

**CENTRO BIOMEDICO BERGAMASCO
CLINICAL ANALYSIS LABORATORY
SERVICES CARD CSCBB01.18**

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DATE: 22-12-2020

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INTRODUCTION

The Clinical Analysis Laboratory "Centro Biomedico Bergamasco" adopts the "Health Services Card" or "Service Features Document" in order to meet the requirements of the DPCM 19.05.95, to illustrate the services provided to the users and to fully meet the expectations of themselves.

1.1. "Services Card" rules and purpose

The main legislative references of the services card are:

D. Decree No. 30 -12-1992 502 and following amendments thereto (Legislative Decree no. 12.07.93, No. 517)

- Ministers Council President's Directive dtd 27.01.94 (Principles of public services provision) Published in OG 02/22/94 No. 43.
- Decree of Ministers Council President published in OG 05.19.95 31.05.95 No. 65.
Services Card system is composed of the following elements:
 - a) basic principles identification which public services supply must be in accordance to: equality, impartiality, continuity, choice right, participation, efficiency and effectiveness;
 - b) information to users. The information has to relate to the services offered and to the supply conditions. The information has to be made in different ways, ensuring, however, the text clarity and comprehension as well as their accessibility to the public;
 - c) the quality standards recruitments assuring both the protection of general aims (i.e. referred to all the services offered) and specific ones (that means directly verifiable by individual users);
 - d) services quality assessment, shown by the annual reports about users satisfaction survey;
 - e) application of users rights protection through the complaints procedures.

2. LABORATORY INTRODUCTION

Clinical Analysis Laboratory "Centro Biomedico Bergamasco" Health Authoris. No. 406/SAN/BG27/4/1976 since 1976 and accreditation No. 52 in compliance with the health care levels defined by the National Health Plan and the Regional Diagnostic Laboratory, provides laboratory services under National agreement and privately.

Those services could be obtained at the following locations:

Headquarters laboratory in Bergamo, Rotonda dei mille, 3/a phone. no. +39 035-222332
3315778797 info@centrobiomedico.it ; accettazione2@centrobiomedico.it

Samples Collection centre Laboratory in Dalmine Via XXV Aprile No. 2 phone. no. +39
035-563707 334 5778766
dalmine@centrobiomedico.it

Samples collection centre Laboratory in Villa d'Almé via Locatelli Milesi No. 5. phone no. + 39 035
543444 331 5778775
villa@centrobiomedico.it

Samples collection centre Laboratory in **Albino** via Mazzini n° 184

Samples collection municipal centre of
Mozzo via Verdi 2/c via Locatelli Milesi No. 5. phone no. + 39 035 543444

Centro Biomedico Bergamasco
Staff Organization Table

Laboratory Director

Dr. Radice Eneina

Head of medical acts

Dr. Francesco Molteni in Bergamo

Samplers Doctors:

Dr. Francesco Benedetti in Bergamo

Dr. Stefano Rossi in Villa D'Alme

Graduates:

Dr. Silvia Monge (Biologist-Biochemist Clinical)

Dr. Roberta Gualandris (Biologist)

Dr. Claudia Colombelli

Dr. Barbara Gazzola

Staff assigned (not directly employed):

No.3 Midwives to smears, vaginal and endocervical swabs

No.5 Nurses to blood samples

Laboratory Technicians:

Laura De Marchi

Nicoletta Martinelli

Elisabetta Zanchi

Luigina Nozza

Employees:

Valeria Molteni

Alba Curnis

Anna Bonetti

Patrizia Gherardi

Daniela Fattori

Antonella Sanchini

Rosaria Magni

Ilaria Pulcini

Laura Maffioli

Manuela Locatelli

Emanuela Pasta

Cleaning staff

Nadia Pelliccioli

Olivana Bronco

The Clinical Laboratory Analysis "Centro Biomedico Bergamasco" employs qualified temporary staff to ensure continuity of service in case of extraordinary events.

The Laboratory is a qualified reference point for clinical diagnostics because of the methods used, the type of examinations performed and the expertise of staff.

- EQUALITY

The Clinical Laboratory Analysis "Centro Biomedico Bergamasco" aims to guarantee to citizens equal access to benefits, without any prior reservation; on request it arranges home samples service, regardless of age, sex, race, language, nationality, religion, political opinions, customs, physical and psychological conditions, economic conditions as well as personality structure.

- IMPARTIALITY

A fair and objective behavior is assured to all citizens by the staff of the laboratory.

□□CONTINUITY

Quantity and quality continuity as well as services supply regularity are guaranteed to the citizens.

- RIGHT TO CHOOSE

Each citizen provided with the request issued by the doctor of the National Health Service could exercise one's own right of "free choice" applying directly to the accredited laboratory chosen.

- PARTICIPATION

Citizens have the right to cooperate with comments and suggestions as concerns performance and service improvement of the laboratory.

- EFFICIENCY

The Clinical Analysis Laboratory "Centro Biomedico Bergamasco" is able to satisfy urgent requests within routine tests by delivering reports in the same day of collection or by giving to the doctor partial data. The above always in accordance to the quality criteria.

- SCIENTIFIC INNOVATION AND EFFECTIVENESS

Centro Biomedico Bergamasco commits itself to promote instrumental innovation, staff training and upgrading of computer systems as well, testing the effectiveness of that updating in terms of a better service and security for users.

Centro Biomedico Bergamasco business lines are as follows:

a) Clinical Chemistry

- b) Hematology and Coagulation
- c) Microbiology and Parasitology
- d) Serology and Immunology
- e) Endocrinology and tumor markers
- f) Molecular Biology
- g) Cytology
- h) Cytogenetics
- i) Toxicology for Occupational Medicine

To carry out some special tests, the Laboratory relies on medical facilities indicated below:

Laboratorio Synlab Italia - Brescia;

Laboratorio Cerba Healthcare – Milano/Abbiategrasso

Laboratorio Genoma-Group Roma/Milano

3. SERVICE ACCESS

3.1 HOW TO REACH THE CENTRAL LABORATORY AND THE OTHER SITES

- Bus Service and Parking;

Main Laboratory - Bergamo

ATB service lines No. 1 and No. 2

Parking P.za Libertà - Via Borfuro and Via Piccinini

Dalmine's branch Laboratory

Bus Service T.B.S.O.

Car service Locatelli

Free parking in Via XXV Aprile

Villa d'Almé's branch Laboratory

Bus Line Service Valbrembana S.A.B.

Free parking in Via Locatelli Milesi

Albino branch Laboratory

Train teb service

Saac Clusone Bergamo (from Leffe changing in Cazzaniga)

Bus Line Valbrembana S.A.B.

3.2 Sampling Hours

SEDI	BERGAMO	DALMINE	ALBINO	MOZZO	VILLA D'ALME'
GIORNI	Rotonda dei Mille 3/a	Via XXV Aprile	Via Mazzini 184	Via Verdi 2/c	Via Locatelli Milesi 5
Mon-sat	7.00 – 10.30	7.00 – 10.00	7.00 – 9.30	Wednesday only 7.00 – 9.30	7.00 – 9.30

3.2 Opening Hours

The above could change in August or during Christmas time

3.3 Reservations.

Centro Biomedico bergamasco due to the COVID 19 health emergency, according to regional legislation must limit accesses to avoid gatherings for which it provides the service by booking online only on the app.centrobiomedico.it/prenota site; fragile categories that are not able to book independently through the site can be helped by the reception staff after the sampling hour exclusively at the counter.

After the booking of particular exams such as Pap Tests, Vaginal and Urethral Swabs, Spermograms, Hair and Urine Tests for Drugs of Abuse, Salivary Cortisol, Quantiferon, Breath Test, Cystic Fibrosis, Prenatal Safe, Glycemic and Insulinemic Curve from patients are contacted by telephone for specific methods of preparation for the exam.

At the moment the pre-acceptance service is suspended both online and at the counter except for the municipal sampling center of Mozzo for which it is necessary to send an email with the referrals, all the personal data and a telephone number to be contacted for acceptance2 @centrobiomedico.it

DOMICILIARY WITHDRAWALS

The Bergamasco Biomedical Center offers a home collection service in the area at a cost of € 25 Those entitled can take advantage of the free withdrawal. To access the service, you must send an email to domiciliari@centrobiomedico.it or a whatsapp message to 3801786130 complete with personal data, all the requests with the required exams and a telephone number to be contacted.

3.4 HEALTH INFORMATION AND STAFF RELATIONSHIPS

DOCUMENTS REQUIRED

The user who wants to do tests under Convention conditions must have a request issued onto regional prescription book, the national services card, possible card free ticket, the taxpayer's code, while the private user must have a private prescription and taxpayer's code. Underage must be accompanied by parents or adult delegates, and have an identity card to make use of the services. Minors under the age of 14 years old are entitled to have services completely free apart from the total family income.

TICKET PAYMENT

The ticket will be paid once the user receives the report and the related invoice. For some types of exams (culture tests, ANA tests, etc.), an integration may be necessary to be paid when the report is collected. In this case, the online report withdrawal cannot be active. Please note the provisions of paragraph 18, Article 4 of Law 412/1991: The User who does not collect the results of the laboratory tests will be charged in full for the cost of the service used even if in possession of an exemption.

STAFF IDENTIFICATION

The user has the right to be informed about the identity and professional qualifications of people looking after him. The staff must show an appropriate identification card with name, surname and qualification

PRIVACY RIGHT

Privacy right is one of the basic rights of the user.

The treatment reserved to the user must be strictly confidential and therefore:

- all information about the user must be kept confidential;
- the whole laboratory staff, (also included the other samples centres), is obliged to keep the professional secret;
- staff who is not involved in test performance, is not allowed to consult the health records.

4. METHODS OF COLLECTION, STORAGE AND TRANSPORTATION OF SAMPLES

All information for the collection, storage and possible transport of the samples is available on the website: www.centrobiomedico.it

In special cases (for example bedridden patients) it may be necessary to collect biological samples at home and therefore it is important to pay the utmost attention to their storage and transport to the laboratory.

In such situations, it is essential to contact the laboratory in advance, which will provide information and material suitable for the collection of biological samples

4.1 SAMPLES TO BE COLLECTED AT HOME

Complete Urine Test.

Use a perfectly cleaned test tube, collect the urine early in the morning and deliver them quickly at the laboratory keeping them at room temperature.

Urine culture test

Urine collected early in the morning or the collection of a sample remained in the bladder for three hours at least.

Use a sterile container, (also available in pharmacy) after having cleaned the external genitalia with soap and after having rinsed them properly, collect urine by removing the first and the last sender. Close the container avoiding any contamination of the interior walls by hands. Rapidly deliver to the laboratory or refrigerate at 4 ° C for a maximum time of 12 hours.

24 hours' Urine

Use a suitable container. Discard the first morning urine, then collect all urine including those issued the next morning at time corresponding to the emptying of the bladder of the previous day. During the urine collection the container should be stored at + 4° C. Once the 24 hours' collection has finished, mix thoroughly and transfer a sample of it into a smaller container for urine indicating diuresis (total urine volume collected during 24 hours). Please note that the reliability of 24-hour analyzes is strictly dependent on correct collection..

Faeces collection for a complete and parasitological examination

Use a container with pallet (also available in Pharmacy). Pick-up 10 grams of faeces at least (corresponding to walnut volume) and place it into the container. Close perfectly and deliver it to the laboratory or store at +4° C for a maximum time of 12 hours.

Faeces collection for occult blood research

The kit and the collection instructions are supplied by the laboratory.

Please contact the Centro Biomedico Bergamasco in Bergamo for any clarification

5. SAMPLES CONSERVATION PERIOD IN CASE OF TESTS ADDITION OR REPEAT

Blood samples utilized for tests will be kept for about four days. Within this time it's possible for most parameters, to run checks on the previous report parameter or add additional tests, against the request of the doctor in charge.

6. REPORTING

6.1 REPORT FEATURES

The report contains personal data, date and unique code of the sample, type of examination, result, reference interval and digital validation signature. When considered important, comments or communications addressed to the treating doctors and / or patients are included.

Any reprints of previously reported exams are performed upon request and reported as a copy.

6.2 Procedures and delivery times for reports

ON LINE

a) In secretariat, before the sampling, the password and how to download the report from the company repository are provided. The link of the repository is <https://referti.centrobiomedico.it/>: the report remains available for 45 days from publication. It is specified that it is not necessary to collect the paper report at the laboratory headquarters once downloaded online from both the regional and laboratory repositories

b) The collection of the reports is possible online using the regional repository by accessing the website: www.crs.regione.lombardia.it and using the credentials for accessing your FSE (electronic health record). At Centro Biomedico Bergamasco it is possible to obtain the access credentials for one's FSE by providing informed consent

6.2 REPORTS CONDITIONS AND LEAD TIME

SEDI	BERGAMO	DALMINE	ALBINO	MOZZO	VILLA D'ALME'
GIORNI	Rotonda dei Mille 3/a	Via XXV Aprile	Via Mazzini 184	Via Verdi 2/c	Via Locatelli Milesi 5
LUN-VEN	Giorno stabilito: 16.00 – 18.30 nei giorni successivi 11.00 – 12.00 14.30 – 18.30	10.00-11.00	10.00-11.00	wednesday only 9:30-10:00	10.00-11.00

The above could change in August or during Christmas time.

- c) On request, the headquarters Laboratory could provide the user with urgent delivery at 12 am of the collection date except for partial or urgent reports (which can be collected online or in Bergamo's main laboratory).
- d) As soon as the acceptance is done, the user will be informed about the report delivery date, normally included between 1 and 3 working days from the date of sample. If the user is unable to collect the report at the fixed date, the report collection can be arranged afterwards as in schedule above
- e) If the user cannot collect the report personally, he must, in compliance with the law on the protection of privacy, fill in all parts of the proxy proposed in the report collection form.
- f) In the event of finding critical values during the analysis phase, the Laboratory Director or his delegate will promptly notify the attending physician according to Sibioc 2017 guidelines.
- g) All the tests concerning SARS COV 2 both serological and RNA research are communicated to the Lombardy region and the relevant ATS at the time of signing the report.

6.3 DELAYS

In case of delay in report delivery due to an unforeseen reason, the laboratory staff will try to limit the user's trouble, as much as possible making themselves available for any further information and when possible forewarning the user.

6.4 CHECK REQUEST OR FURTHER TESTS ENQUIRY

If the sample is still available, on request of the user's family Doctor, the laboratory performs further tests and/or controls; in this case a new request must be sent to the laboratory.

6.5 HISTORICAL REPORTS REQUEST

On customer request the tests previously performed can be printed again (as a copy). All analysis results performed for each patient and date of acceptance will be stored in the Laboratory computer system for 5 years. During this period a copy of the report within 24 hours can be required. Every day all patient data are stored in a disk, that's the reason why traceability for periods prior to 5 years is always possible.

7 CUSTOMER CARE

7.1 TECHNICAL AND CLINICAL QUESTIONS

The Laboratory Director or people in charge for doctors acts are responsible for answering questions about storage and transport of samples, methods and results and possible technical aspects of clinical questions.

7.2 GASS System (Simplified Access Management to Social Health Services)

Our Center is one of the structures authorized by the Lombardy Region to provide citizens with simplified access to SISS online services. The service is available from Monday to Friday during the report collection time. To be able to withdraw the password, a valid identity document and the CRS are required (it is not possible to access the service with expired health cards or provisional in paper form.)

7.3 CLAIMS MANAGEMENT

The Laboratory staff is committed to implement any complaints and to report them immediately to the manager of the Laboratory Quality Assurance who will put in action what is foreseen by the procedures for a quick problem solution. A form of non-conformity reports and customer complaints (RNC) is filled in and periodically subject to review by the Department in order to plan interventions improving the organization of the Laboratory. The protection of the user is guaranteed by the Laboratory and in case of inefficiencies, which could have limited or denied the performance availability, the user will have the opportunity to complain.

7.4 HOW TO MAKE A COMPLAINT

The user can complain directly c/o the Laboratory Director by going directly and/or Quality Assurance Manager by providing them orally with his remarks or by filling in the appropriate form (complaint form) available in the Services Card and distributed at the reception desk of the different sites. The form can be sent to:

Centro Biomedico Bergamasco - Laboratory Management - Rotonda dei mille, 3/A - 24122 Bergamo or put it into the proper box c/o each reception or sent to the following addresses:

info@centrobiomedico.it

urp@centrobiomedico.it

COMPLAINT FORM

ROTONDA DEI MILLE, 3/A BERGAMO
ADDRESSED TO THE Q.A. MANAGER
Dr. Silvia Monge
DIRECTOR
Dr. Eneina Radice

CLAIM REPORT/NOTICE

Name	Surname	
Address	Country	
Phone.		

Object:	
.	
Request:	
Date	Signature

8.1 PATIENT CORRECT SAMPLE IDENTIFICATION

At the acceptance a progressive bar code is assigned to each patient; printed labels with an identification code are stuck both onto the request and onto the blood tube, allowing in that way an univocal identification of the sample.

8.2 SAMPLE COMPLIANCE

The instructions for preparing for the blood collection are available in the waiting room, on the website <http://www.centrobiomedico.it> and it is always possible to contact the laboratory by phone to dispel any doubts.

External samples will be carefully evaluated because of possible non-conformity.

8.3 ANALYTICAL COMPLIANCE

Internal and external quality control programs foresee a test of reproducibility for each analysis. The Laboratory uses the internal QA in order to monitor the precision of the results and in case of not acceptable results, repeats the analysis and looks for causes and solutions of non-conformity. The Laboratory takes part in external Bio-Rad's QA for clinical Chemistry, coagulation, immunoassay, Oxoid for microbiology, Dasit for hematology and coagulation, Biomedical Research for glycated hemoglobin, urine and fecal occult blood and in the external QA of Lombardia Region.

- The comparison of samples measured with different methods (t test) is now part of the operators skill and allows an update of the methods used as well as a quality control of the methods used
- The internal quality controls, if in possession of data on biological variation, are processed in relation to the total error and the QA% trend is constantly monitored
- The Laboratory Director signature as well as the staff's graduate one, certifies that the report complies with the specifications of the agreement drawn up with users but it's also and above all a control of the data consistency obtained: the non-conformity even if apparent will be sometimes in depth by an analysis review, a possible re-execution of the same or a request for additional patient information in particular through dialogue with the family doctor

8.4 SERVICE COMPLIANCE

The constant, systematic and continuous improvement that is implemented daily in our laboratory takes into account the resources available, any requests from patients or GPs as well as national and international guidelines and training meetings promoted by scientific societies and industry leaders.

Patient satisfaction survey proposed by Lombardia Region

QUESTIONARIO AREA AMBULATORIALE
DOO Come ha conosciuto il centro?

<input type="checkbox"/> Già utente	<input type="checkbox"/> Consigliato da altri utenti	<input type="checkbox"/> Internet	<input type="checkbox"/> Brochure informativa	<input type="checkbox"/> Seat pagine gialle	<input type="checkbox"/> Altro
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DO1 Come ha prenotato?

<input type="checkbox"/> Telefonicamente	<input type="checkbox"/> Allo sportello	<input type="checkbox"/> Altro	<input type="checkbox"/> Non so	<input type="checkbox"/> Nessuna prenotazione
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QUANTO E' SODDISFATTO DEI SEGUENTI ASPETTI?
(indicare DA 1 per niente soddisfatto 😞 a 7 molto soddisfatto 😊)

DO2 Servizio di prenotazione e/o preaccettazione

1 😞	2	3	4 😊	5	6	7 😊
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DO3 Tempo di attesa dalla prenotazione alla data della prestazione

1 😞	2	3	4 😊	5	6	7 😊
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DO4 Servizio di accettazione amministrativa e pagamento ticket

1 😞	2	3	4 😊	5	6	7 😊
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DO5 Accessibilità e pulizia degli ambienti

1 😞	2	3	4 😊	5	6	7 😊
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DO6 Rispetto degli orari previsti

1 😞	2	3	4 😊	5	6	7 😊
-----	---	---	-----	---	---	-----

DO7 Attenzione ricevuta dal personale medico

1 😞	2	3	4 😊	5	6	7 😊
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DO8 Chiarezza e completezza delle informazioni e delle spiegazioni ricevute

1 😞	2	3	4 😊	5	6	7 😊
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DO9 Attenzione ricevuta dal personale infermieristico e/o Tecnico

1 😞	2	3	4 😊	5	6	7 😊
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D10 rispetto della riservatezza personale

1 😞	2	3	4 😊	5	6	7 😊
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D11 COMPLESSIVAMENTE QUANTO E' SODDISFATTO DEL NOSTRO SERVIZIO?

1 😊	2	3	4 😊	5	6	7 ☹
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D12 CONSIGLIEREBBE AD ALTRI QUESTA STRUTTURA?

1 😊	2	3	4 😊	5	6	7 ☹
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A13 M F

A14 ETA' _____

A15 ITALIANA EUROPEA EXTRA EUROPEA

SCOLARITA' NESSUNA SCUOLA OBBLIGO SCUOLA SUPERIORE LAUREA

SEDE BERGAMO ALBINO DALMINE VILLA D'ALME' VALBREMBO MOZZO