Hellenic Accreditation System

Annex G1/11 to the Certificate No.**766**-5

SCOPE of ACCREDITATION

of the

Hematology Department

of

Laboratories Division

of

General Hospital of Athens «G. GENNIMATAS»

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
Hematological tests		
1. Whole blood (EDTA)	**Determination of 13 parameters**	**Automated Hematology Analyzers COULTER DxH 800* (1), (2), (3)**
	1. Hemoglobin (HGB)	Photometric *E.AM.640-2, ed. 1, 2/12/2019*
	2. Red Blood Cells (RBC)	Coulter principle (Electrical impedance) *E.AM.640-2, ed. 1, 2/12/2019*
	3. Hematocrit (HCT%)	calculated as: RBC x MCV / 10 *E.AM.640-2, ed. 1, 2/12/2019*
	4. Mean Corpuscular Volume (MCV)	Derived from RBC histogram *E.AM.640-2, ed. 1, 2/12/2019*
	5. Mean Corpuscular Hb (MCH)	calculated as: (Hb / RBC) x 10 *E.AM.640-2, ed. 1, 2/12/2019*
	6. Mean Corpuscular Hb Concentration (MCHC)	calculated as: (Hb / (RBC x MCV)) x 100 *E.AM.640-2, ed. 1, 2/12/2019*
	7. White Blood Cells (WBC)	Coulter principle (Electrical impedance) *E.AM.640-2, ed. 1, 2/12/2019*
	8. Neutrophils (absolute number and %)	VCS technology (Volume, Conductivity, Scatter) *E.AM.640-2, ed. 1, 2/12/2019*
	9. Lymphocytes (absolute number and %)	VCS technology (Volume, Conductivity, Scatter) *E.AM.640-2, ed. 1, 2/12/2019*
	10. Monocytes (absolute number and %)	VCS technology (Volume, Conductivity, Scatter) *E.AM.640-2, ed. 1, 2/12/2019*

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
Whole blood (EDTA) (continued)	11. Eosinophils (absolute number and %)	VCS technology (Volume, Conductivity, Scatter) *E.AM.640-2, ed. 1, 2/12/2019*
	12. Basophils (absolute number and %)	VCS technology (Volume, Conductivity, Scatter) *E.AM.640-2, ed. 1, 2/12/2019*
	13. Platelets (PLTs)	Derived from PLTs histogram Coulter principle (Electrical impedance) *E.AM.640-2, ed. 1, 2/12/2019*
	Determination of 13 parameters	**Automated Hematology Analyzer SYSMEX XN 1000 ROCHE***
	1. Hemoglobin (HGB)	SLS-hemoglobin method
	2. Red Blood Cells (RBC)	Hydrodynamically focussed DC detection method
	3. Hematocrit (HCT%)	RBC pulse height detection method (calculated)
	4. Mean Corpuscular Volume (MCV)	The MCV is calculated from the RBC and HCT, using the following equation: MCV (fl) = ((HCT(%) / RBC(x10^6µL)) x 10
	5. Mean Corpuscular Hb (MCH)	The MCH is calculated from the RBC and HGB, using the following equation: MCH (pg) = (HGB (g/dl) / RBC(x10^6µL)) x 10
	6. Mean Corpuscular Hb Concentration (MCHC)	The MCHC is calculated from the HCT and HGB, using the following equation: MCHC (g/dL) = HGB (g/dl) / HCT(%)) x 100
	7. White Blood Cells (WBC)	Flow cytometry method using semiconductor laser
	8. Neutrophils (absolute number and %)	Flow cytometry method using semiconductor laser
	9. Lymphocytes (absolute number and %)	Flow cytometry method using semiconductor laser
	10. Monocytes (absolute number and %)	Flow cytometry method using semiconductor laser
	11. Eosinophils (absolute number and %)	Flow cytometry method using semiconductor laser
	12. Basophils (absolute number and %)	Flow cytometry method using semiconductor laser
	13. Platelets (PLTs)	Hydrodynamically focused DC detection method
2. Blood smear morphology	**Red Blood Cells' Morphology / Platelets' Count and Morphology/ White Blood Cell Differential Count** (absolute number and %)**:** Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Abnormal Cells **Microscopic detection of parasites**	Microscopic examination O.AM.620-3, version 4, 2/12/2019
3. Blood plasma	**Determination of 4 parameters**	**Automated Coagulation Analyzers**

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
(sodium citrate)		**ACL TOP 750 CTS IL* (1), (2)**
	1. Prothrombin time (PT)	Coagulometric *E.AM.640-2, ed. 1, 2/12/2019*
	2. Activated Partial Thromboplastin time (APTT)	Coagulometric *E.AM.640-2, ed. 1, 2/12/2019*
	3. Fibrinogen (FIB)	Modified Clauss method *E.AM.640-2, ed. 1, 2/12/2019*
	4. DDimers (DD)	Immunoturbidimetric *E.AM.640-2, ed. 1, 2/12/2019*
4. Blood plasma (sodium citrate)	**Determination of 5 parameters**	**Automated Coagulation Analyzer ACL TOP 750 CTS IL* (1)**
	1. Antithrombin III (AT III)	Chromogenic *E.AM.640-2, ed. 1, 2/12/2019*
	2. Protein C (Prot – C)	Chromogenic *E.AM.640-2, ed. 1, 2/12/2019*
	3. Activated Protein C Resistance (APCR)	Coagulometric *E.AM.640-2, ed. 1, 2/12/2019*
	4. Lupus Anticoagulant (LA)	Coagulometric *E.AM.640-2, ed. 1, 2/12/2019*
	5. Free protein S antigen (Free Prot-S)	Immunoturbidimetric *E.AM.640-2, ed. 1, 2/12/2019*
Molecular tests		
1. Whole blood (sodium citrate or EDTA)	Molecular thrombophilia testing for mutations FV Leiden G1691A, FII G20210A, MTHFR C677T, MTHFR A1298C	(i) DNA extraction, (ii) Multiplex amplification with PCR, (iii) reverse hybridization on membrane strips (DNA•STRIP technology CE-IVD kit Thrombotype plus v 3.0* της HAIN) *O.AM.560-1, ed. 2, 2/12/2019*

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

Site of assessment: **Department laboratory facilities, General Hospital of Athens «G. Gennimatas» 154 Mesogeion Av. 11527, Athens, Greece.**

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Primary Sample Collection Site: General Hospital of Athens «G. Gennimatas» 154 Mesogeion Av. 11527, Athens, Greece.

This scope of Accreditation replaces the previous one dated 28.05.2024.
The Accreditation Certificate No. **766**-5, to ELOT EN ISO 15189:2022, is valid until 07.09.2028.

Athens, 30th of July 2025

Konstantinou Evangelos Apostolos
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