

SERVICE CARD

TOMA Advanced Biomedical Assays S.p.A.

Single member company

Subject to management and coordination by Impact Lab S.p.A.

Via Francesco Ferrer 25/27 · 21052, Busto Arsizio (VA)

Tel: 0331-652911 · Fax: 0331-652919 www.tomalab.it

toma@tomalab.com

C.S. € 2,050,000.00 - Unique SDI no. W7YVJK9

Varese Chamber of Commerce, Economic Administrative Index no. 155

Tax ID Code and VAT no. 00772010120

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Certification

ISO 9001:2015

Quality in Medical Laboratories: 2013



SIGUCERT - Quality Management System

in Medical Genetics Laboratories 2018



LAB N° 2007 L

Accreditation of the standard ISO/IEC 17025:2018 Forensic Genetics, Testing Laboratory n°2007L



MED N° 0028 M

Accreditation of the standard UNI EN ISO 15189:2013 Medical Laboratory n°0028M for some tests of Medical Genetics and Cytogenetics

Details of the accredited exams on the site www.tomalab.com

TOMA Advanced Biomedical Assays S.p.A., a private structure accredited with the S.S.N. belonging to ATS Insubria it is reclassified according to DGR 7044

Three Clinical Laboratories pertain to EntityTOMA:

- General Clinical Laboratory with Clinical Pathology and Microbiology and Virology
- Pathological Anatomy Specialist Laboratory with Somatic Molecular Diagnostics

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Legal Offices

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- Specialist Laboratory of Medical Genetics with Cytogenetics and Molecular Genetics which also includes an area dedicated to Forensic Genetics.

Within the structure there is also a **Research and Development** area whose purpose is to promote clinically useful innovation and implement the diagnostic offer.

Direction

Legal Representative and Chief Executive Officer: Dr. Vittorio Grazioli

Laboratory Director: Dr.ssa Grazia Letizia Puccetti

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Laboratory Directors

GENERAL CLINICAL SPECIALIST LABORATORY with Clinical Pathology and Microbiology and Virology

Responsible Director: Dr.ssa Grazia Letizia Puccetti

PATHOLOGICAL ANATOMY SPECIALIST LABORATORY with Somatic Molecular Diagnostics

Responsible Director: Prof. Gaetano Pietro Bulfamante

SPECIALIST MEDICAL GENETIC LABORATORY with Cytogenetics and Molecular Genetics

Responsible Director: Dr.ssa Elena Repetti

SERVICES PROVIDED

1. Withdrawal points - via F.Ferrer 25/27, Busto Arsizio

Open: from Monday to Friday from 7:30 am to 1:00 pm and from 05:00 pm to 06:00 pm
Saturday from 07:30 am to 12:00 pm

Laboratory tests

Pick-up without appointment: from Monday to Saturday from 07:30 am to 10:00 am

Medical report collection: from Monday to Friday from 05:00 pm to 06:00 pm, Saturday from 10:30 am to 12:00 pm.

Home withdrawals: in dedicated time slots

An appointment is required for the collection of samples for the dosage of narcotic / psychotropic substances and for molecular testing related to the SARS CoV-2 virus (COVID) : telephone number 0331-652911 from Monday to Friday from 10: 30 am to 01: 00 pm / from 02: 00 pm to 4: 00 pm, or by e-mail at segreteria@tomalab.com

Genetic tests, NIPT (Harmony and Panorama tests)

ONLY by appointment: telephone number 0331-652911 from Monday to Friday 10: 30 am to 01: 00 pm / from 02: 00 pm to 04: 00 pm, or by e-mail at segreteria@tomalab.com

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2. Home services

The home sampling and collection service is offered throughout the national territory: in the areas surrounding Busto Arsizio for clinical biochemistry tests, throughout the national territory for genetic tests.

To request it, call 0331-652911 from Monday to Friday 10: 30 am to 01: 00 pm / from 02: 00 pm to 4: 00 pm, or by e-mail at segreteria@tomalab.com. In the case of services that include pre- and post-test consultancy, this will be offered online.

ACCEPTANCE PROCEDURES

The services are provided following:

- request from a general practitioner or specialist
- by free will of the user

The **rates** of the services in agreement with the SSR are identical in both public and private structures that have an agreement.

Patients between the ages of 14 and 65 years are required to pay the ticket for each individual service in accordance with the regional tariff for a maximum of € 36 per prescription (8 tests per prescription).

The payment of the ticket must be done when the invoice is issued.

Patients with exemptions for pathology, age and income reported on the referral are exempt from the ticket.

SERVICES PROVIDED

For the complete list and details of the services provided in the Laboratory, it is possible to check the website www.tomalab.it on the page exams.

Most of the analyzes do not require special preparations, with the exception of fasting for at least 8 hours for Clinical Biochemistry analyzes; for special examinations, information is available for users with specific instructions for collecting samples in two languages (Italian and English). The usability of the services is in any case guaranteed to ethnic or linguistic minorities and the deaf.

REPORTING TIMES

On our portal www.tomalab.it, the relative execution times are specified for each exam.

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For all exams, compliance with the maximum reporting times established by the Lombardy Region is guaranteed.

WITHDRAWAL OF REPORTS

The day of collection is specified on the appropriate forms delivered at the time of acceptance.

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There are several ways to collect the report:

- ✦ In Busto Arsizio it is possible to print the report independently from the totem in the reception area or to collect the report directly at the admission desks
- ✦ By e-mail with dedicated credentials
- ✦ On the web: on our portal www.tomalab.it there is a reserved area where you can print the report using dedicated credentials

EQA

The Laboratories participate in internal and external Quality control activities promoted by the Lombardy Region.

For the General Clinical Laboratory there are specific external evaluation programs promoted by ProBioQual and QCMD.

For the Specialist Laboratory of Pathological Anatomy there are specific external evaluation programs promoted by the UK NEQAS, EQMN and GenQA.

For the Specialist Laboratory of Medical Genetics there are specific external evaluation programs promoted by the Istituto Superiore di Sanità, EMQN and GenQA and CTS

PRIVACY

Compliance with the European Data Protection Regulation nr 2016/679 (GDPR) is guaranteed.

231 MODEL

An organizational model has been adopted, in compliance with Legislative Decree June 8, 2001 no. 231, appointing a Supervisory Body.

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CUSTOMER SATISFACTION

The Responsible Director of the Laboratory and the Managers of the Specialized Sections are available to patients for any clarification and elucidation.

RIGHTS AND DUTIES OF PATIENTS

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TOMA Advanced Biomedical Assays S.p.A. provides services to the community in compliance with the legal and ethical standards that protect patients' rights, inspired by the principles established by the Directive of the President of the Council of Ministers of January 27, 1994 and by the European Charter of Patients' Rights enunciated in 2002 by [https://www .activecitizenship.net/](https://www.activecitizenship.net/)

The rights of patients

- 1. Right to care:** every person has the right to receive appropriate and evidence-based services, with professionalism and attention, without discrimination based on age, gender, race, language, religion and political opinion.
- 2. Right to respect for time:** everyone has the right to know the times in which they can receive services, as well as to be promptly notified in the event of problems or delays.
- 3. Right to participation and information:** every person has the right to participate in an aware, active and safe way in the service. Everyone has the right to be informed about their health conditions, the benefits and risks, the possible alternatives, any existing paths.

4. Right to Participation, Free Choice and Informed Consent:

each person has the right to choose between different procedures for the provision on the basis of adequate information, communicated in an understandable and timely manner, which allows them to express informed consent.

- ✦ everyone has the right to be accurately informed and to express their consent regarding participation in clinical trials;
- ✦ the patient also has the right to totally or partially refuse to perform the proposed tests and to be informed about the consequences of the refusal and about the alternatives.

5. **Right of second opinion:** every patient has the right to request a consultation from another professional, in order to have a medical opinion on their clinical situation, also through the evaluation of health records.
6. **Right to privacy and confidentiality:**
 - ✦ every patient has the right to respect for their confidentiality in the performance of medical and assistance services and in the processing of personal data;
 - ✦ the patient also has the right to prohibit the disclosure and dissemination of information relating to his state of health to persons other than those indicated by him.
7. **Right to avoid unnecessary suffering and pain:** Every person has the right to avoid as much suffering as possible, at every stage of their illness, through appropriate pain assessment and management.
8. **Right to patient-centred care:** every person has the right to diagnostic-therapeutic programs that are as suitable as possible for their personal needs and to dignified and human assistance in all phases of treatment.
9. **Right to access to clinical documentation:** every patient has the right to receive a written clinical report in an understandable way, with useful information for the continuity of care. Furthermore, every patient has the right to request a copy of their clinical documentation.
10. **Right to express one's opinion:** every person has the right to express his or her opinion through the methods made available and to contact the appropriate office if he/she deems one's rights violated.

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The duties of patients

All patients belonging to the Toma Laboratory, in the spirit of a relationship of mutual trust, have the duty to:

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1. maintain a responsible and respectful attitude towards other patients, staff, environments and equipment, to collaborate with staff;
2. comply with the behavioral instructions received, in order to facilitate the success of the service;
3. communicate with healthcare personnel with transparency and trust, expressing any doubts about the proposed tests, so as to actively foster a relationship of trust.

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