FACILITY SERVICE CHARTER

CENTRO DIAGNOSTICO
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CLINICAL CONTROL DIAGNOSTIC CENTER

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this document is prepared in accordance with the service charter displayed in the reception hall

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02	4.01.2024			
03				
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Rev.	DATA REV.	Emessa dal Responsabile Del processo	**Verificata dal RGQ**	**Approvata dalla DIR**

1. COMPANY PRESENTATION

The Company "Clinical Control S.r.l." was established in the year 1980, with the initial corporate name of "Centro Diagnostico Alarico S.r.l.", based in Cosenza, carrying out the activity of chemical-clinical analysis service for medical diagnostics.

During 1990 the corporate structure underwent a substantial transformation with the entry into the corporate structure of Dr. Emilio Cribari, a professional specializing in chemistry-clinical and toxicology, at the same time establishing the new headquarters in Taverna di Montalto Uffugo

The business is located in the town center, clearly visible from the road. The facility has been present for several years and can be defined as a reference point in the area for the health service offered.
The activity provides for the admission of disabled patients through the use of a freight elevator.
The services provided are in the field of laboratory diagnostics. The catchment area extends beyond the municipality of Montalto Uffugo, also involving neighboring towns.

It is an ANALYSIS LABORATORY is a BASIC GENERAL LABORATORY finally accredited by the Calabria region by Decree 909 of February 4, 2010 with the following specialized areas:
- CLINICAL CHEMISTRY
- TOXICOLOGY
- SEROIMMUNOLOGY
- MICROBIOLOGY

2. OUR KEY NATIONAL INDUSTRY LEGISLATIVE AND REGULATORY REFERENCES

- **D.Lgs. 30.12.1992, n. 502 -** *Reorganization of health care regulations, pursuant to Article 1 of Law No. 421 of October 23, 1992, as amended and supplemented.*
- **D.Lgs. 07.12.1993, n. 517** - *Amendments to Legislative Decree No. 502 of December 30, 1992, reorganizing the discipline in health care, pursuant to Article 1 of Law No. 421 of October 23, 1992.*
- **D.P.R. 14.01.1997-** *Approval of the act of guidance and coordination to the regions and autonomous provinces of Trento and Bolzano on minimum structural, technological and organizational requirements for the exercise of health care activities by public and private facilities.*
- **D.Lgs. 19.06.1999 n. 229 -** *Regulations for the rationalization of the National Health Service, pursuant to Article 1 of Law No. 419 of November 30, 1998.*
- **L. 27.12.2006 n. 296 -** (Finanziaria 2007) **art. 1 comma 796, lettere s), t), e u)** *On accreditation of private health care facilities.*
- **L. 08.03.2017 n. 24 -** *Provisions on the safety of care and the assisted person, as well as on the professional responsibility of health professionals.*
- **L. 27.12.2019 n. 160 -** *State budget for fiscal year 2020, Art. 1, Paragraph 446, abolition of cost-sharing fee for outpatient specialist care services (**c.d. Super Ticket**).*
- **D.P.C.M. del 27.01.1994 -** *Principles on the Provision of Public Services, which identifies the principles to which the provision of public services, including those carried out under concession or by agreement, must be progressively conformed to in general.* **D.P.C.M. 19.05.1995 -** *Schema generale di riferimento della Carta dei servizi pubblici sanitari.*
- **D.P.C.M. 12.01.2017** - *Definition and updating of the essential levels of care, referred to in Article 1, paragraph 7, of Legislative Decree No. 502 of December 30, 1992.*

- **Ministry of Health - Guidelines No. 2/95.** Implementation of the Service Charter of the National Health Service.

REGIONALS

- **L. R. 19.10.2004 n. 25** et seq. amendments - Statute of the Region of Calabria.
- **L. R. 18.07.2008 n. 24** - *Regulations on authorization, accreditation, contractual agreements and inspections of public and private health and social care facilities, as amended.*
- **L. R. 07.07.2022 n. 22** - *Measures to cope with the health emergency situation. Art. 1 Supplement to R.L. No. 24/2008.*
- **D.C.A. 22.07.2016 n. 81** - *New Implementation Regulations Regional Law 24/2008.*
- **D.C.A. 31.10.2017 n. 142** - *Amendment-integration of DCA No. 112 of Nov. 2, 2016 and Proposal No. 148 of Sept. 27, 2017 and related DCA No. 122 of Sept. 28, 2017 - P.O. 2016-2018, Program 2.1.5 Laboratory Network. Private Laboratories.*
- **D.C.A. 20.07.2018 n. 153** - *Amendment and Supplementation of DCA 89/2018 in application of DCA 142/2017. Update applications for Aggregation or Autonomous Activity- Regional Network Private Laboratories.*
- **D.C.A. 22.02.2019 n. 36** - *Defining maximum funding levels to Provincial Health Boards for the purchase of outpatient specialty care services at the expense of the SSR- Year 2019.*
- **D.C.A. 05.05.2021 n. 68** - *Amendment and Supplementation of DCA 82/2020 in application of DCA 142/2017. Update applications for Aggregation or Autonomous Activity- Regional Network Private Laboratories.*
- **D.C.A. 19.03.2021 n. 50** - *Defining maximum funding levels to provincial health agencies for the purchase of services provided by the accredited private outpatient specialist network at the expense of the SSR- Year 2021.*
- **D.C.A. 22.03.2021 n. 51** - *Proceedings for renewal of institutional accreditation. Determinations for the year 2021.*
- **D.C.A. 16.03.2022 n. 22** - *Amendments and additions to DDCA No. 82/2020 and No. 68/2021- Update deadline for compliance with the expected standard (performance threshold at 200 thousand laboratory examinations per Dispensing Center) - Update lists related to applications for aggregation or autonomous activity for the year 2021 - Regional Network Private Laboratories.*
- **D.C.A. 18.11.2022 n. 162** - *Approval of Operational Program 2022-2025 prepared pursuant to Article 2, Paragraph 88 of Law No. 191 of December 23, 2009, as amended.*
- **D.C.A. 24.01.2023 n. 39** - *Amendment and supplementation of DDCA No. 68/2021 and No. 22/2022 - Update of the list of accredited private laboratories related to applications for aggregation or independent activity for the year 2022 - Regional Network Private Laboratories.*
- **D.D.G. 04.02.2010 n. 909** - *Final Accreditation of Private Health and Social Care Facilities in the Region of Calabria.*
- **D.D.G. 24.03.2010 n. 3854** - *Final Accreditation of Private Health and Social Care Facilities in the Region of Calabria: Update.*
- **D.G.R. 14.09.2004** - *Amendments and additions to Resolution No. 478 of July 13, 2004, of the Regional Council on the approval of procedures and methods for the formulation and submission of applications for authorization and accreditation of public and private facilities and facilities of professionals subject to authorization.*
- **D.G.R. 05.04.2008 n. 275** - *Reconnaissance measure of health and social care facilities.*
- **D.G.R. 05.05.2009 n. 247** - *Approval of the Regulation on Health Care Cost Sharing - co-payment.*
- **D.G.R. 02.09.2009 n. 545** - *Regulations and manuals for accreditation of the regional health care system-noting opinion regional council.*
- **D.D.G. 17.12.2007 n. 21269** - First registry, provisional, of public health facilities.
- **Circular n. 1 del 2017 prot. n.137662** - Issuance of health permits by municipalities.

<u>OTHER FUNDAMENTAL MANDATORY STANDARDS:</u>

- **D.lgs. 09.04.2008 n. 81** - Workers' Health and Safety Consolidation Act.
- **Reg. UE n. 2016/679** of the European Parliament and of the Council of April 27, 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of

such data and repealing Directive 95/46/EC (General Data Protection Regulation) and Legislative Decree 30/06/2003 no. 196, Code on the Protection of Personal Data laying down provisions for the adaptation of the national system to Regulation (EU) No. 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC.

- **D.M. 37/08** - Regulatory text Plant Safety.
- **D.lgs. 08.06.2001 n. 231** - Discipline of the administrative responsibility of legal persons, companies and associations, including those without legal personality, pursuant to Article 11 of Law No. 300 of 29.09.2000.
- **L. 07.08.1990 n. 241** - New rules on administrative procedure and right of access to administrative documents.

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- **UNI EN ISO 9001:2015 (Quality Management System)**

3. ORGANIGRAM

NAME	MANSION
SANTO SERGI	physician
CRIBARI EMILIO	Technical director
LIRANGI VITTORIA	Biologist
SPINA ROSSELLA	Biologist
GUIDO FIORINA	Secretariat
GUIDO ELENA	Secretariat
MIRAGLIA MONICA	Laboratory technician
BENINCASA TIZIANA	nurse
CRIBARI VANESSA	Administrator
GINESE ASSUNTA TERESA	Biologist
MILETO ANTONINO	Laboratory technician
PETRUZZELLI ANTONIETTA	Nurse
FOGLIA SAVERIO	secretary
POENARU MARIA	Housekeeper
FUNARO VINCENZO	Professional apprentice
PISARRO FRACESCO MARIA	Professional apprentice

4. LIST OF SERVICES

The complete list of examinations that can be performed at the laboratory can be viewed at the reception desk.

5. HEALTH TICKET

Health services are subject, according to the latest regional provisions set forth in Regional Council

Resolution No. 247/09, subject to exemptions, to the payment (ticket) of an additional fixed fee equal to the tariff value of individual services according to the national tariff nomenclator for time in force, up to the maximum limit for each prescription of € 45.00 in addition to the fixed fee of € 1.00 per prescription.

Article 1, paragraph 446, of Law 160/2019 provided for the abolition, as of next September 1, of the so-called "super co-payment," regardless of the date of prescription of the prescription, with the aim of promoting greater equity in access to care, on the national territory. The abolition of the super co-payment paid for healthcare services is, therefore, contained in the Budget Law 2020, and is part of a package of measures adopted in the healthcare sector.

The healthcare super co-payment was introduced by Law 296/2006 and provided for the payment of a share in the cost of outpatient specialist healthcare services equal to 10.00 euros (the so-called "prescription fee"). This amount was due, it should be recalled, by non-exempt citizens, and has been applied over time in different ways depending on the region.

Therefore, as of September 1, 2020, the so-called super co-payment for outpatient specialist services provided, nationwide, was abolished.

Exemptions from co-payment:
Current regulations provide for exemption from co-payment for certain categories. In order to be granted the right to exemption for pathology, disability or organ transplantation, it is necessary to go to the administrative offices of the competent District Service and request an appropriate certificate to be shown to the family doctor and the ASL. In the case of persons who are disabled or unable to move, documentation can be completed at home and delivered on behalf of others to the appropriate offices.

The necessary documents, to be submitted to these offices, are:

- the statement of the specialist doctor of a public facility certifying the pathology or documentation attesting to the disability condition
- the health card
- the social security number

In addition, the attending physician must indicate on the prescription slip the exemption code for the above categories and also the exemption code for pregnant women.

6. EXEMPTIONS

EXAMINATIONS EXEMPT FROM CO-PAY IN PREGNANCY
(D.M. 10.09.1998- ALLEGATO B- pubb. G.U. 20/10/1998 n. 245)

Exempt services by the 13th week and, in any case, at the first checkup when indicated by the physician:

- Hemochrome: Hb, GR, GB, HCT, PLT, IND. DERIV., F. L. H.;
- ABO SANGUAGE GROUP and Rh (D), when not performed preconceptionally.
- ASPARTATE AMINOTRANSFERASE (AST) (GOT) [S];
- ALANINE AMINOTRANSFERASE (ALT) (GPT) [S/U];
- VIRUS ROSOLIA ANTICORPI: in case of negative IgG, by week 17;
- TOXOPLASMA ANTICORPI (E.I.A.): in case of negative IgG repeat every 30-40 days until delivery;
- TREPONEMA PALLIDUM ANTICORPI (Quant. search by passive hemagglutin.) [TPHA]: if not performed in preconceptional function extended to partner;
- TREPONEMA PALLIDUM ANTICORPI ANTI CARDIOLIPIN (Flocculation) (VDRL) (RPR): when not performed in partner-extended preconceptional function;
- VIRUS IMMUNODEF. ACQUIRED [HIV 1-2] ANTIBODIES;
- GLUCOSY [S/P/U/dU/La];
- URINE PHYSICAL CHEMICAL AND MICROSCOPIC EXAMINATION;
- INDIRECT COOMBS TEST (in case of Rh negative women the test should be repeated monthly; in case of AB0 incompatibility the test should be repeated at 34th to 36th week)

Exempt services between the 14th and 18th weeks

- URINE PHYSICAL CHEMICAL AND MICROSCOPIC EXAMINATION

Exempt benefits between the 19th and 23rd weeks

- URINE PHYSICAL CHEMICAL AND MICROSCOPIC EXAMINATION

Exempt services between the 24th and 27th weeks

- GLUCOSE
- URINE PHYSICAL CHEMICAL AND MICROSCOPIC EXAMINATION

Benefits exempt between 28th and 32nd week

- HEMOCROMO: Hb, GR, GB, HCT, PLT, IND. DERIV., F. L.
- FERRITINE [P/(Sg)Er]: if mean globular volume is reduced
- URINE PHYSICAL CHEMICAL AND MICROSCOPIC EXAMINATION

Exempt services between 33rd and 37th weeks

- VIRUS EPATITE B [HBV] ANTIGENE HBsAg
- HEPATITIS C VIRUS [HCV] ANTIBODIES
- HEMOCROME: Hb, GR, GB, HCT, PLT, IND. DERIV., F. L.
- URINE PHYSICAL CHEMICAL AND MICROSCOPIC EXAMINATION
- VIRUS IMMUNODEF. ACQUIRED [HIV 1-2] ANTIBODIES in case of anamnestic risk

Exempt services between 38th and 40th weeks

- URINE PHYSICAL CHEMICAL AND MICROSCOPIC EXAMINATION

IN CASE OF THREATENED ABORTION ARE TO BE INCLUDED ALL SPECIALIST SERVICES NECESSARY FOR MONITORING THE 'EVOLUTION OF PREGNANCY.

EXEMPTION RELATED TO HEALTH STATUS

n.	Tipologia di esenzione	Cod.	SubCod.	Note	Quota Fissa di 1 € a ricetta
1	Soggetti affetti da patologie croniche e invalidanti esenti ai sensi del D.M. 28,05,1999 n. 329 e succ. modifiche e integrazioni (ultimo D.M. 21,5,2001 n. 296)	**0** malattie croniche	da 01 a nn	*Vedi Nota (1)*	
2	Soggetti affetti da patologie rare esenti ai sensi del D.M. 18,05,2001 n. 279	**R** Rare	da Aannn a Qannn	*Vedi Nota (2)*	
3	Prestazioni richieste su sospetto diagnostico di malattia rara (ex art. 5 comma 2 del D.M. 18,05,2001 n. 279).		99	*Vedi Nota (3)*	
4	Invalidi di guerra appartenenti alle categorie dalla 1a alla 5a titolari di pensione diretta vitalizia e deportati in campo di sterminio (ex art. 6 comma 1 lett. a del D.M. 01,02,1991)	**G** Guerra	01		
5	Invalidi di guerra appartenenti alle categorie dalla 6a alla 8a (ex art. 6 comma 2 lett. A del D.M. 01.02.1991)		02		
6	Grandi invalidi del lavoro -dall'80% al 100% di invalidità - (ex art. 6 comma 1 lett. B del D.M. 01,02,1991)	**L** Lavoro	01		

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7	Invalidi del lavoro con riduzione della capacità lavorativa > 2/3 - dal 67% al 79% di invalidità - (ex art. 6 comma 1 lett. b del D.M. 01,02,1991)	S Servizio	02		*
8	Invalidi del lavoro con riduzione della capacità lavorativa < 2/3 - dall'1% al 66% di invalidità - (ex art. 6 comma 2 lett. b del D.M. 01,02,1991)		03		*
9	Infortunati sul lavoro o affetti da malattie professionali (ex art. 6 comma 2 lett. c del D.M. 01,02,1991)		04		
10	Grandi invalidi per servizio appartenenti alla 1a categoria - titolari di specifica pensione - (ex art. 6 comma 1 lett. c del D.M. 01,02,1991)		01		
11	Invalidi per servizio appartenenti alle categorie dalla 2a alla 5a (ex art. 6 comma 1 lett. c del D.M. 01,02,1991)		02		*
12	Invalidi per servizio appartenenti alle categorie dalla 6a alla 8a (ex art. 6 comma 2 lett. d del D.M. 01,02,1991)		03		*
13	Obiettori di coscienza in servizio civile (ex art. 6, comma 1, L. 8 luglio 1998, n. 230)		04		*
14	Invalidi civili al 100% di invalidità senza indennità di accompagnamento (ex art. 6 comma 1 lett. d del D.M. 01,02,1991)	C Civili	01		
15	Invalidi civili al 100% di invalidità con indennità di accompagnamento (ex art. 6 comma 1 lett. d del D.M. 01,02,1991)		02		
16	Invalidi civili con riduzione della capacità lavorativa > 2/3 - dal 67% al 99% di invalidità - (ex art. 6 comma 1 lett. d del D.M. 01,02,1991)		03		*
17	Invalidi civili minori di 18 anni con indennità di frequenza ex art. 1 L. n. 289/90 (ex art. 5 comma 6 del D.Lgs. 124/1998)		04		
18	Ciechi assoluti o con residuo visivo non superiore ad un decimo ad entrambi gli occhi - con eventuale correzione - riconosciuti dall'apposita Commissione Invalidi Ciechi Civili - ai sensi dell'art. 6 comma 1 lett. f del D.M. 01,02,1991 - (ex art. 6 L. n. 482/68 come modificato dalla L. n. 68/99)		05		
19	Sordomuti (da intendersi coloro che sono colpiti da sordità dalla nascita o prima dell'apprendimento della lingua parlata) - ai sensi dell'art. 6 comma 1 lett. f del D.M. 01,02,1991 - (ex art. 7 L. n. 482/68 come modificato dalla L. n. 68/99)		06		
19bis	Prestazioni richieste in sede di verifica dell'invalidità civile ex D.M.20,7,1989, n. 293 e succ. mod.		07		*

20	Pazienti in possesso di esenzione in base alla L. n. 210 del 25,02,1992 -Danneggiati da complicanze di tipo irreversibile a causa di vaccinazioni obbligatorie, trasfusioni e somministrazione di emoderivati - (ex art. 1 comma 5 lett. d del D.Lgs. 124/1998)	**N** Legge n. 210	01		
21	Vittime del terrorismo e della criminalità organizzata (ex art. 15 L. n. 302/90 art. 5 comma 6 del D.Lgs. 124/1998) vittime del terrorismo e delle stragi di tale matrice con invalidità < 80% e loro familiari (ex art. 9 della l. 206/2004), vittime del dovere e familiari superstiti (ex.dPR 7 luglio 2006, n. 243)	**V** Vittime	01		
21bis	Vittime del terrorismo e delle stragi di tale matrice con invalidità > 80% (art. 4, legge 3,8,2004, n. 206)		02		
22	Esente per stato di gravidanza (ex D.M. del 10/09/1998)- in epoca pre-concezionale	**M** Maternità	00		
23	esente per stato di gravidanza (ex D.M. del 10/09/1998) - in gravidanza ordinaria oppure		da 01 a 41	così composto: M + nn (settimana di gravidanza)	
24	Esente per stato di gravidanza (ex D.M. del 10/09/1998) – in gravidanza ordinaria		99	*Vedi Nota (4)*	
25	Esente per stato di gravidanza (ex D.M. del 10/09/1998) - in gravidanza a rischio		50		
25bis	Ulteriori prestazioni in gravidanza erogate al personale navigante		52		
26	Prestazioni diagnostiche nell'ambito di campagne di screening autorizzate dalla Regione (ex art. 1 comma 4 lett. a del D.Lgs. 124/1998)	**D** Diagnosi precoce	01		
27	Prestazioni diagnostiche per la diagnosi precoce dei tumori (ex art. 85 comma 4 della L. 388/2000) - citologico		02		*
28	Prestazioni diagnostiche per la diagnosi precoce dei tumori (ex art. 85 comma 4 della L. 388/2000) - mammografico		03		*
29	Prestazioni di diagnostiche per la diagnosi precoce dei tumori (ex art. 85 comma 4 della L. 388/2000) - colon-retto		04		*
30	Prestazioni di approfondimento diagnostico correlate alla diagnosi precoce del tumore della mammella (ex art. 85 comma 4 della L. 388/2000)		05		*
30bis	Prestazioni incluse nel protocollo della campagna di monitoraggio sulle condizioni sanitarie dei soggetti operanti nei territori della Bosnia-Herzegovina e del Kosovo (ex d.m. 22		06		*

	ottobre 2002)				
31	Prestazioni specialistiche correlate all'attività di donazione (ex art. 1 comma 5 lett. c del D.Lgs. 124/1998)	**T** donazione	01		
32	Prestazioni diagnostiche a soggetti a rischio di infezione HIV (ex art. 1, comma 4 lett. b del D.Lgs. 124/1998 – prima parte)	**B**Hiv	01		
33	Prestazioni specialistiche finalizzate alla tutela della salute collettiva, disposte a livello locale in caso di situazioni epidemiche (ex art. 1 comma 4 lett. b del D.Lgs. 24/1998 – seconda parte -)	**P** Prevenzione	01		
34	Prestazioni specialistiche finalizzate all'avviamento al lavoro derivanti da obblighi di legge e non poste a carico del datore di lavoro – attualmente eseguibili nei confronti dei soggetti maggiorenni apprendisti - (ex art. 1 comma 4 lett. b del D.Lgs. 124/1998 – ultima parte -)		02		*
35	Prestazioni correlate alla pratica vaccinale obbligatoria o raccomandata (ex art. 1 comma 4 lett. b del D.Lgs. 124/1998 – prima parte -)profilassi antitubercolare ex DPR 7 novembre 2001, n. 465		03		
36	Prestazioni a favore di detenuti ed internati (ex art. 1, comma 6, D.Lgs. 22. 6. 1999 n. 230)	**F** detenuti	01		
37	Prestazioni richieste per il rilascio di certificati di idoneità alla pratica sportiva, all'adozione e affidamento, allo svolgimento del servizio civile (ex D.P.C.M. 28 novembre 2003)	**I** Idoneità	01		*
38	Prestazioni medico legali ai naviganti in ambito SASN	**PML**		*Vedi nota (5)*	*
39	Prestazioni ambulatoriali urgenti o comunque essenziali ai cittadiniextracomunitari non in regola con le norme relative all'ingresso e al soggiorno, privi di risorse economiche sufficienti (art. 35, c. 3, D.lgs. 25 luglio 1998, n. 286; art. 43, comma 4, DPR 31 agosto 1999, n. 394.	**X** Extracomunitari	01	*Vedi nota (6)*	
40	Terapia del dolore severo	**TDL**	01	*Vedi nota (7)*	

Notes to Tab. 1

Note (1) The characters identifying the exemption (code+sub-code) correspond to the first 3 digits of the exemption condition identification code (ONN - where N represents a number). For "Diseases of the circulatory system" and "Hypertensive disease," the code consists of 4 characters: 0A02 for "Diseases of the heart and pulmonary circulation"; 0E302 for "Cerebrovascular diseases"; 00O2 for "Diseases of the arteries, arteries, capillaries, veins, lymphatic vessels"; 0A31 for "Hypertension"; 0031 for "Hypertension in the presence of organ damage

Note (2) The identifying characters of the exemption (code+sub-code) are 6 and correspond to the complete identification code of the disease or group of diseases: according to the prevailing scheme RAANNN (where A represents an alphabetic character and N represents a numeric character)

Note (3) In the case of subjects for whom a diagnostic suspicion of a rare disease has been formulated by the specialist, the indication of the R code and sub-code 99 is sufficient. The same identifying characters should be used for coding genetic investigations of the patient's family members when necessary to diagnose (to the patient) a rare disease of hereditary origin.

Note (4) Alternative code that can be used by the GP, if the same doctor is not operationally able to quantify exactly the week of gestation of the patient. also because of the long periods between the date of prescription and the date of ercgation of the requested specialist service. In this case, the verification of the correlation between ia week of pregnancy and the type of service requested, for the purpose of exemption from health care expenditures, would be the responsibility of the dispensing facility.

Note (5) The medico-legal services provided free of charge to maritime and air sailors enrolled in the SASN under the PML code (M.D. February 22, 1984 and other technical regulations in the field), including specialist services and instrumental and laboratory diagnostics related to the formation of the medico-legal judgment, are: preventive embarkation examination for seafarers with seaman's booklet, of Italian, foreign or stateless nationality; preventive embarkation examination for those embarking as personnel in the service of the ship, embarking with passport of Italian or foreign nationality on ships flying the Italian flag; biennial periodic examinations of seafarer fitness; examinations for the issuance or renewal of aviation licenses and certificates (for only 1st and 2nd class personnel in constant employment in civil aviation; diagnostic examinations required by the Permanent Medical Commission of 1st degree; diagnostic examinations required by the I. M.L. in extraordinary examination: disembarkation examination for illness occurring during the period of embarkation (or arising within 28 days of disembarkation for seafarers embarked or for personnel embarked in the service of the ship and enrolled at I.P.Se.Ma.); issuance of a judgment of fitness or unfitness for work.

Note (6)11 code X01 should be used when the assisted foreign national does not enjoy, for other title (e.g. pregnancy, chronic illness, etc.) of the exemption from participation in expenditure

Note (7)The code TDL must be used on the prescription for the prescription of drugs for the treatment of severe pain in the course of neoplastic or degenerative pathology for a therapy not exceeding thirty days. 11 same code may be used by the regions for the purpose of exemption on the cost-sharing fee.

Note (8) A fixed fee of lE per prescription is payable for services marked with an asterisk.

7. HOW LONG YOU NEED TO WAIT TO ACCESS EXAMS; WHEN YOU CAN PICK UP EXAMS; HOW TO BOOK EXAMS.

It is possible to take examinations every morning Monday through Friday from 7:30 a.m. to noon and from 4 p.m. to 6 p.m. Examinations can be picked up in relation to what is indicated on the receipt given at the time of acceptance, within a time that can vary from 1h to 8 days (average time 2 days), depending on the type of examination and urgency, Monday through Friday from 7:30 am to 6 pm and Saturday from 7:30 am to 1 pm

After verification of identity and possible right to exemption to co-pay, personal data, upon explicit written consent in accordance with EU Regulation 2016/679, are recorded on the computer.
A copy of the acceptance document accompanies the patient to the collection room and is given to the patient as an indispensable receipt to collect the reports or to delegate a trusted person.
In addition, the reports can be sent online, upon appropriate consent and according to a procedure that will be explained by the staff present in the reception to the user concerned.

8. THE DOCUMENTATION NEEDED TO PERFORM THE EXAMINATIONS AND HOW TO KNOW IF YOU ARE ELIGIBLE FOR A CO-PAY EXEMPTION

In order to perform a diagnostic assessment under the convention system, it is necessary to present, at the time of acceptance, the referral from the attending physician, complete with the user's data, accompanied by an ID and health card. To find out the categories that are entitled to exemption from co-payment, information can be requested from the acceptance staff, or consult Regional Resolution No. 247/09, D.C.A. No. 150 of 10.11.2017, D.P.C.M. 12.01.2017, definition and updates of the essential levels of care (chronic and rare diseases) and annexes, published in Ordinary Supplement No. 15 G.U. General Series No. 65 of 18.03.17.
Only income exemption cases must be self-certified to the ASP by the user with the ISEE declaration. To find out what the costs of determinations are, you can consult the "list of examinations" at the reception desk or ask the acceptance staff for a quote.

9. PRIVACY

The analytical laboratory guarantees the protection of privacy in accordance with the provisions of EU Regulation 2016/679 and Legislative Decree 196/2003.
During acceptance, in fact, the patient must affix his signature, after careful reading, on the form "Information pursuant to Art. 13 of EU Regulation NR. 679/2016," in which the inconveniences that may occur as a result of venous sampling are also described. Failure to sign will not authorize us to process the patient's personal data and therefore will not allow us to offer the requested services.
(Please refer to the information below).

10. INFORMATION PURSUANT TO ART. 13 OF EU REGULATION NR. 679/2016.

We hereby inform you that EU Regulation No. 679/2016, together with Legislative Decree 101/18, provides for the protection of persons and other subjects with regard to the processing of personal data. According to the aforementioned legislation, the processing of your personal data, by our Organization will be based on the principles of (Art. 5 GDPR):
- fairness, lawfulness and transparency,
- purpose limitation,
- minimization of data,
- accuracy,
- limitation of storage,
- integrity and confidentiality,
- accountability,

and general protection of the confidentiality of personal identity. Pursuant to Article 13 of EU Regulation No. 679/2016, we provide you with the following information:

Subject

The nature of the service you have requested from our Organization, requires that you provide us with certain of your personal data, necessary for the provision of the service. The data requested from you are:
- specific information on the health service requested (prescription or prescription);
- data on the income bracket (exemption code) in order to take advantage or not of certain exemptions;
- identification data (First and Last Name, place and date of birth, social security number);
- health card and ID;
- name and contact information of primary care physician;
- contact information (location, telephone number and e-mail address);
- information about the technique for collecting the biological sample;
- information about any known diseases or allergies, if inherent in the tests requested;
- for women of childbearing age, date of last cycle where necessary for the specific service requested.

These data are the minimum necessary, and their provision is essential to proceed to provide you with the requested service. The service provided will bring our Organization and you to know additional personal data about you, related to your health status, as it relates to the service itself. These are:
- values of the biological parameters you requested;
- evaluation of the same according to reference scales and methods.

Method of processing

Your personal data, collected for the purposes set forth below, will be processed as follows:
- collected verbally during acceptance (those conferred);
- recorded in the company's computer system and on paper templates (both those conferred and those determined by analytical activities);
- archived, for the time indicated below:

o in access-controlled rooms those paper ones;
o on company server those dematerialized;

- communicated, as indicated below, for reasons related to the service you requested;
- deleted after the storage time.

Purpose of processing and legal basis

Your personal and health-related data will be processed exclusively for the following purposes:
- to provide the service you have requested from our Organization;
- To report the activities performed to the organs of the N.H.S. for accounting purposes;
- to maintain, for the time required by law (National and Regional) the specific data collected, to protect your health;
- for the administrative-accounting fulfillments of the enterprise in accordance with obligations under tax regulations.

The legal basis of reference for the purpose of processing your data is provided by the National and Regional Public Health Regulations and tax regulations.

The processing of your data requires that we obtain your specific written consent. Should you not wish to give it, we will not be able to provide you with the requested service.

Recipients or Categories of recipients of personal data

Your personal and health-related data will be disclosed to the following parties for the purpose of performing the requested services and for the purposes indicated above:
- ASP responsible for the area, for purposes of accounting reporting and monitoring of public expenditure;
- External service where applicable in order to process requests not directly handled by our Organization;
- to our collaborators and employees specifically appointed and within the scope of their duties;
- to family members of the data subject upon his/her delegation.

Your only personal data will be communicated to the following subjects to take care of the administrative-accounting management of the company according to the obligations provided for by the fiscal regulations, or to protect our rights:
- natural and/or legal persons collaborating with our Organization to whom we are required by law to communicate the data, or if such communication is necessary to protect a legitimate interest of the Data Controller.

The data collected are not subject to dissemination.

Why is the communication of data required

The communication of the data you provide to the above-mentioned parties is:
- a legal obligation, provided for by National and Regional regulations, as far as the ASP is concerned;
- a contractual obligation, provided for by the agreements with our Organization, as far as the Service is concerned;
- a legal obligation, provided for by National legislation, with regard to fiscal aspects to the individuals who deal with them for our Organization;

The interested party has the obligation to provide the requested personal data. Failure to provide the data means that we cannot provide the requested service.

Intentions of the Data Controller

For the same purposes, the data in question will not, however, be transferred outside the national territory.

Period of data retention or criteria for choosing the period

The retention period of your data, indicated in the Register of Processing Activities, is established by the National and Regional regulations on public health, and is differentiated in relation to the type of data and its importance. Where such regulatory indication does not exist, the criterion for defining the period of data retention is that it should not exceed a period of time that exceeds the achievement of the purposes of processing.

Rights of the data subject

Pursuant to Article 13 paragraph 2 letter b) you have the right at any time to request from the Data Controller access to your personal data, their rectification, deletion, restriction of data processing, as well as to object to the processing itself, and you have the right to data portability.

Additional rights of the data subject

Pursuant to Article 13 paragraph 2 letter c) you have the right at any time to ask the Data Controller to revoke the consent initially given, without affecting the lawfulness of the processing based on the consent given before revocation.
Pursuant to Article 13 paragraph 2 lett. d) you have the right at any time to lodge a complaint with a Supervisory Authority.

Automated processes

There are no automated decision-making processes that process your data, including profiling.

Data Controller and its Representative, Data Processor

The Data Controller (the one who determines the purposes and means of the processing of personal data) is the CENTRO DIAGNOSTICO CLINICAL CONTROL- Corso d'Italia 154, Taverna di Montalto Uffugo, (CS
The legal representative of the Data Controller as well as the Data Processor is Dr. Emilio Cribari

MANIFESTATION OF CONSENT TO THE PROCESSING OF DATA OF THE DATA SUBJECT
(art. 7 EU Regulation No. 679/2016)

The Undersigned

❑ As interested party	❑ As the Legal Guardian of the Interested Party:

❒ Gives consent ❒ Withholds consent
to the processing of personal data in the manner and for the purposes indicated in the notice.

❒ Gives consent ❒ Withholds consent
to the processing of health-related data in the manner and for the purposes indicated in the information notice.

❒ Gives consent ❒ Withholds consent
to the communication of data limited to the areas and bodies specified in the information notice.

By signing this, the undersigned declares that he/she has carefully read the content of the information notice provided by you pursuant to Article 13 of EU Regulation No. 679/2016.

Date_____

Signature of the Interested Party

_____

11. HOW TO PREPARE FOR EXAMS

USEFUL INSTRUCTIONS FOR COLLECTING BIOLOGICAL MATERIALS FOR EXAMINATION

Instructions for stool collection :
For the following tests: complete stool examination - parasite search - occult blood, coproculture and calprotectin search, proceed as follows: collect a small portion of stool in the appropriate sterile container with a tight-fitting cap and send it to the laboratory as soon as possible after labeling it with name, surname, date and time of collection. Urine-contaminated samples are not suitable.

For fecal parasitology, the Scotch test can be performed on 3 samples.

Instructions for Scotch test:
Collection should be done before getting out of bed and before defecation and local toilet in the morning.
Use scissors to cut a small piece of clear tape about 7-10 cm long. Adhere the rubberized part to the perianal folds.
Apply the tape to a glass slide, available from the Laboratory (using gauze or a cotton ball press gently so that the tape adheres to the slide).

Instructions for urine sampling for urine culture test:
The most suitable moment is in the morning, 3-6 hours (on average 5 hours) since the last urination. It is necessary to wash the external genitalia with water.
The first urine stream will need to be discarded because it is contaminated by urethral bacterial flora. The next urine stream, which is the intermediate one, must be collected in a sterile container, opened at the moment.
The urine collection with a plastic bag (intended for newborns or patients unable to collaborate) requires careful cleaning of the skin and the external genitalia. If the patient has not urinated within an hour of applying the plastic bag, this one has to be removed and replaced with another one, after a new, careful cleansing of the area.

Instructions per 24 hours urine sampling:
The first urine stream of the morning has to be discarded (at 7 o' clock for example) and it is necessary to collect every urine stream until the first urination of the day after (at 7 o' clock). The entire collection must be brought or you have to measure the volume and place a smaller quantity (at least 50 ml) in the appropriate urine container. In this case you have to indicate the volume collected.

Immunological pregnancy test on urine:
The test is executed on the firs morning urine sample.

Instructions for sputum collection:
You have to collect the deep spit, possibly helping yourself with coughing in the appropriate container. Superficial samples, like salivary samples, are not suitable.

Instructions for other exams not specified here, please contact the acceptance service at Telephone 0984/939777 cell.3294936946

12. WHAT THE REPORT CONTAINS

The results of laboratory tests are reported on reports containing:
NAME, SURNAME, ADDRESS, INTERNAL CUSTOMER CODE, DATE OF BIRTH, REPORT NUMBER, DATE OF ACCEPTANCE, EXAMINATION PERFORMED, REFERENCE VALUES, RESULT, METHOD USED, ADDITIONAL NOTES.

The exams are delivered in a folder, if directly delivered to the holder, otherwise, in the presence of a proxy, the reports are delivered in a sealed envelope in accordance with the provisions of the rules for the protection of privacy.

13. WHAT ARE THE OPENING HOURS FOR THE PUBLIC?

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Sampling	7.30-12.00 16.00 – 18.00	7.30-12.00 16.00 – 18.00	7.30-12.00 16.00 –18.00	7.30-12.00 16.00 – 18.00	7.30-12.00 16.00 – 18.00	7.30-11.00
Delivery of reports	7.30-18.00	7.30-18.00	7.30-18.00	7.30-18.00	7.30-18.00	7.30 – 13.00
Laboratory activities	7.30-18.00	7.30-18.00	7.30-18.00	7.30-18.00	7.30-18.00	7.30-13.00

14. HOW QUALITY OF SERVICE IS MEASURED

The analysis laboratory has a Quality System that complies with UNI EN ISO 9001:2015 standards, so it periodically measures the Quality perceived by its customers.
This is done through information questionnaires, written anonymously and placed in a special bin, which provide elements for new improvement objectives.

15. HOW CAN A COMPLAINT BE FILED?

The Analysis Laboratory protects its customers by giving them the opportunity to submit complaints or reports.
It may happen that despite continuous efforts to improve the quality of our service, there are incidents of "reason for complaint". These can be formalised by means of a "Customer Complaint", signed by the patient. Such a complaint will be carefully handled and analyzed in order to identify appropriate corrective actions. All complaints received in writing, and not anonymously, will be answered in writing within 60 days.

Public Protection Regulations
TITLE I
Submission of observations, oppositions, complaints and complaints.

Article 1

Users, relatives or relatives, or voluntary or rights protection organizations accredited by the Region or by the ASP may submit observations, oppositions, complaints or complaints against acts or behaviors that deny or limit the usability of health and social assistance services.

Article 2

Users and other subjects as identified by art. 1, exercise their right with:
1) Letter on plain paper, addressed and sent to the ASP or delivered to the Public Relations Office, in its articulations;
2) Compilation of a specific form signed by the user, distributed at the U.S. R.P.;
3) Telephone or fax reporting to the above-mentioned Office;
4) Interview with the head of the U.S. R.P.
For telephone reports and interviews, a special verbal form will be made, noting what has been reported with the acquisition of data for communications on the merits.
The verbal report will be taken in the presence of a witness.

Article 3

Observations, oppositions, complaints or complaints must be submitted, in the manner listed above, within 15 days from the time the interested party became aware of the act or conduct detrimental to his or her rights, in accordance with the provisions of art. 14, paragraph 5, of Legislative Decree No. 502 of 30 December 1992, as amended by Legislative Decree No. 517 of 7 December 1993.

Article 4

Observations, oppositions, complaints or complaints, however presented or received in the manner indicated above by the Public Relations Offices, if they are not immediately resolved, must be investigated and transmitted to the ASP Management within a maximum period of 3 days, or in any case within the time frame related to the urgency of the case.

Article 5

The U.S. R.P., within the following three days, will communicate to the Service Managers concerned, notice of the opposition, observation, complaint or complaint so that they take all the necessary measures to avoid the persistence of any disservice and provide the requesting office, within 7 days, with all the information necessary to communicate an appropriate response to the user.

Article 7

The Head of the U.S. R.P., identified pursuant to Law no. 241 of 7 August 1990, carries out the following tasks:

a) accepts the complaints, oppositions and observations submitted administratively pursuant to art. 1 of this Regulation;
b) prepare and define reports that can be easily resolved;
c) orders the investigation of complaints and distinguishes those that are easier to resolve, giving a prompt response to the user;
d) sends the response to the user and at the same time sends a copy to the Head of the Service, to the Head of the Operational Unit concerned and to the Sector Coordinator for the adoption of the necessary measures and provisions;
e) activates the procedure for reviewing the complaint if the user declares the response received to be unsatisfactory.

a. QUALITY INDICATORS AND STANDARDS

QUALITY FACTOR	INDICATOR : good and excellent reviews	Units of Measurement	Quality standard
Customer Satisfaction	Waiting time in the reception room	%	90.00
	Waiting time in the pick-up room	%	100.00
	Waiting time for report collection	%	90.00
	Courtesy Acceptance	%	100.00
	Courtesy in the pick-up room	%	100.00
	Clarity of the report	%	90.00
	Assessment of privacy respect	%	90.00
	Assessment of environments	%	100.00
Customer Complaints	//	n°	00.00