Hellenic Accreditation System

Annex G1/Δ8 to the Certificate No. **958**-7

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

LABNET MEDICAL S.A.
ATHENS BRANCH

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
Biochemical testing		
Blood Serum	**Determination of 39 parameters**	**Automated biochemical analyzer Alinity A cii (AC01334) ABBOTT* (ΕΞΟ-12/05/01-11-2025)**
	1. Albumin (ALB)	Colorimetric (Bromocresol Green)
	2. Total Protein (TP)	Colorimetric (Biuret)
	3. Total globulin	Calculated from total protein (TP) and albumin (ALB)
	4. Albumin / Total globulin ratio	Calculated from total protein (TP) and albumin (ALB)
	5. Glucose (GLUC)	Enzymatic – colorimetric (HEX-G6PDH)
	6. Urea (UREA)	Enzymatic – colorimetric (Urease)
	7. Blood Urea Nitrogen (BUN)	Calculated from urea (UREA)
	8. Uric acid (UA)	Enzymatic – colorimetric (Uricase)
	9. Creatinine (CREA)	Enzymatic – colorimetric (Jaffe)
	10. Cholesterol Total (CHOL)	Enzymatic – colorimetric (CHO-OEP-HBA)
	11. Triglycerides (TRIG)	Enzymatic – colorimetric (GPO)
	12. HDL Cholesterol (HDL-Chol)	Enzymatic – colorimetric (ASD)

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
Blood Serum (continued)	13. LDL Cholesterol (LDL-Chol)	Enzymatic – colorimetric
	14. Calculated from triglycerides (TRIG)	VLDL Cholesterol (VLDL-Chol)
	15. Atherogenic index	Calculated from total cholesterol (CHOL) and HDL cholesterol (HDL-Chol)
	16. Total lipids (LIPIDS)	Calculated from total cholesterol (CHOL) and triglycerides (TRIG)
	17. Phospholipids (PH-LIP)	Calculated from total cholesterol (CHOL)
	18. Alanine Aminotransferase (ALT/SGPT)	Enzymatic –Kinetic – Colorimetric (NADH)
	19. Aspartate Aminotransferase (AST/SGOT)	Enzymatic –Kinetic - Colorimetric (NADH)
	20. Gamma-Glytamyl Transferase (γ-GT)	Enzymatic
	21. Alkaline Phosphatase (ALP)	Enzymatic –Kinetic – Colorimetric (Para-nP)
	22. Bilirubin Total (TBIL)	Enzymatic –Kinetic - Colorimetri (Diazonium)
	23. Bilirubin direct (DBIL)	Enzymatic –Kinetic – Colorimetric (Diazo)
	24. Bilirubin indirect (IBIL)	Calculated from bilirubin total (TBIL) and bilirubin direct (DBIL)
	25. Amylase (AMY)	Enzymatic - Colorimetric (GNPG3)
	26. Creatine Kinase (CK/CPK)	Enzymatic –Kinetic – Colorimetric (NAC)
	27. Creatine Kinase MB (CKMB)	Immunoinhibition (IFCC)
	28. Lactate Dehydrogenase (LDH)	Enzymatic - Kinetic (IFCC)
	29. Iron (Fe)	Colorimetric (Ferene)
	30. Magnesium (Mg)	Enzymatic
	31. Phosphorus (Phos)	Colorimetric (Phosphomolybdate)
	32. Calcium (Ca)	Colorimetric (Arsenazo III)
	33. Potassium (K)	Ion Selective Electrodes (ISE)
	34. Sodium (Na)	Ion Selective Electrodes (ISE)
	35. Chloride (Cl)	Ion Selective Electrodes (ISE)
	36. Serum Osmolality	Calculated from glucose (GLUC), urea (UREA) and sodium (Na)
	37. C-reactive protein (CRP)	Turbidimetry (TA) / Immunoturbidimetry (ITA)
Urine	38. Total Protein urine (uPRO)	Immunoturbidimetry (ITA)
	39. Microalbumin urine (uALB)	Turbidimetry (TA) / Immunoturbidimetry (ITA)

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
Blood serum	**Determination of 43 parameters**	**Automated biochemical analyzer Alinity B ci (AC01993) ABBOTT* (ΕΞΟ-12/05/01-11-2025)**
	1. Complement C3	Immunoturbidimetry (ITA)
	2. Complement C4	Immunoturbidimetry (ITA)
	3. Immunoglobulin A (IgA)	Immunoturbidimetry (ITA)
	4. Immunoglobulin G (IgG)	Immunoturbidimetry (ITA)
	5. Immunoglobulin M (IgM)	Immunoturbidimetry (ITA)
	6. C-reactive protein (CRP)	Turbidimetry (TA) / Immunoturbidimetry (ITA)
	7. Rheumatoid factor (RF)	Immunoturbidimetry (ITA)
	8. Lipoprotein a (Lpa)	Turbidimetry (TA) / Immunoturbidimetry (ITA)
	9. Antistreptolysin-O (ASTO)	Latex agglutination/ Turbidimetry (TA)
	10. Valproic acid (VPA)	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)
	11. Apolipoprotein A (ApoA)	Immunoturbidimetry (ITA)
	12. Apolipoprotein B (ApoB)	Immunoturbidimetry (ITA)
	13. Immunoglobulin E (IgE)	Immunoturbidimetry (ITA)
	14. Albumin (ALB)	Colorimetric (Bromocresol Green)
	15. Total Protein (TP)	Colorimetric (Biuret)
	16. Total globulin	Calculated from total protein (TP) and albumin (ALB)
	17. Albumin / Total globulin ratio	Calculated from total protein (TP) and albumin (ALB)
	18. Glucose (GLUC)	Enzymatic – colorimetric (HEX-G6PDH)
	19. Urea (UREA)	Enzymatic – colorimetric (Urease)
	20. Blood Urea Nitrogen (BUN)	Calculated from urea (UREA)
	21. Uric acid (UA)	Enzymatic – colorimetric (Uricase)
	22. Creatinine (CREA)	Enzymatic – colorimetric (Jaffe)
	23. Cholesterol Total (CHOL)	Enzymatic – colorimetric (CHO-OEP-HBA)
	24. Triglycerides (TRIG)	Enzymatic – colorimetric (GPO)
Blood serum (continued)	25. HDL Cholesterol (HDL-Chol)	Enzymatic – colorimetric (ASD)

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
	26. LDL Cholesterol (LDL-Chol)	Enzymatic – colorimetric
	27. Calculated from triglycerides (TRIG)	VLDL Cholesterol (VLDL-Chol)
	28. Atherogenic index	Calculated from total cholesterol (CHOL) and HDL cholesterol (HDL-Chol)
	29. Total lipids (LIPIDS)	Calculated from total cholesterol (CHOL) and triglycerides (TRIG)
	30. Phospholipids (PH-LIP)	Calculated from total cholesterol (CHOL)
	31. Alanine Aminotransferase (ALT/SGPT)	Enzymatic –Kinetic – Colorimetric (NADH)
	32. Aspartate Aminotransferase (AST/SGOT)	Enzymatic –Kinetic – Colorimetric (NADH)
	33. Gamma-Glytamyl Transferase (γ-GT)	Enzymatic
	34. Amylase (AMY)	Enzymatic - Colorimetric (GNPG3)
	35. Creatine Kinase (CK/CPK)	Enzymatic –Kinetic - Colorimetric (NAC)
	36. Lactate Dehydrogenase (LDH)	Enzymatic - Kinetic (IFCC)
	37. Iron (Fe)	Colorimetric (Ferene)
	38. Magnesium (Mg)	Enzymatic
	39. Calcium (Ca)	Colorimetric (Arsenazo III)
	40. Potassium (K)	Ion Selective Electrodes (ISE)
	41. Sodium (Na)	Ion Selective Electrodes (ISE)
	42. Chloride (Cl)	Ion Selective Electrodes (ISE)
	43. Serum Osmolality	Calculated from glucose (GLUC), urea (UREA) and sodium (Na)
Immunochemical Testing		
Blood Serum	**Determination of 16 parameters**	**Automated immunoassay analyzer Alinity A cii (AI01615) ABBOTT* (ΕΞΟ-12/05/01-11-2025)**
	1. Ferritin (FERR)	Chemiluminescent Microparticle Immunoassay (CMIA)
	2. Thyroid-Stimulating Hormone (TSH)	Chemiluminescent Microparticle Immunoassay (CMIA)
	3. Anti-Thyroglobulin antibodies (anti-TG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	4. Anti-Thyroid Peroxidase antibodies (anti-TPO)	Chemiluminescent Microparticle Immunoassay (CMIA)
Blood serum (continued)	5. Free Triiodothyronine (FT3)	Chemiluminescent Microparticle Immunoassay (CMIA)
	6. Free Thyroxine (FT4)	Chemiluminescent Microparticle Immunoassay

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
		(CMIA)
	7. Total Triiodothyronine (TT3)	Chemiluminescent Microparticle Immunoassay (CMIA)
	8. Total Thyroxine (TT4)	Chemiluminescent Microparticle Immunoassay (CMIA)
	9. Insulin (Insulin)	Chemiluminescent Microparticle Immunoassay (CMIA)
	10. C-peptide (C-peptide)	Chemiluminescent Microparticle Immunoassay (CMIA)
	11. Sex Hormone-Binding Globulin (SHBG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	12. Testosterone (TESTO)	Chemiluminescent Microparticle Immunoassay (CMIA)
	13. Free Androgen Index (FAI)	Calculated from Testosterone (TESTO) and Sex Hormone-Binding Globulin (SHBG)
	14. Thyroglobulin (TG)	Chemiluminescent Microparticle Immunoassay (CMIA)
Blood Plasma (EDTA) or Blood Serum	15. intact Parathyroid Hormone (iPTH)	Chemiluminescent Microparticle Immunoassay (CMIA)
	16. Homocysteine (HCY)	Chemiluminescent Microparticle Immunoassay (CMIA)
Blood Serum	**Determination of 10 parameters**	**Automated immunoassay analyzer Alinity A cii (AI22295) ABBOTT* (ΕΞΟ-12/05/01-11-2025)**
	1. 25-OH Vitamin D (25-OH VitD)	Chemiluminescent Microparticle Immunoassay (CMIA)
	2. Vitamin B12 (B12)	Chemiluminescent Microparticle Immunoassay (CMIA)
	3. Folate acid (FOLATE)	Chemiluminescent Microparticle Immunoassay (CMIA)
	4. Alpha Fetoprotein (AFP)	Chemiluminescent Microparticle Immunoassay (CMIA)
	5. Prostate-Specific Antigen (PSA)	Chemiluminescent Microparticle Immunoassay (CMIA)
	6. Free Prostate-Specific Antigen (free-PSA)	Chemiluminescent Microparticle Immunoassay (CMIA)
	7. Free-PSA / PSA ratio	Chemiluminescent Microparticle Immunoassay (CMIA)
	8. Carcinoembryonic antigen (CEA)	Chemiluminescent Microparticle Immunoassay (CMIA)
	9. Cancer antigen 125 (CA125)	Chemiluminescent Microparticle Immunoassay (CMIA)
	10. Cancer antigen 15.3 (CA15.3)	Chemiluminescent Microparticle Immunoassay (CMIA)
Blood Serum	**Determination of 27 parameters**	**Automated immunoassay analyzer Alinity B ci (AI02931) ABBOTT* (ΕΞΟ-12/05/01-11-2025)**
	1. Ferritin (FERR)	Chemiluminescent Microparticle Immunoassay

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
		(CMIA)
	2. Thyroid-Stimulating Hormone (TSH)	Chemiluminescent Microparticle Immunoassay (CMIA)
	3. 25-OH Vitamin D (25-OH VitD)	Chemiluminescent Microparticle Immunoassay (CMIA)
	4. Vitamin B12 (B12)	Chemiluminescent Microparticle Immunoassay (CMIA)
	5. Folate acid (FOLATE)	Chemiluminescent Microparticle Immunoassay (CMIA)
	6. Troponin I high sensitivity (TnI hs)	Chemiluminescent Microparticle Immunoassay (CMIA)
	7. β-Human Chorionic Gonadotropin (β-hCG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	8. Anti-Thyroglobulin antibodies (anti-TG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	9. Anti-Thyroid Peroxidase antibodies (anti-TPO)	Chemiluminescent Microparticle Immunoassay (CMIA)
	10. Free Thyroxine (FT4)	Chemiluminescent Microparticle Immunoassay (CMIA)
	11. Prostate-Specific Antigen (PSA)	Chemiluminescent Microparticle Immunoassay (CMIA)
	12. Hepatitis B surface antigen (HBsAg)	Chemiluminescent Microparticle Immunoassay (CMIA)
	13. Hepatitis B core antigen antibodies (anti-HBc)	Chemiluminescent Microparticle Immunoassay (CMIA)
	14. Hepatitis B surface antibodies (anti-HBs)	Chemiluminescent Microparticle Immunoassay (CMIA)
	15. Human immunodeficiency virus type 1/2 antigen/antibodies (HIV 1/2 Ag/Ab)	Chemiluminescent Microparticle Immunoassay (CMIA)
	16. Hepatitis C antibodies (anti-HCV)	Chemiluminescent Microparticle Immunoassay (CMIA)
	17. Toxoplasma IgG antibodies (Toxo IgG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	18. Toxoplasma IgM antibodies (Toxo IgM)	Chemiluminescent Microparticle Immunoassay (CMIA)
	19. Rubella IgG antibodies (Rubella IgG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	20. Rubella IgM antibodies (Rubella IgM)	Chemiluminescent Microparticle Immunoassay (CMIA)
	21. Cytomegalovirus IgG antibodies (CMV IgG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	22. Cytomegalovirus IgM antibodies (CMV IgM)	Chemiluminescent Microparticle Immunoassay (CMIA)
	23. Hepatitis B core antigen IgM antibodies (anti-HBc IgM)	Chemiluminescent Microparticle Immunoassay (CMIA)
Blood Serum (continued)	24. Hepatitis A IgG antibodies (anti-HAV IgG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	25. Hepatitis A IgM antibodies	Chemiluminescent Microparticle Immunoassay

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
	(anti-HAV IgM)	(CMIA)
	26. Epstein barr viral capsid IgG antibodies (EBV VCA IgG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	27. Epstein barr viral capsid IgM antibodies (EBV VCA IgM)	Chemiluminescent Microparticle Immunoassay (CMIA)
Blood serum	**Determination of 10 parameters**	**Automated immunoassay analyzer Cobas e601 ROCHE* (ΕΞΟ-12/05/01-11-2025)**
	1. Estradiol (E2)	Elecrochemiluminescence Immunoassay (ECLIA)
	2. Follicle Stimulating Hormone (FSH)	Elecrochemiluminescence Immunoassay (ECLIA)
	3. Luteinizing Hormone (LH)	Elecrochemiluminescence Immunoassay (ECLIA)
	4. Prolactin (PRL)	Elecrochemiluminescence Immunoassay (ECLIA)
	5. Progesterone (PRG)	Elecrochemiluminescence Immunoassay (ECLIA)
	6. Dehydroepiandrosterone Sulfate (DHEA-S)	Elecrochemiluminescence Immunoassay (ECLIA)
	7. Cortisol (CORT)	Elecrochemiluminescence Immunoassay (ECLIA)
	8. Adrenocorticotropic hormone (ACTH)	Elecrochemiluminescence Immunoassay (ECLIA)
	9. Calcitonin (CT)	Elecrochemiluminescence Immunoassay (ECLIA)
	10. Cancer antigen 19.9 (CA 19.9)	Elecrochemiluminescence Immunoassay (ECLIA)
Immunological Testing		
	Determination of 2 parameters	**Automated chemiluminescence analyzer Liaison XL DIASORIN* (ΕΞΟ-12/05/01-11-2025)**
Blood serum	1. Aldosterone (ALDO)	Chemiluminescence (CLIA)
Blood Plasma (EDTA)	2. Renin (Renin)	Chemiluminescence (CLIA)
Blood serum	**Determination of 10 parameters**	**Automated immunoassay analyzer Zenit Ra MENARINI* (ΕΞΟ-12/05/01-11-2025)**
	1. Extractable nuclear antigen antibodies (anti-ENA)	Chemiluminescence (CLIA)
	2. Anti-double stranded DNA antibodies (anti-ds DNA)	Chemiluminescence (CLIA)
	3. Cardiolipin antibodies IgG (αCL IgG)	Chemiluminescence (CLIA)
Blood serum (continued)	4. Cardiolipin antibodies IgM (αCL IgM)	Chemiluminescence (CLIA)
	5. β2-Glycoprotein I antibodies	Chemiluminescence (CLIA)

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
	IgG (β2-GPI IgG)	
	6. β2-Glycoprotein I antibodies IgM (β2-GPI IgM)	Chemiluminescence (CLIA)
	7. Deamidated gliadin peptides antibodies IgG (anti-DGP IgG)	Chemiluminescence (CLIA)
	8. Deamidated gliadin peptides antibodies IgA (anti-DGP IgA)	Chemiluminescence (CLIA)
	9. Tissue transglutaminase antibodies IgG (t-TG IgG)	Chemiluminescence (CLIA)
	10. Tissue transglutaminase antibodies IgA (t-TG IgA)	Chemiluminescence (CLIA)
Hematological Testing		
Whole Blood (EDTA)	**Determination of 1 parameter**	**Automated High Performance Liquid Chromatography HBNEXT (A), (B) MENARINI** (ΕΞΟ-12/05/01-11-2025)**
	1. Glycated Haemoglobin A_1c (HbA_1c)	High Performance Liquid Chromatography
Whole Blood (EDTA)	**Determination of 10 parameters**	**Automated hematological analyzer Alinity HQ, EMERALD 22 ABBOTT* (ΕΞΟ-12/05/01-11-2025)**
	1. Hemoglobin (HGB)	Spectrophotometric
	2. Hematocrit (HCT)	Calculated from RBC and MCV
	3. Red Blood Cells (RBC)	Electrical impedance
	4. Mean Corpuscular Volume (MCV)	Calculated from red blood cell size distribution data
	5. Mean Corpuscular Hemoglobin (MCH)	Calculated from HGB and RBC
	6. Mean Cell Hemoglobin Concentration (MCHC)	Calculated from HGB and HCT
	7. Red blood cell Distribution Width (RDW)	Calculated from RBC histogram
	8. White Blood Cells (WBC)	Optical count (WOC) / Impedance count (WIC)
	9. Platelets (PLT)	Electrical impedance
	10. Mean Platelet Volume (MPV)	Calculated from PLT histogram
Blood Coagulation Testing		
Blood Plasma (citrate)	**Determination of 7 parameters**	**Automated coagulation analyzer STAR Max3 STAGO* (ΕΞΟ-12/05/01-11-2025)**

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
	1. Prothrombine time (PT sec)	Clot detection
	2. Prothrombine time (PT %)	Clot detection
	3. Prothrombine time (International Normalized Ratio, PT INR)	Calculated from Prothrombin time (PT patient and PT normal)
	4. Activated partial prothrombine time (aPTT)	Clot detection
	5. Fibrinogen (FIB)	Clot detection
	6. Antithrombin III (ATIII)	Colorimetric
	7. D-Dimer (D-Dimer)	Latex / Turbidimetry (TA)
Molecular Testing		
Whole blood and plasma, amniotic fluid, biopsies, upper and lower respiratory system speciments (nasopharyngeal swabs, bronchial secretions)	Detection and quantification of human cytomegalovirus DNA (hCMV)	Manufacturers' kit GeneProof a.s., GeneProof™ Cytomegalovirus (CMV) PCR Kit (IVDR) CE_{2797} IVD (REF: CMV/GP/100), Taqman technology real-time PCR with the use of the thermocycler Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System***** **(ΕΞΟ-12/05/01-11-2025)**
Upper and lower respiratory system speciments (nasopharyngeal swabs, oropharyngeal swans, nasal swabs, nasal washing, sputum, bronchial secretions)	Quantitative detection of SARSCoV-2 virus DNA, genes*ORF1ab, N and E*.	Manufacturers' kit Maccura Biotechnology Co., Ltd., SARS-CoV-2 Fluorescent PCR (CE-IVD), Taqman technology real-time RT-PCR with the use of the thermocycler SaCycler-96 Real-Time PCR System***** **(ΕΞΟ-12/05/01-11-2025)**
Cervical swabs, urethral swabs, vaginal swabs, semen, urine	Simultaneous detection of *Chlamydia trachomatis*, *Ureaplasma parvum* & *urealyticum* and *Mycoplasma hominis* & *genitalium* bacterial DNA	Manufacturers' kit Genmark Sağlık Ürünleri, geneMAP™ STI Panel 1 Assay (CT, MG, MH, UU, UP) (CE-IVD) CAT NO.: STI1-RT50 (CE-IVD), Taqman technology multiplex real-time PCR with the use of the thermocycler Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System***** **(ΕΞΟ-12/05/01-11-2025)**
Whole blood, bone marrow	Detection of the genetic point mutation V617F of the JAK2 gene	Manufacturers' kit SNP Biotechnology R&D Ltd, (*JAK2-V617F* Mutation) JAK2 REAL-TIME PCR KIT Cat. No: 21R-10-01 (CE-IVD), Taqman technology real-time PCR with the use of the thermocycler Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System*****

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
		(ΕΞΟ-12/05/01-11-2025)
Cervical specimen collected in the collection, preservation and transport system of Alinity m cervi-collect specimen collection kit Cervical specimen collected in ThinPrep PreservCyt Solution και SurePath Preservative Fluid	DNA detection of 14 high risk genotypes (16,18,31,33,35,39,45,51,52, 56,58,59,66,68) Human Papillomavirus (HPV) in clinical samples and specifically identifies HPV16, HPV18, HPV45	Automated molecular diagnostics analyzer Alinity m polymerase chain reaction (PCR) real-time (Abbott, Abbott Park, Illinois, U.S.A.)* **(ΕΞΟ-12/05/01-11-2025)**

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

Site of assessment: **Laboratory Permanent premises: Athens Branch, Antigonis 95 and Kifisou 54, P.O. 10442, Kolonos, Athens, Greece.**
Approved signatures: **P. Chatzivasileiou, G. Mayorkinis.**

This scope of Accreditation replaces the previous one dated 07.03.2025.
The Accreditation Certificate No. **958**-7, to ELOT EN ISO 15189:2022, is valid until 02.12.2027.

Athens, 18th of May 2026

Konstantinou Evangelos Apostolos
CEO of ESYD