ROMANIAN ACCREDITATION ASSOCIATION - RENAR

Bucharest, Calea Vitan nr. 242, sector 3, code 031301 Tax Identification Code **RO 4311980**

[Emblem]

ACCREDITATION CERTIFICATE No. IC 007

The Romanian Accreditation Association - RENAR, being recognised as National Accreditation Body by the Government Decision 23/2009, hereby certifies that the organisation:

NOBIS LABORDIAGNOSTICA S.R.L.

Cluj-Napoca, Str. Aurel Vlaicu nr. 164, Cluj County

through

NOBIS LABORDIAGNOSTICA SRL / Proficiency Testing Provider

meets the requirements of SR EN ISO/CEI 17043:2010 and it is competent to carry out activities of PROFICIENCY TESTING PROVISION, as detailed in the Annex to this Accreditation Certificate.

This accreditation is valid provided that the accreditation criteria established by the Romanian Accreditation Association - RENAR are continuously met.

This certificate is accompanied by Annex No. 1/12.01.2017 (6 pages), an integral part of it.

The Accreditation Certificate is an essential accreditation document, which can be reviewed and issued periodically by RENAR. The latest version of the Accreditation Certificate is available on the RENAR website, www.renar.ro.

Date of initial accreditation: 04.02.2016

Date of update: 12.01.2017

Expiration date of accreditation: 03.02.2020

MANAGING DIRECTOR OF THE EXECUTIVE STRUCTURE

Alina Elena Taina

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PRESIDENT OF THE ACCREDITATION BOARD

Dr. Ing. Dumitru DINU [Illegible signature]

The Accreditation Certificate does not relieve the CAB form the obligation to obtain all permits and authorisation required for its functioning according to the law.

The partial reproduction of this certificate is prohibited.



NOBIS LABORDAIAGNOSTICA SRL through NOBIS LABORDIAGNOSTICA SRL / Proficiency Testing Provider Place of business: Cluj Napoca, Str. Aurel Vlaicu nr. 164, Cluj County

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No.	Identification of the scheme (Code and name)	Technical Field	Object submitted for Proficiency Testing	Property / parameters
1.	NQSCC Clinical Chemistry	Clinical Chemistry - Serum	Lyophilized serum of human origin	Albumin, alkaline phosphatase alpha amylase, alpha HBDH, phosphorus, total bilirubin, direct bilirubin, CK CK-MB, gamma-GT, glucose, GOT GPT, uric acid, IgA, IgG, IgM, calcium urea, chloride, total cholesterol HDL-cholesterol LDL-cholesterol cholinesterase, potassium, creatinine, LDH lactate, lipase, lithium, magnesium, sodium, total protein, pancreatic amylase copper, triglycerides, iron, CTLF, zinc, total acid phosphatase, prostatic acid phosphatase, bicarbonate, calcium ion
2.	NQSPS Special proteins	Clinical Chemistry - Special proteins	Serum ready for use	ASLO, CRP rheumatoid factor, IgA, IgG, IgM α1-antitrypsin, α1 -glycoprotein α2-macroglobulin, complement C3 complement C4, ceruloplasmin, haptoglobulin ferritin, transferrin
3.	NQSCU Urine exam	Clinical Chemistry - Urine	Lyophilized urine	ά-amylase, ά1 and β2 microalbumin phosphate, glucose, uric acid, IgG, calcium, potassium, chloride, urea, creatinine, microalbumin magnesium, sodium, total protein osmolarity, copper, transferrin, iron
4.	NQSUR Urine exam Strip and urine microscopy	Clinical Chemistry - Urine	Liquid urine of human origin	ascorbic acid, bilirubin, specific gravity, leukocytes, glucose HCG, ketones, microalbumin nitrites, total protein, pH, urobilinogen red blood cells, urinary sediment identification of microscopic elements
5.	NQSEP Protein electrophoresis	Clinical Chemistry	Lyophilized serum	total protein, albumin, globulin alphal, alpha2- globulins, beta-globulin gamma globulin
6.	NQSHG Glycosylated hemoglobin	Clinical Chemistry	Lyophilized blood	HBA1C
7.	NQSCO hemostasis	Hematology	Lyophilized plasma of human origin	Prothrombin time, INR prothrombin activity, activated partial thromboplastin time, fibrinogen
8.	NQSHE Automatic blood count	Hematology	Human blood with human and simulated cells	hemoglobin, red blood cells (RBC) mean corpuscular volume (MCV) hematocrit, white blood cells (WBC) platelet (PLT), lymphocytes (%) neutrophils (%), monocytes (%) eosinophils (%), basophils (%) MCH, MCHC, RDW



No.	Identification of the scheme (Code and name)	Technical Field	Object submitted for Proficiency Testing	Property / parameters
9.	NQSGS Blood types	Hematology	Liquid blood	Determining blood group, Rh factor identification A and B cells Rh phenotype Kell antigen, DAT, irregular antibodies
10.	NQSVS VSH	Hematology	Liquid blood	VSH
11.	NQSFS Blood smear	Hematology	Liquid blood	Identifying pathological aspects Issuing a presumptive diagnosis
12.	NQSRE Reticulocytes	Hematology	Liquid blood	Reticulocyte count
13.	NQSIM Hormones and tumor markers	Immunology	Lyophilized serum of human origin	Alpha-feto-protein (AFP), ACTH aldosterone, 17 alpha hydroxy progesterone CEA, C-peptide, DHEA, DHEAS vitamin D, FSH, FT3, FT4, T3, T4 gastrin, HCG total B-HCG, HGH, IgE insulin, calcitonin, cortisol, HT estradiol, estriol, progesterone, prolactin, total testosterone, free testosterone total PSA, free PSA, TSH, ferritin digoxin, anti TPO, thyroglobulin anti-thyroglobulin, PTH, CA125, CA19-9 CA15-3
14.	NQSSE Serology	Immunology	Serum of human origin	HAV IgG, HAV IgM, HbsAg, HbsAb HCV, HIV, HIV 1-2 Syphilis (VDRL, RPR, TPHA) Antibody Helicobacter pylori
15.	NQSBG General Bacteriology	Bacteriology	Lyophilized bacterial strains that can be isolated from: urine, faeces, vaginal secretion, pharyngeal exudate, blood, urethral discharge, sputum, nasal discharge, conjunctival discharge, purulent discharge, otic discharge	Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)
16.	NQSBU Bacteriology Uroculture	Bacteriology	Lyophilized bacterial strains, which can be isolated from urine	Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)
17.	NQSBU Bacteriology Coproculture	Bacteriology	Lyophilized bacterial strains, which can be isolated from coproculture	Culture, antibiotic susceptibility testing and identification of bacterial isolates
18.	NQSBS Bacteriology Vaginal discharge	Bacteriology	Lyophilized bacterial strains, which can be isolated from vaginal discharge	(antiobiogram) Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)
19.	NQSBT Bacteriology Pharyngeal exudate	Bacteriology	Lyophilized bacterial strains, which can be isolated from pharyngeal exudate	Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)
20.	NQSHM Bacteriology Blood culture	Bacteriology	Lyophilized bacterial strains, which can be isolated from blood	Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)
21.	NQSSU Bacteriology - urethral discharge	Bacteriology	Lyophilized bacterial strains, which can be isolated from urethral discharge	Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)



No.	Identification of the scheme (Code and name)	Technical Field	Object submitted for Proficiency Testing	Property / parameters
22.	NQSBP Bacteriology - sputum	Bacteriology	Lyophilized bacterial strains, which can be isolated from urethral sputum	Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)
23.	NQSSN Bacteriology - nasal discharge	Bacteriology	Lyophilized bacterial strains, which can be isolated from nasal discharge	Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)
24.	NQSSC Bacteriology - conjunctival discharge	Bacteriology	Lyophilized bacterial strains, which can be isolated from conjunctival discharge	Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)
25.	NQSSP Bacteriology - purulent discharge	Bacteriology	Lyophilized bacterial strains, which can be isolated from purulent discharge	Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)
26.	NQSSO Bacteriology - otic discharge	Bacteriology	Lyophilized bacterial strains, which can be isolated from otic discharge	Culture, antibiotic susceptibility testing and identification of bacterial isolates (antiobiogram)
27.	NQSPA Coproparasitology	Parasitology - faecal	Formalinized human faeces	Identification of species and evolutionary state of the body / parasitic organisms.
28.	NQSHO Occult bleeding	Immunology	Lyophilized faeces	FOB
29.	NQSHP Helicobacter pylori	Immunology	Lyophilized faeces	Antigen Helicobacter pylori
30.	NQSHP General Mycology	Mycology	Lyophilized fungal cultures, which can be isolated from: urine, faeces, vaginal secretion, pharyngeal exudate, blood, urethral discharge, sputum, nasal discharge, conjunctival discharge, purulent discharge, otic discharge.	Culture, identification and antifungal susceptibility testing of yeasts isolated from (antifungigram)
31.	NQSMU Mycology uroculture	Mycology	Lyophilized fungal cultures, which can be isolated from urine.	Culture, identification and antifungal susceptibility testing of yeasts isolated from (antifungigram)
32.	NQSMU Mycology Coproculture	Mycology	Lyophilized fungal cultures, which can be isolated from faeces.	Culture, identification and antifungal susceptibility testing of yeasts isolated
33.	NQSMV Mycology Vaginal discharge	Mycology	Lyophilized fungal cultures, which can be isolated from vaginal discharge.	from (antifungigram) Culture, identification and antifungal susceptibility testing of yeasts isolated from (antifungigram)
34.	NQSMT Mycology Pharyngeal exudate	Mycology	Lyophilized fungal cultures, which can be isolated from pharyngeal exudates.	Culture, identification and antifungal susceptibility testing of yeasts isolated from (antifungigram)
35.	NQSMR Mycology Urethral discharge	Mycology	Lyophilized fungal cultures, which can be isolated from urethral discharge.	Culture, identification and antifungal susceptibility testing of yeasts isolated from (antifungigram)
36.	NQSMN Mycology Nasal discharge	Mycology	Lyophilized fungal cultures, which can be isolated from nasal discharge.	Culture, identification and antifungal susceptibility testing of yeasts isolated from (antifungigram)



No.	Identification of the scheme (Code and name) NQSMA Mycology Conjunctival discharge	Technical Object submitted for Proficiency Testing		Property / parameters	
37.		Mycology	Lyophilized fungal cultures, which can be isolated from conjunctival discharge.	Culture, identification and antifunga susceptibility testing of yeasts isolated from (antifungigram)	
38.	NQSML Mycology Purulent discharge	ycology which can be isolated from		Culture, identification and antifungal susceptibility testing of yeasts isolated from (antifungigram)	
39.	NQSMO Mycology Otic discharge	MO Mycology Lyophilized fungal cultures which can be isolated from		Culture, identification and antifungal susceptibility testing of yeasts isolated from (antifungigram)	

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MANAGING DIRECTOR OF THE EXECUTIVE STRUCTURE

Alina Elena Taina

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