Hellenic Accreditation System

Annex G1/3 to the Certificate No.**1131**-2

SCOPE of ACCREDITATION

of the

Clinical Laboratory

AIMODIAGNOSI-Private Diagnostic Laboratory, Private Company

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Biochemical Testing		
Blood serum	**Determination of 19 parameters**	**Automated analyzer Architect ci8200 ABBOTT***
	1. ALT/SGPT	Enzymatic – Kinetic - Colorimetric (NADH) 307220/R03 B7D5G0
	2. Total Cholesterol	Enzymatic colorimetric (CHO – OEP –HBA) 307220/R03 B7D5G0
	3. Glucose	Enzymatic Colorimetric (HEX – GPDH) 307268/R06 B3L8X0
	4. γ-GT	Colorimetric (L γ- Glutamyl-3-carboxy-4-nitroanillide) 305249/R04 7D65
	5. Triglycerides	Enzymatic colorimetric (GPO) 307193/R04 B7D7E0
	6. Urea	Enzymatic colorimetric (Uricase) 307236/R05 B7D5F0
	7. Uric Acid	Enzymatic colorimetric (Urease) 307219/R06 B3P390
	8. Creatinine	Enzymatic colorimetric (Jaffe) G10667/R08 B8L240
	9. Total Billirubin	Enzymatic colorimetric (DIAZONIUM) 307147/R04 B6L4U0
	10. HDL-Cholesterol	Enzymatic colorimetric (ASD) 307196/R04 B3K3W0
	11. Aspartate	Enzymatic – Kinetic - Colorimetric (NADH)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	aminotransferase (AST/GOT)	307225/R03 B7D8
	12. C-Reactive Protein (CRP)	Turbidimetry (TA) / Immunoturbidimetry (ITA) 306731/R04 B6K260
	13. Iron	Colorimetric (Ferene) 307184/R05 B6K950
	14. Total Protein	Colorimetric (Biuret) 307181/R05 B7D7D0
	15. Albumin	Colorimetric (Bromcresol Green) 306758/R03 B7DU30
	16. Amylase	Enzymatic Colorimetric (GNPG3) 306719/R04 B7DUI0
	17. Calcium	Colorimetric (Arsenazo III) 306781/R06 B3L7J0
	18. Phosphates (inorganic)	Colorimetric (Phosphomolybdate) 306349/R05 B7DHB0
	19. Alkaline phosphatase	Enzymatic – Kinetic - Colorimetric (Para-nP) 307217/R01 B7DVF0
Immunochemical testing		
Blood serum	**Determination of 16 parameters**	**Automated analyzer Architect ci8200 ABBOTT***
	1. Thyroxin (T4)	Chemiluminescent Microparticle Immunoassay (CMIA) G65409R02 B7K6T0
	2. Free Thyroxin (FT4)	Chemiluminescent Microparticle Immunoassay (CMIA) G59250R03 B7K6F0
	3. Thyrotropin Hormone (TSH)	Chemiluminescent Microparticle Immunoassay (CMIA) G6-2729/R06 B7K620
	4. Thyreoglobulin Antibodies (anti- TG)	Chemiluminescent Microparticle Immunoassay (CMIA) G1-0384/R06 B2K460
	5. Anti-TPO	Chemiluminescent Microparticle Immunoassay (CMIA) G1-0392/R04 B2K470
	6. Ferritin (Ferr)	Chemiluminescent Microparticle Immunoassay (CMIA) G6-2659/R08 B7K590
	7. Carcinoembryonic antigen (CEA)	Chemiluminescent Microparticle Immunoassay (CMIA) G6-2827/R04 B7K6R0
	8. Tumor marker CA 19-9	Chemiluminescent Microparticle Immunoassay (CMIA) 613-031 11/16/R03 B2K9

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	9. Tumor marker CA 15-3	Chemiluminescent Microparticle Immunoassay (CMIA) 614-001_R02 B2K4V0
	10. Tumor marker CA-125	Chemiluminescent Microparticle Immunoassay (CMIA) 615-001_R02 B2K470
	11. Prostate Specific Antigen (PSA)	Chemiluminescent Microparticle Immunoassay (CMIA) G47685R06 B7K700
	12. β-Human Chorionic Gonadotropin (β-HCG)	Chemiluminescent Microparticle Immunoassay (CMIA) G47685R06 B7K700
	13. Estrogens (E2)	Chemiluminescent Microparticle Immunoassay (CMIA) G67636R10 B7K720
	14. Progesterone	Chemiluminescent Microparticle Immunoassay (CMIA) G6-5477/R08 B7K770
	15. Follicle Stimulating Hormone (FSH)	Chemiluminescent Microparticle Immunoassay (CMIA) G6-5315/R11 B7K750
	16. Luteinizing Hormone (LH)	Chemiluminescent Microparticle Immunoassay (CMIA) G6-0462/R05 B2P400
Blood serum	**Determination of 12 parameters**	**Automated analyzer Architect i1000 ABBOTT***
	1. Hepatitis B surface antigen (HBsAg)	Chemiluminescent Microparticle Immunoassay (CMIA) G3-4444/R05 B2G220
	2. Hepatitis B core antigen antibodies (anti-HBc)	Chemiluminescent Microparticle Immunoassay (CMIA) G4-7715/R08 B8l440
	3. Hepatitis B surface antibodies (anti-HBc)	Chemiluminescent Microparticle Immunoassay (CMIA) G8-0543/R02 B7C1R0
	4. Human immunodeficiency virus type 1/2 antigen/antibodies (HIV 1/2 Ag/Ab)	Chemiluminescent Microparticle Immunoassay (CMIA) G4-5772/R05 B4J250
	5. Hepatitis C antibodies (anti-HCV)	Chemiluminescent Microparticle Immunoassay (CMIA) G5-9209/R01 B6C2Q0
	6. Hepatitis A antibodies (HAVAn IgG)	Chemiluminescent Microparticle Immunoassay (CMIA) G81707R02 L6CW79
	7. Toxoplasma IgG antibodies (Toxo IgG)	Chemiluminescent Microparticle Immunoassay (CMIA) G4-7734/R05 B6C190
	8. Toxoplasma IgM antibodies (Toxo IgM)	Chemiluminescent Microparticle Immunoassay (CMIA) G4-7818/R03 B6C200
	9. Rubella IgG antibodies (Rubella IgG)	Chemiluminescent Microparticle Immunoassay (CMIA) G8-0773/R03 B6C1H0

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	10. Rubella IgM antibodies (Rubella IgM)	Chemiluminescent Microparticle Immunoassay (CMIA) G8-1880/R08 B6C180
	11. Cytomegalovirus IgG antibodies (CMV IgG)	Chemiluminescent Microparticle Immunoassay (CMIA) G4-5812/R08 B6C150
	12. Cytomegalovirus IgM antibodies (CMV IgM)	Chemiluminescent Microparticle Immunoassay (CMIA) G5-3004/R04 B6C160
Hematological Testing		
Whole Blood (EDTA)	**Determination of 11 parameters**	**Automated hematological analyzer** **Celldyn Ruby ABBOTT***
	1. Hemoglobin (HGB)	Spectrophotometric OE_MΔ_03_EN01(Version 1)
	2. Hematocrit (HCT)	Calculated from RBC and MCV OE_MΔ_03_EN01(Version 1)
	3. Red Blood Cells (RBC)	Laser OE_MΔ_03_EN01(Version 1)
	4. Mean Corpuscular Volume (MCV)	Calculated from red blood cell size distribution data OE_MΔ_03_EN01(Version 1)
	5. Mean Corpuscular Hemoglobin (MCH)	Calculated from HGB and RBC OE_MΔ_03_EN01(Version 1)
	6. Mean Cell Hemoglobin Concentration (MCHC)	Calculated from HGB and HCT OE_MΔ_03_EN01(Version 1)
	7. White Blood Cells (WBC)	Laser/ M.A.P.S.S technology OE_MΔ_03_EN01(Version 1)
	8. Platelets (PLT)	Laser OE_MΔ_03_EN01(Version 1)

**Reference to the commercial name of a specific analyzer, refers to a specific analytical method and protocol*
*** IFCC: International Federation of Clinical Chemistry*

Site of assessement : **Permanent Laboratory premises, 45 Kyprou str, 412 22 Larissa, Greece.**
Approved signatories: **E. Labronikou, Our. Soultouki.**

This Scope of Accreditation replaces the previous one dated 28.07.2020.
The Accreditation Certificate No. **1131**-2, to ELOT EN ISO 15189:2012, is valid until 18.06.2022.

Athens, September 29, 2021

Spyridon Podaras
CEO of ESYD