Service Charter (v.2.5)

Cancer Genetic Test Laboratory (CGT Lab)

Dear All,

The Cogentech Cancer Genetic Test Laboratory (CGT Lab), a specialized laboratory medicine service without a point of collection, aims to achieve excellence in the field of molecular diagnosis of cancer diseases. Constant attention to the quality of 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.

The 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 – Istituto Fondazione di Oncologia Molecolare ETS
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 - 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
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I. Foreword

Cogentech SRL is a Sole Proprietorship Benefit Company specializing in the provision of technology services for biomedical and clinical research, developed in light of 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.

The Project led to the establishment of the Cancer Genetic Test Laboratory (CGT Lab), Cogentech's high-tech laboratory, entirely dedicated to genetic testing, and accredited with the ATS. With a track record of more than 18,000 genetic tests performed, the CGT Lab provides its academic and clinical partners with efficiency and accuracy, thanks to the expertise of a highly qualified staff and a large and up-to-date technology park. This is complemented by a careful and documented Quality Management System.

Since 2011, the CGT Lab of Cogentech S.R.L has been **accredited with the National Health Service (resolution no. 929 ASL Milano dated 07/22/2011)**, and is registered in the Regional Register of Accredited Facilities (registration no.1118 dated 08/31/2011). The laboratory completed on 07/21/2023 the reclassification process pursuant to D.G.R. no.XI/7044 of 09/16/2022 as a **Specialist Laboratory of Medical Genetics with Molecular Genetics area**.

Cogentech S.R.L holds the **UNI EN ISO 9001:2015** conformity certificate **issued by Bureau Veritas Italia spa on 08/08/2017 (Certificate No IT256850), renewed on 24/08/2020 and 19/06/2023**.

The CGT Lab is **certified by the Italian Society of Human Genetics (SIGUCERT Certificate No. IT282620 issued by Bureau Veritas Italia spa on 22/05/2015, renewed on 03/06/2021)**.

UNI EN ISO 15189:2013 Accreditation: Cogentech S.R.L's CGT Lab obtained **accreditation from ACCREDIA (number 0015M) for Medical Genetics examinations on 18/12/2019**. The list of accredited examinations is available on the website Cogentech, on the page www.cogentech.it/test-genetici.php (UNI EN ISO 15189:2013 accredited examinations list).

Cogentech S.R.L has entered into an agreement with **ACCREDIA** in which mutual obligations are defined; maintenance of accreditation involves periodic verification by **ACCREDIA** of the laboratory's technical and managerial competence in accordance with the requirements of **UNI EN ISO 15189:2013** and additional **ACCREDIA** requirements.

II. Basic principles

A Charter at your service

On January 27, 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' rights, available to anyone interested.

Cogentech has developed the Service Charter for its Cancer Genetic Test laboratory (CGT Lab), and is committed to disseminating its knowledge and use to the public so that it becomes a true participatory tool available to users.

The 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 continuous Improvement of the service provided.

The basic principles by which the CGT Lab service charter is inspired are to provide reliable, accurate and timely services with effective methods and maintaining an open communication relationship with users.

III. The Structure of Cogentech

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 perspectives offered by the advent of postgenomics.

The company is based at the **IFOM-IEO Campus**, 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. Also located at the same site is TTO, the technology transfer company that promotes the rapid transfer of biomedical research results to industry.

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 identifying neoplastic molecular targets (genes, proteins, protein groups, and mechanisms that play key roles 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.

IV. The Cancer Genetic Test Laboratory (CGT Lab)

Identity

Cogentech's CGT Lab is a Specialized Medical Genetics Laboratory with Molecular Genetics area, accredited by the National Health Service. This means that the facility has demonstrated that it meets the technical-professional, organizational and relational quality requirements necessary for the satisfaction and protection of user rights.

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-genomics, 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:

1. **Continuous improvement** of the effectiveness of the Quality System, through processes of analysis and implementation of improvement plans, in which there is full involvement of all Personnel.
2. **Optimization of service** to the Client, both researcher and clinician, through:
    - 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.
3. **Enhancement of human capital** through:
    - Constant education, training and increasing professional knowledge;
    - Motivation and involvement of all staff;
    - Awareness of roles and responsibilities.
4. **Improvement and updating of equipment** and its constant maintenance.
5. **Occupational Health and Safety**.

Personale

Marco Alessandro Pierotti	Laboratory Director - Biologist
Valeria Pensotti	Medical Laboratory Manager, Deputy Laboratory Director, Molecular Genetics Section Manager, Analytical Quality Liaison - Biologist
Giovanna De Vecchi	Medical Laboratory Manager - Biologist
Sara Volorio	Medical Laboratory Manager, Bioinformatics Analysis Referent - Biologist
Frédérique Mariette	Medical Laboratory Manager, CGT Lab Quality Manager - Biologist
Paolo Mariani	NGS and Sequencing Staff - Biologist
Laura Tizzoni	Specialist QPCR - Biologist
Valentina Dall'Olio	Specialist Q PCR - Biologa
Stefano Fortuzzi	NGS and Sequencing Staff - Biologist
Fabio Capra	Acceptance area contact person - Biologist
Domenico Sardella	NGS and Sequencing Staff - Biomedical Technician
Mirko Riboni	NGS Staff - Biomedical Technician
Barbara Bazolli	Quality Management Manager, Communication Manager - Biologist

Staff regularly attend refresher courses, participate in national and international conferences, and Collaborates on scientific publications and industry guidelines.

Quality Controls

The CGT Lab participates annually in the Istituto Superiore di Sanità (http://www.ceqtestgenetici.it) Quality Controls for Oncology Molecular Genetics and the International Quality Controls (EMQN) European Molecular Genetics Quality Network (http://www.emqn.org/emqn/Home).
Last years' results are available on Cogentech's website (www.cogentech.it/test-genetici.php).

Diagnostic Activity

The laboratory is organized into three sections:

- Genetic Testing Area
- Sequencing Area
- qPCR area.

The Sequencing Area and qPCR Area also provide services to researchers from organizations affiliated with the IFOM-IEO Campus, and possibly to external facilities. They also actively collaborate with the Genetic Testing Area for part of the workflow (Sequencing Area), confirmation of MLPA data (qPCR Area), and development of new protocols.
The CGT Lab performs molecular genetic testing on behalf of the Oncology Genetic Counseling Services (CGOs), which are internal to the Hospital Facilities, who then interface with the patient.
The laboratory offers scientific and technical advice to its clients, in order to identify the genetic test to be performed or the insights useful for a better definition of the result. It also discusses clinical cases with the geneticist, in relation to the interpretation of the significance of the variants identified or to be researched, in the case of predictive tests.
The CGT Lab performs analysis of hereditary cancer predisposition genes using Next Generation Sequencing (NGS), Sanger Sequencing, and Multiplex Ligation-dependent Probe Amplification (MLPA) methods. For therapeutic purposes, somatic analysis on tumor tissue may be required.

Types of analysis

The laboratory performs the following types of analysis

1. the search for **unknown** point mutations (substitutions or small deletions/insertions) in individuals with cancer, belonging to families in which such a mutation has not been previously identified (**probands testing**, by NGS). The laboratory also performs mutation searching from genomic DNA extracted from paraffin-embedded tissue (FFPE). Primarily, analysis of *BRCA1* and *BRCA2* genes is performed for evaluation of sensitivity to PARP inhibitor treatment.
2. the search for **unknown** genomic rearrangements (deletions or insertions of one or more exons or the entire gene) in individuals from families in which such a mutation has not been previously identified (**testing of probands**, by NGS or by MLPA).
3. the detection of the presence of a point mutation or extensive **known** deletions/duplications in individuals from families in which such mutations have been previously identified (**collateral testing**, by Sanger direct sequencing or MLPA, depending on the type of mutation). The result is confirmed on a second aliquot of blood or DNA. Investigations are also performed to check for previously identified variants on tumor tissue, and MS-MLPA can be performed to assess *MLH1*, *BRCA1*, *BRCA2*, and *RAD51C* promoter methylation status.
4. The evaluation of *Homologous Recombination Deficiency (HRD) status* on genomic DNA extracted from paraffin-embedded tissue (FFPE). The test is performed for the assessment of sensitivity to Parp inhibitors, and uses the OncoHRD workflow. It takes advantage of the OncoPan® kit for the experimental part, both for the analysis of *BRCA1* and *BRCA2* genes (including copy number variation - CNV) and for the generation of low pass whole genome (lpWGS) data, which allow to derive the biomarker of genomic instability (GI index). Bioinformatic analysis of such lpWGS data is performed with the GIInger tool, sold by the company Sophia Genetics.

Methodology

The diagnostic protocol uses the NGS panels, OncoPan® and OncoPed, developed by the Laboratory, which allow the detection of both point mutations (substitutions, small deletions/insertions or SNVs) and large rearrangements (CNVs) due to deletion/duplication of one or more exons of the genes under investigation, and thus allow the identification of the main unknown alterations (mutations) causative of the hereditary cancer predisposition syndromes that the Laboratory mainly deals with.

The OncoPan® panel, introduced in November 2019, was granted trademark registration in 2020. OncoPan is continuously undergoing refinement so as to facilitate the needs of customers (physicians of Genetic Counseling Services), as well as the peculiar possibility of requesting the analysis of additional genes at a later time, using the NGS data from the first analysis.

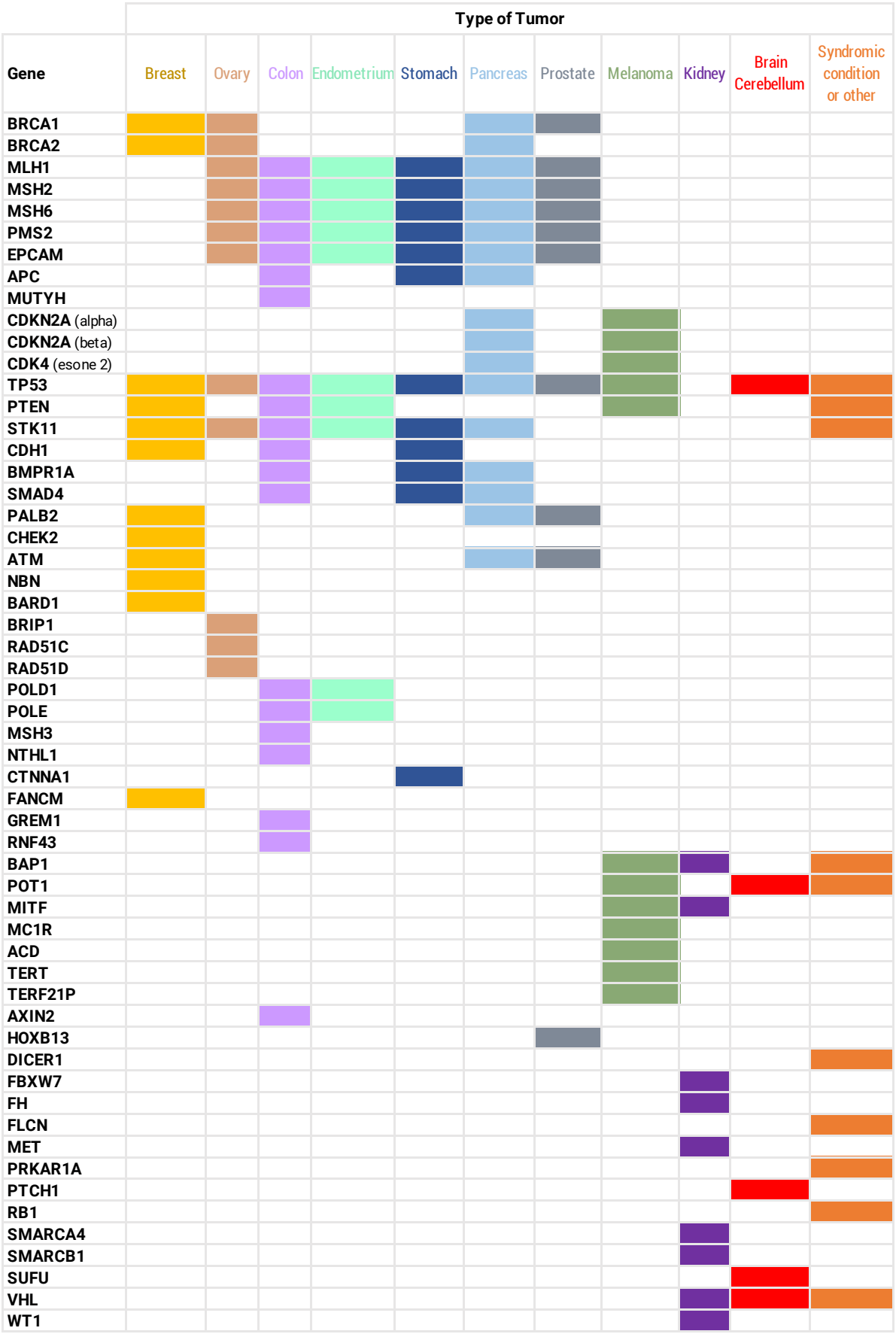
The OncoPed panel, introduced in April 2023, is designed to identify individuals at genetic risk and offer molecular diagnostic insights to patients with pediatric cancers or rare syndromes.

The NGS panels capture fragments of DNA by probe hybridization using Agilent Sure Select technology, 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 (library), which is then sequenced by an advanced process employing NGS techniques and the use of Illumina's MiSeqDX or NextSeq 550Dx instruments. The advantage of the method is that it can simultaneously analyze multiple genes (multi-gene panels) from multiple patients in a single run. DNA sequences obtained from the NGS technique (reads) are processed through a series of advanced bioinformatic analyses (pipelines), developed in collaboration with the company enGenome (Pavia).

Sanger sequencing occurs following amplification of regions of interest using a standard protocol.

The MLPA method makes use of commercial kits (SALSA® MLPA® Probemix from MRC Holland)

The laboratory offers mutation analysis in the following genes for associated diseases. For the distribution of genes in the two available panels, OncoPan® and OncoPed, see price list MOD7.1.9.
You can request the CGT Lab Price List by sending an email to: sales-desk@cogentech.it.



In addition, the OncoPan® panel contains the following genes, which are useful for somatic analysis for therapeutic purposes in various tumor types.

Gene (Reference Transcript)	
ERBB2 o HER2	(NM_004448)
EGFR	(NM_005228)
PIK3CA	(NM_006218)
KRAS	(NM_033360)
NRAS	(NM_002524)
BRAF	(NM_004333)
KIT	(NM_000222)
PDGFRA	(NM_006206)

Reporting

The reports contain the information required by DGR X/7466 of 04/12/2017 and DGR XI/7044 of 09/26/2022
Guidelines or recommendations are followed in formulating the report:

ACMG	(American College of Medical Genetics and Genomics) Standards and Guidelines for the interpretation of sequence variants, Genetics in Medicine 17(5):405- 424, 2015, with review by Nykamp et al, Genet Med 19(10):1104-1117, 2017 and clarifications given in ACGS Best Practice Guidelines for Variant Classification in Rare Disease 2020 (Ellard et al. https://www.acgs.uk.com/media/11631/uk-practice-guidelines-for-variant-classification-v4-01-2020.pdfhttps://www.acgs.uk.com/media/11631/uk-practice-guidelines-for-variant-classification-v4-01-2020.pdf.) Where available, gene-specific criteria developed by the ClinGen expert panel (https://www.clinicalgenome.org) are applied.
ENIGMA	ClinGen ENIGMA BRCA1 and BRCA2 Expert Panel Specifications to the ACMG/AMP Variant Interpretation Guidelines for BRCA1 Version 1.0.0 ClinGen ENIGMA BRCA1 and BRCA2 Expert Panel Specifications to the ACMG/AMP Variant Interpretation Guidelines for BRCA2 Version 1.0.0
Insight	(International Society Gastrointestinal Hereditary Tumors) Mismatch Repair Gene Variant Classification Criteria (v. 2.4 June 2018).
SIGU	(Italian Society of Human Genetics - https://www.sigu.net) -Genetic counseling and genetic testing in oncology. Critical aspects and proposals of AIOM SIGU (December 2021) -The interpretation of sequence variants in tumor preshisposition genes: operational guidance for the diagnostic laboratory" (v.1.0 dated 10/02/2016). -Guideline on BRCA1 and BRCA2 gene analysis in clinical settings: test access criteria, update on diagnostic platforms, and somatic test interpretation (Rev 01.dated 03/30/2021). -Directions for reporting genetic analysis performed by Next-Generation Sequencing (NGS) method (Rev. 07 of 08/30/2022)

The nomenclature used for reporting refers to the Human Genome Variation Society (HGVS, http://varnomen.hgvs.org).

MANE Select sequences (http://tark.ensembl.org/web/mane_GRCh37_list) are used as the reference sequences of the analyzed genes.

Arrangements for the preservation of materials and documentation

The "Guideline on the Preservation of Biological and Documentary Material Related to Genetic Testing," drafted by the Sigu Health Working Group (03/30/2021), is applied.

All documentation related to the analyses performed is stored digitally for an unlimited time, with the exception of the transport document, which is kept for one year.

Samples are stored for as long as necessary to conduct the genetic test, including consideration of the possible repeatability of the test. After that, they are returned or destroyed, depending on the instructions received from the client.

Testing times (from acceptance to report issuance)

Expected time frame for testing	Routine/Urgent in working days
Testing of collaterals with Sanger sequencing or MLPA	10 days
MLPA any gene, MS-MLPA (MLH1 promoter methylation)	10 days
CGT-EXTRA-1 gene (re-analysis)	10 days
CGT-EXTRA-2/50 genes (re-analysis)	15 days
CGT- 1 gene (of your choice)	15 days
CGT- 2/10 genes-G (your choice, in the same panel)	20 days / 15 days
CGT-11/50 genes-G (your choice, in the same panel)	25 days / 20 days
CGT- 1 gene-S (your choice)	15 days
CGT- 2/10 genes-S (choice)	15 days
CGT-11/50 genes-S (choice)	15 days
CGT-OncoHRD and EXTRA-OncoHRD	15gg

How to Request a Molecular Genetic Analysis

Below are the codes of the Lombardy Region Tariff Schedule, corresponding to the type of analysis performed by the Laboratory.

From the list of Benefits in Sub Annex 4 rev.01 (6-04-2023) to DGR XI/7044 dated 26-09-2023	
Ø 91.30.3	Analysis of DNA segments by sequencing (blocks of about 400 bp) - Search for specific mutation.
Ø 91.29.7	Analysis of gene sequences by Next Generation Sequencing (NGS) and assimilated techniques for mutational analysis of disease, including where applicable confirmatory testing of reported variants requiring only one gene for diagnosis. (NGS = >1200 bp to 1 gene)
Ø 91.29.7 A	Analysis of gene sequences by Next Generation Sequencing (NGS) and assimilated techniques for mutational analysis of disease, including where applicable confirmatory testing of referenced variants requiring 2 up to a maximum of 10 referenced genes for diagnosis. (NGS >1≤ 10 genes)
Ø 91.29.7 B	Analysis of gene sequences by Next Generation Sequencing (NGS) and assimilated techniques for mutational analysis of disease, including where applicable confirmatory testing of referenced variants requiring 11 up to a maximum of 50 referenced genes for diagnosis. (NGS >10≤ 50 genes)
Ø 91.29.7 C	Analysis of gene sequences by Next Generation Sequencing (NGS) and assimilated techniques for mutational analysis of disease, including where applicable confirmatory testing of referenced variants requiring >50 genes referenced for diagnosis. (NGS >50 genes)
Ø 91.29.I	BRCA1 and BRCA2 Reflex. Complete sequencing of BRCA1 and BRCA2 genes, any Method. If sequencing negative for pathogenic mutations or in case of double familiality or uninformative family, perform RESEARCH FOR BRCA1 and BRCA2, any method.
Ø 91.29.T	BRCA1 mutations in family members. Targeted testing. Search for gene mutations (by any method).
Ø 91.29.U	Rearrangements in BRCA1 by MLPA.
Ø 91.29.X	BRCA2 mutations in family members. Targeted testing. Search for gene mutations (by any method).
Ø 91.29.Y	Rearrangements in BRCA2 by MLPA.
Ø 91.29.Z	Rearrangements (deletions and duplications) of other human genes by MLPA and assimilated techniques (for each gene).

Requests

The above tests can be accessed by filling out the request form (attached to the contract) for each examinee, to be sent along with the biological material for analysis. A single list of all submitted specimens should also be completed and sent for each shipment. **Only requests submitted by a specialist in Medical Genetics or related branch and within a pathway of genetic counseling (pre- and post-test)**, as per DGR 2989 of 12/23/2014 and reiterated by DGR 7044 of 09/26/2022 (Italian Regional Law), **will be considered**.

In addition to the Paper Request Form, since January 2022 Cogentech has activated a new opportunity to access genetic testing: **the online Request Management Portal (PGR)** has been implemented.

Physicians will have access to the portal through their personal credentials. In addition, through the same portal, the physician will be able to upload consents and other documents useful for 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.

Samples needed for genetic testing

To perform the genetic test, it is necessary to deliver to the Cancer Genetic Test Laboratory:

- 2 Standard CBC tubes, at least 3ml blood in EDTA (10 mM)..

Or

- 2 tubes of 500 nanograms each of genomic DNA from independent extractions (if possible use 1.5 ml Eppendorf-type tubes).

For special situations it is possible to send two saliva samples (to be arranged in advance with the laboratory) in special tubes.

For tests on paraffin-embedded tissue, the following material should be sent after evaluation of the tumor cellularity content on the slide, which should not be less than 50 % if possible, to ensure better analytical sensitivity. For HRD analysis, however, a cellularity higher than 30% is required

- 8 slides with 8-µm sections cut from the tumor block and 1 section stained with Hematoxylin-Eosin on which the tumor region to be microdissected should be highlighted. The stained section should be centered, in the cutting procedure, so that it is representative of the submitted sections.

Or

- gDNA extracted from FFPE tissue, preferably by microdissection of the tumor region, at least 500ng with a concentration of not less than 25ng/µl. In addition, submission of 1 slide stained with Hematoxylin-Eosin is requested, highlighting the tumor region where microdissection was performed before gDNA extraction.

It is the 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, FFPE tissue slides) must be accompanied by a copy of the **informed consent** (uploaded to the portal or physically attached to the sample), 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.

Where to send the biological sample

The biological sample should be sent to the following address:
Cogentech – Cancer Genetic Test Laboratory (CGT Lab)
c/o IFOM - Via Adamello, 16 – 20139 Milano
c.a. Dr. Valeria Pensotti (02.574303205) / Dr. Fabio Capra (02574303207)
mail reference: gtic-service@cogentech.it

Laboratory opening hours

The laboratory is open Monday through Friday from 9:00 am to 6:00 pm. The presence of at least one Health Executive and one biomedical laboratory technician is always guaranteed during this time slot

Shipping methods

Transportation of the biological specimen can be done by hospital employee or through Cogentech's paid transportation service (carrier). The optimal transport of biological specimens should be in a rigid, combination-locked, temperature-controlled container, regardless of external seasonal and climatic aspects. *The container should therefore be equipped with cooling elements*.

Upon arrival of the samples at the laboratory, the staff will ascertain the conformity of the contents and notify the hospital/contracting entity's reported mailing address with an email that the sample has been received.

Listening and improvement

Cogentech Management has initiated an annual program to monitor the satisfaction of its customers, in line with the principles 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 focus on the qualifying points of our service and to implement corrective actions where areas or behaviors that can be improved are perceived instead.

Protection and verification

Complaints

We consider your complaints, if any, as a valuable tool of quality and, therefore, the starting point for stimulating actions to improve CGT Lab services and our relationship with the user, involving all operators.

To this end, CGT Lab considers it essential to respond to each complaint to verify the incident. Therefore, a complaint procedure has been put in place involving the Service Managers, who are called to report about the incident to enable a clarifying response to be provided to resolve the problem

Complaint Procedure

1. The user submits the complaint via e-mail to gtic-service@cogentech.it
2. The complaint is entered into Cogentech's Complaint Register.
3. The Quality Manager collects information, initiates the necessary checks, and reports to management
4. CGT Lab management responds to the user as quickly as possible

Review of commitments and organizational adjustment

CGT Lab ensures verification of the implementation of the standards through an annual report on the results achieved

Privacy

Data Securityi

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, also in accordance with art.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 CGT Lab through the genetic counseling laboratories

For the acquisition of informed consent for the performance of medical genetics laboratory medicine analysis, the directives of the regional circular dated May 28, 2013 No. 13 "Directions on Procedures for Performing Medical Genetics Laboratory Medicine Analyses referred to in DGR No. IX/4716/2013" are followed. According to these guidelines, the laboratory accepting samples must forward a copy of the informed consent to the laboratory performing the analysis.

The data controller is:

Cogentech S.R.L. Sole Proprietorship Benefit Society
Via Adamello, 16
20139 Milan, Italy

The Data Controller, in accordance with the provisions of Article 37 of Regulation (EU) 2016/679 has appointed a Data Protection Officer (DPO), who can be contacted at: dpo@cogentech.it

General Information

CGT Lab (Cancer Genetic Test Laboratory) - Via Adamello, 16 - 20139 Milan	
Office phone	02 574303205/210
Lab phone	02 574303207
Cogentech switchboard	02 574303200
E-mail	gtic-service@cogentech.it | cogentech@pec.it
Opening hours	Monday - Friday; 9 a.m. - 6 p.m.

CGT Lab Service Charter (V 2.5)

Updated by the Standing Group on the Service Charter:

- Frédérique Mariette
- Valeria Pensotti
- Sara Volorio
- Barbara Bazolli

Approved by the Laboratory Manager: _____

(Marco Alessandro Pierotti)

Update Date: September 2023