Εθνικό Σύστημα Διαπίστευσης

Annex G1/9 to the Certificate No. **893**-3

SCOPE of ACCREDITATION
of the
Clinical Laboratory
of the
PRIVATE DIAGNOSTIC LABORATORY BIOCHEMIA S.A

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Immunochemical testing		
Blood serum	**Determination of 32 parameters**	**Automated analyzer Atellica IM, SIEMENS * (catalog E.550-1_V4_12-10-2021)**
	1. a-Fetoprotein (α-FP)	Electrochemiluminescence (ECLIA) (non-competitive sandwich)
	2. Carcinoembryonic antigen (CEA)	
	3. Tumor marker CA 125	
	4. Tumor marker CA 15-3	
	5. Tumor marker CA 19-9	
	6. Total Prostate Specific Antigen (TPSA)	
	7. β-Human Chorionic Gonadotropin (β-HCG)	
	8. Prolactin (PRL)	
	9. Parathormon (PTH intact)	
	10. Insulin(IRI)	
	11. Follicle Stimulating Hormone (FSH)	

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Blood serum (cont.)	12. Luteinizing Hormone (LH)	
	13. Thyrotropin Hormone (TSH)	
	14. Detection of IgM antibodies to Toxoplasma gondii (TOXO IgM)	
	15. Detection of IgG antibodies to Toxoplasma gondii (TOXO IgG)	
	16. Ferritin	
	17. Detection of HIV1 antigen p24 and antibodies to human immunodeficiency virus type 1/O and type 2 (HIV1/O&HIV2) (HIV Combi PT)	
	18. Antibodies IgG to hepatitis C virus (anti-HCV)	
	19. Thyroglobulin Antibodies (anti-TGII)	
	20. Immunoglobulin E(IgE)	
	21. Free Triidothyronine (FT3)	Chemiluminescence (CLIA) (competitive)
	22. Total Triidothyronine (total T3)	
	23. Free Thyroxin (FT4)	
	24. Total Thyroxin (total T4)	
	25. Thyroid Peroxidase Antibodies (anti-TPO)	

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
	26. Estradiol (E2)	
	27. Testosterone Total (TESTO)	
	28. Cortisol	
	29. Progesterone (PRG)	
	30. Folic acid	
	31. Vitamin B_{12}	
	32. Vitamin 25 OH D TOTAL	
	Determination of 4 parameters	**Automated analyzer Cobas e411, ROCHE * (catalog E.550-1_V4_12-10-2021)**
	33. Hepatitis B surface antigen (HBsAg)	Electrochemiluminescence (ECLIA) (non-competitive sandwich)
	34. Antibodies to the hepatitis B surface antigen (HBsAb)	
	35. Detection of IgG antibodies to Cytomegalovirus (CMV IgG)	
	36. Detection of IgM antibodies to Cytomegalovirus (CMV IgM)	
Biochemical testing		
Blood serum	**Determination of 29 parameters**	**ATELLICA CH (SIEMENS) * (catalog E.550-1_V4_12-10-2021)**
	37. Glucose (GLUH)	Glucose hexokinase (G6PD)
	38. Urea (UN)	UV-urease
	39.Creatinine (CREA)	Alkaline picrate-kinetic (Jaffe)
	40 .Uric acid (UA)	Uricase
	41.Sodium (Na)	ISE Indirect multisensor
	42.Potassium (K)	ISE Indirect multisensor
	43.Total protein (TP)	Biuret, end point
	44.Albumin (ALB)	Bromocresol green (BCG)
	45.Total Globulins	Calculated from TP and ALB
	46.Total Cholesterol (CHOL)	Cholesterol oxidase, esterase, peroxidase
	47.Triglycerides (TRIG)	Glycerol phosphate oxidase
	48.HDL-Cholesterol (D_HDL)	Direct without precipitation

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
	49.Total Lipids	Calculated from CHOL and TRIG
	50.Phospholipids	Calculated from CHOL
	51.LDL -Cholesterol	Calculated from CHOL ,TRIG, HDL
	52.VLDL -Cholesterol	Calculated from TRIG
	53.Total Bilirubin (TBIL)	Colorimetric (Vanadate Oxidation)
	54.Calcium (Ca)	Colorimetric (o-cresolphthalein in alkaline conditions)
	55.Phosphate (P)	UV-phosphomolybdate
	56.Magnesium (Mg)	Xylidyl blue
	57.Iron (Fe)	Ferrozine
	58.Alkaline phosphatase (ALP)	AMP Buffer (IFCC** modified)
	59.γ-Glutamyltranspeptdase (γGT)	IFCC** modified, G-glutamyl-carboxy-nitroanilide
	60.Lactate dehydrogenase (LDLP)	Lactate to Pyruvate
	61.Creatine kinase (CK_L)	IFCC** modified (G6PD)
	62.Aspartate aminotranferase (AST)	IFCC** modified, UV without P-5'-P
	63.Alanine aminotransferase (ALT)	IFCC** modified, UV without P-5'-P
	64.Amylase (AMY)	G_7-PNP blocked
	65. C-Reactive Protein (CRP-quantitative)	Immunoturbidimetric
Hematology Tests		
Whole blood (EDTA)	**Determination of 1 parameter**	**High performance liquid chromatography (HPLC) analyzer G8 TOSOH* (catalog E.550-1_V4_12-10-2021)**
	1. Glycated Hemoglobin A_{1C} (HbA_{1C})	Ion-exchange high performance liquid chromatography(HPLC)

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

Site of assessment : **Laboratory permanent premises, 144, 3rd Septemvriou str., 112 51 Athens, Greece.**
Approved signatories : **V.Siampani, A.Tsiropoula, R.Andronikou.**

This Scope of Accreditation replaces the previous one dated 22.11.2021.
The Accreditation Certificate No. **893**-3, to ELOT EN ISO 15189:2012, is valid until 26.11.2025.

Athens, 21.01.2022

Christos Nestoras
CEO of ESYD