Hellenic Accreditation System

Annex G1/6 to the Certificate No. **965**-3

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

BIODIAGNOSTICS Ltd.

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Biochemical Tests		
1. Blood serum	**Determination of 20 parameters**	**Automated biochemical analyzer Dimension RXL-MAX, SIEMENS* SOP-PR-15/ΣΤ-22/03/2021 L-43**
	1. Glucose (GLUC)	Enzymatic Chromatometric Reaction: Hexokinase
	2. Urea (BUN)	Enzymatic Chromatometric Reaction Kinetic: Urease
	3. Uric Acid (URCA)	Enzymatic Chromatometric Reaction: Uricase
	4. Aspartate Aminotransferase (AST)	Enzymatic Chromatometric Reaction: Siemens/ Date, Standard nonIFCC
	5. Alanine Aminotransferase (ALTI)	Enzymatic Chromatometric Reaction: Siemens/ Date, Standard IFCC
	6. Gamma-glutamyl trasferase (GGT)	Chromatometric Reaction: Siemens/ Date, L-Gamma-Glytanyl 3-Carboxy 4-Nitroanilide Substrate
	7. Triglycerides (TGL)	Enzymatic Chromatometric Reaction: Lipase – Glycerol -Dehydrogenase
	8. Creatinine (CREA)	Kinetic Chromatometric Reaction: Picrate JAFFE
	9. Alkaline phosphatase (ALP)	Chromatometric Reaction: AMP buffer
	10. Cholesterol HDL (AHDL)	Chromatometric Reaction: direct HDL, PPD
	11. Calcium (Ca)	Chromatometric Reaction: Cresolphthalein Complexone
	12. Iron (IRN)	Ferene/Colorimetric without PPT

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Blood serum (continued)	13. Phosphate Inorganic (P)	Chromatometric Reaction: Phosphomolybdate UV
	14. Total Cholesterol (CHOL)	Chromatometric Reaction: Siemens/ Date Cholesterol Esterase (CE)
	15. Potassium (K)	Indirect Potentiometric ISE
	16. Sodium (Na)	Indirect Potentiometric ISE
	17. Creatine kinase (CKI)	Enzymatic Reaction IFCC CP(ADP)/NADP to NADPH
	18. Lactate dehydrogenase (LDI)	Enzymatic Reaction L-lactated NAD to NADH
	19. Magnesium (Mg)	Chromatometric Reaction Methylthymol blue
	20. Total Protein (TP)	Chromatometric Reaction Biuret
2. Total Blood (EDTA)	**Determination of 1 parameter**	**Automated analyzers Automated biochemical analyzer Dimension RXL-MAX, SIEMENS* SOP-PR-15/ΣΤ-22/03/2021 L-43**
	1. Determination of Clycated Hemoglobin A1C (HBA1C)	Turbidimetric
Hematological Test		
1. Total Blood (EDTA)	**Determination of 8 parameters**	**Automated analyzers SYSMEX XS-1000i, ROCHE* SOP-PR-15/ΣΤ-22/03/2021 L-40**
	1. Haemoglobin (HB)	Colorimetric Method with HGB SLS
	2. Red Blood Cells (RBC)	Hydrodynamic Focusing (DC Detection)
	3. Platelets (PLTs)	Hydrodynamic Focusing
	4. White Blood Cells (WBC)	Flow Cytometry
	5. Hematocrit (HCT)	Hydrodynamic Focusing
	6. Mean Corpuscular Volume (MCV)	Automatic Calculation From RBC+HCT
	7. Mean Corpuscular Hemoglobin Concetration (MCHC)	Automatic Calculation From HGB+HCT
	8. Mean corpuscular hemoglobin (MCH)	Automatic Calculation From HGB+RBC
2. Blood plasma (citrate)	**Determination of 2 parameters**	**Semi-Automated Coagulation analyzer BFT *II*, SIEMENS SOP-PR-15/ΣΤ-22/03/2021 L-42**
	1. Prothrombin time (PT sec)	Mechanical and photo-optical clot detection-Turbodensitometric
	2. Prothrombin time (INR)	

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Immunochemical Tests		
1. Blood serum	**Determination of 12 parameters**	**Automated immunochemical analyzer COBAS 6000, ROCHE* SOP-PR-15/ΣΤ-22/03/2021 L-41**
	1. Carcinoembryonic antigen (CEA)	Electrochemiluminescence Immunoassay (ECLIA)
	2. Prostate Specific Antigen (PSA)	
	3. Ferritin	
	4. Triidothyronine total (T3)	
	5. Thyroxin total (T4)	
	6. Thyrotropin Hormone (TSH)	
	7. Free Triidothyronine (Free T3)	
	8. Free Thyroxin (Free-T4)	
	9. Antibodies to Thyroid Peroxidase (ANTI-TPO)	
	10. Antibody to Thyroglobulin (ANTI-TG)	
	11. Vitamin B12	
	12. Folate	

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

Site of assessment : **Laboratory permanent premises, 4, Iroon Polytexneiou str., 18531, Piraeus.**
Approved signatories : **Christos Karaiskos.**

This scope of Accreditation replaces the previous one dated 30.07.2020.
The Accreditation Certificate No. **965**-3, to ELOT EN ISO 15189:2012, is valid until 26.01.2023.

Athens, June 11, 2021

Spyridon Podaras
CEO of ESYD