HELLENIC ACCREDITATION SYSTEM

Annex G1/8 to the Certificate No.**1044**-3

SCOPE of ACCREDITATION

of the

Department of Biopathology (frm. Microbiology)

of

General Hospital of Nea Ionia «Konstantopouleio - Patission»

Tested materials / products	Types of tests / Properties to be measured	Applied Standards / Techniques to be used
Microbiology testing		
1. Blood	Blood culture	BACTEC FX (Becton-Dickinson Laboratory Instruction O.MK.530.03 Version 6 (29.12.2022) Subculture Laboratory Instruction O.MK.530.03 Version 6 (29.12.2022) GRAM stain Laboratory Instruction O.MK.530.06 Version 2 (27.09.2022)
2. Urine	Quantitative urine culture	Laboratory Instruction O.MK.530.04 Version 4 (29.12.2022)
3. Microbial isolate from cultures of human biological samples	Identification: Biochemical test-based	VITEK 2® COMPACT cards (bioMérieux): Colorimetry Laboratory Instruction O.MK.530.07 Version 7 (01.04.2022)
4. Microbial isolate from cultures of human biological samples	Antimicrobial susceptibility testing: Automated broth micro-dilution - Determination of Minimum Inhibitory Concentration (MIC)	VITEK 2® COMPACT cards (bioMérieux): Turbidimetry Laboratory Instruction O.MK.530.07 Version 7 (01.04.2022)
Immunology testing		

1. Blood serum	**Determination of 5 parameters**	**Automated immunoassay analyzer Cobas e-411, Roche***
	alpha-Fetoprotein (AFP)	Electrochemiluminescence/ Magnetic particle (ECL technology) Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
	Carcinoembryonic antigen (CEA)	Electrochemiluminescence/ Magnetic particle (ECL technology) Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
	Cancer Antigen 15-3 (CA 15-3)	Electrochemiluminescence/ Magnetic particle (ECL technology) Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
	Cancer Antigen 125 (CA 125)	Electrochemiluminescence/ Magnetic particle (ECL technology) Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
	Cancer Antigen 19-9 (CA 19-9)	Electrochemiluminescence/ Magnetic particle (ECL technology) Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
2. Blood serum	**Determination of 8 parameters**	**Automated analyzer Cobas Integra 400, Roche***
	1. C-Reactive Protein (CRP)	Immunoturbidimetric assay Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
	2. Antistreptolysin O (ASO)	Immunoturbidimetric assay Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
	3. Immunoglobulin A (IgA)	Immunoturbidimetric assay Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
	4. Immunoglobulin G (IgG)	Immunoturbidimetric assay Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
	5. Immunoglobulin M (IgM)	Immunoturbidimetric assay Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
2. Blood serum (continued)	6. Complement C3	Immunoturbidimetric assay

		Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
	7. Complement C4	Immunoturbidimetric assay Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
	8. Rheumatoid factor (RF)	Immunoturbidimetric assay Laboratory Form E.MK.530-1 Version 2 (22.03.2022)
Urine tests		
1. Urine	**Determination of 12 parameters**	**Analyzer FUS-2000, DIRUI**
	1. Color	RGB color sensor Laboratory Instruction O.MK.530.05 Version 6 (04.04.2023)
	2. Turbidity (appearance)	Light-scattering detection Laboratory Instruction O.MK.530.05 Version 6 (04.04.2023)
	3. Specific gravity	Refractometry Laboratory Instruction O.MK.530.05 Version 6 (04.04.2023)
	4. pH	Photoelectric colorimetry Laboratory Instruction O.MK.530.05 Version 6 (04.04.2023)
	5. Leukocytes (leukocyte esterase)	
	6. Nitrates	
	7. Protein	
	8. Glucose	
	9. Ketones	
	10. Urobilinogen	
	11. Bilirubin	
	12. Erythrocytes (blood)	
2. Urine sediment 2. Urine sediment (continued)	**Determination of 8 parameters**	Microscopic examination (x100, x400) Laboratory Instruction O.MK.530.05 Version 6 (04.04.2023)
	1. Leucocytes (number and type)	
	2. Red blood cells (number and type)	

	3. Epithelial cells of urinary system (number and type)	
	4. Bacteria (microorganisms)	
	5. Fungi	
	6. Casts (number and type)	
	7. Crystal (number and type)	
	8. Amorphous salts (type)	

**Η αναφορά της εμπορικής ονομασίας του αναλυτή παραπέμπει σε συγκεκριμένη αναλυτική μέθοδο και ανάλογο πρωτόκολλο εργασίας*

Site of assessment: **Permanent premises of Department Biopathology (fmr. Microbiology): 3-5 Theodorou Konstantopoulou, 14233, N. Ionia, Athens Greece.**

Site of primary sample collection: **Permanent premises of General Hospital Nea Ionia "Konstantopouleio-Patision": 3-5 Theodorou Konstantopoulou, 14233, N. Ionia, Athens Greece.**
Approved signatories: **E. Palla, K. Zourla, A. Psina**

This Scope of Accreditation replaces the previous one dated 03.10.2024.
The Accreditation Certificate No. **1044**-3, to ELOT EN ISO 15189:2022, is valid until 28.06.2029.

Athens, 3rd of August 2026

Konstantinou Evangelos Apostolos
CEO of ESYD