Hellenic Accreditation System

Annex G1/3 to the Certificate No. 1227

SCOPE of ACCREDITATION
of the
Biochemistry Department
of the
General Cancer Hospital "AGIOS SAVVAS"

Tested materials/products	Types of test/Properties to be measured	Applied standards/Techniques
BiochemicalTests		
Blood Serum	**Determination of 31 parameters**	**Automated biochemical analyzers Architect c8000 (ARC I and ARC II)*** Δ.410/1/01.03.15, E410-1/3/28.11.21
	1. Glucose	Enzymatic (HK,G6P-DH)
	2. Albumin	Colorimetric (BCG)
	3. Protein (total)	Colorimetric (biuret)
	4. Magnesium	Colorimetric (xylidylblue)
	5. Bilirubin Total	Colorimetric (DPD)
	6. Bilirubin Direct	Colorimetric (DPD)
	7. Iron	Colorimetric (Ferrozin)
	8. Cholesterol Total	Enzymatic (CHOD-POD)
	9. HDL- Cholesterol	Enzymatic – colorimetric with Selective Immunointerference
	10. Triglycerides	Enzymatic (GPO-POD)
	11. Alkaline phosphatase	IFCC**
	12. γ-GT	IFCC**

Tested materials/products	Types of test/Properties to be measured	Applied standards/Techniques
Blood Serum (continued)	13. CPK	IFCC**
	14. LDH-L	IFCC**
	15. ALT/SGPT	Modified IFCC without pyridoxal phosphate
	16. AST/GOT	Modified IFCC without pyridoxal phosphate
	17. Cholinesterase	Kinetic catalytic (butyrylthiocholine)
	18. UIBC	Iron saturation of transferrin – Colorimetric (nitroso-PSAP)
	19. Total Bilirubin	Colorimetric
	20. Direct Bilirubin	Colorimetric
	21. UIBC	Colorimetric
Blood Serum, Urine	22. Calcium	Colorimetric (Arsenazo III)
	23. Phosphorus	Colorimetric (ammonium heptamolybdate)
	24. Urea	Enzymatic (urease, UV)
	25. Creatinine	Enzymatic
	26. Uric acid	Enzymatic (uricase- PAP)
	27. α-Amylase	IFCC**
	28. Sodium	Indirect potentiometric, ISE
	29. Potassium	Indirect potentiometric, ISE
	30. Chloride	Indirect potentiometric, ISE
Urine, CSF	31. Protein	Turbidimetric (Benzethonium Chloride)
Blood Serum, Urine	**Determination of 1 parameter**	**Osmometer Knauer*** Δ.410/1/01.03.15, E410-1/3/28.11.21
	1. Osmolality	Freezing point depression
Blood Serum	**Determination of 6 parameters**	**Automated clinical capillary electrophoresis system V8 HELENA*** Δ.410/1/01.03.15, E410-1/3/28.11.21

Tested materials/products	Types of test/Properties to be measured	Applied standards/Techniques
	1. Albumin	Capillary Electrophoresis
	2. α1	
	3. α2	
	4. β1	
	5. β2	
	6. γ	
ImmunochemicalTests		
Blood Serum	**Determination of 20 parameters**	**Automated immunochemical analyzer Cobas 6000* (A and Z), Roche** Δ.410/1/01.03.15, E410-1/3/28.11.21
	1. Carcinoembryonic antigen (CEA)	Electro-Chemiluminescence
	2. Alpha Fetoprotein (α-FP)	Electro-Chemiluminescence
	3. Tumor marker CA 15-3	Electro-Chemiluminescence
	4. Tumor marker CA 125	Electro-Chemiluminescence
	5. Tumor marker CA 19-9	Electro-Chemiluminescence
	6. Total Prostate Specific Antigen (PSA-total)	Electro-Chemiluminescence
	7. Free Prostate Specific Antigen (PSA-free)	Electro-Chemiluminescence
	8. Ferritin	Electro-Chemiluminescence
	9. Folate	Electro-Chemiluminescence
	10. Vitamin B12	Electro-Chemiluminescence
	11. Marker S-100	Electro-Chemiluminescence
	12. Marker NSE	Electro-Chemiluminescence
	13. Tumor marker CA 72-4	Electro-Chemiluminescence
	14. Tumor marker CYFRA 21-1	Electro-Chemiluminescence
	15. Triidothyronine total (T3)	Electro-Chemiluminescence
	16. Thyroxin total (T4)	Electro-Chemiluminescence
	17. Thyrotropin Hormone (TSH)	Electro-Chemiluminescence

Tested materials/products	Types of test/Properties to be measured	Applied standards/Techniques
	18. Free Triidothyronine total (Free T3)	Electro-Chemiluminescence
	19. Free Thyroxin (Free T4)	Electro-Chemiluminescence
	20. Thyroglobulin (TG)	Electro-Chemiluminescence
Blood Serum	**Determination of 4 parameters**	**Automated immunochemical analyzer, Integra 400plus*, Roche** Δ.410/1/01.03.15, E410-1/3/28.11.21
	1. Valproic acid	FPIA (mouse monoclonal)
	2. Carbamazepine	FPIA (sheep antiserum)
	3. Phenytoin	FPIA (mouse monoclonal)
	4. Digoxin	KIMS
Hematological Tests		
Whole blood (EDTA)	**Determination of 1 parameter**	**HPLC Analyzer Adams HA8160, Menarini*** Δ.410/1/01.03.15, E410-1/3/28.11.21
	1. Glycozylated Hemoglobin HbA1c	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: Biochemistry Department of the General Cancer Hospital "AGIOS SAVVAS", 171, Alexandras Av., 11522, Athens.**
Approved signatories: **N. Courtis, V. Karagiannis, E. Lykoka, A. Papandreou, K. Piperaki, Ch. Sakellaridis.**

This scope of Accreditation replaces the previous one dated 01.02.2022
The Accreditation Certificate No. 1227, to ELOT EN ISO 15189:2012, is valid until 16.11.2024

Athens, 16th October 2023

Christos Nestoras
CEO of ESYD