Hellenic Accreditation System

Annex G1/A11 to the Certificate No. **913**-5

SCOPE of ACCREDITATION

of the

Microbiology Laboratory &
National Reference Laboratory for Mycobacteria

of the

Laboratories Division

of

"Sotiria" Chest Diseases General Hospital of Athens

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Microbiological Tests		
Whole blood	Detection of aerobic and anaerobic bacteria and fungi (blood culture)	Fluorescence method Automated incubation and detection system BACTEC 9240 (Becton Dickinson, USA)* ΕΔ.ΚΟΙΝ.01 ver. 5/03.04.2025
All Biological samples	Detection of acid fast bacteria	Acid fast stain Ziehl-Neelsen (Non automated method) ΕΔ.ΜΥΚ.01 ver. 1/03.04.2025

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

Site of assessment: **Permanent laboratory premises, 152 Mesogeion ave., GR-11527, Athens, Greece.**
Primary Sample Collection Site: **Permanent laboratory premises, 152 Mesogeion ave., GR-11527, Athens, Greece.**
Approved signatories: **S. Karabela, S. Mavrea, A. Mavrommati, l. Marinou, D. Giannousoglou, V. Lavouta, P. Rodopoulou, M. Stagas.**
This Scope of Accreditation replaces the previous one dated 23.03.2023.
The Accreditation Certificate No. **913**-5, to ELOT EN ISO 15189:2022 is valid until 27.04.2027.

Athens, 27th of July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD

Hellenic Accreditation System

Annex G1/A11 to the Certificate No. **913-**5

SCOPE of ACCREDITATION

of the

Biochemical Laboratory

of the

Laboratories Division

of

"Sotiria" Chest Diseases General Hospital of Athens

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Biochemical Tests		
	Determination of 28 parameters	**Automated Biochemical Analyzer Architect c16000, Abbott ***
Blood serum, plasma, CSF	l. Glucose	Enzymatic method hexokinase ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma, urine	2. Urea	Urease enzymatic reaction with GLDH ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma, urine	3. Creatinine	JAFFE Method ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, urine	4. Potassium	Potentiometric Abbott EA.BIOX.OI ver2/12-05-2020 and E.42.01 ver 012025
Blood serum, urine	5. Sodium	Potentiometric Abbott ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, urine	6. Chloride	Potentiometric Abbott ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma	7. Aspartate aminotransferase (AST/GOT)	Modified without P-S-P ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma	8. Glutamic-pyruvate transaminase (GPT/ALT)	Modified without P-S-P ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma	9. Creatinine Kinase (CK)	ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma	10.Creatinine Kinase-MB	Enzymatic M-subgroup immuno-inhibition

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
	(CKMB)	ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma	I l . Total Bilirubin	DPD ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma	12.Direct Bilirubin	DPD ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum	13. Gamma-glutamyl trasferase (Y-GT)	IFCC* * ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma	14.Alkaline phosphatase (ALP)	IFCC* * ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma, pleural effusion, ascites	15 .Lactate dehydrogenase (LDH)	IFCC* *(L->P) ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma, urine, CSF	16. Total Protein	BIURET Method ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma,	17. Albumin	Colorimetric BROMOCRESOL GREEN ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma,	18.Amylase	IFCC* * ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma, urine	19.Calcium	ARSENAZO Method ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, urine	20.1norganic Phosphorus	MOLYBDATE UV ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma, urine	21 .Magnesium	XYLIDYL BLUE ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma, urine	22.Uric acid	Enzymatic colorimetric reaction with uricase/peroxidase ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma	23.1ron	FERROZINE Method ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma, pleural effusion	24. Cholesterol	Enzymatic CHOD-POD ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Blood serum, plasma,	25. Triglycerides	Enzymatic kinetic GPO-POD ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma	26.HDL-cholesterol	Immuno-inhibition ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum, plasma	27.LDL-cholesterol	Calculated ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
Blood serum	28.CRP	Immuno-turbitrimetric ΕΔ.BIOX.01 ver 2/12-05-2020 and E.42.01 ver 012025
	Determination of 3 parameters	**Automated Immunoassay Analyzer Architect i1000SR, Abbott***
Blood serum, plasma	1. Valproic Acid	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum, plasma	2. Vancomycin	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Plasma (EDTA)	3. BNP	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
	Determination of 13 parameters	**Automated Immunoassay Analyzer Architect i2000SR Abbott***
Blood serum, plasma (heparin)	1. TSH	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum, plasma (heparin)	2. FT4	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum, plasma (heparin)	3. FT3	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum, plasma (heparin)	4. Ferritin	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum, plasma	5. Vitamin B12	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum, plasma	6. Folic acid	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Blood serum	7. AFP	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum	8. CA-125	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum	9. CA-19-9	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum	10. CA-153	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum	l l . CEA	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum	l 2 . PSA	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
Blood serum, plasma	13. High Sensitive Troponin I hsTnI	CMIA ΕΔ.BIOX.02 ver1/16-05-2019 and E.42.01 ver 012025
	Determination of 1 parameter	**G8 Variant Glycated Heamoglobin Analyser, Tosoh**
Whole blood	1. HblAc	HPLC ΕΔ.BlOX.03 ver1/16-09-2022 and E.42.01 ver 012025

*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: **Permanent laboratory premises, 152 Mesogeion ave,, GR-11527, Athens**, Greece.

Primary Sample Collection Site: **Permanent laboratory premises, 152 Mesogeion ave., GR-11527, Athens, Greece.**

Approved signatories: **M. Elkouris, K. Kanellopoulou, C. Kantza, M. Logotheti, B. Margariti, A. Ramantani, E. Vlachogianni, P. Zacharatos.**

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Athens, 27th of July 2025

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CEO of ESYD

Hellenic Accreditation System

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SCOPE of ACCREDITATION

of the

Heamatology Laboratory

of the

Laboratories Division

Of

"Sotiria" Chest Diseases General Hospital of Athens

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Hematological Tests		
	Determination of 13 parameters	**Automated Analyzers ADVIA SIEMENS* and RUBY ABBOTT***
Whole blood (EDTA)	1. Hemoglobin (HGB)	Photometric ΕΔ.AIMAT.01 VER 1 24/06/2019
	2. Red Blood Cells (RBC)	Flow Cytometry ΕΔ.AIMAT.01 VER 1 24/06/2019
	3. Hematocrit (HCT%)	Calculated: HCT = (RBC*MCV)/10 ΕΔ.AIMAT.01 VER 1 24/06/2019
	4. Mean CorpuscularVolume (MCV)	Flow Cytometry ΕΔ.AIMAT.01 VER 1 24/06/2019
	5. Mean Corpuscular Hemoglobin (MCH)	Calculated: MCH = (HGB/RBC)*10 ΕΔ.AIMAT.01 VER 1 24/06/2019
	6. Mean Corpuscular Hemoglobin Concentration (MCHC)	Calculated: MCHC=(HGB/HCT)*100 ΕΔ.AIMAT.01 VER 1 24/06/2019
	7. White Blood Cells WBC	ΕΔ.AIMAT.01 VER 1 24/06/2019
	8. Neutrophils (absolute count, %)	Flow Cytometry with peroxidase staining- MAPSS technology ΕΔ.AIMAT.01 VER 1 24/06/2019
	9. Lymphocytes (absolute count,	Flow Cytometry with peroxidase staining- MAPSS technology ΕΔ.AIMAT.01 VER 1 24/06/2019
Whole blood (EDTA) (continued)	10. Monocytes (absolute count, %)	Flow Cytometry with peroxidase staining- MAPSS technology ΕΔ.AIMAT.01 VER 1 24/06/2019

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
	11. Eosinophils (absolute count, %)	Flow Cytometry with peroxidase staining- MAPSS technology ΕΔ.AIMAT.01 VER 1 24/06/2019
	12. Baseophils (absolute count, %)	Flow Cytometry- MAPSS technology EA. ΕΔ.AIMAT.01 VER 1 24/06/2019
	13. Platelets (PLT)	Flow Cytometry ΕΔ.AIMAT.01 VER 1 24/06/2019

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Site of assessment: **Permanent laboratory premises, 152 Mesogeion ave., GR-11527, Athens, Greece.**
Primary Sample Collection Site: **Permanent laboratory premises, 152 Mesogeion ave., GR-11527, Athens, Greece.**

Approved signatories: **E. Mantzabinou, M.Aggelopoulou, M. Giannakaki, S.Mavrea, P.Rodopoulou.**

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