Hellenic Accreditation System

Annex G1/2 to the Certificate No.**1417**-2

SCOPE of ACCREDITATION

of the

Immunology – Histocompatibility Department

of

Evangelismos – Policliniki General Hospital

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used / Equipment
Immunology Tests		
1. Peripheral blood in EDTA	*1.PB lymphocyte immunophenotype (percentages and absolute numbers / cells/μl CD3+, CD3+CD4+, CD3+CD8+, CD19+, CD3-CD16/56+ lymphocytes)*	Flow cytometry 1.FLOW CYTOMETER NAVIOS EX (Beckman Coulter) 2. FLOW CYTOMETER DxFlex (Beckman Coulter) 3. FLOW CYTOMETER NAVIOS (Beckman Coulter) 4. FLOW CYTOMETER Facs Lyric (BD Biosciences) Methods M.AN.02/26-03-2025 & M.AN.03/20-12-2023.
2. Bone Marrow in EDTA or in heparin	2. *BM lymphocyte immunophenotype (percentages CD3+, CD3+CD4+, CD3+CD8+, CD19+, CD3-CD16/56+ lymphocytes).*	Flow cytometry 1. FLOW CYTOMETER NAVIOS EX (Beckman Coulter) 2. FLOW CYTOMETER DxFlex (Beckman Coulter) 3. FLOW CYTOMETER NAVIOS (Beckman Coulter) method M.AN.03/20-12-2023)
3. Peripheral blood in EDTA, cell apheresis sample.	3. Determination of the percentage on total leukocytes and of the absolute number (cells/μl) of CD34+ hematopoietic stem cells.	Flow cytometry 1. FLOW CYTOMETER NAVIOS EX (Beckman Coulter) 2. FLOW CYTOMETER DxFlex (Beckman Coulter) Method M.AN.01/20-12-2023
4. Peripheral blood in EDTA and Bone Marrow in EDTA or in heparin	B lymphoproliferative diseases immunophenotype	Flow cytometry 1. FLOW CYTOMETER NAVIOS EX (Beckman Coulter) 3. FLOW CYTOMETER NAVIOS (Beckman Coulter) Method M.AN.05, 20-12-2023

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used / Equipment
5. Peripheral blood in EDTA and Bone Marrow in EDTA or in heparin	Acute myeloid leukemia immunophenotype	Flow cytometry 1. FLOW CYTOMETER NAVIOS EX (Beckman Coulter) 2. FLOW CYTOMETER NAVIOS (Beckman Coulter) Method M.AN.04, 20-12-2023
6. Peripheral blood in EDTA and Bone Marrow in EDTA or in heparin	B acute lymphoblastic leukemia immunophenotype	Flow cytometry 1. FLOW CYTOMETER NAVIOS EX (Beckman Coulter) 2. FLOW CYTOMETER NAVIOS (Beckman Coulter) Method M.AN.04, 20-12-2023
7. Peripheral blood in EDTA and Bone Marrow in EDTA or in heparin	T acute lymphoblastic leukemia immunophenotype	Flow cytometry 1. FLOW CYTOMETER NAVIOS EX (Beckman Coulter) 2. FLOW CYTOMETER NAVIOS (Beckman Coulter) Method M.AN.04, 20-12-2023
8. Serum	Protein electrophoresis	CAPILLARY ZONE ELECTROPHORESIS ANALYZER SEBIA E.AN.530-1, 20-12-2023
9. Serum and urine	Protein immunofixation	AGAROZE METHOD SEMIAUTOMATIC IMMUNOFIXATION SYSTEM SEBIA E.AN.530-1, 20-12-2023
10. Serum	Determination of 13 parameters	
	1. IMMUNOGLOBULIN IgG	NEPHELOMETRY (KINETIC TECHNIQUE) NEPHELOMETER IMAGE BECMAN COULTER E.AN.530-1, 20-12-2023
	2. IMMUNOGLOBULIN IgA	NEPHELOMETRY (KINETIC TECHNIQUE) NEPHELOMETER IMAGE BECMAN COULTER E.AN.530-1, 20-12-2023
	3. IMMUNOGLOBULIN IgM	NEPHELOMETRY (KINETIC TECHNIQUE) NEPHELOMETER IMAGE BECMAN COULTER E.AN.530-1, 20-12-2023
	4. COMPLEMENT FACTOR C3	NEPHELOMETRY (KINETIC TECHNIQUE) NEPHELOMETER IMAGE BECMAN COULTER E.AN.530-1, 20-12-2023
	5. COMPLEMENT FACTOR C4	NEPHELOMETRY (KINETIC TECHNIQUE) NEPHELOMETER IMAGE BECMAN COULTER E.AN.530-1, 20-12-2023
	6. REUMATOID FACTOR RF	NEPHELOMETRY (KINETIC TECHNIQUE) NEPHELOMETER IMAGE BECMAN COULTER E.AN.530-1, 20-12-2023

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used / Equipment
10. Serum (continued)	7. KAPPA FREE LIGHT CHAINS	NEPHELOMETRY (FINAL POINT technique) NEPHELOMETER, SIEMENS E.AN.530-1, 20-12-2023
	8. LAMBDA FREE LIGHT CHAINS	NEPHELOMETRY (FINAL POINT technique) NEPHELOMETER, SIEMENS E.AN.530-1, 20-12-2023
	9. ANTINUCLEAR ANTIBODIES (ANA) DETERMINATION	IMMUNOFLUORESCENCE IMMUNOFLUORESCENCE AUTOMATIC ANALYZER AP 22 SPEEDY IF DAS M.AN.06, 04-12-2023
	10. ANTI - DOUBLE STRANDED DNA ANTIBODIES (anti--ds DNA) DETERMINATION	IMMUNOFLUORESCENCE IMMUNOFLUORESCENCE AUTOMATIC ANALYZER AP22 SPEEDY IF DAS M.AN.07, 04-12-2023
	11. ANTIBODIES AGAINST EXTRACTABLE NUCLEAR ANTIGENS DETERMINATION (anti-ENA)	ELISA AUTOMATIC ENZYME-LINKED IMMUNOSORBENT ASSAY ANALYZER ELISA DSX SYSTEM THERMOLAB M.AN.08, 04-12-2023
	12. ANTIBODIES AGAINST CYCLIC CITRULLINATED PEPTIDE DETERMINATION (anti-CCP)	ELISA AUTOMATIC ENZYME-LINKED IMMUNOSORBENT ASSAY ELISA DSX SYSTEM THERMOLAB M.AN.10, 04-12-2023
	13. ANTIBODIES AGAINST TISSUE TRANSGLUTAMINASE DETERMINATION (anti-tTG)	ELISA AUTOMATIC ENZYME-LINKED IMMUNOSORBENT ASSAY ANALYZER ELISA DSX SYSTEM THERMOLAB M.AN.09, 04-12-2023

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

Site of assessment: **Laboratory permanent premises: Immunology- Histocompatibility Department, "Evangelismos – Polikliniki" General Hospital Of Athens, Ipsilantou 45-47, 10676, Athens.**

Approved signatories: **Tsirogianni Alexandra, Kakkas Ioannis, Gregoriou Eirini, Kontou Elisavet, Antaraki Despoina.**

This scope of Accreditation replaces the previous one dated 29.07.2024.
The Accreditation Certificate No. **1417**-2, to ELOT EN ISO 15189:2022, is valid until 29.07.2029

Athens, 31st of July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD