Hellenic Accreditation System

Annex G1/13 to the Certificate No. **666**-6

SCOPE of ACCREDITATION

of the

Hematology Department

of the

Laboratories Division

of

KONSTANTOPOULEIO General Hospital of N. Ionia

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Hematological testing		
1. Whole Blood (EDTA)	**Determination of 1 parameter**	**Automated Hematology analyzer ADVIA2120 (Siemens)***
	1. Reticulocyte Count (%)	Staining combiened with cytometry Ε.ΑΛ. 340-1 (6/2/2024)
	Determination of 8 parameters	**Automated Hematology analyzer ADVIA2120 (Siemens)***
	1.White blood cell (WBC)	Volume analysis combiened with flow cytometry Ε.ΑΛ. 340-1 (6/2/2024)
	2.Red blood cell (RBC)	Volume analysis combiened with flow cytometry Ε.ΑΛ. 340-1 (6/2/2024)
	3.Hemoglobin(HGB)	Photometric Ε.ΑΛ. 340-1 (6/2/2024)
	4.Hematocrit (HCT%)	Calculated Ε.ΑΛ. 340-1 (6/2/2024)
	5.Mean corpuscular volume (MCV)	Volume analysis with flow cytometry Ε.ΑΛ. 340-1 (6/2/2024)
	6. Mean corpuscular Hemoglobin (MCH)	Calculated Ε.ΑΛ. 340-1 (6/2/2024)

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Whole Blood (EDTA) (continued)	7. Mean corpuscular Hemoglobin concentration(MCHC)	Calculated Ε.ΑΛ. 340-1 (6/2/2024)
	8. Platelets (PLTs)	Volume analysis combiened with flow cytometry Ε.ΑΛ. 340-1 (6/2/2024)
	White Blood Cell Automated Differential Count	Staining combiened with flow cytometry Ε.ΑΛ. 340-1 (6/2/2024)
	1.Neutrophil (number and %)	
	2.Lymphocyte (number and %)	
	3.Monocyte (number and %)	
	4.Eosinophil (number and %)	
	5.Basophil (number and %)	
	6.Atypical- Large unstained cells (number and %)	
	Determination of 8 parameters	**Automated Hematology analyzer COULTER DHX600***
	1.White blood cell (WBC)	Volume analysis Ε.ΑΛ. 340-1 (6/2/2024)
	2.Red blood cell (RBC)	Volume analysis Ε.ΑΛ. 340-1 (6/2/2024)
	3.Hemoglobin(HGB)	Photometric Ε.ΑΛ. 340-1 (6/2/2024)
	4.Hematocrit (HCT%)	Calculated Ε.ΑΛ. 340-1 (6/2/2024)
	5.Mean corpuscular volume (MCV)	Calculated Ε.ΑΛ. 340-1 (6/2/2024)
	6. Mean corpuscular Hemoglobin (MCH)	Calculated Ε.ΑΛ. 340-1 (6/2/2024)
	7. Mean corpuscular Hemoglobin concentration(MCHC)	Calculated Ε.ΑΛ. 340-1 (6/2/2024)
	8.Platelets (PLTs)	Volume analysis Ε.ΑΛ. 340-1 (6/2/2024)

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Whole Blood (EDTA) (continued)	**White Blood Cell Automated Differential Count**	**Automated Hematology analyzer COULTER DHX600***
	1.Neutrophil (number and %)	Volume analysis combiened with laser scattering and high frequency current conduction (RF) Ε.ΑΛ. 340-1 (6/2/2024)
	2.Lymphocyte (number and %)	
	3.Monocyte (number and %)	
	4.Eosinophil (number and %)	
	5.Basophil (number and %)	
2. Blood films	**1. White Blood Cell Differential Count**	**Microscopy** Ε.ΑΛ. 340-1 (6/2/2024)
	2. RBC Morphology	
	3. PLT Morphology	
3. Blood plasma (sodium citrate)	**Determination of 5 parameters**	**Automated Coagulation analyzer BCS-XP* (A3) & BCS-XP (A6) (Siemens)***
	1. Prothrombin time (PT)	Clotting Ε.ΑΛ. 340-1 (6/2/2024)
	2. INR (International Normalized Ratio)	Calculated Ε.ΑΛ. 340-1 (6/2/2024)
	3.Activated Partial Thromboplastin time (APTT)	Clotting Ε.ΑΛ. 340-1 (6/2/2024)
	4. Fibrinogen(FIB)	Modified Clauss technique Ε.ΑΛ. 340-1 (6/2/2024)
	5. DDimers (DD)	Immunoturbidimetry Ε.ΑΛ. 340-1 (6/2/2024)
	Determination of 5 parameters	**Automated Coagulation analyzer BCS-XP (A6) (Siemens)***
	1. Antithrombin	Chromogenic Ε.ΑΛ. 340-1 (6/2/2024)
	2. Protein C	Chromogenic Ε.ΑΛ. 340-1 (6/2/2024)
	3. Activated Protein C Resistance (APC-R)	Clotting Ε.ΑΛ. 340-1 (6/2/2024)

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Blood plasma (sodium citrate) (continued)	4. Factor VIII (Activity)	Clotting Ε.ΑΛ. 340-1 (6/2/2024)
	5. Factor IX (Activity)	Clotting Ε.ΑΛ. 340-1 (6/2/2024)
Immunochemical testing		
1. Blood serum	**Determination of 3 parameters**	**Automated analyzer ACCESS (Beckman Coulter)***
	1.Ferritin	Chemiluminescent Immunoassay Ε.ΑΛ. 340-1 (6/2/2024)
	2. Vitamin B12	Chemiluminescent Immunoassay Ε.ΑΛ. 340-1 (6/2/2024)
	3. Folate acid	Chemiluminescent Immunoassay Ε.ΑΛ. 340-1 (6/2/2024)

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

Site of assessment: **Laboratory permanent premises: 3-5 Aghias Olga str., 14233 N. Ionia, Greece.**
Primary Sample Collection Site: Laboratory permanent premises: 3-5 Aghias Olga str., 14233 N. Ionia, Greece

Approved signatories: **D. Theodoridis, M. Scoura, M. Giannoula, A. Galanopoulou**

This Scope of Accreditation replaces the previous one dated 22.11.2024.
The Accreditation Certificate No.**666**-6, to ELOT EN ISO 15189:2022, is valid until 25.03.2027.

Athens, 23rd of June 2026

Konstantinou Evangelos Apostolos
CEO of ESYD