inquire at the reception desk or send an email to: [info@biogenet.it](mailto:info@biogenet.it).*

### **5 STRUCTURE ACTIVITIES**

#### **5.1 Information and Reception**

The BIOGENET Staff is always available to provide users with any information regarding the laboratory's activities, the types of services offered, the possibility of utilizing them, and the procedures to follow.

Additionally, the service managers are always ready to provide scientific explanations to help users fully understand the nature of the services provided, even in the absence of an explicit request for analysis. This is done with the aim of addressing any scientific queries that frequently arise in this specialized field.

For any type of request, citizens can visit our center in person during opening hours or alternatively contact BIOGENET staff by phone at 0984-846425 or fax at 0984-1632662.

The person responsible for public relations is Dr. Elena Falcone, who is designated to handle complaints, suggestions, and reports from users.

Additionally, an email address is available for sending reports, complaints, and requests for information: [info@biogenet.it](mailto:info@biogenet.it).

In any case, requests for information will be met with the utmost courtesy and willingness by all laboratory staff, who will strive to fully meet the needs of the users.

The information contained in this service charter is readily accessible to all users who request it, in order to ensure the transparency of our activities.

#### **5.2 Access and Appointment Booking**

The specialized services offered by BIOGENET are available by appointment, which can be scheduled at any time during business hours via phone call or by visiting the facility in person. The necessity of scheduling appointments for these analyses stems from our desire to offer a comprehensive service to the user, where the sample collection is preceded by:

Adequate informational counselling providing the user with all necessary information regarding the test.

A meticulous data collection process aimed at gathering the personal and family information required to construct a complete picture of the patient's condition.

Thus, the appointment becomes an essential tool to ensure the quality of the service offered, as it allows us to always schedule the meeting between the user and the Healthcare Manager and to allocate sufficient time for such a delicate task to provide the patient with extensive and exhaustive counselling capable of addressing all their concerns.

The maximum time between the appointment request and the provision of the service accompanied by counselling is 5 working days if the test is performed privately. Conversely, for tests performed with a referral from the Regional Health System, the waiting time is an average of 90 days. This is because the healthcare services purchased by the Region are significantly fewer than the number of services requested by citizens (demand). The maximum volume of services that Biogenet can provide on behalf of the Regional Health System is established in the contract between Biogenet and the Provincial Health Authority of Cosenza. The services purchased by the Health System must be distributed and provided throughout the year (contractual obligation). Therefore, since the demand far exceeds the assigned resources, waiting lists inevitably form.

Cancellations can be made by phone without any additional charge to the customer; however, please provide at least 24 hours' notice.

### **Informational Counseling and Anamnesis Data Collection**

The user is welcomed into the facility and, after completing the check-in process, is accompanied to the sample collection room, where one of the Laboratory Managers (Scientific Technical Director and/or Laboratory Analyst) awaits.

The meeting between the user and the Manager is extremely delicate and important for the correct procedure of the service.

The Manager explains in a simple and clear manner the significance of the genetic test the user intends to undergo, its limitations and potentials, the implications the result may have for the user and their future choices, and potentially for their partner and/or family members as well. The Manager is ready and available to respond to and explain any questions or concerns that inevitably arise during these sessions.

In summary, during the informational consultation, the following points are explicitly addressed:

- Purpose of the Analysis, Potentialities, And Limitations
- Methods of Sample Collection
- Future Treatments and Interventions
- Test Execution Methods
- Test Execution Times
- Data Protection
- Communication and Delivery of Results
- Sample Storage
- Right of the Individual to Restrict Access to Results and Sample Availability for other purposes

The preliminary counselling is an extremely important moment for the client. Through a direct discussion with the Responsible Officer, the client acquires all relevant information about the test they are undergoing. The next step of the preliminary interview prior to the analysis involves a careful and detailed collection of the user's family and personal data, which are recorded in a dedicated section of the software for clinical data.

The information collected includes the following:

**Personal Data, Reason for the Analysis, Family Medical History (Excluded for Forensic Analyses), Personal Medical History (Excluded for Forensic Analyses), Information on Current Pregnancy (only for Relevant Tests), Information Relating to the Sample Collection, Any Additional Notes**

At this stage, the Objective of the Responsible Officer is to put the user at ease, ensuring they are able to provide all necessary and useful information for an accurate and complete personal and family medical history, including all genetic information that can assist the laboratory team in performing the analysis and interpreting the results.

The Responsible Officer collects the data by asking specific questions to the client. Through conversation, the Responsible Officer also seeks to gather data and information that may seem marginal or of little importance to the user but could prove useful for genetic analysis. Should the Responsible Officer identify the need for additional tests beyond those prescribed, following the consultation, they will communicate this to the user and, more importantly, to the specialist physician, who will assess the appropriateness of conducting these additional tests.

### **5.3 Signature of Informed Consent for Tests and Privacy Information Notice**

The outcome of the genetic consultation is the signing of the Informed Consent, which represents the user's acceptance of the analyses to be performed, with the content varying depending on the requested test. The informed consent and the data privacy information notice are read and signed digitally on a Wacom tablet.

### **Sample Collection**

At the end of the data collection, the biological sample is taken and labelled before being transferred to the locations designated for analysis execution.

**The biological sample collection conducted in the laboratory may involve a blood draw or a buccal swab, depending on the type of examination to be performed.**

**Fasting is not required for the sample collection.**

### **Report Delivery and Consultation**

If the user has chosen to receive the report via an online platform, the report will be sent by the DTS immediately after the test has been validated. If the user has chosen to receive a paper report, it will be printed immediately after validation, and the user will be notified by a phone call from the STA that it is ready for collection. The report can be delivered directly to the user or, alternatively, it can be given in a sealed envelope to an individual who presents a receipt attesting to the delegation made by the patient.

In cases where the genetic test results are positive, the delivery of the report requires the support of an appropriate consultation by the Medical Director. The patient will be contacted by phone to schedule an appointment for the consultation. During the consultation, all necessary information for the accurate interpretation of the results will be provided, along with any relevant referrals to specialized centres depending on the issue at hand. In some situations, it is recommended to undergo a second-level genetic consultation with a clinical geneticist. The patient may choose to have this consultation with a geneticist of their choice or with the clinical geneticist provided by Biogenet, available monthly on-site at the facility, or remotely via telemedicine, at a date agreed upon by all parties.

The expected times for report collection are indicated in the price list available at the front desk.

## **6 PUBLIC RELATIONS**

The constant presence of "Responsible Officers" at the Biogenet facility ensures that users always can provide suggestions, proposals, or any complaints and grievances that may arise due to some inconvenience.

Additionally, a section dedicated to the staff's perception of user satisfaction has been added to the patient registration forms. This perception is recorded at the end of the process, namely at the time of report delivery.

To involve the user in Biogenet's annual continuous improvement plan, they can access the following data:

- Customer satisfaction analysis conducted through anonymous questionnaires administered to users.
- List of training courses attended by the Technical Director and laboratory staff to maintain their level of professionalism.
- Performance of the Laboratory Quality Control (External Quality Assessment - EQA)

The above-described documents are included annually as an attachment to the Service Charter, available at the front desk or by calling 0984 846425 to schedule an appointment with the Quality Manager, Dr. Falcone. The Quality Management Officer is available for any clarifications.

## 7 COMPLAINTS

The user can file a complaint following a service disruption, act, or behaviour that has denied or limited the accessibility of the service.

Complaints are valuable opportunities for improvement, and each report will be recorded and handled according to Biogenet's Quality System procedures.

Complaints can be submitted:

- By letter
- By email
- By phone to the Quality Manager.

Biogenet commits to providing a response within three working days, and in more complex cases, within fifteen days. The response will be provided using the same method as the complaint. If necessary, appropriate corrective actions will be undertaken.

## 8 PRIVACY

Biogenet ensures the protection of client privacy in accordance with Decree No. 101/18 of August 10, 2018, and Regulation (EU) 2016/679 (GDPR), as well as in compliance with the general authorization for the processing of genetic data No. 8/2016 issued by the Privacy Authority (published in the Official Gazette No. 303 of December 29, 2016) and its subsequent updates (No. 146 of June 5, 2019).

The user is invited to read the entire information notice attached to this document and available at the reception desk before giving consent to the data processing.

## 9 RIGHTS AND DUTIES OF THE PATIENT

### 9.1 Rights

**The patient has the right to:**

- Receive the requested services attentively and comprehensively.
- The confidentiality of all data related to their illness and any other personal circumstances.
- Complete and comprehensible information regarding the tests performed and the services offered by the Laboratory.

### 9.2 Duties

The patient must:

- Cooperate with all Laboratory staff to enhance the effectiveness of the requested services.
- Consider the needs of other patients when using the common areas of the laboratory (waiting room, restrooms).
- Respect elderly individuals and, if possible, give them priority for seating while waiting for registration.
- Avoid causing disturbances and maintain strict silence during waiting and sample collection phases.

### **Useful Information**

In accordance with legal regulations and out of respect for their own health and that of others, smoking is strictly prohibited in all areas and facilities within the Laboratory (offices, corridors, restrooms, waiting room, reception, laboratories).

## 10 QUALITY POLICY AND IMPROVEMENT PROJECTS

Biogenet's Quality Policy is to provide services with reliability and quality levels that exceed the explicit and implicit needs and expectations of the User. The aim is to achieve recognition for professionalism and innovation, gaining the trust of Users, doctors, and healthcare facilities in consulting and diagnostics in the specialized field of Medical and Forensic Genetics. This is done by adopting the best available and economically sustainable technologies, reducing critical issues, and continuously improving performance. To this end, a Quality Management System has been established, compliant with the UNI EN ISO 9001:2015 standard. Personnel are required to adhere to the guidelines prescribed in the Quality Manual and the procedures referenced therein when performing activities. Biogenet applies the principles of continuous improvement to all its processes to better meet the expectations of its Users.

The Sole Director personally commits to the development and maintenance of the Quality Management System (QMS) to ensure its effectiveness in achieving objectives and increasing User satisfaction. Specifically, human, instrumental, and economic resources are provided to pursue the following objectives:

- Implementing an effective process of internal and external communication and continuously monitoring user satisfaction.
- Achieving high management, production, and economic performance.
- Maintaining a high level of professionalism through continuous updating and collaboration with technical and scientific organizations.
- Promoting the laboratory's image.
- Engaging and motivating all company personnel to develop a sense of responsibility and commitment at every level to continuously improve service quality.
- Making the quality policy available to employees, collaborators, clients, suppliers, and the public, ensuring it is adequate and proportionate to the nature and impact of its activities.
- Activating all preventive measures to reduce risks.

To measure corporate performance, the Sole Director has defined methodologies to verify the achievement of the set objectives. Data derived from the analysis of indicators form the basis for continuous improvement actions.