Hellenic Accreditation System

Annex G1/8 to the Certificate No.**1154**-3

SCOPE of ACCREDITATION

of the

Department of Immunology and Histocompatibility

of the

Laboratories Division

of

“Helena Venizelou” Hospital

of the

“Helena Venizelou-Alexandra” Hospital

Tested materials/ products	Types of test/Properties to be measured	Applied Standards/Techniques to be used
Immunological Tests		
1. Blood Serum	**Determination of 9 parameters:**	**ABBOTT ARCHITECT, i1000SR automated analyzer** (sn i1SR54885). **OE-XM-01/1.3 24-4-2025**
	1. CEA	CMIA Chemiflex
	2. AFP	
	3. Ca 125	
	4. Ca 15-3	
	5. Ca 19-9	
	6. Prostate Specific antigen (PSA)	
	7. Free Prostate Specific antigen (FPSA)	
	8. Thryroid peroxidase antibodies (anti-TPO)	
	9. Thyroglobulin antibodies (anti-Tg)	
2. Blood serum	**Determination of 11 parameters**	**DSH automated ELISA system DYNEX technologies DSX** (sn 1DXA0072) **Generic Assays** **OE-EL-01/1.3 24-4-2025**
	1. anti Cardiolipin antibodies IgG	ELISA
	2. anti Cardiolipin antibodies IgM	

Blood serum (continued)		
	3. anti-β2GPI IgG	
	4. anti-β2GPI IgM	
	5. ENA antibodies Screening test	
	6. ENA SS-A/Ro antibodies	
	7. ENA SS-B/La antibodies	
	8. ENA RNP antibodies	
	9. ENA Sm antibodies	
	10. ENA Scl-70 antibodies	
	11. ENA Jo-1 antibodies	
3. Blood serum	**Determination of 3 parameters:**	**Indirect immunofluorescence (IFA)** Microscope NIKON, Eclipse E400 Generic Assays, Zenit Reagents autoimmunity, Zeus, Euroimmun **ОЕ-АФ-01/1.6 1-10-2024** **ОЕ-АФ-01-01-EUR DNA 1-10-2024** **ОЕ-АФ-01-01-EUR AMA 1-10-2024**
	1. antinuclear antibodies ANA	IFA
	2. antibodies against double stranded DNA (dsDNA)	
	3. Anti-motochondrial antibodies AMA	
4. Whole blood	**Determination of 12 parameters:**	**Beckman Coulter FC500 Flow Cytometer** (sn AL07038) **ОЕ-КР-01/1.3 24-4-2025**
	CD3+ cells	Flow cytometry
	CD3+CD4+ cells	
	CD3+CD8+ cells	
	CD3-CD(16/56)+ cells	
	CD2+ cells	
	CD3+CD(16/56)+ cells	
	CD19+ cells	
	CD5+/CD19+ cells	
	TCRγδ+ T-cells	
	TCR Vγ9+ T-cells	

	CD4/CD8+ cells	ratio
	TCR Vγ9+/ TCR PANγδ+ T-cells	

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

Site of assessment: **Laboratory permanent premises: "Helena Venizelou" Hospital, 2 Helen's Venizelou Sq, 11521 Athens, Greece**

Primary Sample Collection: **Laboratory permanent premises: "Helena Venizelou" Hospital, 2 Helen's Venizelou Sq, 11521 Athens, Greece**

Approved signatories: **Theodora Keramitsoglou, Dimitra Oikonomopoulou**

This Scope of Accreditation replaces the previous one dated 15.11.2022.
The Accreditation Certificate No. **1154**-3 to ELOT EN ISO 15189:2022, is valid until 27.01.2028.

Athens, 29.07.2025

Konstantinou Evangelos Apostolos
CEO of ESYD