

I.R.C.C.S.
OSPEDALE SAN RAFFAELE

version October 2024

SERVICE CHARTER LABORATORY MEDICINE SERVICE

icc

The Service Charter is a document created in compliance with the Prime Ministerial Decree of 19 May 1995 "General outline of the Public Services Charter healthcare" and subsequent updates and represents the instrument with which the San Raffaele Hospital intends to establish a dialogue with its own patients, promoting their information, protection and participation. The information contained in the Service Charter is updated to October 2024. The Service Charter of the Medicine Laboratory Service of San Raffaele Hospital is connected via link to the site institutional <https://medicinadilaboratorio.hsr.it/>

It is possible that after the month of updating the Card yes check for changes to regulations, services or other information indicated in the document: it is possible to receive any clarifications or further information by telephone by contacting the Quality Manager Tel. 02.2643.4305.

Istituto di Ricovero e Cura a Carattere Scientifico



SUMMARY

General presentation	3
The story	4
The mission	4
The objectives	5
the Laboratory Medicine Service and the San Raffaele Hospital	5
The staff	6
The headquarters	7
How to reach us	7
The locations of the Withdrawal Points	8
Contacts	10
Information on the facilities and services provided	11
Areas of analysis	12
Access to services	13
How to carry out an exam	15
Preparation for exams	16
Rates and payment methods	17
Delivery times	18
Collecting reports	19
Online Report Collection	20
Quality standards, commitments and programs	21
Quality	22
Indicators	22



Objectives 22

Protection and verification mechanisms 23

Reporting of complaints 24

Rights and duties of users 25



General presentation

The story

The Laboratory Medicine Service of the San Raffaele Hospital has developed and differentiated since 1970 in specialized analysis sectors to include over 26 specialist branches; all equipped with instrumentation cutting-edge and capable of making use of the most modern diagnostic investigation techniques.

Since 1998 all sectors of the laboratory have been certified UNI EN ISO 9002, since 2002 UNI EN ISO 9001:2000, since November 2009 UNI EN ISO 9001:2008, since November 2017 UNI EN ISO 9001:2015 (Certifying Body Certiquality, certificate n° 1432).

The mission

We intend to carry out an effective, safe and appropriate Laboratory Medicine Service, based on the most recent ones scientific and technological acquisitions, efficient both in the containment of production times and in the use of resources, attentive to the full satisfaction of customers, both internal and external to the San Raffaele Hospital.

We want to promote Scientific Progress in the field of Laboratory Medicine, with particular focus on preventive and predictive medicine through

- Scientific contributions for the most authoritative international journals
- Invited participation in the most prestigious international scientific events
- Creation and protection of original know-how in specific areas

We deal with teaching Laboratory Medicine, both in scientific and managerial contents, first and foremost at the Ateneo Vita - Salute San Raffaele

The objectives

The mission is implemented daily through precise actions:

- get close to customers thanks to the withdrawal points located throughout the area and the withdrawal service at home;
- produce and provide laboratory analyzes with constant attention to the effectiveness and appropriateness of performance and their correct interpretation, as well as customer satisfaction;
- provide services in line with the most recent scientific and technological acquisitions and with maximum efficiency both in the containment of production times and in the use of resources;



- aim for excellence by developing scientific and technological-organizational research activities;
- place itself at the service of national and international institutions to centralize specialist exams in a laboratory facility of the highest quality.

The Laboratory Medicine Service and the San Raphael Hospital

As an integral part of the San Raffaele Hospital, it uses all the services provided by the Institute. The IT system is closely integrated with the hospital system: it is possible to request analyzes and display of results in real time at all sampling locations.

The staff is made up of around 200 operators including medical doctors, biologists, engineers, laboratory technicians and administrators; it comes from the San Raffaele Institute itself and is managed by the Personnel and Organization Directorate of the Hospital.

In collaboration with San Raffaele Hospital and Vita-Salute San Raffaele University, it shares three areas of intervention:

- Diagnostics

It guarantees its users a high number of diagnostic performances and the highest levels of safety in the pre- and post-analytical phase, as well as throughout the entire analysis process.

- Research

It carries out research in the context of the Biotechnology Department of the San Raffaele Scientific Institute, one of the major basic research centers in Italy and Europe. In collaboration with important companies pharmaceuticals and diagnostics develops research protocols in:

- Molecular Biology
- Medical Genetics
- Coagulation
- Virology
- Clinical Chemistry and Pharmacology

With the birth of the Faculty of Medicine and Surgery of the Vita-Salute San Raffaele University they came assign the Chair of Clinical Biochemistry to Prof. Giuseppe Banfi and prof. Tomaiuolo Rossella and D.ssa Chiara Di Resta,, the Chair of Microbiology and Virology to Prof. Roberto Burioni and to the I Prof. Nicola Clementi responsible of Molecular Microbiology and Virology.

The laboratories are home to internships for students of the Faculties of Medicine and Surgery of postgraduate courses and specialization schools.

The staff



The Laboratory Medicine Service has around 200 operators including doctors, laboratory technicians, researchers and administrators divided into the various laboratories and sectors of intervention.

- Director of the General Clinical Laboratory with specialist areas: Clinical Pathology and Substances of Abuse - Microbiology and Virology - Dr. Massimo Locatelli
- Director of the Medical Genetics Laboratory: Molecular Genetics and Cytogenetics – Dr. Paola Carrera
- Director of the Immunohematology Laboratory – Prof. Fabio Ciceri

- Quality Assurance system Manager: Dr. Annunziata Spina
- Procurement and logistics Manager: Dr. Iannace Giusy
- Laboratory informatics Responsible: Dr. Massimo Locatelli

The headquarters

The Laboratory Medicine Service is based at the IRCCS San Raffaele Hospital Palazzo S. Gabriele, Via Olgettina, 60 – Milan, Italy
Tel. 02.26431.2316

How to reach us

From Linate airport

Atm 923 bus to the terminus at San Raffaele Hospital

From Malpensa airport

Train or shuttle “Malpensa Express” then MM2, Cascina Gobba stop, + Bus Atm 925 towards Milan 2

(same ticket) or Automatic Metro indicating “San Raffaele” (additional ticket)

From Orio al Serio airport

Motorway or shuttle bus then MM2, Cascina Gobba stop, + Atm 925 bus towards Milan 2

(same ticket) or Automatic Metro indicating “San Raffaele” (additional ticket)

By public transport

MM2, Cascina Gobba stop, + Atm 925 bus towards Milan 2 (same ticket) or Automatic Metro indication “San Raffaele” (additional ticket)

By car

Eastern ring road:

- from the north, exit Cascina Gobba
- from the south, Segrate exit

The locations of the Withdrawal Points

Call Center: Tel. 02.2643.2316 Mon-Fri 8.30-16.00

- ZONE 1 – Historic Centre, at the Trenord railway station, Piazza Cadorna 14, Milan – tunnel commercial
- ZONE 2 – Central Station, Gorla, Turro, Greco, Crescenzago near San Raffaele Turro, Via Stamira D'Ancona 20, Milan
- ZONE 3 – Città Studi, Lambrate, Venice
- at San Raffaele Hospital, via Olgettina 60, Milan
- via Spallanzani 15, Milan
- ZONE 4 - viale Umbria 76, Milan
- ZONE 6 – Barona, Lorenteggio
- via Ponti 31, Milan
- via Solari 19, Milan
- ZONE 9 – Garibaldi Station, Niguarda, Bovisa, at the Cardinal Schuster Polyclinic, via Nicostrato



Castellini 7, Milan

- SAN DONATO MILANESE – METANOPOLI hamlet, at the San Raffaele clinic in San Donato Milanese, via A. De Gasperi 5a, San Donato Milanese (MI)
- Montenero - Viale Montenero 8, Milan

Contacts

SERVICE

Toll-free number: 800-232111 - opening hours: 10.00-12.00 and 14.00-16.00

Business Unit Secretariat: 02.2643.3488 - E-mail business.unit@hsr.it

CLINICAL TRIAL

Toll-free number: 800-232111 opening hours: 10.00-12.00 and 14.00-16.00

Clinical Trial Secretariat: 02.2643.4192 - hours: 8.00 -14.30 - trial.unit@hsr.it

SECRETARIAT

Tel. 02.2643.2316

Fax 02.2643.5919

FOR ADMINISTRATIVE INFORMATION

Tel. 02.2643.2316 - opening hours: 8.30 - 16.00

MEDICAL GENETIC

E-mail laboratorio.genetica@hsr.it

E-mail citogenetica.lab@hsr.it

Tel. 02 2643 2130, dalle 9.30 – 15.00

Information on the facilities e on the services provided

Settori di analisi Il Servizio di Medicina di Laboratorio esegue circa 1200 tipologie di analisi nei seguenti settori:

General Laboratory with specialistics areas – Director Dr. Locatelli Massimo

Clinical Chemistry, Coagulation , Work-cell automation , STAT TEST - responsible Dr. Andrea Motta

Protein e Urine - responsible Dr. Trbos Mladen

Autoimmune and Special immunochemistry test - Responsabile D.ssa Stefania Del Rosso

Ematology responsible Ematologia: Paola Ronchi

Molecular Ematology: Responsabile : D.ssa Tresoldi Cristina

Citofluorimetry - Responsible: D.ssa Raffaella Milani

Microbiologia, Responsible D.ssa Carletti Silvia

Virologia - Responsible D.ssa Racca Sara

Sierology - Responsible D.ssa Rolla Serena

Tossicology and Drugs abuse – Responsible Dr. ssa Sabetta Eleonare



Medical Genetics Laboratory: Molecular Genetics and Cytogenetics - Director: Dr. Paola Carrera
Molecular genetics – responsible Dr. Zanussi Monica
Cytogenetics – responsible Dr. Recalcati Paola

Immununoematology Laboratory – Director Prof. Ciceri Fabio

For information contact: 02 2643 2316

Access to benefits

To carry out a Laboratory Medicine exams, simply go to one of the sampling points without reservation required, on the days and times indicated.

(WITHDRAWAL) SAMPLING POINT

Central sampling room in San Raffaele Hospital - sector R and DIBIT room 2, floor - 1 (basement)
Via Olgettina 60, Milan - Tel. 02.2643.2316
Withdrawal times: Mon - Fri from 7.00 to 11.00 AM; Saturday (Central hall only) from 7.00 to 11.00 AM

SPALLANZANI SAMPLING POINT

Via Spallanzani 15, Milan - Tel. 02.9737.2987 - Fax: 02.3652.0761
Withdrawal times: Mon – Saturday from 7.30 to 10.30 AM

SAMPLING POINT

PONTI SAMPLING POINT Via Ettore Ponti 31, Milan - Tel. 02.8915.1916 - Fax: 02.8139.012
Sampling hours: Mon – Fri from 7.30 to 11.00; Saturday from 7.30 to 10.30 AM

SOLARI SAMPLING POINT Via Solari 19, Milan - Tel. 02.8940.3367 Sampling hours: Mon - Saturday from 7.30 to 10.30 AM

CADORNA SAMPLING POINT at Cadorna Station, Piazzale Cadorna, Milan - Tel. 02.860.770
Sampling times: Mon - Fri from 7.30 - 11.00 AM

SCHUSTER SAMPLING POINT at the Cardinal Schuster Polyclinic via Nicostrato Castellini 7, Milan - Tel. 02.2643.6300 Sampling hours: Mon - Saturday from 7.30 to 11.00 AM

S. DONATO SAMPLING POINT c/o Poliambulatorio di San Donato Milanese via De Gasperi 5, San Donato Milanese (MI) - Tel. 02.2643.5982 Sampling hours: Mon – Saturday from 7.30 to 11.00 AM

MONTENERO SAMPLING POINT – Viale Montenero 8, Milan. Sampling hours: Mon – Saturday from 7.30 to 10.30 AM



UMBRIA SAMPLING POINT - viale Umbria 76, Milan. Sampling hours: Mon – Saturday from 7.30 to 10.30 AM

TURRO SAMPLING POINT c/o San Raffaele Turro - via Stamira D'Ancona 20, Palazzina B, Milan (MI) - Tel. 02.2247.3220 - Sampling hours: Mon – Saturday from 7.00 to 11.00

How to do an exam

To carry out a test, simply go to one of the sampling points of the Laboratory Medicine Service OSR without the need for reservations, on the days and times indicated.

In most cases the tests do not require any special preparations, other than simple fasting before the blood sampling.

Reservation is only necessary for the following exams:

- spermograms (performed at the Birth Sciences Centre) (call 02 2643.6820)
- Sperm DNA fragmentation (call 02 2643.6820)
- vaginal swabs (call **02.2643.2643**)
- basophil degranulation test (batall or basotest) (call 02 2643.2643)
- complete HLA typing for bone marrow donation (call 02.2643. 2340)
- pre-test genetic counseling for informed consent (call the Call Center - Tel. 02.2643.2316)

The following tests are performed only on Tuesdays and Thursdays:

- hourly blood sugar levels
- circadian cortisol
- homocysteine after methionine loading

The following exams are not accepted on Saturdays:

- HIV DNA
- cytomegalovirus antigens
- EBV cell (EBV research on lymphocytes)
- Genetic Molecular Biology Test without informed consent
- Haematological Molecular Biology Test
- Cytology
- Spermograms
- Platelets antibodies

It is possible to make a booking request for laboratory tests at the San Raffaele offices through a few simple steps through the “Book Online” Online Booking Service.

It is also possible, by making a telephone reservation, to request PREPARATIONS for home collection.

Tel. 02.2643.2316 - Hours: from 8.30 to 16.00



Preparations for exams

In most cases the tests do not require any special preparations, other than simple fasting before the blood sampling.

In the case of the analyzes listed below, however, it is necessary to collect the sample as follows special preparation instructions

- Preparations for blood sampling
- Collection of urine for urine culture and complete urinalysis
- 24 hour urine collection
- 24 hour urine collection for measurement of urinary porphyrins
- 24 hour urine collection for the measurement of hydroxyindoleacetic acid, catecholamines and vanillylmandelic acid
- 24 hour urine collection for creatinine clearance
- 24 hour urine collection to measure urinary iron
- Urine collection to measure the albumin excretion rate
- 24 hour urine collection for hydroxyproline measurement
- 2 hours Urine collection for the measurement of pyridinolines + hydroxyproline
- Urine collection for cytological examination (container with preservative)
- Urine collection for cytological examination (container without preservative)
- 2 hours Urine collection for hydroxyproline measurement
- 2 hours Urine collection for the measurement of pyridinolines
- Urine collection for BK culture and microscopic examination for mycobacteria
- Collection of sputum for culture examination
- Sputum collection for BK research
- Collection of sputum for cytological examination
- Stool collection for: complete e.g., parasitological examination (only 1 sample), occult blood (only one sample), cover culture (container without preservative)
- Stool for parasitological examination on 3 samples (container with ecofix)
- Stool for occult blood on 3 samples (container with preservative)
- Collection of seminal fluid for spermiogram
- 5-hour urine collection to measure urinary xylose
- 24-hour urine collection method for the dosage of free and bound κ and λ light chains;
- Preparation for Breath Test;
- 24 hours urine collection method for oxalate dosage;
- Data collection for HLA typing for bone marrow transplant;
- Urine collection method for Chlamydia research;
- Method of urine collection for urine culture, complete urinalysis and Chlamydia research;
- Method of collecting sterile urine for urine culture using a bag (for child) applied at home;
- Preparation for urine collection to search for urinary parasites and *Schistosoma haematobium* (Bilharzia);
- 2 hours urine collection method for Calcium/Creatinine ratio;
- Sample collection mode for Intestinal Microbiome.



The forms containing the instructions are available in the blood sampling rooms or can be consulted on the website. It is possible to collect containers for the collection of biological samples (urine, feces occult blood) free of charge at the Sampling Points.
For information please call 02 2643.2316

Rates and payment methods

It is possible to carry out the tests in agreement with the National Health Service or in solvency. The payment operations for the ticket and the credit exam take place concurrently with the operations of acceptance of analyzes at all sampling sites.

For payment you can use cash, debit and credit cards.

It is possible to request information about the cost of services by calling the number indicated below.

Information calling 02 2643.2316 from 8.30 AM to 4.00 PM

NOTICE TO USERS

The provision of the Lombardy Region [Decree 32731 of 12.18.2000] gives the specialist the right to Laboratory to perform certain services, not expressly specified in the prescription, in this case are necessary for carrying out the requested test or for the correct completion of the diagnostic process.

This Decree allows us to provide a more complete service in a series of situations listed below without

the need for further samples or further requests from the treating doctor:

- positive culture tests => automatic execution of identification and antibiogram
- presence of electrophoresis anomalies => execution of immunofixation to identify the monoclonal component
- positivity of serological tests for HIV, HCV, LUE => execution of the relevant confirmatory tests
- positivity of anti-nucleus antibodies => automatic execution of the titration
- positivity to anti-neutrophilic granulocyte antibodies (ANCA) => Execution of anti-antibodies myeloperoxidase and anti-proteinase 3 (AAMPO, AAPR3)
- presence of blood group variants => Du variant execution

In all cases indicated the execution of any additional analyzes (which will be carried out only if Indispensable - they will not be repeated confirmatory tests in already known patients) may result in the payment of a co-pay additional fee which will be communicated and charged to you upon collection of the report.

It is therefore recommended to always show up when collecting the report with the previously paid invoice for the report possible regularization of the practice.

For any further clarification, please contact the analysis laboratory secretary Tel. 02.2643.2316.

Delivery times

The delivery date of the report is indicated on the analysis collection form.



Delivery times are between 1 and 4 business days for routine tests, but many results, are available already in a day.

If analyzes are required with production times greater than 4 working days, the report is divided into two parts: a first part immediately available and a second for long-term analyses. In this case to the user

two collection dates will be indicated. However, it will be possible to withdraw both practices at the end of the second delivery date.

By telephone contacting the secretariat it is possible to obtain a partial printout of the report, with the results ready until then.

No results are given over the phone.

Collection of reports

To guarantee respect for everyone's privacy, the reports will be delivered only to the person concerned (prior presentation of the appropriate collection slip and an identity document).

It is possible to make a delegation for collection using the appropriate space on the delivery slip.

The locations and delivery times of the reports are indicated below:

- Centralized delivery of reports to San Raffaele Hospital
Sector R floor minus 1, Galleria delle Botteghe, house number 26 - Tel. 02 2643.7799
Estimated delivery day: Mon to Fri: 3.30pm to 5.30pm
The following days: from Monday to Friday: from 9.00 to 17.30; Saturday from 8.30 to 12.00
- Self Service for the collection of laboratory reports only, accessible 24 hours a day including holidays at San Raffaele Hospital, Sector R floor minus 1, Galleria delle Botteghe, house number 26. To use the automatic service you must have the patient's health card and coupon with your withdrawal received at the time of the exam.
- Via Spallanzani 15, Milan
Mon – Fri from 11.00 to 13.30; Saturday from 11.00 to 12.00
- Via Ettore Ponti 31, Milan
Mon - Fri from 11.00 to 13.30; Saturday from 11.00 to 12.00
- Via Solari 19, Milan
Mon - Fri from 11.00 to 13.30 PM; On Saturday from 11.00 to 12.00
- via Nicostrato Castellini 7, Milan
Mon - Fri from 11.00 to 17.00; Saturday from 10.30 to 12.00
- at Cadorna Station, Piazzale Cadorna, Milan



Mon - Fri from 11.00 to 13.30

• via De Gasperi 5, San Donato Milanese (MI)

Mon – Fri from 11.00 to 17.00; Saturday from 11.00 to 12.00

• Viale Umbria 76, Milan

Mon - Fri from 11.00 to 13.30; Saturday from 11.00 to 12.00

• Via Stamira D'Ancona 20, Milan (MI)

Mon - Fri from 12.00 to 16.00 PM, Saturday from 8.00 to 12.00

• Viale Montenero 8 Milano

lun - ven dalle 11.00 alle 13.30; sabato dalle 11.00 alle 12.00

Given the characteristics of your computer system (reports printed at the time of delivery), in case of necessity, it is possible to collect the reports even in sampling point other than the one where the sample was taken.

It is important to present the appropriate collection slip and check the delivery times of the reports which are different in various sampling point.

Online Report Collection

San Raffaele Hospital has created a free service for viewing and downloading laboratory reports clinical analyses, called "Online Report Collection".

- From dall'Area dei Servizi Online of Gruppo San Donato;
- From App di Gruppo San Donato available on Play Store or App Store.

Quality standards, commitments and programs

Quality

The Laboratory Medicine Service has been UNI EN ISO 9002 certified since 17 July 1998, UNI EN since 20 July 2002, ISO 9001:2000 and since November 2009 UNI EN ISO 9001:2008, since November 2017 UNI ISO 9001:2015 (Body certifier Certiquality certificate n° 1432).

Quality Assurance Manager: D.ssa Annunziata Spina.



The ISO 9001 certification guarantees the laboratory's constant attention not only to type of analytical issues, but also to the entire organizational context that precedes, accompanies and follows the analysis.

- Pre-analytical phase: written procedures guarantee the correct identification, transport and conservation of biological samples.

- Analytical phase: the process is kept under control through careful preventive maintenance of the equipment and their constant calibration. The results are verified with Quality control programs for all

the analyzes carried out and participation in national and international External Quality Verification programmes (VEQ).

- Staff training is planned and controlled; the suppliers are carefully evaluated, the methods and the analytical instruments are carefully checked before being used in the routine.

- Post-analytical phase: strict procedures guarantee the correct attribution of results to users, promptly

reporting anomalous results, recording and managing any problems and complaints. One is guaranteed

constant attention and availability to user needs.

Indicators

The quality of the laboratories performance is constantly monitored:

- recording the number of patients called back to repeat the blood sample

- evaluating the causes that caused the need to repeat an examination

- considering delays in the delivery of reports and the related causes

- TAT according to Regional Indication

- using the number and type of complaints as indicators of the level of service and program data internal and external quality control as indicators of the analytical quality achieved.

Goals

It pursues a strategy of constant improvement of the service provided through improving the efficiency of the service with:

- strengthening of the network of sampling points in the area

- reduction of delivery times

- the continuous expansion of the menu of tests in the catalog by incorporating new types of exams

- improving communication with users by implementing an electronic signature process and creating a transmission of reports electronically



Protection and verification mechanisms

Reporting of complaints

Complaints are valuable opportunities for improvement and are managed according to a precise procedure. The user is invited to report all situations of unsatisfactory service and each complaint will be carefully examined.

You can lodge a complaint:

- by letter
- using the appropriate forms available in the Blood Testing Room or the Reports Secretariat
- by telephone to the Quality Office
- by telephone to the Reports Secretariat

The Laboratory Medicine Service undertakes to provide a response within three working days and, in cases more complex, indications within fifteen days.

If necessary, consequent corrective actions will be taken.

The Laboratory Medicine Service collaborates with the Public Relations Offices (URP) of the San Raffaele Hospital and San Raffaele Turro to resolve problems affecting the laboratory.

The Laboratory Medicine Service periodically collects the opinions of its users with specific questionnaires.

Patient privacy is guaranteed first and foremost by the ethics and professionalism of the operators and in any case from the use of computer systems protected by keywords according to the indications of the modified text of the Code in regarding the protection of personal data (Legislative Decree 196/2003), updated with the new legislative decree (Legislative Decree 101/2018) to adapt Italian legislation to the European regulation on privacy (EU Reg. no. 679/2016, GDPR).

Quality Assurance office (02 2643 4305), Reports Secretariat (02 2643 2316)

Rights and duties of users

The user has the right to:

- Receive the best possible service with the use of the most advanced technologies and scientific knowledge.
- Benefit from assistance provided in a professional and personalized manner.
- Receive complete information regarding the diagnostic tests to which he will be subjected.
- Be informed about possible alternative analyzes even if they can only be performed in other facilities.
- Have the guarantee of maximum confidentiality of personal data and data relating to the diagnosis.
- Be welcomed in a comfortable and hospitable structure that takes common habits into consideration.
- Express your opinion on the quality of the services and services provided and receive a prompt response, clear and comprehensive to any complaints.

and duty to:



- Collaborate with doctors and staff, providing clear and accurate information about your health.
- Demonstrate respect and consideration for the work of all staff by using kindness in relationships and reasonableness in requests.
- Avoid any behavior that could create situations of disturbance or discomfort for other users.
- Use the environments, equipment and furnishings of the Institute appropriately.
- Report any malfunctions found in order to contribute to improving the quality of services.
- Respect the smoking ban in all areas of the hospital and sampling points.