



# SERVICE CHARTER



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Prebiomics S.r.l.

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## REVISION HISTORY

Rev.	Data	Description of the changes
00	21/02/2024	Release for use.
01	23/10/2025	Paragraph 1.2: Indication of provincial authorization for healthcare activities and indicated start of UNI EN ISO 15189:2024 accreditation process with Accredia definition. Paragraph 1.4: Removed reference to NovaSeq 6000Dx. Paragraph 3: PreBiomics Implant Test (PIT) <sup>TM</sup> removed. Paragraph 4: Integrated Quality Policy with ISO 15189 values. Paragraph 4.1: Indication of ISO/IEC 27001 certification and provincial authorization for healthcare activities. Added paragraph 5 of Complaints and Reports Management. Paragraph 6 Paragraph 6: Integration of contact information.



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## 1. COMPANY OVERVIEW

Prebiomics S.r.l. (“Prebiomics”) owns and operates a Next Generation Sequencing (“NGS”) laboratory, the Prebiomics Biotech Hub, which has been providing sequencing and analysis services since 2022, with a specific focus on the human microbiome. Through advanced technologies, cutting-edge instruments, and internationally recognized scientific expertise, Prebiomics offers innovative tools to support the development of personalized treatment and wellness strategies.

### 1.1. History

Prebiomics was founded in 2017 as an academic start-up stemming from research activities carried out by its founders at the Department of Cellular, Computational and Integrated Biology (CIBIO) of the University of Trento.

The company’s first major innovation was the development of the **PreBiomics Implant Test™ (“PIT™”)**, a revolutionary test designed to support oral health professionals in the prevention, early diagnosis, and personalized treatment of peri-implant diseases based on metagenomic analysis of oral plaque samples. The PIT™ represents the first step of an innovative process that currently sees Prebiomics engaged in research and development activities, also supported by important European funding, to further evolve the original test by validating new clinical and therapeutic indications.

With the establishment of the Prebiomics Biotech Hub, Prebiomics launched its activity as a service provider in both shotgun NGS sequencing and bioinformatic analysis, targeting research centers, healthcare facilities, and private companies.

In parallel, Prebiomics continues its research and development activity in constant dialogue with research groups from the most important universities at an international level to contribute to the development of new microbiome-based solutions for personalized wellbeing and health.

### 1.2. Mission and goals

Prebiomics offers state-of-the-art services in the field of the human microbiome, with the goal of transforming the scientific knowledge of its founders into innovative solutions for personalized wellbeing and health. In this context, the Prebiomics Biotech Hub is provincially authorized and is currently initiating the accreditation process to the UNI EN ISO 15189:2024 standard, to offer accredited tests and ensure standards of quality, competence, safety, and reliability in analytical processes.



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Accreditation is an official attestation of the technical competence and impartiality of laboratories performing tests and analyses. It is not a generic recognition but concerns specific activities or examinations and is maintained through periodic audits. For medical laboratories, it represents an additional guarantee of scientific rigor and result reliability.

With this approach, Prebiomics places scientific research at the service of health, collaborating with researchers, universities, and companies to translate microbiome research findings into practical solutions that improve quality of life. This pioneering approach is based on rigorous scientific research and cutting-edge technology, with the aim of developing tools that enable a deeper understanding of the human microbiota and its role in health and prevention.

### **1.3. Team**

Prebiomics employs a young and highly qualified team composed of graduates and PhDs in **Biotechnology** and **Bioinformatics**, supported by a **Scientific Advisory Board** with international expertise in oral health, microbiome science, computational metagenomics, and artificial intelligence.

### **1.4. NGS Laboratory – Prebiomics Biotech Hub**

The laboratory is internally identified within Prebiomics as the **Prebiomics Biotech Hub**. It is a center of excellence built between late 2022 and the first quarter of 2023, designed for **high-throughput shotgun** sequencing. The Prebiomics Biotech Hub is structured to manage all stages of the process internally, from DNA extraction to sequencing data delivery and metagenomic analysis, ensuring consistent quality at every step. The laboratory is not open to the public and operates exclusively on behalf of research institutions, healthcare facilities, and public and private institutional clients.

Thanks to a **semi-automated pipeline**, the entire workflow is efficient and precise, reducing the risk of manual errors and improving the reliability of results. A customized Laboratory Information Management System (**LIMS**) also ensures full sample traceability and organization.

The laboratory employs state-of-the-art sequencing platform, the Illumina **NovaSeq X Plus**, enabling rapid processing of large numbers of samples. Services are applicable to research and the development of microbiome-based diagnostic solutions from a variety of human body sites. Prebiomics supports academic institutions, research centers, hospitals, and private companies, contributing to complex studies and large-scale projects.



## 2. SERVICES

Prebiomics offers advanced Next Generation Sequencing services tailored to the needs of research institutions, universities, hospitals, and private companies.

Each project is carefully reviewed by our scientific team, which works closely with clients to define objectives, technical specifications, budget constraints, and timelines. This collaborative approach enables the development of fully customized solutions, precisely tailored to the specific needs of each project. Once the operational details have been discussed and agreed upon, the assignment is formalized, ensuring clear organization and well-defined timelines aligned with the complexity and volume of the work required. Thanks to this methodology, Prebiomics provides a reliable and flexible service, optimizing processes to deliver high-quality results within efficient timeframes.

Among the core services offered is **metagenomics**, which leverages state-of-the-art sequencing technologies to perform detailed analyses of microbial communities in biological samples. This approach enables the identification and characterization of bacteria, viruses, fungi, and other microorganisms, providing insights into their functional capabilities, interactions, and potential applications in biomedical research.

The **metatranscriptomics** service focuses on analyzing gene expression within microbial communities, allowing for a deeper functional evaluation. By studying RNA, it becomes possible to understand how microbial populations respond to specific biological conditions or treatments.

For data management, Prebiomics offers **advanced bioinformatics solutions**, including strain-level microbial profiling, functional analysis, and biomarker discovery through machine learning tools. These data are essential for uncovering associations between the microbiome and health conditions, as well as for monitoring antimicrobial resistance-supporting both clinical and research studies.

Additionally, the **R&D study design support service** includes the development of customized protocols, statistical planning, and endpoint selection. Prebiomics ensures the use of validated methods in compliance with regulatory standards, enabling analytical workflows to be tailored to specific project needs without compromising quality or compliance.

The integration of these competencies makes Prebiomics a trusted partner for scientific research and the development of innovative solutions.



### 3. QUALITY MANAGEMENT POLICY

Prebiomics invests daily in ensuring customer satisfaction and regulatory compliance, continuously seeking to improve its processes. The company is guided by principles of precision and analytical reliability, as well as transparency and promptness in the services it offers. This policy is grounded in the expertise of its personnel, the use of cutting-edge technologies, and adherence to international standards.

To support the quality of its services, Prebiomics is committed to ensuring:

- **Equality and impartiality:** services are delivered equally to all individuals, regardless of gender, race, language, or religion, through impartial and professional conduct.
- **Service continuity:** services are provided consistently within established operating hours; any temporary interruptions or delays are promptly communicated to users.
- **Freedom of choice:** users have the right to freely choose their trusted service provider, in accordance with applicable regulations.
- **Efficiency and effectiveness:** laboratory services are designed to ensure operational efficiency and effectiveness.
- **Data confidentiality and availability:** patient data and diagnostic results are processed in compliance with applicable data protection regulations, including Regulation (EU) 2016/679 (“GDPR”), Legislative Decree No. 196/2003 (“Italian Privacy Code”), as amended by Legislative Decree No. 101/2018, and subsequent amendments, as well as the Italian Data Protection Authority’s Decision No. 146 of June 5, 2019, concerning the processing of special categories of data. Data are ensured to be accessible at all times and remain available even in the event of substantial changes to the laboratory’s organizational structure.
- **Risk management:** ensuring the safety of users and staff through explicit risk management aimed at preventing avoidable errors and containing potential harmful effects.

This policy ensures that Prebiomics operates with integrity, transparency, and respect for user rights, fostering trust in its services and continually improving quality.

#### 3.1. Quality Management System

Prebiomics is committed to ensuring the quality and reliability of its services through a Quality Management System designed to meet the needs of clients, collaborators, and partners. Since 2019, Prebiomics has been certified to the UNI EN ISO 9001:2015 standard, demonstrating the effectiveness and transparency of its processes. In 2024, the company



expanded its commitment by obtaining additional certifications, including ISO 14001 for environmental management, ISO 45001 for occupational health and safety, UNI/PdR 125:2022 for gender equality, and ISO 30415 for inclusion and diversity.

In May 2025, Prebiomics achieved ISO/IEC 27001 certification, further strengthening information security and data protection across its processes. The company is also authorized at the provincial level to operate healthcare activities and is currently pursuing UNI EN ISO 15189:2024 accreditation for selected tests.

To ensure result reliability, we have incorporated both negative and positive controls directly into our analytical workflows, an approach that guarantees repeatability and precision. Since 2025, Prebiomics has participated in international External Quality Assessment (EQA) programs, including the “Bacterial Genome Detection – Molecular Genetic Analysis of the Human Microbiome (580)” scheme. This milestone marks a further demonstration of our commitment to continual improvement and alignment with the highest global standards.

#### **4. COMPLAINTS AND REPORTS MANAGEMENT**

Prebiomics considers customer complaints, reports, and suggestions as a fundamental tool for the continuous improvement of the quality of services offered.

The client may submit a complaint if they believe that the service received does not comply with expectations, contractual agreements, or the standards declared in this Service Charter.

Complaints can be submitted through the following methods:

- Through the automatic submission service available on the Prebiomics website;
- By sending a direct email communication to the address [segnalazioni@prebiomics.com](mailto:segnalazioni@prebiomics.com);
- By filling out the MOD-08 - Presentation of Complaints and Compliments form, downloadable from the company website and sending it according to the methods indicated in the form itself.

All complaints are registered, analyzed, and managed according to the procedures of Prebiomics' Quality Management System. The company undertakes to provide a timely response, evaluating the causes of the report and, where necessary, activating corrective and preventive actions to avoid the recurrence of non-conformities. The submission of a complaint does not result in any form of discrimination or penalization against the client



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and is managed in compliance with the principles of impartiality, confidentiality, and transparency.

## 5. HOURS AND CONTACTS

The laboratory is not open to the public and does not perform direct collection or acceptance of biological samples. All services are provided exclusively on behalf of research institutions, universities, healthcare facilities, and institutional clients with whom a contractual or collaborative relationship is in place.

Requests for analyses or services may be submitted via email to [info@prebiomics.com](mailto:info@prebiomics.com) specifying the type of project or analysis required. The Prebiomics technical-scientific team will provide assistance in defining the most appropriate service, as well as guidance on sampling and shipping procedures, and in planning sequencing and data analysis activities. It is specified that the Laboratory assumes no responsibility for the packaging, shipment, or delivery of samples, which remain under the sender's responsibility. The Laboratory is responsible for the assessment of samples upon receipt and will promptly notify the client of any anomalies or non-conformities identified.

For administrative matters, quotes, or contracts, please contact [administration@prebiomics.com](mailto:administration@prebiomics.com).

All official communications and legally binding documents must be sent via certified email (PEC) to [prebiomics@pec.it](mailto:prebiomics@pec.it).

The laboratory is open Monday to Friday from 8:30 AM to 5:30 PM. Further information about the services offered is available on our website.

- **Opening hours:** Monday–Friday, 8:30 AM – 5:30 PM
- **For information/service and analysis requests:** [info@prebiomics.com](mailto:info@prebiomics.com)
- **For administration:** [administration@prebiomics.com](mailto:administration@prebiomics.com)
- **Certified email (PEC):** [prebiomics@pec.it](mailto:prebiomics@pec.it)
- **Website:** [www.prebiomics.com](http://www.prebiomics.com)

## 6. PRIVACY AND DATA PROTECTION

Prebiomics is equipped with validated and/or certified IT systems that ensure full traceability of every phase of sample handling: pre-analytical, analytical, and post-analytical. Please note that the management of informed consent for the processing of patients' personal data is



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not the direct responsibility of Prebiomics, but is handled by the healthcare facility or institutional client providing the sample. The servers hosting the databases and the laboratory's LIMS within the current IT infrastructure are ISO 9001 certified and fully compliant with Regulation (EU) 2016/679 (GDPR).

The infrastructure and key service providers have agreements in place to ensure recovery and backup capabilities that allow the replacement or repair of critical equipment within three days, ensuring operational continuity and a robust disaster recovery plan. With a strong focus on the reliability of internal processes, this approach prevents operational interruptions exceeding one day and guarantees business continuity.

The sequencing platforms in use support comprehensive security, privacy, and compliance functionalities, including data encryption, permission management, audit logging, and OAUTH2 authentication. These platforms are certified under the EU-U.S. Data Privacy Framework (2024).