Hellenic Accreditation System

Annex G1/A8 to the Certificate No. **916**-6

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

MICROANALYSIS ATHENS S.A.

Material / Products tested	Types of test / Properties measured	Applied methods / techniques used
Biochemical tests		
Blood serum	**Determination of 26 parameters**	**Automated Biochemical Analyzers Alinity ci S/N 1389 & 1540, Abbott* E.320-1/5η/11.12.2024**
	1.Alanine Aminotransferase (ALT-SGPT)	NADH (without P-5'-P)
	2. Albumin	Bromcresol green
	3. Alkaline Phosphatase (ALP)	Para-nitrophenylphosphate
	4. Amylase	CNPG-3 Substrate
	5. Asparate Aminotransferase (AST-SGOT)	NADH (without P-5'-P)
	6.Bilirubin direct	Diazo reaction
	7. Bilirubin total	Diazonium salt
	8. Calcium	Arsenazo III
	9.Chloride	ISE (indirect)
	10.Cholesterol	Enzymatic
	11. Cholesterol HDL	Accel. SelectiveDetergent
	12. C-Reactive Protein (CRP)	Immunoturbidimetric
	13. Creatinine	Jaffe
	14. Creatinine Kinase (CK)	NAC
	15. Glucose	Hexokinase / G-6-PDH
	16. Iron	Colorimetric FERENE
	17.Lactate Dehydrogenase (LDH)	Lactic Acid to Pyruvate (IFCC)
	18.Magnesium	Enzymatic
	19.Phosphorus	Colorimetric Phosphomolybdate
	20.Potassium	ISE (indirect)

Material / Products tested	Types of test / Properties measured	Applied methods / techniques used
	21.Protein total	Colorimetric Biuret
	22.Sodium	ISE (indirect)
	23.Triglycerides	Glycerol Phosphate Oxidase
	24.Urea	Urease
	25.Uric acid	Uricase
	26.γ-Glutamyl Transferase (γGT)	GCNA Substrate
	Determination of 13 parameters	**Automated Biochemical Analyzer Alinity ci S/N 1389, Abbott*** **E.320-1/5η/11.12.2024**
	12.Cholesterol LDL	Homogeneous enzymatic colorimetric
	28. Apolipoprotein A1	Immunoturbidimetric
	29. Apolipoprotein B	Immunoturbidimetric
	30.Cholinesterase	DGKC Butyrylthiocholine
	31. ComplementC3	Immunoturbidimetric
	32.ComplementC4	Immunoturbidimetric
	33.Total Iron Binding Capacity (TIBC)	Calculated
	34.Transferrin	Immunoturbidimetric
	35. Immunoglobulin A(IgA)	Immunoturbidimetric
	36. Immunoglobulin E(IgE)	Immunoturbidimetric
	37. Immunoglobulin G (IgG)	Immunoturbidimetric
	38. Immunoglobulin M(IgM)	Immunoturbidimetric
	39. Lipoprotein(α)	Immunoturbidimetric
	Determination of 1 drug parameter	**Automated Biochemical AnalyzerAlinity ci S/N 1389, Abbott*** **E.320-1/5η/11.12.2024**
	1**.** Lithium	Colorimetic
	Determination of 3 parameters	**Automated Biochemical Analyzer Alinity ci S/N 1540, Abbott*** **E.320-1/5η/11.12.2024**
	1. Antistreptolysin-O (ASO)	Immunoturbidimetric
	2. β2-Microglobulin	Immunoturbidimetric
	3. Rheumatic Factor (RF)	Immunoturbidimetric
	Determination of 3 drug parameters	**Automated Biochemical Analyzer Alinity ci S/N 1540, Abbott*** **E.320-1/5η/11.12.2024**
	1. Digoxin	Immunoturbidimetric
	2. Valproic acid	Immunoturbidimetric
	3. Carbamazepine	Immunoturbidimetric
Whole blood EDTA	**Determination of 1 parameter**	**Automated Biochemical Analyzer Alinity ci S/N 1389, Abbott*** **E.320-1/5η/11.12.2024**

Material / Products tested	Types of test / Properties measured	Applied methods / techniques used
	1.Glycated Haemoglobin A1c(HbA1c)	Enzymatic
Urine	**Determination of 7 parameters**	**Automated Biochemical Analyzer Alinity ci S/N 1389, Abbott*** **E.320-1/5η/11.12.2024**
	1. Amylase in urine	CNPG-3 Substrate
	2. Calcium in urine	ArzenazoIII
	3.Creatinine in urine	Jaffe
	4. Potassium in urine	ISE (indirect)
	5. Sodium in urine	ISE (indirect
	6. Urine Protein	BenzethoniumChloride
	7. Urine albumin	Immunoturbidimetric
Haematology Tests		
Whole blood EDTA	**Determination of 8 parameters**	**Automated Haematological Analyzer αναλυτής Alinity hq*** **E.320-1/5η/11.12.2024**
	1.White blood cells (WBC)	Flow cytometry
	2.Red blood cells (RBC)	DC Detection
	3.Haemoglobin (HGB)	Photometric
	4.Hematocrit (HCT)	Calculated
	5.Mean corpuscular volume (MCV)	DC Detection
	6.Mean corpuscular hemoglobin (MCH)	Calculated
	7.Mean corpuscular hemoglobin concentration (MCHC)	Calculated
	8.Platelets (PLTs)	DC Detection
Whole blood EDTA	**Determination of 1 parameter**	**Capillarys3 TERA, SEBIA Analyzer*** **E.320-1/5η/11.12.2024**
	1.Glycated Haemoglobin A1c (HbA1c)	Capillary
Coagulation Tests		
Blood plasma Citrate	**Determination of 6 parameters**	**Coagulation Analyzer BCS, Siemens*** **E.320-1/5η/11.12.2024**
	1. Prothrombine Time (PTsec)	Clot Detection
	2. Prothrombine Time (PT %)	Clot Detection
	3. Prothrombine Time, International Normalized Ratio (PT INR	Clot Detection
	4. Activated Partial Prothrombine Time (aPTT)	Clot Detection

Material / Products tested	Types of test / Properties measured	Applied methods / techniques used
	5. Fibrinogen (Activity)	Clot Detection
Molecular Testing		
Whole Blood EDTA	Detection of ΔF508del (F508del) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene	Manufacturer's kit ViennaLab Diagnostics GmbH, CF F508del RealFast Assay (CE-IVD), real-time PCR (TaqMan assay) with the use of Applied Biosystems™ QuantStudio™ 5 Dx Real-Time PCR System* **E.320-1/5η/11.12.2024**
Immunochemical Tests		
Blood serum	**Determination of 6 parameters**	**Automated Biochemistry-Immunoassay Analyzer Alinity i S/N 2119, Abbott* E.320-1/5η/11.12.2024**
	1.α-Fetoprotein (AFP)	Chemiluminescence Microparticle Immunoassay (CMIA)
	2. Cancer Antigen CA125	
	3 Cancer Antigen CA 15-3	
	4.Cancer Antigen CA 19-9	
	5.Carcinoembryonic Antigen (CEA)	
	6.Troponin-I	
Blood serum	**Determination of 1 parameter**	**Automated Biochemistry-Immunoassay Analyzers Alinity i S/N 1450 & 2119 E.320-1/5η/11.12.2024**
	1.Vitamin D 25-OH	Chemiluminescence Microparticle Immunoassay (CMIA)
	Determination of 1 parameter	**Automated Biochemistry-Immunoassay Analyzer Alinity i S/N 1450 E.320-1/5η/11.12.2024**
	1. Homocysteine	Chemiluminescence Microparticle Immunoassay (CMIA)
	Determination of 8 parameters	**Automated Biochemistry-Immunoassay Analyzer Alinity i S/N 1452 E.320-1/5η/11.12.2024**
	1. Free Prostate Specific Antigen (FPSA)	Chemiluminescence Microparticle Immunoassay (CMIA)
	2. Free Thyroxine (FT4)	
	3. Insulin	
	4. Cortisol	
	5. Free Triidothyronine (FT3)	
	6. Triidothyroninetotal (T3)	
	7. T Dehydroepiandrosterone Sulfate (DHEA-S)	

Material / Products tested	Types of test / Properties measured	Applied methods / techniques used
	8. C-Peptide	
Blood serum	**Determination of 14 parameters**	**Automated Biochemistry-Immunoassay Analyzer Alinity i S/N 1452** **E.320-1/5η/11.12.2024**
	1. β-Human Chorionic Gonadotropine (β-HCG)	Chemiluminescence Microparticle Immunoassay (CMIA)
	2. Estradiol (E2)	
	3. Ferritin	
	4. Follicle Stimulating Hormone (FSH)	
	5. Folate acid	
	6. Luteinizing Hormone (LH)	
	7. Parathyroid Hormone intact (PTH)	
	8. Progesterone (PRG)	
	9. Prolactin (PRL)	
	10. Prostate Specific Antigen (PSA)	
	11. Testosterone	
	12.Thyroid Stimulating Hormone (TSH)	
	13. Thyroxine total (T4)	
	14. VitaminB12	
Blood plasma EDTA	**Determination of 1 parameter**	**Automated Analyzer Maglumi 800, Snibe diagnostic S/N 2302** **E.320-1/5η/11.12.2024**
	1.AdrenocorticotropicHormone (ACTH II)	Chemiluminescence Immunometric Assay (CLIA)
Blood serum	**Determination of 1 parameter**	**Automated Analyzer Maglumi 800, Snibe diagnostic S/N 0101** **E.320-1/5η/11.12.2024**
	1.Calcitonin (CT II)	Chemiluminescence Immunometric Assay (CLIA)
	Determination of 2 parameters	**Immunology Analyzer LIASON XL, Diasorin*** **E.320-1/5η/11.12.2024**
	1. Aldosterone	Chemiluminescence Immunometric Assay (CLIA)
	3. Neuron Specific Enolase (NSE)	
Immunology Tests		
Blood serum	**Determination of 1 parameter**	**Automated Immunoassay Analyzer Alinity i S/N 2121, Abbott*** **E.320-1/5η/11.12.2024**

Material / Products tested	Types of test / Properties measured	Applied methods / techniques used
	1.CKMB-Mass	Chemiluminescence Immunometric Assay (CLIA)
	Determination of 10 parameters	**Automated Immunoassay Analyzer Alinity i S/N 1450, Abbott*** **E.320-1/5η/11.12.2024**
	1. HepatitisB Virus e-Antigen (HBeAg)	Chemiluminescence Microparticle Immunoassay (CMIA)
	2. Hepatitis B Virus urface Antigen (HBsAg)	
	3Antibodies to Hepatitis B Virus e-Antigen (Anti-HBe)	
	4Antibodies to Hepatitis B Virus Surface Antigen (Anti-HBs)	
	5. Antibodies to Hepatitis B Virus Core Antigen (Anti-HBc)	
	6.IgM Antibodies to Hepatitis B Virus Core Antigen	
	7. IgG Antibodies to Hepatitis A Virus	
	8. IgM Antibodies to Hepatitis B Virus	
	9. Antibodies to Hepatitis C Virus (Anti-HCV)	
	10. HIVp24 Antigen and Antibodies to Human Immunodeficiency Virus Type 1 and/or Type 2	
	Determination of 2 parameters	**Automated Immunoassay Analyzer Alinity i S/N 1452, Abbott*** **E.320-1/5η/11.12.2024**Chemiluminescence Microparticle Immunoassay (CMIA)
	1. IgG Autoantibodies to Thyroglobulin (Anti-Tg)	
	2.IgG Autoantibodies to Thyroid Peroxidase (Anti- TPO)	
	Determination of 8 parameters	**Automated Immunoassay Analyzer Alinity i S/N 2119, Abbott*** **E.320-1/5η/11.12.2024**
	1. IgG Antibodies to Rubella Virus	
	2. IgM Antibodies to Rubella Virus	
	3. IgG Antibodies to Cytomegalovirus (CMV IgG)	Chemiluminescence Microparticle Immunoassay (CMIA)
	4.IgM Antibodies to Cytomegalovirus (CMV IgM)	
	5. IgG Antibodies to Toxoplasma gondii	
	6.IgM Antibodies to Toxoplasma gondii	
	7. EBV-VCA IgG Antibodies	
	8. EBV-VCA IgM Antibodies	

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

Site of assessment : **Laboratory permanent premises, A. Panagouli 104 & Timfristou 2 str., 15343, Ag. Paraskevi, Greece.**

Approved signatories : **L. Kouros, I. Chalkias.**

This scope of Accreditation replaces the previous one dated 23.02.2024.
The Accreditation Certificate No. **916-**6, to ELOT EN ISO 15189:2022, is valid until 13.05.2027.

Athens, 18th of July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD