

CYPRUS ORGANIZATION FOR THE PROMOTION OF QUALITY
CYPRUS ACCREDITATION BODY



ACCREDITATION CERTIFICATE no. L019-3

The Board of Governors
of the Cyprus Organization for the Promotion of Quality,
the National Accreditation Body,
in accordance with the Article 7 of the Law 156(I)/2002

GRANTS ACCREDITATION to

RUDAS LABORATORY LTD

in Nicosia

The above Laboratory was assessed according to the Accreditation
Criteria for Medical Laboratories, as defined in the Standard

CYS EN ISO 15189:2012

and was found technically competent to carry out the **Tests** included
in the Scope of Accreditation which is described in the **Annex** to this
Certificate as an **integrated part of it. The Scope of Accreditation** can
change only after approval from the Cyprus Accreditation Body.

The current Accreditation Certificate, no. **L019-3**, is issued on the
16th July 2021 and is valid until the 14th January 2022.

Accreditation was awarded for the first time on January 15th 2010.

Antonios Ioannou
Director

Date: 16th July 2021

*This laboratory is accredited in accordance with the recognised International
Standard ISO 15189:2012. This accreditation demonstrates technical
competence for a defined scope and the operation of a laboratory quality
management System (ISO-ILAC-IAF Communiqué, September 2015).*



Annex
to the Accreditation Certificate no. L019-3

SCOPE OF ACCREDITATION

for the

RUDAS LABORATORY LTD

* Valid from 16th of April 2019 to 14th of January 2022.

** Valid from 23th of June 2020 to 14th of January 2022.

*** Valid from 16th of July 2021 to 14th of January 2022.

Materials /Products tested	Types of test/Properties measured	Applied methods/ Techniques used
BIOCHEMISTRY TESTS		
	Determination of 28 parameters	COBAS Integra 400
	1. Alkaline Phosphatase (ALP) 2. Aspartate Aminotransferase (ALT/SGOT) 3. Total Bilirubin (T Bili) 4. Calcium (Ca) 5. Cholesterol (Chol) 6. Creatinine (Creat) 7. Creatin Kinase CK (CPK) 8. γ -Glutamyl Transferase (GGT) 9. Iron (Fe) 10. Lactate Dehydrogenase (LDH) 11. Truglycerides (Trig) 12. Urea (U) 13. Uric Acid (UA) 14. HDL-Cholesterol 15. LDL- Cholesterol 16. ARC (Chol/HDL)	1. Kinetic IFCC AMP buffer 2. Kinetic IFCC activation with Pydidoxal Phosphate 3. Photometry Dichloroaniline DCA 4. Photometry Arsenazo III 5. Kinetic CHOD-PAP 6. Kinetic Jaffe without deproteinization 7. Kinetic IFCC UV 8. Enzymatic Chromometric 9. Photometry Ferene 10. Enzymatic IFCC UV 11. Enzymatic PAP 12. Enzymatic GLDH UV 13. Enzymatic PAP 150 14. Direct Enzymatic 15. Calculated 16. Calculated

	17. LDH/HDL Ratio 18. Magnesium (Mg) 19. Phosphorous (P) 20. Alanine Aminotransferase (ALT/SGPT) 21. eGFR 22. Total Proteins (TP) 23. Blood Urea Nitrogen (BUN) 24. Glucose (Glu) 25. Albumin (Alb) 26. Amylase (Amyl) 27. Globulins 28. A/G ratio	17. Calculated 18. Photometry Chlorphosphonazo III 19. UV end point with Annonium Molibdate 20. Kinetic IFCC activation with Pydidoxal Phosphate 21. Calculated 22. Photometry Biuret 23. Calculated 24. Enzymatic GOP 25. Photometric BPG 26. Kinetic IFCC with 5 EPS-G7 27. Calculated 28. Calculated
	Determination of 3 parameters	SmartLyte ISE
Serum	1. Sodium (Na) 2. Potassium (K) 3. Chloride (Cl)	Ion Selective Electrodes
	Determination of 4 parameters	Waters Alliance UV/VIS ECD
Blood (EDTA)	1. Glycolised Haemoglobin (HbA _{1c}) 2. HbA ₂ 3. Foetal Haemoglobin (HbF) 4. Haemoglobin HbS	High Performance Liquid Chromatography HPLC
URINE CHEMICAL ANALYSIS**		
	Determination of 10 parameters	Urilyzer 100 Pro
Urine	1. Bilirubin 2. Blood 3. Glucose 4. Ketones 5. Leukocytes 6. Nitrites 7. pH 8. Proteins 9. Specific gravity 10. Urobilino	Refractometer/colorimetric

	Determination of 8 parameters	Sysmex XT 1800 i
Blood (EDTA)	<ol style="list-style-type: none"> 1. Haemoglobin (HGB) 2. Haematocrit (HCT%) or PCV% 3. Mean Cell Haemoglobin Concentration (MCHC) 4. Mean Cell Volume (MCV) 5. Mean Corpuscular Haemoglobin (MCH) 6. White Blood Cells (WBC) 7. Red Blood Cells (RBC) 8. Platelets (PLTs) 	<ol style="list-style-type: none"> 1. Colorimetric 2. Electronic Integration 3. Calculation from HGB and PCV 4. Calculation from RBC and PCV 5. Calculation from HGB and RBC 6. Impedance change 7. Impedance change 8. Impedance change
IMMUNOASSAY TESTS		
	Determination of 8 parameters	*Elecsys e411
Serum	<ol style="list-style-type: none"> 1. Dehydroepiandrosterone sulfate (DHEA's) 2. Ferritin (FER) 3. Free Thyroxine (FT4) 4. Free Triiodothyronin (FT3) 5. Prolactin (PRL) 6. Prostate Specific Antigen Total (tPSA) 7. Thyrotropin Hormone (TSH) 8. Testosterone (TESTO) 	Enzyme Immunochemiluminescence Technique
	Determination of 2 parameters***	Snibe M-1000
Serum	<ol style="list-style-type: none"> 1. SARS CoV-2 IgG 2. SARS CoV-2 IgM 	Immunochemiluminescence (CLIA)
IMMUNOFLUORESCENCE TESTS		
	Determination of 2 parameters	Microscope Nikon IF/EF-D Mercury
Serum	<ol style="list-style-type: none"> 1. Anti Nuclear Antibody (ANA) 2. Varicella Zoster Antibodies (VZV) 	<ol style="list-style-type: none"> 1. Indirect Immunofluorescence (IFA) with Hep2 cells substrate 2. IFA with VZV infected cells substrate

All report should be signed by Mr F. Rudas

Comments

This Annex refers **only to tests** carried out **in the premises of the Laboratory**,
Address : 8, Kyriacos Matsis Avenue (Office 401), 1082, Nicosia.

Antonis Ioannou
Director

Date: **16th July 2021**