HELLENIC ACCREDITATION SYSTEM

Annex G1/7 to the Certificate No.**1204**-2

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

REA GYNECOLOGY - MATERNITY - SURGICAL - THERAPEUTIC - DIAGNOSTIC CLINIC S.A.

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Hematological testing		
1. Whole blood (EDTA)	**Determination of 8 parameters**	Automatic Hematological Analyzer ADVIA 2120 (1) and ADVIA 2120 (2), Siemens*.
	1. White blood cells (WBC)	Flow Cytometry 067D0165-01 Rev.05, 2019-03 (p.9.21-9.23)
	2. Red blood cells (RBC)	Flow Cytometry 067D0165-01 Rev.05, 2019-03 (p.9.21-9.23)
	3. Haemoglobin (HGB)	Colorimetric 067D0165-01 Rev.05, 2019-03 (p.9.21-9.23)
	4. Haematocrit (HCT%)	Automatic calculation (RBC x MCV)/10 067D0165-01 Rev.05, 2019-03 (p.9.21-9.23)
	5. Mean cell volume (MCV)	Flow Cytometry 067D0165-01 Rev.05, 2019-03 (p.9.21-9.23)
	6. Mean corpuscular haemoglobin (MCH)	Automatic calculation (HGB/RBC)x10 067D0165-01 Rev.05, 2019-03 (p.9.21-9.23)
	7. Mean corpuscular haemoglobin volume (MCHC)	Automatic calculation (HGB/[RBC*MCV])x1000 067D0165-01 Rev.05, 2019-03 (p.9.21-9.23)
	8. Platelets (PLTs)	Flow Cytometry 067D0165-01 Rev.05, 2019-03 (p.9.21-9.23)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Biochemical testing		
1. Blood serum	**Determination of 24 parameters**	Automated biochemical analyzers Atellica CH 930 (1) Siemens* and Atellica CH 930 (2) Siemens*
	1. Glucose (Glu)	Hexokinase Atellica CH Glucose Hexokinase_3 (GluH_3) 11097592 Rev. 04, 2020-08
	2. Triglycerides (Trig)	LPL, GK, GPO, POD Atellica CH Triglycerides_2 (Trig_2) 11537222 Rev. 04, 2022-03
	3. Total Cholesterol (Chol)	Enzymatic oxidase, esterase, peroxidase Atellica CH Cholesterol_2 (Chol_2) 11097609 Rev. 04, 2020-11
	4. Uric acid (UA)	Uricase/Peroxidase Atellica CH Uric Acid (UA) 11097608 Rev. 03, 2019-05
	5.Urea Nitrogen	Urease with GLDH Atellica CH Urea Nitrogen (UN_c) 11097593 Rev. 03, 2020-08
	6.Creatinine (Crea)	Jaffe, alkaline picrate, Atellica CH Creatinine_2 (Crea_2) 11097596 Rev. 04, 2019-07
	7. Total Bilirubin (TBil)	Vanadate oxidation Atellica CH Total Bilirubin_2 (TBil_2) 11097531 Rev. 04, 2020-08
	8.Calcium (Ca)	Arsenazo III Atellica CH Calcium_2 (CA_2) 11097644 Rev. 03, 2019-03
	9.Phosphorus (Phos)	Phosphomolybdate/UV Atellica CH Inorganic Phosphorus (IP) 11097611 Rev. 2020-07
	10.Iron	Ferrozine Atellica CH Iron_2 (Iron_2) 11097601 Rev. 02, 2019-07
	11.Total Protein (TP)	Biuret method Atellica CH Total Protein II (TP) 11097604 Rev. 03, 2020-08
	12.Albumin (Alb)	BCG Dye Binding Atellica CH Albumin (Alb) 11097590 Rev. 03, 2019-07
	13.Potassium (K)	IMT A-LYTE Integrated Multisensor (IMT Na K Cl) 11099315 Rev. 03, 2019-09
	14.Sodium (Na)	IMT A-LYTE Integrated Multisensor (IMT Na K Cl) 11099315 Rev. 03, 2019-09
	15.Serum glutamic-oxaloacetic transaminase (SGOT/ AST))	Oxalacetate NADH Atellica CH Aspartate Aminotransferase (AST)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood serum (continued)		11097607 Rev. 03, 2020-08
	16. Serum glutamic-pyruvic transaminase (SGPT/ ALT)	Pyruvate NADH Atellica CH Alanine Aminotransferase (ALT) 11097605 Rev. 05, 2020-08
	17.Gamma-glutamyl trasferase (γ-GT)	L-γ-glutamyl-3-Carboxy-4-nitroanilide, glycylglycine Atellica CH Gamma-Glutamyl Transferase (GGT) 11097597 Rev. 03, 2022-12
	18.Alkaline phosphatase (ALP)	P-NPP, AMP Atellica CH Alkaline Phosphatase, Concentrated (ALP_2c) 11097600 Rev. 03, 2019-07
	19.Lactate dehydrogenase (LDH)	Lactate/NAD Lactate-to-pyruvate Atellica CH Lactate Dehydrogenase L-P (LDLP) 11097594 Rev. 04, 2019-
	20. Amylase (AMY)	Ethylidene Blocked-Pnpg7 Atellica® CH Amylase_2 (AMY_2) 11097649 Rev. 02, 2019-08
	21. Magnesium (Mg)	Xylidyl Blue Atellica CH Magnesium (Mg) 11097612 Rev. 02, 2019-06
	22. Chloride (Cl)	IMT A-LYTE Integrated Multisensor (IMT Na K Cl) 11099315 Rev. 03, 2019-09
	23. Direct Bilirubin (DBil)	Vanadate oxidation Atellica CH Direct Bilirubin 2 (DBil_2) 11097532 Rev. 2020-08
	24. High Density Cholesterol (HDL)	Oxidase/ peroxidase Atellica CH HDL Cholesterol (HDLC) 11537213 Rev. 04, 2022-03
Immunochemical tests		
2.Blood serum	**Determination of 16 parameters**	Automated analyzer ~~(2)~~ Atellica IM 1600 (1) and Atellica IM 1600 (2) Immunoassay System, Siemens*.
	1. Testosterone (Testo)	Competitive immunoassay - Direct chemiluminescent Atellica IM Testosterone II (TSTII) 10995708 Rev. 07, 2023-03
	2. Prolactin (PRL)	Sandwich immunoassay - Direct chemiluminescent Atellica IM Prolactin (PRL) 10995655 Rev. 05, 2023-03
	3. Progesterone (PRG)	Competitive immunoassay - Direct chemiluminescent technology Atellica IM Progesterone (PRGE) 10995659Rev. 05, 2023-03

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood serum (continued)	4. Follicle Stimulating Hormone (FSH)	Sandwich immunoassay - Direct chemiluminometric Atellica IM Follicle Stimulating Hormone (FSH) 10995581 Rev. 07, 2023-03
	5. Luteinizing Hormone (LH)	Two-site sandwich immunoassay - Direct chemiluminescent Atellica IM Luteinizing Hormone (LH) 10995634 Rev. 05, 2023-03
	6. Estradiol (E2)	Competitive assay - Direct chemiluminescent Atellica IM Enhanced Estradiol (eE2) 10995562 Rev. 06, 2023-03
	7. Thyrotropin Hormone (TSH)	Direct chemiluminescent Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)
	8. Thyrotropin Hormone (TSH3-Ultra II (TSH3ULII)	Competitive immunoassay - Direct chemiluminescent Atellica IM TSH3-Ultra II (TSH3ULII) 11208706 Rev. 02, 2025-02
	9. Triidothyronine total (T3)	Competitive immunoassay - Direct chemiluminescent Atellica IM Total Triiodothyronine (T3) 10995678 Rev. 03, 2020-06
	10. Free Thyroxin (Free-T4)	Competitive immunoassay - Direct chemiluminescent Atellica IM Free Thyroxine (FT4) 10995588 Rev. 06, 2020-11
	11. Thyroxin total (T4)	Competitive immunoassay - Direct chemiluminescent Atellica IM Total Thyroxine (T4) 10995685
	12. Ferritin (Fer)	Sandwich immunoassay - Direct chemiluminescent Atellica IM Ferritin (Fer) 10995568 Rev. 04, 2023-03
	13. β-Human Chorionic Gonadotropin (β-HCG)	Two-site Sandwich immunoassay - Direct chemiluminescent Atellica IM Total hCG (ThCG) 10995689 Rev. 04, 2022-06
	14. Antithyreoperoxidase Antibodies (Anti-TG)	Bridging immunoassay, acridirium ester chemiluminescent technology – Direct chemiluminescent Atellica IM Anti-Thyroglobulin II (aTgII) 11201761 Rev. 02, 2023-01
	15. Antithyreoperoxidase Antibodies (Anti-TPOII)	Competitive immunoassay - Direct chemiluminescent Atellica IM Anti-Thyroid Peroxidase II (aTPOII) 11206076 Rev. 02, 2025-05
	16. Insulin (Ins)	Two-site Sandwich immunoassay - Direct chemiluminescent Atellica IM Insulin (IRI) 10995628 Rev. 06, 2022-11

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood serum (continued)	**Determination of 9 parameters**	Automated analyzer Atellica IM 1600 (2) Immunoassay System, Siemens*.
	1. Carcinoembryonic antigen (CEA)	Two-site Sandwich immunoassay - Direct chemiluminescent Atellica IM Carcinoembryonic Antigen (CEA) 10995523 Rev. 05, 2022-10
	2. Cancer antigen CA 125	Competitive immunoassay - Direct chemiluminescent Atellica IM CA 125II (CA 125II) 10995481 Rev. 05, 2022-09
	3. Cancer antigen CA 15-3	Competitive immunoassay - Direct chemiluminescent Atellica IM CA 15-3 (CA 15-3) 10995485 Rev. 05, 2022-09
	4. Cancer antigen CA 19-9	Competitive immunoassay - Direct chemiluminescent Atellica IM CA 19-9 (CA 19-9) 10995490 Rev. 04, 2022-10
	5. Prostate Specific Antigen (PSA)	Two-site Sandwich immunoassay - Direct chemiluminescent Atellica IM Prostate-Specific Antigen (PSA) 10995662 Rev. 05, 2022-10
	6. Alpha-Fetal Protein (AFP)	Two-site Sandwich immunoassay - Direct chemiluminescent Atellica IM Alpha Fetoprotein (AFP) 10995441 Rev. 05, 2023-03
	7. Cortisol (Cor)	Competitive immunoassay - Direct chemiluminescent Atellica IM Cortisol (Cor) 10995538 Rev. 03, 2020-03
	8. Folate (Fol)	Competitive immunoassay - Direct chemiluminescent Atellica IM Folate (Fol) 10995572 Rev. 04, 2020-11
	9. Vitamin B12 (B12)	Competitive immunoassay - Direct chemiluminescent Atellica IM Vitamin B12 (VB12) 10995714Rev. 02, 2019-08

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

Site of assessment : **Laboratory permanent premises, 383 Syggrou Av. & 17 Pentelis St. · 175 64, Paleo Faliro, Attiki, Greece.**

Primary Sample Collection Site (Blood): **383 Syggrou Av. & 17 Pentelis St. · 175 64, Paleo Faliro, Attiki, Greece.**

Approved signatories: **Apostolakopoulos Panagiotis, Kannabos Georgios, Sanidopoulos Nikolaos, Mpouri Kristallia.**

This scope of Accreditation replaces the previous one dated 14.02.2025.
The Accreditation Certificate No. **1204**-2, to ELOT EN ISO 15189:2022, is valid until 12.05.2029.

Athens, 19 June 2026

Konstantinou Evangelos Apostolos
CEO of ESYD