Hellenic Accreditation System

Annex G1/A17 to the Certificate No. **662**-10

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of the

PRIVATE COOPERATIVE DIAGNOSTIC LABORATORIES MEDISYN MEDICAL S.A.- THESSALONIKH BRANCH

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Immunochemical Tests		
Blood Serum	**Determination of 42 parameters**	**Automated immunology analyzers SIEMENS Atellica*** **Δ.550, E.550-1, E550-2**
	1. β-Human Chorionic Gonadotropine (β-HCG)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM1
	2. Progesterone (PRG)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1
	3. Estradiol (E2)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1
	4. Carcinoembryonic Antigen (CEA)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 2 IM
	6. Cancer Antigen 15-3 (CA 15-3)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM1, Atellica 2 IM
	7. Cancer Antigen 125 (CA 125)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM1, Atellica 2 IM
	8. α-Fetoprotein (AFP)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM1, Atellica 2 IM
	9. Prostate Specific Antigen (PSA)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM 2, Atellica 2 IM
	10. Free Prostate Specific Antigen (FPSA)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 2 IM
	11. Ratio: FPSA/ PSA	Calculated from: FPSA and PSA Atellica 1 IM 2, Atellica 2 IM

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood Serum (continued)	12. Ferritin	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM2, Atellica 2 IM
	13. Vitamin B12	Chemiluminescence (CLIA) (competitive) Atellica 1 IM2, Atellica 2 IM
	14. Folate	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1, Atellica 2 IM
	15. Follicle Stimulating Hormone (FSH)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM1
	16. Luteinizing Hormone (LH)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM1
	17. Prolactin (PRL)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM1
	18 Thyroid-stimulating hormone (TSH)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM1, Atellica 1 IM2, Atellica 2 IM
	19. Total Thyroxine (TT4)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1
	20. Total Triidothyronine (TT3)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1
	21. Free Thyroxine (FT4)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1, Atellica 2 IM
	22. Free Triidothyronine (FT3)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1, Atellica 2 IM
	23. Anti-thyroglobulin antibodies (anti-TG)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1, Atellica 2 IM
	24. Anti-thyroid peroxidase antibodies (anti-TPO)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1, Atellica 2 IM
	25. 25-OH Vitamin D	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1, Atellica 1 IM2, Atellica 2 IM
	26. Testosterone Total (TT)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM2
	27. Cortisol	Chemiluminescence (CLIA) (Competitive) Atellica 1 IM2
	28. Dihydroepiandrosterone Sulfate (DHEA-S)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM2
	29. Sex hormone-binding globulin (SHBG)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM2
	30. Insulin	Chemiluminescence (CLIA) (non-competitive) Atellica 1 IM2
	31. Index of insulin resistance /HoMA-IR	Calculated from GLU and Islulin Atellica 1 IM2
	32. Δ4 Androstenedione	Chemiluminescence (CLIA) (Competitive) Atellica 1 IM2
	33. Troponine I high sensitivity (hs-TnI)	Chemiluminescence (CLIA) (non-

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood Serum (continued)		competitive) Atellica 1 IM2
	34. FAI, Free androgen index	Calculated from:Total Testo (T.T) and (SHBG) Atellica 1 IM2/AT1CH,AT2CH
	35. Hepatitis C IgG antibodies (Anti-HCV)	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1, Atellica 2 IM
	36. Human immunodeficiency virus type 1/O & 2 (HIV-1/O & 2) antibodies	Chemiluminescence (CLIA) (competitive) Atellica 1 IM1, Atellica 2 IM
	37. Cytomegalovirus IgG antibodies (CMV IgG)	Chemiluminescence (CLIA) Atellica 1 IM1, Atellica 2 IM
	38. Cytomegalovirus IgM antibodies (CMV IgM)	Chemiluminescence (CLIA) Atellica 1 IM1, Atellica 2 IM
	39. Toxoplasma IgG antibodies (TOXO IgG)	Chemiluminescence (CLIA Atellica 1 IM1, Atellica 2 IM
	40. Toxoplasma IgM antibodies (TOXO IgM)	Chemiluminescence (CLIA Atellica 1 IM1, Atellica 2 IM
	41. Rubella virus IgG antibodies (Rubella IgG)	Chemiluminescence (CLIA) Atellica 1 IM1, Atellica 2 IM
	42. Rubella virus IgM antibodies (Rubella IgM)	Chemiluminescence (CLIA) Atellica 1 IM1, Atellica 2 IM
Blood serum or blood plasma (EDTA)	43. Parathyroid hormone (intact) (iPTH)	Chemiluminescence (CLIA) (non-competitive sandwich) Atellica 1 IM2, Atellica 2 IM
Blood Serum	**Determination of 2 parameters**	**Automated immunology analyzer Maglumi Snibe * Δ.550, E.550-1, E550-2**
	1. 17-OH Progesterone	Chemiluminescence (CLIA) (competitive)
	2. Free Testosterone (FTc)	Chemiluminescence (CLIA) (competitive)
	Determination of 1 parameter	**AP16IF PLUS / Immunofluorescence microscopy**
	1.Antinuclear antibodies (ANA)	Indirect Immunofluorescence (IFA)
	Determination of 5 parameters	**Automated immunology analyzer BIOCLIA 500* Δ.550, E.550-1, E550-2**
	1. Anti-Extractable Nuclear Antigen antibodies (ANTI-ENA)	Chemiluminescence (CLIA) BIOCLIA 1
	2. Anti-double stranded DNA (Anti-dsDNA) antibodies	Chemiluminescence (CLIA) BIOCLIA 1
	3. Anti-tissue transglutaminase immunoglobulin A antibodies (ANTI-Ttg IgA)	Chemiluminescence (CLIA) BIOCLIA 2
	4. Anticardiolipin antibodies IgG (acl IgG)	Chemiluminescence (CLIA) BIOCLIA 2
	5. Anticardiolipin antibodies IgM (acl IgM)	Chemiluminescence (CLIA) BIOCLIA 2
	Determination of 4 parameters	
Blood Serum (continued)	1. Direct Renin	Chemiluminescence (CLIA)
	2. Aldosterone	Chemiluminescence (CLIA)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	3. Insulin-like Growth Factor 1 (IGF-1)	Chemiluminescence (CLIA)
	4. 1,25-dihydroxy vitamin D (Vit-D 1,25)	Chemiluminescence (CLIA)
	Determination of 9 parameters	**Automated immunology analyzers Abbott Alinity*** Δ.550, E.550-1, E550-2
	1. Hepatitis B virus surface antigen (HBsAg)	Chemiluminescence (CMIA)
	2. Hepatitis B virus core total antibodies (HBcAb)	Chemiluminescence (CMIA)
	3. Hepatitis B virus surface antibodies (HBsAb)	Chemiluminescence (CMIA)
	4. Hepatitis A virus IgG antibodies (Anti-HAV IgG)	Chemiluminescence (CMIA)
	5. Hepatitis A virus IgM antibodies (Anti-HAV IgM)	Chemiluminescence (CMIA)
	6. Epstein-Barr IgG antibodies (EBV anti-VCA IgG)	Chemiluminescence (CMIA)
	7. Epstein-Barr IgM antibodies (EBV anti-VCA IgM)	Chemiluminescence (CMIA)
	8. Anti-Cyclic Citrullinated Peptide (ANTI-CCP)	Chemiluminescence (CMIA)
	8. Thyroglobulin Tg	Chemiluminescence (CMIA)
Blood serum or blood plasma (EDTA)	9. Total Homocystein (HCY)	Chemiluminescence (CMIA)
Blood Serum	**Determination of 1 parameter**	**Automated immunochemical analyzers Immulite 2000 SIEMENS*** **Δ.550, E.550-1, E550-2**
	1. Cancer Antigen CA19.9 (CA19.9)	Chemiluminescence (non-competitive) (CLIA)
	2. Calcitonin (CT)	Chemiluminescence (CLIA)
Biochemical Tests		
Blood Serum	**Determination of 46 parameters**	**Automated biochemistry analyzers Siemens Atellica*** **Δ.550, E.550-1, E550-2**
	1. Complement C3	Immunoturbidimetry (ITA) Atellica 1 CH1
	2. Complement C4	Immunoturbidimetry (ITA) Atellica 1 CH1
	3. Antistreptolysine O (ASTO)	Immunoturbidimetry (ITA) Atellica 1 CH1, Atellica 2 CH2
	4. Reumatoid Factor (RF) - quantitative	Immunoturbidimetry (ITA) Atellica 1 CH1, Atellica 2 CH2
	5. C Reactive Protein (CRP) - quantitative	Immunoturbidimetry (ITA) Atellica 1 CH1, Atellica 2 CH2
Blood Serum (continued)	6. Immunoglobulin A (IgA)	Immunoturbidimetry (ITA) Atellica 1 CH1, Atellica 2 CH2
	7. Immunoglobulin G (IgG)	Immunoturbidimetry (ITA) Atellica 1

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
		CH1, Atellica 2 CH2
	8. Immunoglobulin M (IgM)	Immunoturbidimetry (ITA) Atellica 1 CH1, Atellica 2 CH2
	9. Total Cholesterol(TC)	Enzymatic - Colorimetric (CHOD - PAP) Atellica 1 CH1, Atellica 2 CH2
	10. HDL Cholesterol (HDL-C)	Enzymatic - Colorimetric (PEG) Atellica 1 CH1, Atellica 2 CH2
	11. Triglycerides (TGs)	Enzymatic - Colorimetric (GPO - PAP) Atellica 1 CH1, Atellica 2 CH2
	12. VLDL Cholesterol (VLDL-C)	Calculated from TRIG Atellica 1 CH1, Atellica 2 CH2
	13. Atherogenic index ((TC)/ (HDL-C))	Calculated from: (TC) / (HDL-C) Atellica 1 CH1, Atellica 2 CH2
	14. Non-HDL-C	Calculated from: (TC) - (HDL-C) Atellica 1 CH1, Atellica 2 CH2
	15. Total Lipids	Calculated from CHOL and TRIG Atellica 1 CH1, Atellica 2 CH2
	16. Phospholipids	Calculated from CHOL Atellica 1 CH1, Atellica 2 CH2
	17. Iron (Fe)	Colorimetric (Ferrozine) Atellica 1 CH1, Atellica 2 CH2
	18. Albumin (ALB)	Colorimetric (BCP) Atellica 1 CH1, Atellica 2 CH2
	19. Total Proteins (TP)	Colorimetric (Biuret) Atellica 1 CH1, Atellica 2 CH2
	20. Total globin (SF)	Calculated from: (TP) - (ALB) Atellica 1 CH1, Atellica 2 CH2
	21. Albumin/Globin ratio	Calculated from: (ALB) / SF Atellica 1 CH1, Atellica 2 CH2
	22. Calcium Total (Ca)	Colorimetric (OCPC) Atellica 1 CH1, Atellica 2 CH2
	23. Magnesium (Mg)	Colorimetric (Xylidyl blue) Atellica 1 CH1, Atellica 2 CH2
	24. Phosphate (P)	Colorimetric (Phosphomolybdate) Atellica 1 CH1
	25. Glucose(GLU)	Enzymatic - Colorimetric (GOD - PAP) Atellica 1 CH1, Atellica 2 CH2
	26. Creatinine (CREA)	Enzymatic - Colorimetric (Jaffe) Atellica 1 CH1, Atellica 2 CH2
	27. Urea (UREA)	Enzymatic - kinetic - Colorimetric (Urease) Atellica 1 CH1, Atellica 2 CH2
	28. Serum osmolality	Calculated from:(GLU) (Na) and (UREA) Atellica 1 CH1, Atellica 2 CH2
	29. Nitrogen serum	Calculated from: (UREA) Atellica 1 CH1, Atellica 2 CH2
	30. Uric Acid (UA)	Enzymatic - Colorimetric (Uricase -Peroxidase) Atellica 1 CH1, Atellica 2 CH2
Blood Serum (continued)	31. Aspartate Aminotransferase (AST/SGOT)	Colorimetric (IFCC**) Atellica 1 CH1, Atellica 2 CH2

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	32. Alanine Aminotransferase (ALT/SGPT)	Colorimetric (IFCC**) Atellica 1 CH1, Atellica 2 CH2
	33. Gamma-Glutamyl transferase (γGT)	Enzymatic - Colorimetric γ-Glutamyl-3-carboxy-4nitroanillide Atellica 1 CH1, Atellica 2 CH2
	34. Lactate Dehydrogenase (LDH)	Enzymatic - Colorimetric (L-P) (DGKC***) Atellica 1 CH1, Atellica 2 CH2
	35. Alkaline Phosphatase (ALP)	Colorimetric (IFCC**) Atellica 1 CH1, Atellica 2 CH2
	36. Creatine Kinase (CK/CPK)	Enzymatic - Colorimetric (IFCC**) Atellica 1 CH1, Atellica 2 CH2
	37. Total Bilirubin (TBIL)	Colorimetric DPD Atellica 1 CH1
	38. Direct Bilirubin (DBIL)	Colorimetric DPD Atellica 1 CH1
	39. Indirect Bilirubin (IBIL)	Calculated fromTBIL and DBIL Atellica 1 CH1
	40. Amylase (AMY)	Enzymatic - Colorimetric IFCC** (G7-PNP) Atellica 1 CH1
	41. Potassium (K)	Ion Selective Electrode (ISE) Atellica 1 CH1, Atellica 2 CH2
	42. Sodium (Na)	Ion Selective Electrode (ISE) Atellica 1 CH1, Atellica 2 CH2
	43. Chlore (Cl)	Ion Selective Electrode (ISE) Atellica 1 CH1, Atellica 2 CH2
	44.LDL Cholesterol	Elimination/catalase Atellica 1 CH1, Atellica 2 CH2
Urine	45. Urine Microalbumin	Immunoturbidimetry Atellica 1 CH1, Atellica 2 CH2
	46. Urine Total Protein	Colorimetric Atellica 1 CH1, Atellica 2 CH2
Hematological Tests		
Whole blood (EDTA)	**Determination of 10 parameters**	**Automated haematological analyzers ADVIA 2120i, SIEMENS* Δ.550, E.550-1, E550-2**
	1. Haemoglobin (HBG)	Photometric
	2. Red blood cells (RBC)	Flow cytometry
	3. Mean corpuscular volume (MCV)	Flow cytometry
	4. White blood cells (WBC)	Flow cytometry
	5. Platelets (PLTs)	Flow cytometry
	6. Haematocrit (HCT)	Calculated: % = RBC x MCV/10
	7. Mean corpuscular haemoglobin (MCH)	Calculated : HBG /RBC
	8. Mean cell haemoglobin concentration (MCHC))	Calculated : (HBG /RBC) x MCV
Whole blood (EDTA) (continued)	9. Red blood cell distribution width (RDW)	Flow cytometry
	10. Mean platelet volume (MPV)	Flow cytometry

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	Determination of 1 parameter	**High performance liquid chromatography (HPLC) analyzers G11, TOSOH Biosciences* Δ.550, E.550-1, E550-2**
	1.Determination of Glycated Haemoglobin A1C (HbA1C)	Ion-exchange high performance liquid chromatography (HPLC) TOSOH G11/1, TOSOH G11/2, TOSOH G11/3
Coagulation Tests		
Blood plasma (citrate)	**Determination of 4 parameters**	**Automated Coagulation Analyzer Sysmex CS5100 *** Δ.550, E.550-1, E550-2
	1. D-Dimer	Immunoturbidimetry INNOVENCE D-DIMERS
	2. Activated partial prothrombin time (APPT)	Clot detection
	3. Fibrinogen activity (FIB)	Clot detection
	4. Prothrombine Time (PT)	Clot detection
Molecular diagnosis Tests		
Whole blood (EDTA)	**Determination of 6 parameters**	**LightCycler 480 II Magna Pure 24**
	1. Detection of HLA B27 allele	LightMix Kit HLA B27 (TIB MOLBIOL)
	2. Detection of Factor II G20210A mutation	LightMix®KIT Factor II G20210A (TIB MOLBIOL)
	3. Detection of Factor V G1691A (FV-Leiden) mutation	LightMix®KIT Factor V (Leiden) (TIB MOLBIOL)
	4. Detection of MTHFR C677T mutation	LightMix®KIT MTHFR C677T (TIB MOLBIOL)
	5. Detection of MTHFR A1298C mutation	LightMix®KIT MTHFR A1298C (TIB MOLBIOL)
	6. Detection of ΔF508 p.Phe508del mutation in gene CFTR	Real-time PCR (qPCR) (LightSNiP CFTR Δ508F, TIB MOLBIOL)

**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 assessement : **Permanent Laboratory premises, 42, 26th October str., 54627, Thessaloniki, Greece.**
Approved signatories: **Ch. Dinas, S. Vytiniotis, A. Nalbanti, A. Kassomenaki, C. Papakosta**

This scope of Accreditation replaces the previous one dated 16.03.2026.
The Accreditation Certificate No. **662**-10, to ELOT EN ISO 15189:2022, is valid until 21.03.2031.

Athens, 08th April 2026

Evangelos Apostolos Konstantinou
CEO of ESYD