Hellenic Accreditation System

Annex G1/5 to the Certificate No. **1205**-2

SCOPE of ACCREDITATION

of the

Biochemistry-Microbiology Laboratory

of

Elefsina General Hospital "THRIASIO"

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Biochemical Tests		
Blood serum	**29 parameters determination**	**Automated Biochemical Analyzers PURE (B2) & COBAS PRO (B1), ROCHE*** E.530-1, edition 4, 5/11/2024
	1. Albumin	Colorimetric assay (BCG)
	2. Alkaline phosphatase	Colorimetric assay acc. IFCC**
	3. Alanine aminotransferase	Acc. to IFCC** with pyridoxal phosphate activation
	4. Amylase	Enzymatic colorimetric assay acc. to IFCC**
	5. Aspartate aminotransferase	Acc. to IFCC** with pyridoxal phosphate activation
	6. Calcium	Photometric assay with NM-BAPTA
	7. Total cholesterol	Enzymatic colorimetric
	8. Creatinine kinase	UV test
	9. Creatinine	Kinetic colorimetric assay, based on the Jaffé method
	10. Direct Bilirubin	Colorimetric diazomethod (Jendrassik-Grof)
	11. Total Bilirubin	Colorimetric diazomethod
	12. Glucose	Enzymatic reference method with hexokinase

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Blood serum (continued)	13. Potassium	ISE method
	14. Sodium	ISE method
Blood serum	15. Chloride	ISE method
	16. Lactate dehydrogenase	UV assay acc. to IFCC** (Lactate to Pyruvate)
	17. Cholesterol (LDL)	Homogeneous enzymatic colorimetric
	18. Cholesterol (HDL)	Homogeneous enzymatic colorimetric
	19. Magnesium	Colorimetric endpoint method (Xylidyl Blue)
	20. Phosphate (Inorganic)	Molybdate UV
	21. Total protein	Colorimetric assay (biuret)
	22. Triglycerides	Enzymatic colorimetric test
	23. Uric acid	Enzymatic colorimetric test (uricase)
	24. Urea	Kinetic test with urease and glutamate dehydrogenase
	25. γ-Glutamyltransferase	Enzymatic colorimetric assay stand against Szasz
	26. Indirect Bilirubin	Calculated
	27. Iron	Colorimetric (Ferrozine) without deproteinization
	28. Globulins	Calculated
	29. Atherogenic Index	Calculated
Hormones		
	2 parameters determination	**Automated Biochemical Analyzer COBAS PRO (B1), ROCHE*** E.530-1, edition 4, 5/11/2024
Blood serum	1. Vitamin D Total	Electrochemiluminescense «ECLIA"
Blood Plasma	2. Parathyroid hormone	Electrochemiluminescense "ECLIA"
Blood serum	**6 parameters determination**	**Automated Immunochemical Analyzer Alinity i, ABBOTT** E.530-1, edition 4, 5/11/2024
	1. Total β- human chorionic gonadotropin (Total β -HCG)	Chemiluminescent microparticle immunoassay (CMIA)
	2. Triidothyronine total T3	Chemiluminescence microparticle immumoassay "CMIA"
	3. Thyroxin total T4	Chemiluminescence microparticle immumoassay "CMIA"

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Blood serum (continued)	4. Thyrotropin Hormone TSH	Chemiluminescence microparticle immumoassay "CMIA"
	5. Free Triidothyronine total FT3	Chemiluminescence microparticle immumoassay "CMIA"
	6. Free Thyroxin FT4	Chemiluminescence microparticle immumoassay "CMIA"
Cardiac Markers		
Blood serum	**3 parameters determination**	**Automated Biochemical Analyzers PURE (B2) & COBAS PRO (B1), ROCHE*** E.530-1, edition 4, 5/11/2024
	1. Troponin T Hs	Electrochemiluminescense "ECLIA"
	2. CK-MB	Electrochemiluminescense "ECLIA"
	3. NT PRO BNP	Electrochemiluminescense "ECLIA"
Drugs		
Blood serum	**3 parameters determination**	**Automated Biochemical Analyzer COBAS PRO (B1), ROCHE*** E.530-1, edition 4, 5/11/2024
	1. Digoxin	Kinetic interaction of microparticles in solution (KIMS)
	2. Carbamazepine	Kinetic interaction of microparticles in solution (KIMS)
	3. Valproic acid	Homogeneous enzyme immunoassay (EIA)
Tumor Markers		
Blood serum	**7 parameters determination**	**Automated Immunochemical Analyzer Alinity i, ABBOTT** E.530-1, edition 4, 5/11/2024
	1. CA-125	Chemiluminescent microparticle immunoassay (CMIA)
	2. CA 15-3	Chemiluminescent microparticle immunoassay (CMIA)
	3. CA 19-9	Chemiluminescent microparticle immunoassay (CMIA)
	4. Carcioembryonic antigen (CEA)	Chemiluminescent microparticle immunoassay (CMIA)
	5. Total Prostate Specific Antigen (Total PSA)	Chemiluminescent microparticle immunoassay (CMIA)
	6. Free FPSA	Chemiluminescent microparticle immunoassay (CMIA)
	7. Alfa – fetoprotein (AFP)	Chemiluminescent microparticle immunoassay (CMIA)
Serology Tests		
Blood serum	**1 parameter determination**	**Automated immunology analyzers Atellica NEPH 360, SIEMENS (A1 & A2)** E.530-1, edition 4, 5/11/2024
	1. C- Reactive Protein High Sensitive (hsCRP)	Immunonephelometry

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Blood serum (continued)	**9 parameters determination**	**Automated immunology analyzer Atellica NEPH 360, SIEMENS (A1)** E.530-1, edition 4, 5/11/2024
	1. Immunoglobulin E (IgE)	Immunonephelometry
	2. Rheumatology Factor (RF)	Immunonephelometry
	3. Antistreptolysin – O (ASL)	Immunonephelometry
	4. Immunoglobulin G (Ig G)	Immunonephelometry
	5. Immunoglobulin A (Ig A)	Immunonephelometry
	6. Immunoglobulin M (Ig M)	Immunonephelometry
	7. Complement factor - C3c	Immunonephelometry
	8. Complement factor- C4	Immunonephelometry
	9. β2- Microglobulin (B2M)	Immunonephelometry

**Reference to the commercial name of a specific analyzer, refers to a specific analytical method and protocol*
***IFCC: International Federation of Clinical Chemistry*

Site of assessment: **Laboratory permanent premises:** G. Gennimata Ave.**, Magoula, Athens**
Primary Sample Collection: **Laboratory permanent premises:** G. Gennimata Ave.**, Magoula, Athens**
Approved signatories: **Giannopoulou Panagiota, Charalampaki Nikoletta, Pantiora Vasiliki, Kappou Pinelopi, Avramidou Elissavet, Liosi Maria-Kalliopi, Markou Anastasia**

This Scope of Accreditation replaces the previous one dated 06.11.2024.
The Accreditation Certificate No.**1205**-2, to ELOT EN ISO 15189:2022, is valid until 12.05.2029.

Athens, 7th of May 2025

Konstantinou Evangelos Apostolos
CEO of ESYD