Hellenic Accreditation System

Annex G1/8 to the Certificate No. **1161**-3

SCOPE of ACCREDITATION

of the

Clinical Laboratory

«Protipos Diagnostiki»

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
Biochemical Tests		
1.Blood Serum	**Determination of 43 parameters**	**Biochemical Analyzer Cobas Pure c303, Roche** **List of Methods E.530-1 / Version 4, 10-10-2024**
	1. Glucose (GLU)	Enzymatic reference method with hexokinase.
	2. Urea (UREA)	Kinetic test with presence of urease and glutamate dehydrogenase
	3. Creatinine (CREA)	Kinetic colorimetric assay based on the Jaffé method.
	4. Uric Acid (UA)	Enzymatic colorimetric method with presence of uricase and peroxidase
	5. Aspartate aminotransferase (SGOT/AST)	Method according to IFCC with L-aspartate and oxaloacetate
	6. Alanine aminotransferase (SGPT/ALT)	Method according to IFCC with pyruvate and L-glutamate
	7. Alkaline Phosphatase (ALP)	Colorimetric method using p-nitrophenyl phosphate
	8. Gamma – Glutamyltransferase (γGT)	Enzymatic colorimetric method using L-γ-glutamyl-3-carboxy-4-nitroanilide as substrate
	9. Creatine Kinase (CPK)	UV-test producing NADPH
	10. CK-MB	UV immunological method
	11. Lactate Dehydrogenase (LDH)	UV-assay according to IFCC's recommendations. Conversion of L-lactate to pyruvate
	12. C- Reactive Protein (CRP)	Immunoturbidimetric method (Latex particles)
Blood Serum (continued)	13. D-Dimers	Immunoturbidimetric method (Latex

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
		particles)
	14. Iron (Fe)	Colorimetric method with FerroZine.
	15. Calcium (Ca)	Method using-NM-BAPTA complex
	16. Phosphorus (PHOS)	Endpoint method using ammonium molybdate in the presence of sulfuric acid
	17. Magnesium (Mg)	Colorimetric method using a purple complex with xylidyl blue
	18. Chloride (Cl)	ISE method
	19. Potassium (K)	ISE method
	20. Sodium (Na)	ISE method
	21. Amylase (AMY)	Enzymatic kinetic colorimetric method according to IFCC
	22. Total Bilirubin (TBIL)	Colorimetric endpoint diazomethod in a strongly acidic medium
	23. Direct Bilirubin (DBIL)	Diazomethod using diazotized sulfanilic acid
	24. Albumin (ALB)	Colorimetric endpoint method using the anionic dye, bromcresol green
	25. Total Protein (TP)	Colorimetric endpoint method that forms the characteristic purple-colored biuret complex
	26. Cholesterol (CHOL)	Enzymatic colorimetric method using cholesterol esterase, cholesterol oxidase and peroxidase
	27. HDL – Cholesterol (HDL-C)	Homogeneous enzymatic colorimetric method using PEG-modified enzymes
	28. LDL – Cholesterol (LDL-C)	Method using cholesterol esterase, cholesterol oxidase and peroxidase
	29. Triglycerides (TRIG)	Enzymatic colorimetric method using lipoprotein lipase and peroxidase
	30. Apolipoprotein-A (ApoA)	Immunoturbidimetric method
	31. Apolipoprotein-B (ApoB)	Immunoturbidimetric method
	32. Lipoprotein-α Lp(a)	Immunoturbidimetric method
	33. Homocystein (HCY)	Enzymatic
	34. Atherogenic index	Automatic calculation
	35. Total lipids	Automatic calculation
	36. Globulins	Automatic calculation
	37. A/G ratio	Automatic calculation
	38. Immunoglobulin A (IgA)	Immunoturbidimetric method
	39. Immunoglobulin G (IgG)	Immunoturbidimetric method

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
	40. Immunoglobulin M (IgM)	Immunoturbidimetric method
	41. Immunoglobulin E (IgE)	Immunoturbidimetric method
	42. C3	Immunoturbidimetric method
	43. C4	Immunoturbidimetric method
Immunochemical Tests		
1.Blood Serum	**Determination of 24 parameters**	**Automated immunochemistry analyzer Cobas Pure e402, Roche** **List of Methods E.530-1 / Version 4, 10-10-2024**
	1. Triiodothyronine (T3)	Electrochemiluminescence
	2. Thyroxine (T4)	Electrochemiluminescence
	3. Thyrotropin Hormone (TSH)	Electrochemiluminescence
	4. Free Triiodothyronine (FT3)	Electrochemiluminescence
	5. Free Thyroxine (FT4)	Electrochemiluminescence
	6. Prostatic Antigen (PSA)	Electrochemiluminescence
	7. Ferritine (Fer)	Electrochemiluminescence
	8. Folic Acid (Fol)	Electrochemiluminescence
	9. Vitamin B12 (B12)	Electrochemiluminescence
	10. β-HCG	Electrochemiluminescence
	11. 25-OH Vitamin D	Electrochemiluminescence
	12. Parathyroid Hormone (PTH)	Electrochemiluminescence
	13. Follicle Stimulation Hormone (FSH)	Electrochemiluminescence
	14. Luteinizing Hormone (LH)	Electrochemiluminescence
	15. Estradiol (E2)	Electrochemiluminescence
	16. Prolactin (PRL)	Electrochemiluminescence
	17. Antithyroglobulin antibody (Anti-TG)	Electrochemiluminescence
	18. Thyroid peroxidase antibody (Anti-TPO)	Electrochemiluminescence
	19. Troponin (TNT)	Electrochemiluminescence
	20. Alpha Fetoprotein (AFP)	Electrochemiluminescence
	21. Cancer Antigen CA125	Electrochemiluminescence
	22. Cancer Antigen CA 15-3	Electrochemiluminescence
Blood Serum (continued)	23. Cancer Antigen CA 19-9	Electrochemiluminescence
	24. CarcinoEmbryonic Antigen (CEA)	Electrochemiluminescence

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
Hematological Tests		
1.Whole Blood (EDTA)	**Determination of 21 parameters**	**Automated Analyzer** **SYSMEX XN 550*** **List of Methods E.530-1 / Version 4, 10-10-2024**
	1.Red Blood Cells (RBC)	Hydro Dynamic Focusing (DC Detection)
	2.White Blood Cells (WBC)	Flow cytometry with fluorescence method
	3.Platelets (PTLs)	Hydro Dynamic Focusing (DC Detection)
	4.Haematocrit (HCT%)	Hydro Dynamic Focusing (DC Detection)
	5.Hemoglobin (HGB)	Photometric method Hemoglobin SLS
	6.Mean Corpuscular Volume (MCV)	Automatic calculation
	7. Mean Corpuscular Haemoglobin (MCH)	Automatic calculation
	8. Mean corpuscular hemoglobin concentration (MCHC)	Automatic calculation
	9. Red blood cell distribution width (RDW)	Automatic calculation
	10. Mean platelet volume (MPV)	Automatic calculation
	11. Plateletcrit (PCT)	Automatic calculation
	LEUKOCYTE TYPE	Flow cytometry with fluorescence method
	1. Neutrophils (number & %)	
	2. Lymphocytes (number & %)	
	3. Mononuclear (number & %)	
	4. Eosinophils (number & %)	
	5. Basophils (number & %)	
2.Blood films	**Red Blood Cells' Morphology /** **Platelets' Morphology/** **White Blood Cell Differential Count** (absolute number and %)**:** Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Abnormal Cells	**Microscopic examination** **List of Methods E.530-1 / Version 4, 10-10-2024**
3. Blood plasma (sodium citrate)	**Determination of 4 parameters**	**Semi-automated analyzer BFT II (Siemens)*** **List of Methods E.530-1 / Version 4, 10-10-2024**
	1.Prothrombin time (PT)	Optomechanical method
	2.International Normalized Ratio (INR)	Optomechanical method
	3. Activated Partial Thromboplastin Time (APTT)	Optomechanical method

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
	4.Fibrinogen (FIB)	Optomechanical method
4. Whole Blood (EDTA)	**Determination of 1 parameter**	**Analyzer Lifotronic H8*** **List of Methods E.530-1 / Version 4, 10-10-2024**
	1. Glycated Haemoglobin (HbA1c)	High Performance Liquid Chromatography (HPLC)
Molecular Biology Tests		
Nasopharyngeal swab, Oropharyngeal swab	Molecular detection of SARS-CoV-2 RNA	Real Time PCR method by the use of thermal cycler LongGene Q1000+, according to the instructions of the manufacturer of PathoFinder's Real Accurate Quadruplex SARS-CoV-2 PCR Kit. *O.530-2, version 1, 01/04/2022*
Nasopharyngeal swab, Oropharyngeal swab	Molecular detection of SARS-CoV-2 RNA	Real Time PCR method by the use of thermal cycler LongGene Q1000+, according to the instructions of the manufacturer of PhoenixDx SARS-CoV-2 Multiplex IVD kit *O.530-2, version 1, 01/04/2022*
Nasopharyngeal swab, Oropharyngeal swab	Molecular detection of SARS-CoV-2 RNA	Real Time PCR method by the use of thermal cycler LongGene Q1000+, according to the instructions of the manufacturer of LabSystems Diagnostics COVID-19 Real Time Multiplex RT-PCR Kit *O.530-2, version 1, 01/04/2022*

**Reference to the commercial name of a specific analyzer/kit, refers to a specific analytical method and protocol*

Site of assessment: **Laboratory permanent premises: Lavriou Avenue 41, Kantza Attiki, 15351, Greece**.
Primary Sample Collection Site: **Lavriou Avenue 41, Kantza Attiki, 15351, Greece**.

Approved signatories: **Faviou Elsa.**

This scope of Accreditation replaces the previous one dated 29.02.2024.
The Accreditation Certificate No. **1161**-3, to ELOT EN ISO 15189:2022, is valid until 13.03.2028.

Athens, 18th of July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD