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.

Antonis 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)	1. Kinetic IFCC AMP buffer
	2. Aspartate Aminotransferase (ALT/SGOT)	2. Kinetic IFCC activation with Pydidoxal Phosphate
	3. Total Bilirubin (T Bili)	3. Photometry Dichloroaniline DCA
	4. Calcium (Ca)	4. Photometry Arsenazo III
	5. Cholesterol (Chol)	5. Kinetic CHOD-PAP
	6. Creatinine (Creat)	6. Kinetic Jaffe without deproteinization
	7. Creatin Kinase CK (CPK)	7. Kinetic IFCC UV
	8. γ-Glutamyl Transferase (GGT)	8. Enzymatic Chromometric
	9. Iron (Fe)	9. Photometry Ferene
	10. Lactate Dehydrogenase (LDH)	10. Enzymatic IFCC UV
	11. Truglycerides (Trig)	11.Enzymatic PAP
	12. Urea (U)	12. Enzymatic GLDH UV
	13. Uric Acid (UA)	13. Enzymatic PAP 150
	14. HDL-Cholesterol	14. Direct Enzymatic
	15. LDL- Cholesterol	15. Calculated

	16. ARC (Chol/HDL) 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	16. Calculated 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
Blood (EDTA)	**Determination of 4 parameters**	**Waters Alliance UV/VIS ECD**
	1.Glycolisaled 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	Refractometer/colorimetric

	9. Specific gravity 10. Urobilino	
Blood (EDTA)	**Determination of 8 parameters**	**Sysmex XT 1800 i**
	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)	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		
Serum	**Determination of 8 parameters**	***Elecsys e411**
	1. Dehydroepiandrosterone sulfate (DHEA's) 2.Ferritin (FER) 3. Free Thyroxine (FT4) 4. Free Triodothyronin (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	1. SARS CoV-2 IgG	Immunochemiluminescence (CLIA)
	2. SARS CoV-2 IgM	
IMMUNOFLUORESCENCE TESTS		
Serum	**Determination of 2 parameters**	**Microscope Nikon IF/EF-D Mercury**
	1. Anti Nuclear Antibody (ANA) 2. Varicella Zoster Antibodies (VZV)	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**