Hellenic Accreditation System

Annex G1/16 to the Certificate No. **466**-6

SCOPE of ACCREDITATION

of the

Biochemistry Department

of the

Laboratories Division

of

General Hospital of Nea Ionia «Konstantopouleio-Patission»

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Biochemical Tests		
1. Blood Serum	**Determination of 22 parameters**	**Automated biochemical analysers Alinity C, CI (Abbott),** AL-C-01, SN: AC05258, AL-CI-02, SN: AC05214 / AI23531, AL-CI-03 EFHMEREIO, SN: AC05155 **E.BX.530-1 v3 17/6/2023)**
	1. Glucose (Gluc)	Enzymatic (Exokinase with G-6-PD)
	2. Urea (BUN)	Ourease
	3. Creatinine (CREA)	Kinetic Alkaline Picrate
	4.Potassium (K^+)	Diluted Ion Selective Electrodes (indirect)
	5.Sodium (Na^+)	Diluted Ion Selective Electrodes (indirect)
	6.Chloride (Cl^-)	Diluted Ion Selective Electrodes (indirect)
	7. Alkaline phosphatase (ALP)	Para-nitrophenyl phosphate (p-NPP)
	8. Glutaminic-pyruvic transaminase (AST)	Enzymatic (NADH, without P-5'-P)
	9. Glutaminic-oxaloacetic transaminase (ALT)	NADH (without P-5'-P)
	10. Creatinine kinase (CK)	NAC (N-acetyl-L-cysteine)

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
1. Blood Serum (continued)	11. Gamma-glutamyl transferase (GGT)	L-gamma-glutamyl-3-carboxy-4-nitroanilide substrate
	12. Total bilirubin (TBiLi)	Diazonic salt
	13.Total Protein (TP)	Biuret
	14. Albumin (ALB)	Colorimetric (Bromocresol Green)
	15.Globulines (G)	Calculated (TP-ALB)
	16.Ratio A/G	Calculated (ALB/G)
	17. Magnesium (Mg)	Enzymatic
	18.Amylase (AMY)	Enzymatic/Colorimetric
	19.Calcium (Ca)	Arsenazo III
	20.Phosphorus (PHOS)	Phosphomolybdate
	21.Uric acid (URAC)	Uricase
	22.Lactate Dehydrogenase (LDH)	Conversion reaction of lactate to pyruvate (IFCC)
2.Blood Serum	**Determination of 6 parameters**	**Automated biochemical analysers** **Alinity C, CI (Abbott),** AL-C-01, SN: AC05258, AL-CI-02, SN: AC05214 / AI23531, **E.BX.530-1 v3(17/6/2023)**
	1. Iron (Fe)	Ferene
	2. High-density lipoprotein cholesterol (HDL)	ASD (Accelerator Selective Detergent)
	3. Low-density lipoprotein cholesterol (LDL)	Selective reagent purification in liquid form
	4. Triglycerides (TGL)	Glycerol phosphate oxidase
	5. Total Cholesterol (CHOL)	Enzymatic
	6. Atheromatic Index	Calculated (TC/HDL)
3. Urine	**Determination of 10 parameters**	**Automated biochemical analysers** **Alinity C, CI (Abbott),** AL-C-01, SN: AC05258,

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
3. Urine (continued)		**E.BX.530-1 v3(17/6/2023)**
	1. Amylase (AMY)	Enzymatic (CNPG3 Substrate)
	2. Urea (BUN)	Urease
	3.Calcium (Ca)	Arsenazo III
	4. Creatinine (CREA)	Kinetic assay ofpicric salt in alkaline environment
	5.Phosphorus (PHOS)	Phosphomolybdate
	6.Uric acid (URAC)	Uricase
	7.Potassium (K^+)	Diluted Ion Selective Electrodes (indirect)
	8.Sodium (Na^+)	Diluted Ion Selective Electrodes (indirect)
	9.Chloride (Cl^-)	Diluted Ion Selective Electrodes (indirect)
	10. Magnesium (Mg)	Enzymatic
4. CSF	**Determination of 2 parameters**	**Automated biochemical analysers Alinity C, CI (Abbott),** AL-CI-02, SN: AC05214 / AI23531 **E.BX.530-1 v3(17/6/2023)**
	1. Glucose (Gluc)	Enzymatic (Exokinase with G-6-PD)
	2. Lactate Dehydrogenase (LDH)	Conversion reaction of lactate to pyruvate (IFCC)
5. Biological fluids	**Determination of 3 parameters**	**Automated biochemical analysers Alinity C, CI (Abbott),** AL-C-01, SN: AC05258, AL-CI-02, SN: AC05214 / AI23531, AL-CI-03 EFHMEREIO, SN: AC05155 **E.BX.530-1 v3(17/6/2023)**
	1.Total Protein (TP)	Diuretic
	2.Glucose (Gluc)	Enzymatic (Exokinase with G-6-PD)
	3. Lactate Dehydrogenase (LDH)	Conversion reaction of lactate to pyruvate (IFCC)

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
6. Whole Blood	**Determination of 1 parameter**	**Automated biochemical analyser Alinity C (Abbott),** AL-C-01, SN: AC05258, **E.BX.530-1 v3 (17/6/2023)**
	1.HbA1c	Enzymatic method (N-amino-terminal fructosyl dipeptides of the β-chain of HbA1c)
7. Blood serum	**Determination of 1 parameter**	**Automated biochemical analysers Alinity C, CI (Abbott),** AL-CI-02, SN: AC05214 / AI23531, AL-CI-03 EFHMEREIO, SN: AC05155 **E.BX.530-1 v3(17/6/2023)**
	1. Troponin I (cTnI)	Chemiluminescent Microparticle Immunoassay (CMIA)
Immunochemical Tests		
1. Blood Serum	**Determination of 9 parameters**	**Automated biochemical analyser Alinity C, CI (Abbott),** AL-CI-02, SN: AC05214 / AI23531, **E.BX.530-1 v3(17/6/2023)**
	1. Triidothyronine total (Total T3)	Chemiluminescent Microparticle Immunoassay (CMIA)
	2. Thyroxin total (Total T4)	
	3. Free Triidothyronine (Free T3)	
	4. Free Thyroxin (Free-T4)	
	5. Thyrotropin Hormone (TSH)	
	6. Procalcitonin (PCT)	
	7. 25-HydroxyvitaminnD serum (Vit D 25-OH)	
	8. Total Human Chorionic Gonadotropin (T-HCG)	
	9. Prostate Specific Antigen (PSA)	
	10. Free Prostate Specific Antigen (FPSA)	
	11. Ratio Free/Total PSA	Calculated (Free / Total PSA)

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

Site of assessment: **Laboratory permanent premises: 3-5 Theodorou Konstantopoulou str., 14233 N. Ionia, Greece.**

Location of primary sample collection: 3-5 Theodorou Konstantopoulou str., 14233 N. Ionia, Greece.

Approved signatories: **S. Likousi, I. Manolis, A. Tsirigotis, A. Heliopoulos, A. Kougioumtzi**

This Scope of Accreditation replaces the previous one dated 25.11.2024.
The Accreditation Certificate No.**466**-6, to ELOT EN ISO 15189:2022, is valid until 05.11.2029.

Athens, 25th of May 2026

Konstantinou Evangelos Apostolos
CEO of ESYD