Hellenic Accreditation System

Annex G1/9 to the Certificate No. **1057**-5

SCOPE of ACCREDITATION

of the

Hematology Laboratory

of the

Hospital Unit "SISMANOGLEIO"

of the

General Hospital of Athens "SISMANOGLEIO AMALIA FLEMING"

Tested materials/ products	Types of tests / Properties measured	Applied Standards / Techniques used
Coagulation Tests		
1. Blood plasma (sodium citrate)	**Determination of 6 parameters**	**Automated Coagulation analyzers BCS-XP (I & II) SIEMENS***
	1. Prothrombin time (PT)	Clotting O 510-15/1, O 510-16/1, O 510-17/1, O 540-1/1, O 540-3/2
	2. International Normalized Ratio - INR	Calculated method O 510-15/1, O 510-16/1, O 510-17/1, O 540-1/1, O 540-3/2
	3. Activated Partial Thromboplastin Time (aPTT)	Clotting O 510-15/1, O 510-16/1, O 510-17/1, O 540-1/1, O 540-3/2
	4. Fibrinogen (FIB)	Modified Clauss technique O 510-15/1, O 510-16/1, O 510-17/1, O 540-1/1, O 540-3/2
	5. D-Dimers (DD)	Immunoturbidimetry O 510-15/1, O 510-16/1, O 510-17/1, O 540-1/1, O 540-3/2
	6. Antithrombin (AT III)	Chromogenic O 510-15/1, O 510-16/1, O 510-17/1, O 540-1/1, O 540-3/2

Tested materials/ products	Types of tests / Properties measured	Applied Standards / Techniques used
Hematological Tests		
1. Whole blood (EDTA)	**Determination of 15 parameters**	**Automated Hematology analyzers SYSMEX SYSMEX XN-1000i (I & II) ROCHE***
	1. White blood cell (WBC)	Volume analysis combined with flow cytometry O 510-16/1, O 540-3/2
	2.Red blood cell (RBC)	Volume analysis combined with flow cytometry O 510-16/1, O 540-3/2
	3. Hemoglobin (HGB)	Photometric O 510-16/1, O 540-3/2
	4. Hematocrit (HCT%)	Calculated O 510-16/1, O 540-3/2
	5. Mean corpuscular volume (MCV)	Volume analysis with flow cytometry O 510-16/1, O 540-3/2
	6. Mean corpuscular Hemoglobin (MCH)	Calculated O 510-16/1, O 540-3/2
	7. Mean corpuscular Hemoglobin Concentration (MCHC)	Calculated O 510-16/1, O 540-3/2
	8. RBC Distribution Width (RDW)	Calculated O 510-16/1, O 540-3/2
	9. Platelets (PLTs)	Volume analysis combined with flow cytometry O 510-16/1, O 540-3/2
	White Blood Cell Automated Differential Count	
	10. Reticulocyte (%)	Staining combined with cytometry O 510-16/1, O 540-3/2
	11. Neutrophil (%)	Staining combined with flow cytometry O 510-16/1, O 540-3/2
	12. Lymphocyte (%)	Staining combined with flow cytometry O 510-16/1, O 540-3/2
	13. Monocyte (%)	Staining combined with flow cytometry O 510-16/1, O 540-3/2
	14. Eosinophil (%)	Staining combined with flow cytometry O 510-16/1, O 540-3/2
	15. Basophil (%)	Staining combined with flow cytometry O 510-16/1, O 540-3/2
2. Blood films	1. White Blood cell Differential Count	Microscopy

Tested materials/ products	Types of tests / Properties measured	Applied Standards / Techniques used
		O 450-1/3, O 450-2/2, O 450-3/2, O 450-4/2, O 450-14/1
	2. RBC Morphology	
	3. PLT Morphology	

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

Site of assessment: **Laboratory permanent premises: end of Sismanogleiou str., 151 26, Marousi, Attiki, Greece.**
Primary Sample Collection Site: Laboratory permanent premises: end of Sismanogleiou str., 151 26, Marousi, Attiki, Greece.

Approved signatories: **Rea Chatzikiriakou, Helen Alafaki, Maria Bakali, Maria Kechagia, Ioannis Maniatis**.

This Scope of Accreditation replaces the previous one dated 02.09.2024.
The Accreditation Certificate No. **1057**-5, to ELOT EN ISO 15189:2022, is valid until 14.09.2029.

Athens, 18th March 2025

Konstantinou Evangelos Apostolos
CEO of ESYD