Hellenic Accreditation System

Annex G1/6 to the Certificate No.**1148**-2

SCOPE of ACCREDITATION
of the
CENTRAL DIAGNOSTIC LABORATORY
of
1st HEALTH REGION OF ATTICA

Tested Materials/ products	Types of Test/Properties to be measured	Applied Standards Methods/Techniques to be used
Biochemical Tests		
Blood Serum	**Determination of 29 parameters**	**Automated Analyzers COBAS PRO (A1, A2) Roche *** E.540-1, version 4, 19/9/2024
	1. Albumin (ALB)	Immunoturbidimetric
	2. Alkaline Phosphatase (ALP)	Colorimetric
	3. Alanine aminotransferase (SGPT/ALT) (ALT)	Colorimetric (IFCC)
	4. α-Amylase (AMY)	Enzymatic kinetic colorimetric method, according to IFCC
	5. Aspartate aminotransferase (SGOT/AST)	Colorimetric (IFCC)
	6. Calcium (CA)	Colorimetric
	7. Cholesterol (CHOL)	Enzymatic Colorimetric
	8. Creatine kinase (CPK)	UV method
	9. Creatinine (CREA)	Kinetic colorimetric based on the Jaffé method.
	10. Bilirubin direct (DBIL)	Colorimetric diazomethod,
	11. Bilirubin total (TBIL)	Colorimetric-diazomethod.
	12. Bilirubin indirect (IBIL)	Calculated (from bilirubin total and direct)

Tested Materials/ products	Types of Test/Properties to be measured	Applied Standards Methods/Techniques to be used
	13. Iron (FE)	Colorimetric assay
	14. Glucose (GLU)	Enzymatic reference method with hexokinase.
	15. Potassium (K)	Ion Selective Electrode (ISE)
	16. Sodium (NA)	Ion Selective Electrode (ISE)
	17. Lactate Dehydrogenase (LDH)	UV assay
	18. LDL - Cholesterol	Homogeneous enzymatic colorimetric method.
	19. LDL - Cholesterol	Calculated
	20. HDL - Cholesterol	Homogeneous enzymatic colorimetric method.
	21. Non-HDL	Calculated
	22. Magnesium (MG)	Calorimetric endpoint method
	23. Phosphorus (PHOS)	Molybdate, UV
	24. Total Protein (TP)	UV method
	25. Triglycerides (TRIG)	Enzymatic colorimetric
	26. Uric acid (UA)	Enzymatic colorimetric
	27. Urea (UREA)	Kinetic photometric
	28. Gamma-Glutamyltransferase (GGT)	Enzymatic colorimetric
	29. C-Reactive Protein (CRP)	Particle – enhanced Immunoturbidimetric assay
Immunochemical Tests		
Blood Serum	**Determination of 32 parameters**	**Automated Analyzers COBAS PRO (A1, A2) Roche *** E.540-1, version 4, 19/9/2024
	1. Vitamin B12 (B12)	Elecrtochemiluminescence “ECLIA”
	2. Ferritine (FERR)	Elecrtochemiluminescence “ECLIA”
	3. 25-OH Vitamin D (VITD)	Elecrtochemiluminescence “ECLIA”
	4. Folic Acid (FOLATE)	Elecrtochemiluminescence “ECLIA”
	5. Parathyroid Hormone (PTH)	Elecrtochemiluminescence “ECLIA”

Tested Materials/ products	Types of Test/Properties to be measured	Applied Standards Methods/Techniques to be used
	6. Chorionic Gonadotropin+ beta subunit (hCG+β)	Elecrtochemiluminescence "ECLIA"
	7. Immunoglobulin E (IgE)	Elecrtochemiluminescence "ECLIA"
	8. Cancer Antigen 125 (CA 125)	Elecrtochemiluminescence "ECLIA"
	9. Cancer Antigen 15-3 (CA 15-3)	Elecrtochemiluminescence "ECLIA"
	10. Cancer Antigen 19-9 (CA 19-9)	Elecrtochemiluminescence "ECLIA"
	11. Carcinoembrionic antigen (CEA)	Elecrtochemiluminescence "ECLIA"
	12. Prostatic Antigen (PSA)	Elecrtochemiluminescence "ECLIA"
	13. Free Prostate Specific Antigen (FPSA)	Elecrtochemiluminescence "ECLIA"
	14. Ratio FPSA/TPSA (PSA RATIO)	Calculated
	15. A-fetoprotein (AFP)	Elecrtochemiluminescence "ECLIA"
	16. Estradiol (E2)	Elecrtochemiluminescence "ECLIA"
	17. Follicle Stimulating Hormone (FSH)	Elecrtochemiluminescence "ECLIA"
	18. Testosterone (TESTO)	Elecrtochemiluminescence "ECLIA"
	19. Progesterone (PRG)	Elecrtochemiluminescence "ECLIA"
	20. Luteinizing Hormone (LH)	Elecrtochemiluminescence "ECLIA"
	21. Prolactin (PRL)	Elecrtochemiluminescence "ECLIA"
	22. Triiodothyronine (T3)	Elecrtochemiluminescence "ECLIA"
	23. Thyroxine (T4)	Elecrtochemiluminescence "ECLIA"
	24. Thyrotropin (TSH)	Elecrtochemiluminescence "ECLIA"
	25. Free Triiodothyronine (FT3)	Elecrtochemiluminescence "ECLIA"
	26. Free Thyroxine (FT4)	Elecrtochemiluminescence "ECLIA"
	27. Anti-thyroglobulin antibodies (ANTI-TG)	Elecrtochemiluminescence "ECLIA"
	28. Anti-thyroid peroxidase antibodies	Elecrtochemiluminescence

Tested Materials/ products	Types of Test/Properties to be measured	Applied Standards Methods/Techniques to be used
	(ANTI-TPO)	"ECLIA"
	29. INSULIN	Elecrtochemiluminescence "ECLIA"
	30. CORTISOL	Elecrtochemiluminescence "ECLIA"
	31. DHEA-S	Elecrtochemiluminescence "ECLIA"
	32. SHBG	Elecrtochemiluminescence "ECLIA"
Blood Serum	**Determination of 4 parameters**	**Automated Analyzer COBAS PRO (A1) Roche *** E.540-1, version 4, 19/9/2024
	1. TRF	Immunoturbidimetric assay
	2. UIBC	Direct determination with Ferrozine
	3. IgG	Immunoturbidimetric assay
	4. IgA	Immunoturbidimetric assay
Blood Serum	**Determination of 6 parameters**	**Automated Analyzer MAGLUMI 4000 (A3)** E.540-1, version 4, 19/9/2024
	1. Thyroglogulin (TG)	Chemiluminescence "CLIA"
	2. CT	Chemiluminescence "CLIA"
	3. ANA	Chemiluminescence "CLIA"
	4. 17(OH)PRG	Chemiluminescence "CLIA"
	5. Δ4	Chemiluminescence "CLIA"
	6. ANTI- S- DNA	Chemiluminescence "CLIA"
Blood Serum	**Determination of 13 parameters**	**Automated Analyzer COBAS PURE (A6) Roche *** E.540-1, version 4, 19/9/2024
	1. Hepatitis B virus surface antigen (HBSAG)	Elecrtochemiluminescence "ECLIA"
	2. Hepatitis C IgG antibodies (ANTI-HCV)	Elecrtochemiluminescence "ECLIA"
	3. HIV p24 Antigen and Antibodies to Human Immunodeficiency Virus Type 1 and/or Type 2 (HIV AG/AB)	Elecrtochemiluminescence "ECLIA"
	4. ANTI HBS	Elecrtochemiluminescence "ECLIA"
	5. CORE TOTAL	Elecrtochemiluminescence "ECLIA"
	6. HAV	Elecrtochemiluminescence

Tested Materials/ products	Types of Test/Properties to be measured	Applied Standards Methods/Techniques to be used
		"ECLIA"
	7. HAV IGM	Elecrtochemiluminescence "ECLIA"
	8. RUBELLA IGM	Elecrtochemiluminescence "ECLIA"
	9. RUBELLA IGG	Elecrtochemiluminescence "ECLIA"
	10. TOXO IGM	Elecrtochemiluminescence "ECLIA"
	11. TOXO IGG	Elecrtochemiluminescence "ECLIA"
	12. CMV IGM	Elecrtochemiluminescence "ECLIA"
	13. CMV IGG	Elecrtochemiluminescence "ECLIA"
Electrophoresis tests		
Blood Serum	**Determination of 6 parameters**	**Automated Analyzer CAPILLARYS 3 TERA* (A4)** E.540-1, version 4, 19/9/2024
	1. Albumin	Capillary Electrophoresis
	2. A1-globulin	Capillary Electrophoresis
	3. A2-globulin	Capillary Electrophoresis
	4. B1globulin	Capillary Electrophoresis
	5. B2globulin	Capillary Electrophoresis
	6. G-globulin	Capillary Electrophoresis
Haematological Tests		
Whole Blood (EDTA)	**Determination of 1 parameter**	**Cappilary electrophoresis** **Analysers CAPILLARY TERA 3 (A4, A5)** E.540-1, version 4, 19/9/2024
	Glycated hemoglobin (HbA_{1C})	**Cappilary electrophoresis**
Cytopathology Tests		
Conventional cervico-vaginal smears	Sample adequacy. Cytomorphologic evaluation. Detection and typing of neoplastic or other pathologic entities (TEST PAP)	1. Papanicolaou Stain 2. Microscopic evaluation 3. According to established classification system

Tested Materials/ products	Types of Test/Properties to be measured	Applied Standards Methods/Techniques to be used
		BETHESDA Δ.530, version 1, 1/4/2018 Ο.530-2, version 1, 1/4/2018

**The use of the analyser's brand name refers to a specific analytical method and the corresponding experimental protocol*

Site of assessment: **Permanent laboratory premises: Χαλκίδος 15-17, Πατήσια, 11143 Athens, Greece.**
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This scope of Accreditation replaces the previous one dated 18.11.2022.
The Accreditation Certificate No. **1148**-2, κατά ΕΛΟΤ EN ISO 15189:2022, is valid until **18.11.2027.**

Athens, 19th May 2025

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CEO of ESYD