Hellenic Accreditation System

Annex G1/B11 to the Certificate No. **356-8**

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

BIOIATRIKI S.A. (BIOMEDICINE)
THESSALONIKI BRANCH

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Biochemical Tests		
Blood serum	**Determination of 42 parameters**	**Automated Biochemical Analyzers ALINITY c Ac04145 Ac04146 Ac004014 Ac04144** MA-001-1 A.6 28-11-2024
	1. Glucose	Enzymatic Photometric
	2. Triglycerides	Enzymatic Photometric
	3. Total Cholesterol	Enzymatic Photometric
	4. Uric acid	Enzymatic Photometric
	5.Urea (blood, urine 24h)	Kinetic Enzymatic
	6. Creatinine	Enzymatic Photometric
	7. Total Bilirubin	Colorimetric
	8. Calcium	Colorimetric
	9. Phosphorus	Colorimetric
	10. Iron	Colorimetric
	11. Total Protein	Colorimetric
	12. Albumin	Colorimetric
	13. Potassium	Potentiometric ISE (Indirect)
	14. Sodium	Potentiometric ISE (Indirect)
	15. Serum glutamic-oxaloacetic transaminase (SGOT)	Enzymatic Photometric
	16. Serum glutamic-pyruvic transaminase (SGPT)	Enzymatic Photometric
	17. Gamma-glutamyl trasferase (γ-GT)	Enzymatic Photometric
	18. Alkaline phosphatase	Colorimetric
	19. Creatinine kinase	Kinetic
	20. Lactate dehydrogenase (LDH)	Kinetic
	21. Amylase	Enzymatic

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	22. Transferrin	Immunoturbimetric
	23. Magnesium (Mg)	Enzymatic
	24. Chloride (Cl)	Indirect Potentiometric (ISE)
	25. Cholesterol HDL	Enzymatic Colorimetric
	26. Bilirubin Direct	Colorimetric
	27. C-reactive protein (CRP)	Immunoturbidimetric
	28. Immunoglobulin A (IgA)	Immunoturbidimetric
	29. Immunoglobulin G (IgG)	Immunoturbidimetric
	30. Immunoglobulin M (IgM)	Immunoturbidimetric
	31. Complement C3	Immunoturbidimetric
	32. Complement C4	Immunoturbidimetric
	33. RA Test	Immunoturbidimetric
	34. Cholinesterasse	Colorimetric
	35. Cholesterol LDL	Enzymatic Colorimetric
	36. Cholesterol VLDL	Calculated
	37. TIBC	Colorimetric
	38. Apolipoprotein A1 (Apo A1)	Immunoturbidimetric
	39. Apolipoprotein AB (Apo B)	Immunoturbidimetric
	40. Lipoprotein a (Lp a)	Immunoturbidimetric
	41. B2 Microglobulin New Test	Immunoturbidimetric
	42. Immunoglobulin E (IgE) New Test	Immunoturbidimetric
Blood serum	**Determination of 4 parameters**	Automate Analyzer cobas e 801 ROCHE SN: 18L7-10 ECLIA MA-002-1 A.7 28/11/2024
	1. High Sensitivity Troponin T (hs-TROPONIN-T) New Test	
	2. Calcitonin (CT) New Test	
	3. PAPP-A New Test	
	4. FBHGG New Test	
Blood plasma	**Determination of 1 parameter**	Automate Analyzer Maglumi X3 SNIBE SN: 0101010034012300847 CLIA MA-002-1 A.7 28/11/2024
	ACTH New Test	

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Blood serum	**Determination of 1 parameter**	Automate Analyzer Maglumi X3 SNIBE SN: 0101010034012300847 MA-002-1 A.7 28/11/2024 ΧΗΜΕΙΟΦΩΤΑΥΓΕΙΑ (CLIA)
	17-OH PRG New Test	
	Monitoring of 5 therapeutic drug levels	**Automated Biochemical Analyzers ALINITY c Ac04145 Ac04146 Ac004014** MA-001-1 A.6 28-11-2024
	1**.** Digoxin	Immunoenzymatic
	2. Carbamazepine	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)
	3. Valproic Acid	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)
	4. Phenytoin	Immunoenzymatic
	5. Phenobarbital	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)
Urine	**Determination of 9 parameters**	**Automated Biochemical Analyzers ALINITY c Ac04145 Ac04146 Ac004014 Ac04144** MA-001-1 A.6 28-11-2024
	Amphetamine levels	
	Barbiturate levels	
	Benzodiazepine levels	
	Cannabinoid urine levels	
	Cocaine levels	
	Urinary Methadone	
	Opiate levels	
	Phencyclidine levels	
	Propoxyphene levels	
Blood serum	**Determination of 2 parameters**	**Electrolytes analyser AVL 9180*** MA-001-1 A.6 28-11-2024
	1.Lithium (Li)	Direct Potentiometry
	2.Calcium Ionized (Ca^{++})	Direct Potentiometry

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Blood serum	1.Serum Protein Electrophoresis 1. A1-globulins 2. A2-globulins 3. Beta globulins 4. Gamma globulins 5. Albumin/Globulins ratio	**Capillary Electrophoresis Capillarys 2 FlexPiercing Sebia SN 96561** MA-004-1/A.3/28-11-2024
Hematological Tests		
Whole blood (EDTA)	**Determination of 1 parameter**	**Automated Biochemical Analyzers ALINITY c* Ac04145 Ac04146 Ac004014 Ac04144** MA-001-1 A.6 28-11-2024
	Determination of glycated hemoglobin A1c (HbA1c)	Enzymatic
Whole blood (EDTA)	**Determination of 8 parameters**	**Automated Hematological Analyzers Alinity HQ00349, Alinity HQ00883, Alinity HQ00682, Alinity HQ00691,** MA-006-1/ B.0 / 28-11-2024
	1. White Blood Cells (WBC)	Fluorescent light scatter flow cytometry (MAPSS technology laser)
	2. Red Blood Cells (RBC)	Light scatter flow cytometry (MAPSS technology laser)
	3. Hemoglobin (HGB)	Absorption Spectrophotometry
	4. Hematocrit (HCT)	Calculated
	5. Mean Cell Volume (MCV)	Light scatter flow cytometry (MAPSS technology laser)
	6. Mean Cell Hemoglobin	Calculated
	7. Mean corpuscular hemoglobin concentration	Calculated
	8. Platelets (PLTs)	Light scatter flow cytometry (MAPSS technology laser)
Whole blood (EDTA)	**White Blood Cell Differential Determination of 5 parameters**	**Automated analyzers Alinity HQ00349, Alinity HQ 00883, Alinity HQ00682, Alinity HQ00691** MA-006-1/ B.0 / 28-11-2024
	1.Neutrophil (number and %)	Fluorescent light scatter flow cytometry (MAPSS technology laser)
	2.Lymphocyte (number and %)	
	3.Monocyte (number and %)	
	4.Eosinophil (number and %)	
	5.Basophil (number and %)	
Whole blood (EDTA)	**Determination of 1 parameter**	**Automated analyzers Alinity HQ00349, Alinity HQ00883** **Alinity HQ00682, Alinity HQ00691** MA-006-1/ B.0 / 28-11-2024
	1.Reticulocyte	Fluorescent light scatter flow cytometry (MAPSS technology laser)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Coagulation Tests		
Blood plasma (Citrate)	**Determination of 4 Parameters**	**Automated Analyzers** **STAGO Compact MAX3 SN 0000007041, STAGO Compact MAX3 SN 0000007042** MA-007-1/A.4/ 07-02-2025
	1.Prothrombin time (PT-INR)	Coagulation Method
	2.Fibrinogen (FIB)	Mechanical detection
	3.Activated partial prothrombine time (APPT)	Coagulation Method
	4.D-Dimers	Immunoturbidimetric
Immunochemical Tests		
Blood serum	**Determination of 34 parameters**	**Automated analyzers** **ALINITY i Ai21747, Ai21748, Ai21750, Ai21760, (SYSTEM 3-4) ABBOTT** MA-001-1/A.5/28-09-2022 MA-001-1 A.6 28-11-2024
	1. Ferritin	Μικροσωματιδιακή Ανοσοχημική Χημειοφωταύγεια (Chemiluminescent Magnetic Microparticle Immunoassay - CMIA)
	2. Alpha Fetoprotein	
	3. Estradiol (E2)	
	4. Testosterone	
	5. β-Human Chorionic Gonadotropin (β-HCG)	
	6. Cortisol	
	7. Dehydroepiandrosterone sulfate (DHEA-S)	
	8. Carcinoembryonic antigen (CEA)	
	9. Cancer antigen CA 125	
	10. Cancer antigen CA 15-3	
	11. Cancer antigen CA 19-9	
	12. Prostate Specific Antigen (PSA)	
	13. Free Prostatic Specific Antigen (Free PSA)	
	14. Sex Hormone Binding Globulin (SHBG)	
	15. Parathyroid Hormone (PTH)	
	16. Vitamin B12	
	17. Follate	
	18. Thyrotropin Hormone (TSH)	
	19. Free Thyroxin (Free-T4)	
	20. Thyroxin total (T4)	
	21. Free Triidothyronine (Free-T3)	
	22. Triidothyronine Total (Total T3)	

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	23. Prolactin (PRL)	
	24. Progesterone (PRG)	
	25. Follicle Stimulating Hormone (FSH)	
	26. Luteinizing Hormone (LH)	
	27. Insulin	
	28. Thyroglobulin (Tg)	
	29. C-peptide	
	30. Thyroid Autoantibodies Against Microsomal Antibodies (ATPO)	
	31. Antithyroglobulin Antibodies (ATG)	
	32. IgE	
	33.25 OH Vitamin D3 (Total)	
Blood serum	**Determination of ~~3~~ 2 parameters**	**Automated Analyzer-Liaison XL Diasorin 01 &- 02 SN: 2210004212** MA-001-1 A.6 28-11-2024
	1.Αντισώματα EBSTEIN BAR IGG	
	2.Αντισώματα EBSTEIN BAR IGM	
Blood serum	**Determination of 1 parameter**	**Automated Analyzer Immulite 2000 XPi Siemens, SN: B0175** MA-001-1 A.6 28-11-2024
	1. Androstenedione (Δ4)	Chemiluminescense
Immunological Tests		
Blood Serum	**Determination of 13 parameters**	**Automated analyzer Alinity i -1 Abbott** Ai01529, Ai02143 MA-001-1 A.6 28-11-2024
	1. Toxoplasma IgG antibodies (TOXO IgG)	Chemiluminescense microparticles immunoassay (CMIA)
	2. Toxoplasma IgM antibodies (TOXO IgM)	
	3. Cytomegalovirus IgM antibodies (Anti-CMV-IgM)	
	4. Cytomegalovirus IgG antibodies (CMV IgG)	
	5. Antibodies to Rubella virus IgM Ab (Rubella IgM Ab)	
	6. Antibodies to Rubella virus IgG Ab(Rubella IgG Ab)	
	7. Antibody to hepatitis B surface antigen (HBsAg)	
	8. Hepatitis B surface antigen (HBsAb)	

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	9. Antibody to hepatitis C virus (Anti-HCV)	
	10. Total antibodies to Hepatitis A virus (Anti- HAV)	
	11. Antibodies to Human Immunodeficiency Virus (HIV Ag (p24) / HIV 1&2 Ab)	
	12. Antibodies to Hepatitis B core antigen (HBcAb)	
	13.CK-MB mass Change Analyzer	
	14.Troponin I – New Test	
Microbiological Tests		
Urine	**Determination of ~~10~~ 11 parameters**	**Automated Analyzer Sysmex UF-4000, Automated Analyzer UC 3500 sn: 14198** MA-022-1/A.3/26-04-2023 MA-022-1 / A.4 / 29-11-2024
	1.Specific Gravity	Refractometry (Specific Gravity) Automated Refractometry
	2. pH	
	3. Red Blood Cells	
	4.Leukocytes	
	5.Nitrite	
	6.Glucose	
	7.Bilirubin	
	8.Urobilinogen	
	9.Protein	
	10.Ketones	
	11. Haemoglobin	
Urine	**Determination of 9 parameters**	**Automated Analyzer Sysmex UF 4000 Microscopy and UD-10 Technology stage scanning method Sysmex Microscope Olympus** MA-022-1 / A.4 / 29-11-2024
	1. Epithelial cells	Microscopic examination and Automated Urine Particle Digital Imaging.
	2. White Blood Cells/ Leukocytes	
	3.Red Blood Cells	

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	4.Bacteria	
	5.Casts	
	6.Crystals	
	7. Fungi	

**Reference to the commercial name of a specific analyzer/kit, refers to a specific analytical method and protocol*
***IFCC: International Federation of Clinical Chemistry*
****DGKC: Deutsche Geselschaft fur Klinische Chemie*

Site of assessment: **Laboratory permanent premises, 154 V. Olgas Str., Thessaloniki, Greece.**
Group Branches:

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3. BIOIATRIKI EVOSMOS - Karaoli & Dimitriou, 56224 Evosmos
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11. BIOIATRIKI AMPELOKIPOI THESS.
12. BIOIATRIKI ILIOUPOLI THESS.
13. BIOIATRIKI OLYMPIADOS
14. BIOIATRIKI SOFOULI
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The Accreditation Certificate No. 356- 8, to ELOT EN ISO 15189:2022, has valid until 30.05.2028.

Athens, 29.05.2025

Konstantinou Evangelos Apostolos
CEO of ESYD