GENERAL CLINICAL LABORATORY

BIANALISI NOVOLABS SAMPLING STATIONS

Head of Laboratory: Dr. Alfredo De Riso

PRESENTATION OF THE LABORATORY

The **NOVOLABS di Bianalisi S.p.a.** Clinical Laboratory in Brescia, via Corfù 71, is a licensed facility, operating in the field of laboratory medicine with Clinical Pathology and Microbiology and Virology as its areas of specialism.

The facility is part of **Bianalisi S.p.A.**, and the **Bianalisi Group** with headquarters in Carate currently operates a number of Laboratory and Polyclinic facilities throughout the country.

INTRODUCTION

This Service Charter constitutes a written pact with users on the quality of the services provided.

With it, Bianalisi undertakes to provide a quality service that complies with the fundamental principles set out below, and to ensure that this service increasingly meets patients' needs.

With the Service Charter, users of the service can confirm that *Bianalisi* is meeting the commitments it assumes and require it to observe them.

The Service Charter is subject to annual review.

This Service Charter is drawn up in compliance with the Prime Minister's Decree of 19 May 1995 "General reference framework of the Public Health Services Charter" and Regional Government Decree VI/41066 Lombardy Region of 22/01/1999.

PURPOSE

Our Mission is to make it possible for all citizens, regardless of their economic situation, to access the highest quality diagnostic health services.

VALUES AND OBJECTIVES

Novolabs di Bianalisi S.p.a. is a laboratory established to offer high quality and affordable healthcare in the field of laboratory diagnostics (medical laboratory analysis).

Novolabs di **Bianalisi S.p.a.** believes in a culture of solidarity and respect for citizens' rights, in particular the right to quality healthcare at affordable prices for all, to avoid the problem of exclusion from healthcare due to income level.

> **SOLIDARITY** - **Novolabs** di **Bianalisi S.p.a.** strongly believes that citizens should never be deprived of health care and treatment for economic reasons.
>
> **QUALITY** - In reducing the price of examinations for citizens, **Novolabs di Bianalisi S.p.a.** does not cut corners on the quality of its services. Quality is a key differentiating factor in our business.
>
> **AVAILABILITY** - **Novolabs** di **Bianalisi S.p.a.** has as its long-term goal to offer its services directly to as many Citizens as possible nationwide.

The laboratory's aim is to offer citizens a state-of-the-art diagnostic service that is fast, efficient and cost-effective.

This led to the Bianalisi service charter, a document intended to make users of our service aware of how we work, as well as providing a set of information to facilitate the relationship with the citizen/user (reception, reporting, delivery times, payment methods, storage and delivery of biological samples).

By analysing the services provided, users can suggest improvements in the service, which Bianalisi will take into consideration.

The **Laboratory**'s activity consists of receiving organic materials from its network of sampling stations. Bianalisi provides users with free access to the sampling point, without waiting times and with fast result turnaround times.
The Novalabs facility operates six days a week. Its activity meets the needs of citizens at local, regional and extra-regional level. Each operator, through the constant technical-scientific updating of its services, works to achieve the primary objective, which is to provide users with analytical excellence in the tests performed.

Notes: The sampling activity is carried out by medical/nursing staff.

Critical results that deviate significantly from the reference values, as soon as they are known, are communicated by telephone to the treating physicians and patients by the staff who sign the medical reports or those responsible at the sampling station.

BASIC PRINCIPLES

Novolabs di **Bianalisi S.p.a.** protects and fully respects the right to Privacy of Users who contact the Laboratory.

Novolabs di Bianalisi S.p.a. is committed to guaranteeing the following fundamental principles of health care enshrined in the General Outline of the 'Charter of Public Health Services' (Prime Minister's Decree of 19/5/1995): equality, impartiality, transparency and quality assurance, continuity, confidentiality, right of choice and to health information, participation, efficiency and effectiveness.

Equality
All citizens are afforded the same services, irrespective of their age, gender race, language, nationality, religion, political opinions, customs, physical condition, mental condition, economic condition, personality structure.

Impartiality
All citizens are assured of the objective approach of the staff working in the facility.

Continuity
Citizens are assured of the quantitative, qualitative continuity and regularity of the services provided.

Participation
The citizen's right to collaborate, through complaints, observations and suggestions, in the provision of the services and in the improvement of the service provided by the facility is guaranteed.

Efficiency and efficacy
The service is provided in such a way as to ensure its efficiency and effectiveness, and the facility takes the appropriate measures to achieve these objectives.

Transparency
The Service ensures the transparency of its administrative action by making available to the public all information on the type of examinations, how and where they are carried out, the response times and the fees charged to private entities

Improvement objectives
Bianalisi considers a quality of the services provided to users to be its main objective. This necessarily entails constant adaptation to the needs and demands of citizens.

1. INFORMATION ON THE SERVICES PROVIDED

1.1. TYPE OF ANALYSES

The type of analyses offered by Novolabs corresponds to the laboratory services listed in the tariff nomenclature of the Lombardy Region (General Regional Decree VI/42606 of 23/04/99 and subsequent amendments).
In particular, Novolabs offers laboratory services in the following branches, either by performing the analyses directly or by passing them on to the relevant laboratory service: Clinical Biochemistry, Haematology, Coagulation, Bacteriology, Endocrinology, Immunology, Virology, Serology, Toxicology, Allergies and Intolerances, Cytology and Pathological Anatomy, Genetics.

1.2. LIST OF EXAMINATIONS PERFORMED

The complete list of all examinations that can be performed at Novolabs, the reporting deadlines, the performing laboratory and the prices charged are listed in the 'Examination List' document. The Examination List is attached to the Service Charter and can be consulted at all Novolabs Sampling Stations. A 'Vademecum' of examinations performed is also available on the Novolabs website, which contains further information on the examinations performed, such as reference values, execution methods and reporting times.

1.3. ACCESS TO SERVICES – locations and opening hours

Access to Sampling stations during opening hours is direct and no booking is necessary. Patients simply turn up at one of the Novolabs sampling stations during the opening hours for Sample Taking and Collection of Results. For a full list of Sampling Points and their respective opening hours, go to our website www.novolabs.it

Patients can enter the sampling station to have blood samples taken or collect test results with a receipt for collection, or, proxy holders can collect test results with a proxy letter from the delegating person and a photocopy of their ID, at the opening times indicated in the list of sampling stations at the end of this document (see attached list of sampling stations and opening hours or consult our website www.novolabs.it).

Novolabs di Bianalisi S.p.a.'s central laboratory is located in Brescia, via Corfù 71, and is not open to the public.

Any citizen can go to Novolabs di Bianalisi S.p.a. on a private basis.

Novolabs is not under contract to the National Health System, so all services are paid for by users (including those exempt).

1.4. RECEPTION

At reception, the user is required to submit:

- personal data and tax code (identification document)
- telephone number for any communications
- the signature of the informed consent to the processing of personal data (privacy)
- the signature of the informed consent for some specific tests

An identification code is assigned to each acceptance in order to guarantee the anonymity and confidentiality of the personal and sensitive data acquired.

1.5. URGENT EXAMINATIONS

Urgent examinations can be carried out by agreement with the laboratory, on medical recommendation or under special conditions (e.g. PT and INR for patients undergoing therapy, Beta HCG dosage, etc.).

The urgency of the examination must be stated on admission.

1.6. PAYMENT OF SERVICES

Services performed at our centre must be paid for at the time of acceptance, except in special and exceptional situations of necessity where payment may be deferred to the time of collection.

Payment can be made in cash by debit card.

An invoice will be attached to the medical report.

The fee schedule is available for consultation at the secretary's office.

1.7. PREPARATION FOR SAMPLING

The user's preparation for clinical examinations is very important as fasting, diet, intake of medication, exercise, posture and the effects of venous stasis are all elements that need to be taken into account in the hours leading up to sampling.

Staff at reception inform the patient about the correct way to take biological samples, and instructions can be obtained from the sampling station or customer services.

Healthcare staff are available to answer any questions regarding aspects of the services to be performed. The user is also provided with an information sheet on how take samples correctly, containing all the information needed for correct sampling and analysis.

Containers for collecting faeces and urine are provided free of charge by the sampling station on request to staff at reception.

We recommend you:

- Not change your dietary habits on the day before the sample is collected and avoid sharp variations in your calorie intake.
- Observe a fasting period of 8-12 hours before taking the sample (refrain from drinking coffee, tea, milk or other drinks except for 1-2 glasses of still water).
- Avoid intense physical exertion in the 12 hours prior to sampling, so as not to cause changes in enzyme activity and in certain analytes originating from skeletal muscles.
- Not smoke between waking up and taking the sample (nicotine can cause erythrocytosis and leucocytosis).
- Not drink alcohol in the 12 hours prior to sampling.
- Not take any medication in the 12 hours prior to sampling, except if absolutely necessary: in this case report the type of medication taken.
- Report any menstrual condition (women).

1.8. DELIVERY OF BIOLOGICAL SAMPLES COLLECTED BY THE USER

In the case of examinations requiring samples to be collected directly by the user, staff at reception will give the user instructions on the examination to be carried out and, if necessary, the container to be used. The biological samples taken by the User must be delivered to medical staff in the Sampling Room after the administrative steps have been completed.

1.9. PERFORMANCE OF THE ANALYSES

All biological samples are promptly transferred to the laboratory to guarantee data security. This is because many analytes are unstable and may give false results if processed and/or analysed several hours after collection.

The laboratory data help to distinguish between a healthy and a morbid state. Their value is therefore semiological and not clinical. To achieve this, all analytical data produced must have a high degree of reliability. Therefore, laboratory examinations must meet the following basic requirements:

- accuracy;
- diagnostic sensitivity;
- diagnostic specificity.

Accuracy depends on the repeatability of results on the same sample at different times and by different operators. This depends on biological variability and analytical variability.

The average individual biological variability between days is known for many serum analytes. Expressed as a coefficient of variation (CV), it is low (1-2%) for sodium, chlorine-calcium, magnesium; 3-5% for protein, between 4-7% for phosphate, potassium, creatinine, glucose, total and HDL cholesterol, ALP, GGT; exceeds 10% for uric acid, urea nitrogen, bilirubin, iron and triglycerides (20-25%) and various enzymes.

Analytical variability depends on the laboratory, methods, sampling, sample processing, etc. This is due to random errors, which constitute inaccuracy, and to systematic deviations from actual values due to overestimation or underestimation, which represent imprecision.

To keep the analytical CV under control, Bianalisi S.p.a.'s Novolabs operates in two ways:

Analytical Quality Control
Quality Control (QC) involves the systematic control of calibrations, intra- and inter-laboratory QC for the various sectors. In this regard, Novolabs of Bianalisi S.p.a. participates in the inter-laboratory quality control of the Lombardy Region and in quality controls of international circuits.

1.10. MEDICAL REPORTS

The results of diagnostic investigations can be collected from the Sampling Stations in the opening hours indicated in the "collection slip" delivered to the user, which indicates, for the examinations requested, the date of collection of the report and the opening hours of the laboratory (see "opening hours" paragraph).

The medical report is delivered to the user or their delegated persons, only if they have the proxy form in their possession.

The results of the HIV1-HIV2 antibody tests are delivered personally to the user and these cannot be collected by any other person.

Reference values
All reference values on the reports were calculated by **Novolabs di Bianalisi S.p.a.** in reference to the analytical methods used. In addition, these values are periodically checked by means of bibliographic surveys of epidemiological studies.

Comments and communications
There are some spaces on the report, which the Head of the Laboratory, who validates and signs the results, uses to insert comments or communications they consider important to be able to properly understand the medical report.

1.11. DOWNLOADING MEDICAL REPORTS FROM THE INTERNET

Online reporting is a service that Bianalisi makes available to its users (with the exception of special conditions indicated by regional regulations).

All patients of legal age who wish to do so will be able to consult their digitally signed laboratory reports from the last 45 days via the Internet. In order to activate the service, which is free of charge, patients, on completing reception, must request access to the specific Bianalisi web page to view their medical report.

An HIV medical report can only be delivered to the person concerned (no proxy is possible).

Staff at reception, after processing in the secretary's office, will print out and hand over the form required to collect the medical report.

The form includes:
- the address of the relevant website you are to use;
- personalised credentials that will allow the first login to download the report.

The reports can be consulted and downloaded at home or at work from the websitewww.novolabs.it

2. QUALITY POLICY

Novolabs is aware that the Quality Policy is an important strategic tool and key to achieving maximum user satisfaction and improving internal efficiency margins.

Novolabs di Bianalisi S.p.a. has defined the following objectives for its quality policy:

USERSATISFACTION
This objective is pursued through the due identification and subsequent verification of the actual fulfilment of explicit (e.g. timely execution of analyses) and implicit (e.g. reliability of the results obtained) requirements requested by users, the detection, analysis and resolution of any complaints, the periodic monitoring of the degree of user satisfaction on aspects considered to be of crucial importance, the statistical processing of data relating to satisfaction/complaints.

EFFIENCY AND EFFICACY
The laboratory's staff is committed to ensuring that an efficient and effective service is provided at all stages, both medical and administrative. **Novolabs di Bianalisi S.p.a.** aims for the highest levels of efficiency through optimal planning and accurate control of the phases of execution of

operational activities, as well as through adequate training and the constant updating of internal resources.

CONTINUAL IMPROVEMENT
To be implemented through the constant detection and management of non-conformities, the identification and implementation of appropriate corrective and preventive actions, the definition of control parameters/indicators of critical processes and the resulting collection of information and reprocessing of data using statistical techniques. The periodic review of the Quality System is aimed at assessing the results achieved and identifying new objectives to be achieved and tools to be used.

3. PROTECTION AND VERIFICATION MECHANISMS

3.1. PROTECTION OF PRIVACY

The right to Privacy is one of the user's fundamental rights. **Novolabs di Bianalisi S.p.a.** has put in place procedures to ensure that analytical data, reports and requests are handled in full compliance with the **General Data Protection Regulation (GDPR**), Regulation (EU) No 2016/679.

To this end, each new User is invited by the secretary's office to sign the consent sheet for the processing of personal and sensitive data in accordance with the **General Data Protection Regulation** (GDPR), **Regulation (EU) No 2016/679** as amended and supplemented; at the same time, he/she is given the information sheet concerning the processing of his/her personal and sensitive data by the laboratory.

To protect privacy, the report is delivered to the holder in a sealed envelope.

Access to computer data is safeguarded by special passwords (for access, consultation and modification).

For reports delivered to third parties, following the presentation of the appropriate proxy, secretary staff must also be provided with a copy of a valid identity document of the delegating party and the delegate.

3.2. ANALYTICAL QUALITY CONTROL

The Laboratory uses two analytical quality control tools:

- The systematic implementation of the Internal Quality Control
- Participation in External Quality Assessment (EQA) programmes

Internal Quality Control encompasses everything in the laboratory that is put in place to ensure the reliability of analytical results through continuous monitoring of work procedures, instrumentation and reagents.

Specifically, **Novolabs** has introduced:

- controls concerning equipment monitoring
- checks involving the analytical steps, whose results are evaluated on a daily basis to validate the results of the analytical set.

Adherence to External Quality Assessment programmes makes it possible to verify, through the use of clinically verifiable samples, the efficiency of internal quality controls; in particular, the External Quality Assessment programme, carried out at the laboratory, makes use of the operational schemes provided by the Lombardy Region and, for some specific examinations, of controls established by international bodies.

Novolabs collaborates with external laboratories for the determination of certain specific tests. These laboratories are constantly monitored by **Novolabs de Bianalisi S.p.a.** in terms of the quality of the services provided and the quality controls carried out both internally (IQC) and externally (VEQ).

3.3. WEBSITE

Further information on the services offered by Novolabs can be found on the website of **Novolabs Bianalisi S.p.a.**: www.bianalisi.it.

3.4. USER SUPPORT (CALL CENTRE)

The assistance activity carried out by the sampling station takes place mainly in two distinct phases: the phase preceding the provision of the service and the phase following that provision.
Customer service is available to provide the following information:

- it provides information on where the service is provided, how to access it
- informs about the opening hours of the collection station and collection times
- lists the documents required for access to NHS and private benefits
- communicates waiting times for medical reports
- receives any reports on the services provided.

These activities involve handing out complaint and observations forms to customers.
Users may report any complaints by filling out the form MOD.14-02 - COMPLAINTS available on request.

USER SATISFACTION AND OBSERVATIONS
Novolabs di Bianalisi S.p.a. constantly monitors the quality level of the services provided, by duly recording User complaints. The information collected is used by **Novolabs di Bianalisi S.p.a.** to identify corrective actions to be taken to ensure continuous improvement of the services provided.
User support is available to users and their families and/or the attending physician during all service hours for all reports or complaints.
Novolabs di Bianalisi S.p.a. undertakes to take action to solve the reported problems as quickly as possible and, if necessary, to provide adequate answers. **Novolabs di Bianalisi S.p.a.** guarantees the strictest confidentiality regarding the identity of the person making the report.

Customer reports are analysed for the initiation of appropriate corrective and improvement actions by Laboratory Management during the “Management Review”, and form the basis for any “targeted” changes or measures by Management.

TEL: 030.220110

MON-FRI 9:00-15:30

callcenter.novolabs@bianalisi.it

Novolabs di Bianalisi S.p.a.

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