Hellenic Accreditation System

Annex G1/B14 to the Certificate No. **662**-10

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of the

PRIVATE COOPERATIVE DIAGNOSTIC LABORATORIES MEDISYN MEDICAL S.A. HERAKLEION BRUNCH

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	Immunochemical Tests	
	Determination of 42 parameters	**Automated immunology analyzers Atellica SIEMENS* Δ.550, E.550-1, E550-2**
Blood Serum	1. Carcinoembryonic Antigen (CEA)	Chemiluminescence (CLIA) (non-competitive sandwich) , IM1 & IM2
	2. Cancer Antigen 15-3 (CA 15-3)	Chemiluminescence (CLIA) (non-competitive sandwich), IM1 & IM2
	3. Cancer Antigen 125 (CA 125)	Chemiluminescence (CLIA) (non-competitive sandwich), IM1 & IM2
	4. α-Fetoprotein (AFP)	Chemiluminescence (CLIA) (non-competitive sandwich) , IM1 & IM2
	5. Prostate Specific Antigen (PSA)	Chemiluminescence (CLIA) (non-competitive sandwich) , IM1 & IM2
	6. Free Prostate Specific Antigen (FPSA)	Chemiluminescence (CLIA) (non-competitive sandwich), IM1
	7. Ratio: FPSA/ PSA	Calculated from: FPSA and PSA
	8. Ferritin	Chemiluminescence (CLIA) (non-competitive sandwich) , IM1 & IM2
	9. Vitamin B12	Chemiluminescence (CLIA) (competitive) , IM1 & IM2
	10. Folate	Chemiluminescence (CLIA) (competitive) , IM1 & IM2
	11. Follicle Stimulating Hormone (FSH)	Chemiluminescence (CLIA) (non-competitive sandwich), IM1 & IM2
	12. Luteinizing Hormone (LH)	Chemiluminescence (CLIA) (non-competitive sandwich), IM1 & IM2
	13. Prolactin (PRL)	Chemiluminescence (CLIA) (non-competitive sandwich), IM1 & IM2
	14. Thyroid-stimulating hormone (TSH)	Chemiluminescence (CLIA) (non-competitive sandwich) IM1 & IM2
	15. Total Thyroxine (TT4)	Chemiluminescence (CLIA)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood Serum (continued)		(competitive), IM1
	16. Total Triidothyronine (TT3)	Chemiluminescence (CLIA) (competitive), IM1
	17. Free Thyroxine (FT4)	Chemiluminescence (CLIA) (competitive), IM1 & IM2
	18. Free Triidothyronine (FT3)	Chemiluminescence (CLIA) (competitive) , IM1 & IM2
	19. Anti-thyroglobulin antibodies (anti-TG)	Chemiluminescence (CLIA) (competitive), IM1 & IM2
	20. Anti-thyroid peroxidase antibodies (anti-TPO)	Chemiluminescence (CLIA) (competitive) IM1 & IM2
	21. 25-OH Vitamin D	Chemiluminescence (CLIA) (competitive) IM1 & IM2
	22. Cortisol	Chemiluminescence (CLIA) (competitive), IM1 & IM2
	23. Insulin	Chemiluminescence (CLIA) (competitive), IM1 & IM2
	24. Index of insulin resistance /HoMA-IR	Calculated from Insulin / Glucose (GLU)
	25. Dihydroepiandrosterone Sulfate (DHEA-S)	Chemiluminescence (CLIA) (competitive), IM1 & IM2
	26. Estradiol (E2)	Chemiluminescence (CLIA) (competitive) , IM1 & IM2
	27. Progesterone (PRG)	Chemiluminescence (CLIA) (competitive)IM1 & IM2
	28. Testosterone Total (TT)	Chemiluminescence (CLIA) (competitive) IM1 & IM2
	29. β-Human Chorionic Gonadotropine (β-HCG)	Chemiluminescence (CLIA) (non-competitive sandwich), IM1 & IM2
	30. Immunoglobulin E (IgE)	Chemiluminescence (CLIA) (non-competitive sandwich) , IM1 & IM2
	31. Δ4 Androstenedione	Chemiluminescence (CLIA) (competitive), IM1
	32. Human immunodeficiency virus type 1/O & 2 (HIV-1/O & 2) antibodies	Chemiluminescence (CLIA) (competitive), IM2
	33. Hepatitis C IgG antibodies (Anti-HCV)	Chemiluminescence (CLIA) (competitive), IM2
	34. Cytomegalovirus IgG antibodies (CMV IgG)	Chemiluminescence (CLIA) (competitive), IM2
	35. Cytomegalovirus IgM antibodies (CMV IgM)	Chemiluminescence (CLIA) (competitive), IM2
	36. Toxoplasma IgG antibodies (TOXO IgG)	Chemiluminescence (CLIA) (competitive), IM2
	37. Toxoplasma IgM antibodies (TOXO IgM)	Chemiluminescence (CLIA) (competitive), IM2
	38. Rubella virus IgG antibodies (Rubella IgG)	Chemiluminescence (CLIA) (competitive), IM2
	39. Rubella virus IgM antibodies (Rubella IgM)	Chemiluminescence (CLIA) (competitive), IM2
Blood serum or blood plasma (EDTA)	41. Intact Parathyroid Hormone (iPTH)	Chemiluminescence (CLIA) (non-competitive sandwich) , IM1 & IM2
Blood Serum	42. Troponine I high sensitivity (hs-TnI)	Chemiluminescence (CLIA) (competitive), IM1 & IM2
	Determination of 2 parameters	**Automated immunochemical analyzer Immulite 2000XPi SIEMENS* Δ.550**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood Serum	1. Calcitonin (CT)	Chemiluminescence (CLIA) (non-competitive)
	2. Cancer Antigen 19-9 (CA-199)	Dry phase two step reaction
Blood plasma (EDTA)	3. Adrenocorticotropic hormone (ACTH)	Chemiluminescence (CLIA) (non-competitive)
	Determination of 6 parameters	**Automated immunochemical analyzer Abbott ARCHITECTi2000sr * Δ.550**
Blood Serum	1. Thyroglobulin Tg	Chemiluminescent microparticle immunoassay (CMIA) (non-competitive)
	2. Anti-cyclic Citrullinated Peptide (Anti-CCP)	Chemiluminescent microparticle immunoassay (CMIA) (non-competitive).
	3.Hepatitis B virus surface antigen (HBsAg)	Chemiluminescent microparticle immunoassay (CMIA) (non-competitive)
	4. Hepatitis B virus surface antibodies (HBsAb)	Chemiluminescent microparticle immunoassay (CMIA) (non-competitive)
	5. Hepatitis B virus core antibodies (HBcAb)	Chemiluminescent microparticle immunoassay (CMIA) (non-competitive)
	6. Homocystein (HCY)	Chemiluminescence (CLIA) (competitive)
	Determination of 1 parameter	**Automated immunology Analyzer Maglumi 800 Snibe * Δ.550, E.550-1, E550-2**
	1. 17-OH Progesterone	Chemiluminescence (CLIA) (competitive)
Biochemical Tests		
Blood Serum	**Determination of 43 parameters**	**Automated Biochemistry analyzer Siemens Atellica* Δ.550, E.550-1, E550-2**
	1. Total Cholesterol(TC)	Enzymatic - Colorimetric (CHOD - PAP)
	2. Calcium Total (Ca)	Colorimetric (OCPC) R
	3. Phosphate (P)	Colorimetric (Phosphomolybdate)
	4. Glucose(GLU)	Enzymatic - Colorimetric (GOD-PAP) Ref. 11097621
	5. Creatinine (CREA)	Colorimetric (Jaffe)
	6. Potassium (K)	Ion Selective Electrode (ISE)
	7. Sodium (Na)	Ion Selective Electrode (ISE)
	8. Chlore (Cl)	Ion Selective Electrode (ISE)
	9. Magnesium (Mg)	Colorimetric (Xylidyl blue)
	10. Alkaline Phosphatase (ALP)	Enzymatic - Colorimetric (pNPP - AMP)
	11. Alanine Aminotransferase (ALT/SGPT)	Enzymatic - Colorimetric
	12. Aspartate Aminotransferase (AST/SGOT)	Enzymatic - Colorimetric
	13. Creatine Kinase (CK/CPK)	Enzymatic - Colorimetric (IFCC)
	14. Direct Bilirubin (DBIL)	Colorimetric vanadate oxidase
	15. Total Bilirubin (TBIL)	Colorimetric vanadate oxidase
Blood Serum (continued)	16. Indirect Bilirubin (IBIL)	Calculated from TBIL and DBIL (Colorimetric)
	17. Gamma-Glutamyl transferase (γGT)	Enzymatic Colorimetric

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	18. VLDL Cholesterol (VLDL-C)	Calculated from TRIG (Enzymatic - Colorimetric)
	19. Atherogenic index ((TC)/ (HDL-C))	Calculated from Total Cholesterol (TC) / HDL Cholesterol (HDL-C)
	20. Non-HDL-C	Calculated from Total Cholesterol (TC) - HDL Cholesterol (HDL-C)
	21. Total Lipids	Calculated from CHOL and TRIG (Enzymatic - Colorimetric)
	22. Phospholipids	Calculated from CHOL (Enzymatic - Colorimetric)
	23. HDL Cholesterol (HDL-C)	Enzymatic Colorimetric
	24. Iron (Fe)	Colorimetric ferrozine
	25. Triglycerides (TGs)	Enzymatic Colorimetric
	26. Urea	Enzymatic -Colorimetric (Urease)
	27. Uric Acid (UA)	Enzymatic Colorimetric
	28. Albumin (ALB)	Colorimetric (BCP)
	29. Amylase (AMY)	Enzymatic - Colorimetric IFCC** (Ed-G7PNP)
	30. Total Proteins (TP)	Colorimetric (Biuret)
	31. Nitrogen serum	Calculated from: UREA
	32. Serum osmolality	Calculated from: GLU, Na, UREA
	33. Total globin (SF)	Calculated from: TP, ALB
	34. Albumin/Globin ratio	Calculated from: ALB, SF
	35. C Reactive Protein (CRP)	Immunoturbidimetry (ITA)
	36. Immunoglobulin G (IgG)	Immunoturbidimetry (ITA)
	37. Immunoglobulin M (IgM)	Immunoturbidimetry (ITA)
	38. Immunoglobulin A (IgA)	Immunoturbidimetry (ITA)
	39. Antistreptolysine O (ASTO)	Immunoturbidimetry (ITA)
	40. Reumatoid Factor (RF) - quantitative	Immunoturbidimetry (ITA)
	41. Complement C3	Immunoturbidimetry (ITA)
	42. Complement C4	Immunoturbidimetry (ITA)
	43. Lactate Dehydrogenase (LDH)	Enzymatic - Colorimetric (L-P)
Urine	1.Albumin (uAlb)	Immunoturbimetric enhanced with PEG
	2.Total protein (UCFP)	Pigment entrapment
	3.Creatinine (U_Crea)	Enzymatic kinetic with blanc correction, Jaffe)
	Determination of 1 parameter	**Automated SEBIA Capillarys Δ.550, E.550-1, E550-2**
Blood Serum	Serum protein electrophoresis	Capillary elctrophoresis
	Determination of 1 parameter	**PCR Lightcycler 480ii**
Blood (EDTA)	Mutation detection ΔF508 p.Phe508del) of gene CFTR	Real-time PCR (qPCR) (LightSNiP CFTR Δ508F, TIB MOLBIOL)* O.590-4
Blood Coagulation Tests		
	Determination of 6 parameters	**Automated Coagulation Analyzer BSC XP SIEMENS* Δ.550**
Blood plasma (citrate)	1. Prothrombin time (PT sec)	Clot detection
	2. Prothrombin time (PT %)	Clot detection
Blood plasma (citrate) (continued)	3. Prothrombin time (International Normalized Ratio, PTINR)	Clot detection
	4. Activated partial prothrombin time (APPT)	Clot detection

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	5. Fibrinogen activity (FIB)	Clot detection
	6. D-Dimer	Immunoturbidimetric assay
Hematological Tests		
	Determination of 10 parameters	**Automated haematological analyzer ADVIA 2120i, SIEMENS* Δ.550, E.550-1, E550-2**
Whole blood (EDTA)	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
	9. Red blood cell distribution width (RDW)	Flow cytometry
	10. Mean platelet volume (MPV)	Flow cytometry
	Determination of 1 parameter	**High performance liquid chromatography (HPLC) analyzers G8 TOSOH Biosciences* Δ.550, E.550-1, E550-2**
	1.Determination of Glycated Haemoglobin A1C (HbA1C)	Ion-exchange high performance liquid chromatography (HPLC)

** Mention of the trade name of the analyte refers to a specific analytical method and corresponding working protocol*
*** IFCC: International Federation of Clinical Chemistry*
****Deutsche Gesellschaft für Klinische Chemie*

Site of assessment: **Permanent Laboratory premises, 14 Archbishop Makariou & Faitakis, 71202, Heraklion, Crete.**
Authorized signatories: **Chr. Dinas, S. Vetiniotis, G. Paterakis, O. Chatzidoukaki.**

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