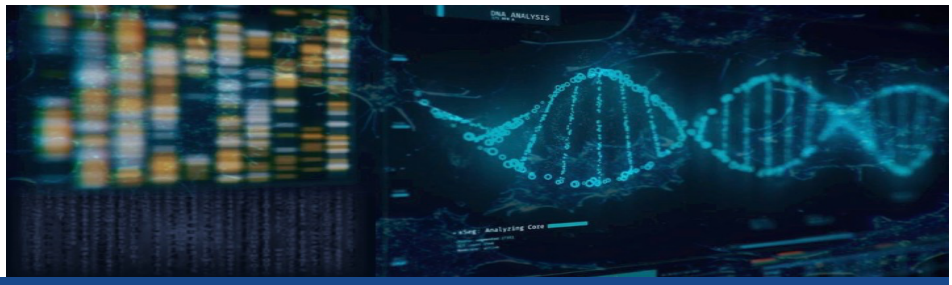

Service Charter (v. 1.04)

In accordance with DPCM 19/05/1995

Integrated Genomics Unit

The Cogentech Integrated Genomics Unit (IGU) Laboratory aims to achieve excellence in the field of molecular diagnostics of cancer diseases. Constant attention to the quality of the services provided, research, development, and implementation of new diagnostic methodologies are our benchmarks in order to provide ever-improving support to physicians and consequently to the people they serve.
This Service Charter represents our ongoing commitment to translate into practice the principles and values that inspire and guide us.

Cogentech S.R.L. Società Benefit a Socio Unico soggetta all'attività di direzione e coordinamento di IFOM ETS– Istituto Fondazione di Oncologia Molecolare
Sede Legale: Via Adamello 16, 20139 Milano, Italia - Capitale Sociale 1.100.000 € I.V.
Unità Locale: c/o Parco Scientifico e Tecnologico della Sicilia S.c.p.a. - Z.I. Blocco Palma I - Stradale V.Lancia, 57 - 95121 Catania
P. IVA, C.F. e iscrizione al Registro delle Imprese di Milano, Monza, Brianza e Lodi n. 04641450962 - R.E.A. MI-1763886 - Codice Univoco SUBM70N
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1 Indice

1 Introduction

Cogentech SRL is a Sole Proprietorship Benefit Corporation specializing in the provision of technology services for biomedical and clinical research, developed in line with the most up-to-date scientific and technological acquisitions and the perspectives offered by the advent of post-genomics.

Cogentech's technology services have been designed and implemented with careful consideration of the needs of the scientific community as well as those of clinical entities that intend to make use of these technologies for diagnostic purposes.

Active since 2005, Cogentech is structurally part of IFOM ETS (Molecular Oncology Foundation Institute ETS), the main nonprofit research center founded by FIRC (Italian Foundation for Cancer Research) and focused since 1998 on researching the molecular processes underlying the development and spread of cancer.

Since its beginnings, Cogentech has distinguished itself in the biomedical research scene for having developed — in association with IFOM, the National Cancer Institute and the European Institute of Oncology, and thanks to the fundamental financial support of FIRC — innovative genetic testing protocols aimed at the diagnosis of mutations associated with the increased risk of developing certain hereditary-familial cancers.

Since 2019, Cogentech has opened a new site in the industrial area of Catania. New laboratories have been established here for the development of a scientific project funded under the National Operational Programme (PON) of the Italian Ministry of Education, Universities and Research (MIUR), entitled "BiLiGeCT – Liquid Biopsies for the Clinical Management of Tumors." The Cogentech Catania site will also be the center of the new OncoHUB project, which has received funding from the Italian Ministry of Economic Development in the field of molecular diagnostics. This new initiative is a demonstration of Cogentech's continued commitment in research, development, and innovation in this sector, as well as its determination to continue contributing to the growth and development of the territory.

With a strong focus on innovation, the unit has expertise in techniques such as ddPCR, various sequencing approaches (from custom panels to RNA-Seq), and genome-wide DNA methylation analysis. Continuous updating and the adoption of cutting-edge technologies such as the NovaSeq 6000Dx sequencer and Digital Droplet PCR ensure excellence and reliability in results, keeping the unit at the forefront of the biotechnology field.

The Integrated Genomics Unit (IGU) of Cogentech Catania ensures efficiency and precision for its academic and clinical partners, thanks to the expertise of highly qualified staff and an up-to-date technological

infrastructure. This is complemented by a carefully designed and well-documented Quality Management System.

On June 16, 2025, the Integrated Genomics Unit (IGU) of Cogentech Catania obtained **Authorization to operate as a specialized laboratory in Biology and Genetics** from the *ASP - Azienda Sanitaria Provinciale di Catania* (Protocol No. 137751/DP).

Cogentech S.r.l. holds the UNI PdR 125:2022 certificate of conformity issued by Bureau Veritas Italia S.p.A. on 6 February 2025 (Certificate No. IT339857).

IGU laboratory also holds the **UNI EN ISO 9001:2015 certificate of conformity issued by Bureau Veritas Italia S.p.A.** (Certificate No. IT324391), attesting to the implementation of a Quality Management System in accordance with internationally recognized standards.

2 Principles and Values

On 27 January 1994, the Italian Government issued a directive aligning ours with other European countries, with the aim of improving public services and increasing public trust and satisfaction. The directive contains the basic principles that should inspire the relationship between entities and the public: from that year on, all public health service providers had to prepare their own **Service Charter** (D.L. No. 163; L. July 11, 1995 No. 273), which gives citizens the opportunity to check the level and quality of services offered. Thus, the Service Charter can be understood as an instrument of control and protection of citizens's rights, available to anyone interested.

Cogentech has developed a **Service Charter** for the Integrated Genomics Unit (IGU) laboratory with the aim of promoting its use as a tool available to users.

The Service Charter provides detailed and up-to-date information about the services offered by the laboratory and how to access those services. The goal is to offer the public a tool that allows for easy evaluation of the laboratory's activities and characteristics, identification of any possible critical issues, while providing insights for the continuous improvement of the services provided. The basic principles by which the IGU laboratory Service Charter is inspired are to provide reliable, accurate, and timely services with effective methods and maintaining an open communication with its clients.
A value of fundamental importance to IGU laboratory is the **principle of impartiality**, which is not compromised for any reason.
In addition, the laboratory has always worked by ensuring the utmost confidentiality to its clients, the availability and **integrity of records and/or samples** even in the event of closure, takeover or merger of the laboratory itself.

3 Cogentech Structure

As anticipated, Cogentech S.R.L. is a Sole Shareholder Benefit Company of IFOM ETS (Molecular Oncology Foundation Institute ETS a non profit research institute), aimed at providing technological services related to the new opportunities offered by the advent of postgenomics.
The company is nonprofit and therefore does not distribute profits or operating surpluses of any kind.
The company is based at the IFOM-IEO Campus in Milan, where there are numerous other organizations involved in research and clinical applications in oncology.
Also based here is the European School of Molecular Medicine (SEMM), which operates in collaboration with the University of Milan, the University of Naples, and the Italian Institute of Technology (IIT) and provides training for PhD students.
The same site also hosts TTO, the technology transfer company that promotes the rapid translation of biomedical research results to the industrial applications.

The Integrated Genomics Unit (IGU) based in Cogentech Catania is a reference point for collaboration with universities, hospital institutions, and private entities. The unit provides a range of advanced services for genomic research, offering technical and technological expertise to support scientific studies and customized projects.
In addition, the IGU laboratory may provide technical and analytical support services to the CGT Lab in Milan, performing sequencing of libraries prepared at the Milan site.
Beyond service provided, the Unit is directly involved in innovative research projects, often in partnership with academic and clinical institutions, contributing to the advancement of knowledge in the field of genomics and its biomedical applications.
This dual activity—support for research and direct participation in scientific projects—highlights the Unit's strategic role in supporting scientific progress and the implementation of practical solutions in the healthcare and research sectors.

3.1 Research and Technology

IFOM Scientists have been engaged in the study of major issues in cancer research for many years. The researchers work in the belief that knowledge of the biological mechanisms responsible for the development and progression of cancer (from primary tumor to metastasis) will lead to the design of new and rational methods for prevention and personalization of treatment.
The most original and innovative research concerns the topic of genomic instability of cancer cells and the role of the chemical and physical properties of the microenvironment in which the tumor develops (mechano-biology), which are particularly important for metastatic spread.
Cogentech supports oncology research with cutting-edge technologies dedicated to the development of new strategies for identifyng neoplastic molecular targets (genes, proteins, protein groups, and

mechanisms that play a key role in cancer and that, when pharmacologically altered, can reduce or even reverse disease).
Great space is also being gained by Translational Medicine, which makes use of both the expertise and technology park of Cogentech.

4 Integrated Genomic Unit (IGU) Laboratory

4.1 Identity

The Integrated Genomics Unit (IGU) is dedicated to providing advanced integrated genomics services, combining different technologies and methodologies for genetic and genomic analysis. The IGU therefore deals complex diagnostic and analytical activities in the field of genetics, supporting research and precision medicine through the use of cutting-edge technologies.

4.2 Mission

The Management of the Company Cogentech S.R.L undertakes to define, as a Quality Policy, the Company Mission, which can be summarized as follows:

To provide high-tech services, arising from the new perspectives offered by the advent of post-genomic, intended both to support basic research in the field of oncology and to develop new therapeutic approaches related to the use of genetic tests capable of identifying mutations relevant to the diagnosis and treatment of cancer diseases. In particular, the mission is aimed at developing and using high-quality diagnostic tools, modeled on the needs of hospital facilities, that ensure effective prevention in the context of hereditary cancer diseases, personalized genetic risk assessment, and better protection of a person's health through the prediction of the effectiveness of therapies.

Management is committed to ensuring that this Policy is disseminated, understood, and implemented at all levels of the Organization.

Management is aware that, in order to achieve the goals set forth in the Quality Policy, it is necessary to operate by meeting precise quality objectives which, in detail, can be stated as follows:

- **Continuous improvement** of the effectiveness of the Quality System, through processes of analysis and the implementation of improvement plans, in which there is full involvement of all personnel.
- **Optimization of service** to the clients, both researcher and clinician, throught:
    - Management's constant commitment to the needs of customers;

  - A commitment to operate according to good practice and professional ethics;
  - Monitoring of complaints and customer satisfaction on the aspects of the service considered crucial, whether explicit (e.g., timeliness) or implicit (e.g., reliability);
  - The analysis of satisfaction/complaint data;
  - The periodic review of the Service Charter.
- **Enhancement of human capital** through:
  - Constant education, training and increasing professional knowledge;
  - Motivation and involvement of all staff;
  - Awareness of roles and responsibilities.
- **Improvement and updating of equipment** and its constant maintenance.
- **Occupational Health and Safety**.

4.3 Staff

Marco Alessandro Pierotti	Laboratory Director
Domenico Scionti	Director of Catania Office
Silvia Conti	Laboratory Manager
Giovanni Carapezza	Bioinformatician
Arianna Nicastro	Data Manager
Valeria Domenica Zingale	Biologist
Maria Carmela Di Rosa	Laboratory Technician
Alessandro Gulino	Laboratory Technician
Barbara Bazolli	Quality Management Manager

4.4 Diagnostic activities

The IGU unit conducts analyses of genes associated with predisposition to hereditary cancers using Next Generation Sequencing (NGS) methods. For therapeutic purposes, somatic analysis on tumor tissue may also be requested.

The IGU laboratory carries out molecular genetic tests on behalf of the Oncology Genetic Counseling (CGO) services of hospital facilities, which then interact directly with the patient.

The laboratory provides its clients with technical and scientific consultancy in order to identify the genetic test to perform or any further analyses useful for a better interpretation of the result.

4.4.1 Types of Analyses

The laboratory performs the following types of analysis:
1. Identification of unknown point mutations (substitutions or small deletions/insertions) in affected individuals belonging to families in which the mutation has not been previously identified (proband testing by NGS). The laboratory also conducts mutation analysis using genomic DNA extracted from formalin-fixed, paraffin-embedded (FFPE) tissue. The analysis of the BRCA1 and BRCA2 genes is primarily carried out to assess sensitivity to treatment with PARP inhibitors.
2. The identification of unknown genomic rearrangements (deletions or insertions of one or more exons or of the entire gene) in individuals belonging to families in which the mutation has not previously been identified (proband testing by NGS).

4.4.2 Methodology

The diagnostic approach offered by the IGU Unit uses advanced next-generation sequencing (NGS) technologies to provide a detailed analysis of patients' DNA, employing different types of sequencing that differ in their level of detail and in the portion of the genome analyzed.

Targeted Sequencing

Targeted Sequencing is a targeted sequencing technique focused on specific regions of the genome selected for their clinical relevance.
The diagnostic protocol uses the OncoPan® and OncoPed® NGS panels, developed by the CGT Laboratory in Milan, which allow the detection of both point mutations (substitutions, small insertions/deletions, or SNVs) and large rearrangements (CNVs) due to the deletion/duplication of one or more exons of the genes under investigation. These panels therefore allow the identification of the main unknown alterations (mutations) responsible for hereditary cancer predisposition syndromes, which represent the laboratory's primary area of activity. The OncoPan® panel, introduced in November 2019, was registered as a trademark in 2020.
OncoPan® is under continuous development to meet the needs of its clients (medical doctors of the Genetic Counseling Services), also offering the possibility of subsequently requesting the analysis of additional genes, using the NGS data from the first analysis.
The OncoPed® panel, introduced in April 2023, obtained trademark registration in 2024 and was designed to identify individuals at genetic risk and provide molecular diagnostic insights to patients affected by cancers in pediatric age or rare syndromes. The panels use capture of fragments from DNA

regions of interest through probe hybridization, including the nucleotide regions of the exons of the selected genes (-21/+7bp from the intron/exon junction). The set of selected genomic fragments represents the enriched regions of the genes of interest (the library), which is subsequently sequenced through an advanced process using NGS technologies and the NovaSeq 6000dx instruments from Illumina. The advantage of this method is the ability to simultaneously analyze multiple genes (multigene panels) in multiple patients in a single run.
The NGS sequencing data generated at the IGU laboratory are subsequently analyzed in collaboration with the CGT Lab through advanced bioinformatics pipelines developed in partnership with the company enGenome (Pavia).

In addition to the OncoPan® and OncoPed® panels, the IGU unit offers the possibility of creating custom panels to analyze genes selected according to the specific clinical case. This flexibility allows the NGS protocol to be adapted to research or diagnostic needs, either expanding or narrowing the analysis to specific gene groups.

Whole Exome Sequencing (WES)

WES analyzes all coding regions of the genome (exons), which represent approximately 1–2% of the total DNA, but contain most of the mutations associated with diseases.

Whole Genome Sequencing (WGS)

Il WGS enables the complete sequencing of the entire genome, including both coding and non-coding regions (introns, regulatory regions, intergenic DNA).
The aim is to provide a comprehensive map of the genome to identify rare variants, complex structural mutations, or alterations in regions that cannot be explored with WES.

4.4.3 Processing Times and Pricing

Nomenclature Code	*Tariff Code*	*Description*	*Price (VAT excluded)*	*Reporting time (Routine/Urgent) in working days*
		OncoPan® Germline Panel - Search for Unknown Variants		
G1.10	**YYCTD001**	CGT-Oncopan 1-10 genes	800,00 €	25 / 20 days
G1.30	**YYCTD002**	CGT-Oncopan 11-30 genes	1.200,00 €	25 / 20 days
G1.47	**YYCTD003**	CGT-Oncopan 30-45 genes	1.400,00 €	30 / 25 days
		Clinical Exome - Search for Unknown Variants		
G1.47	**YYCTD004**	Clinical Exome A	1.100,00 €	30 / 10 days
G1.47	**YYCTD005**	Clinical Exome B	1.250,00 €	30 / 10 days

4.4.4 Procedure Request

The above tests can be accessed by filling out the request form (attached to the contract) for each examinee, to be sent to diagnostic-igu@cogentech.it together with the biological material for analysis.

In addition to the paper request form, Cogentech has introduced a new option to access genetic testing: the online Request Management Portal (PGR) has been implemented. Physicians will have access to the portal through their personal credentials. Through the same portal, the physician will be able to upload consents and other documents useful for the analysis in digital format (histological examinations, previous reports). Finally, again through the portal,it will be possible to download and print reports.
It is recommended that clinical information essential to assess the prescriptive appropriateness of the test and useful for accurate classification of identified variants be provided.

For each shipment, a single list of all samples sent must be completed.
Biological samples must be sent by a courier specialized in the transport of biological material, in compliance with current regulations.

Only requests submitted by a specialist in Medical Genetics or a related specialty will be considered, and only within a genetic counseling pathway (pre- and post-test), as stated in D.A. 1516/15 of 25.09.2015.

For blood sampling performed at our facility, the patient must have a prescription from a genetic specialist or a specialist doctor of the relevant field, together with informed consent. The appointment must be booked through the designated email (diagnostic-igu@cogentech.it). The patient must show up on the agreed date and time. No specific preparation is required.

4.4.5 Required samples

At the IGU laboratory, germline, somatic, and liquid biopsy tests can be performed.
The samples required for **germline testing** are:

- 2 standard blood count tubes containing at least 3 ml of blood in EDTA (10 mM) each (required only for samples originating from outside the region).
- 2 tubes containing 200 nanograms each of genomic DNA, obtained from independent extractions (if possible, use 1.5 mL Eppendorf tubes).
- For special cases, 2 saliva samples collected in dedicated collection tubes, upon prior authorization and agreement with the laboratory.
- 1 lymphocyte pellet.

In specific cases, it is possible to send two saliva samples or exfoliated buccal cells (upon prior agreement with the laboratory) in appropriate collection tubes.

It is responsibility of the applicant to:

1. Ascertain that the indication for testing is correct on the basis of the clinico-pathological and anamnestic findings, in accordance with internationally accepted guidelines
2. Inform the examinee about the meaning, limitations and consequences of the test
3. Obtain informed consent from the examinee to perform the tests

The biological sample (peripheral blood, genomic DNA) must be accompanied by a copy of the informed consent physically attached to the sample and signed by the patient, specifying the type of analysis to which the sample is to be submitted.
Samples not accompanied by this duly completed document cannot be processed until this aspect is regularized.

4.4.6 Sample shipment:

4.4.6.1 Shipping destination, opening hours and contact information

The biological sample should be sent to the following address:

Zona Industriale, Blocco Palma I, Stradale V. Lancia 57 - 95121 Catania, Italy.

The laboratory is open from Monday to Friday, from 09:00 to 17:00.

4.4.6.2 Sample shipping instructions

The biological samples are transported by a courier chosen by the user. To ensure safe transport, the samples must be packed using three levels of protection: a primary container, a secondary container, and a tertiary container. They must also be kept at a controlled temperature, no matter the season or climatic conditions.

The container must be equipped with appropriate cooling devices. Upon arrival of the samples at the laboratory, the staff will check the conformity of the contents and notify the client by email that the sample has been received.

4.4.7 Reporting

The report is the final document of the laboratory activities, containing the results of the genetic analyses performed. The tests detect variations in genomic DNA, reporting the identified variants according to the most recent HGVS nomenclature. Variants are classified into five categories, following international guidelines (ACMG-AMP, IARC), and are periodically reviewed when new scientific evidence emerges.
Only pathogenic variants, variants that are probably pathogenic, and variants of uncertain clinical significance are reported. The process of variant classification and interpretation is carried out by CGT Lab, a Cogentech laboratory located in Milan, and follows a rigorous approach based on scientific data, analytical models, and bioinformatics resources.
The results are notified to the doctor by email within one or two days. Delivery takes place via the DataExchange system, where each client has a protected shared folder. Each new report is notified by email, and the files can be downloaded directly. The files remain available for one month, but can be re-uploaded if necessary.

4.4.8 Storage of materials and documentation

All documentation related to the analyses performed is stored in digital format for an unlimited period, except for the transport document, which is retained for one year. Samples are stored for the time required to perform the genetic test, including the possibility of repeat testing. Then, they are returned or destroyed, according to the instructions received from the client.

5 Feedback and improvement

Cogentech Management has initiated an annual program to monitor customer satisfaction, in line with the principle of continuous improvement of our processes. To this end, it has set up a survey through a Customer Satisfaction form. The results of this survey allow us to better identify the strengths of our service and to implement corrective actions in areas where improvements are needed.

6 Protection and verification

6.1 Complaints

We consider complaints an important quality tool and a starting point for improving IGU laboratory services and our relationship with the client, including all staff. For this reason, the IGU laboratory considers it essential to respond to each complaint in order to verify the reported issue. Therefore, a complaint procedure has been put in place involving the Service Managers, who are responsible for reporting on the incident in order to provide a clear response and resolve the problem.

6.2 Complaint procedure

1. The user submits the complaint by email to diagnostic-igu@cogentech.it
2. The complaint is recorded in Cogentech's Complaint Register.
3. The Quality Manager collects information, initiates the necessary checks, and reports to Management.
4. IGU laboratory Management responds to the user as soon as possible.

6.3 Review of Commitments and Organizational Adjustment

The IGU laboratory ensures the monitoring of the achievement of established standards through an annual report on the results obtained.

7 Privacy

Data security

Cogentech ensures full compliance with the regulations issued by the Privacy Guarantor with Legislative Decree 196/2003 and the new discipline on the subject dictated by the EU legislator with Regulation (EU) 2016/679.

In particular, as established by art. 76 of the aforementioned decree, it guarantees, at the time of acceptance, respect for the patient's privacy and, in accordance with Article 13 of the Regulation, informs him, in writing, about the use of personal data; Cogentech requests consent for use aimed at the activity of the IGU laboratory through the genetic counseling laboratories.

For the acquisition of informed consent for the performance of genetic testing, in accordance with Annex 2 of D.A. 890/2002, D.A. 182/2017, and D.A. 1516/15 of 25.09.2015, the laboratory that collects and accepts the patient's sample must forward a copy of the informed consent to the laboratory performing the analyses.

The Data Controller is:
Cogentech S.R.L. Società Benefit a Socio Unico
Via Adamello, 16
20139 Milan
In accordance with art. 37 of Regulation (EU) 2016/679, a Data Protection Officer (DPO) has been appointed, who can be contacted at the following address: dpo@cogentech.it.

IGU Service Charter V 1.04

Updated by the Permanent Group on the Service Charter:
Arianna Nicastro
Domenico Scionti
Barbara Bazolli

Approved by the Laboratory Director: _____

(Marco Alessandro Pierotti)

Date: 2nd July 2026