Hellenic Accreditation System

Annex G1/6 to the Certificate No. **1201**-3

SCOPE of ACCREDITATION

of the

Cytopathology Department

of the

Laboratories Division

of

General Hospital of Athens
"SISMANOGLIO - AMALIA FLEMING"

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Cytopathology Tests		
Conventional vaginal-cervical-endocervical smears (Pap-test)	Sample adequacy Cytomorphologic evaluation Detection and typing of neoplastic or other pathologic entities	Qualitative-Semiquantitative Method 1. Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 2. Slides coverslipping. O 510-10 (1st ed. 10.07.2024). (automated coverslipper instrument). 3. Microscopic evaluation O 510-1 (1st ed. 28.08.2017). (Microscope) 4. Reporting according to the BETHESDA system.
Spontaneously produced or artificially induced sputum	Sample adequacy Cytomorphologic evaluation Detection and typing of neoplastic or other pathologic entities	Qualitative-Semiquantitative Method 1. Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 2. Slides coverslipping. O 510-10 (1st ed. 10.07.2024). (automated coverslipper instrument). 3. Microscopic evaluation O 510-1 (1st ed. 28.08.2017) (Microscope)
Cytologic material endoscopically collected by washing or brushing from the esophagus, stomach, bile duct	Sample adequacy Cytomorphologic evaluation Detection and typing of neoplastic or other	Qualitative-Semiquantitative Method 1. Centrifugation O510-2, O 510-3 (2st ed. 03.02.2022). 2. Diff-Quik stain

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Pancreatic duct or colon	pathologic entities	O 450-4 (1st ed. 21.04.2017) (staining machine Gemini AS) 3. Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 4. Slides coverslipping. O 510-10 (1st ed. 10.07.2024). (automated coverslipper instrument). 5. Microscopic evaluation O 510-1 (1st ed. 28.08.2017) (Microscope)
Bronchoscopic material (bronchial washing,brushing,TBNA, Post bronchoscopy sputum,spontaneously produced sputum)	Sample adequacy Cytomorphologic evaluation Detection and typing of neoplastic or other pathologic entities	Qualitative-Semiquantitative Method 1. Centrifugation, Cytospin O 510-2, 0 510-3 (2 nd ed. 03.02.2022) 2. Diff-Quik stain O 450-4 (1st ed. 21.04.2017) (staining machine Gemini AS) 3. Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 4. Slides coverslipping. O 510-10 (1st ed. 10.07.2024). (automated coverslipper instrument). 5. Microscopic evaluation O 510-1 (1st ed. 28.08.2017) (Microscope)
Urine samples (Voided urine, catheterized urine,bladder washings.	Sample adequacy Cytomorphologic evaluation Detection and typing of neoplastic or other pathologic entities Presence of normal cells	Qualitative-Semiquantitative Method 1. Centrifugation, Cytospin O 510-2, 0 510-3 (~~1st~~ 2 nd ed. 03.02.2022) 2. Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 3. Slides coverslipping. O 510-10 (1st ed. 10.07.2024). (automated coverslipper instrument). 4. Microscopic evaluation O 510-1 (1st ed. 28.08.2017) (Microscope) 5.Reporting according to the Paris system classification
Nipple secretion (Right and Left)	Sample adequacy Cytomorphologic evaluation Detection and typing of neoplastic or other pathologic entities	Qualitative-Semiquantitative Method 1. Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 2. Slides coverslipping. O 510-10 (1st ed. 10.07.2024). (automated coverslipper instrument). 3. Microscopic evaluation (Microscope) O 510-1 (1st ed. 28.08.2017)
Body cavity fluids (pleural, pericardial, ascitic, peritoneal,	Sample adequacy Cytomorphologic evaluation Detection and typing of	Qualitative-Semiquantitative Method 1. Centrifugation, Cytospin O 510-2, 0 510-3 (2 nd ed. 03.02.2022)

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
cerebrospinal, Synovial fluid, Hydrocele fluid, ovarian cyst fluid, Cul de sac washing, imprints)	neoplastic or other pathologic entities Presence of normal cells	2. Diff-Quik stain O 450-4 (1st ed. 21.04.2017) (staining machine Gemini AS) 3. Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 4. Slides coverslipping. O 510-10 (1st ed. 10.07.2024). (automated coverslipper instrument). 5. Microscopic evaluation O 510-1 (1st ed. 28.08.2017) (Microscope)
FNA Thyroid palpable nodules Lymph noodes (R or L supraclavicular,cervical, inguinal,axillary) Subcutaneous nodules or lesions Palpable breast lesions Salivary glands lesions Thyroglossal duct cysts Branchial cleft cyst	Sample adequacy Cytomorphologic evaluation Detection and typing of neoplastic or other pathologic entities	Qualitative-Semiquantitative Method 1. Centrifugation O 510-2, O 510-3 (2 nd ed. 03.02.2022) 2. Diff-Quik stain O 450-4 (1st ed. 21.04.2017) (staining machine Gemini AS) 3. Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 4. Slides coverslipping. O 510-10 (1st ed. 10.07.2024). (automated coverslipper instrument). 5 Microscopic evaluation O 510-1 (1st ed. 28.08.2017) (Microscope)
FNA under U/S guidance, of thyroid, or breast lesions (R or L)	Sample adequacy Cytomorphologic evaluation Detection and typing of neoplastic or other pathologic entities	Qualitative-Semiquantitative Method 1. Diff-Quik stain O 450-4 (1st ed. 21.04.2017) (staining machine Gemini AS) 2.Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 3. Slides coverslipping. O 510-10 (1st ed. 10.07.2024). (automated coverslipper instrument). 4 Microscopic evaluation O 510-1 (1st ed. 28.08.2017) (Microscope)
FNA under CT guidance of R or L Lung, R or L Kidney or Liver Lesions.	Sample adequacy Cytomorphologic evaluation Detection and typing of neoplastic or other pathologic entities	Qualitative-Semiquantitative Method 1. Centrifugation O 510-2, O 510-3 (2 nd ed. 03.02.2022) 2. Diff-Quik stain O 450-4 (1st ed. 21.04.2017) (staining machine Gemini AS) 3. Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 4. Slides coverslipping. O 510-10 (1st ed. 10.07.2024).

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
		(automated coverslipper instrument). **4**.5 Microscopic evaluation O 510-1 (1st ed. 28.08.2017) (Microscope)
Intraoperative rapid stain smear (pleural,ascitic, Pericardial fluid Cul de sac washings Imprints	Sample adequacy Cytomorphologic evaluation Detection and typing of neoplastic or other pathologic entities	Qualitative-Semiquantitative Method. 1. Centrifugation O 510-2, O 510-3 (~~1st~~ 2 nd ed. 03.02.2022) 2. Diff-Quik stain O 450-4 (1st ed. 21.04.2017) (staining machine Gemini AS) 3. Pap stain O 450-1 (1st ed. 21.04.2017). (staining machine Gemini AS) 4. Slides coverslipping. O 510-10 (1st ed. 10.07.2024). (automated coverslipper instrument). 5. Microscopic evaluation O 510-1 (1st ed. 28.08.2017) (Microscope)

Site of assessment: Laboratory permanent premises: 1 Sismanogliou street, 151 26 Maroussi, Greece.
Primary Sample Collection Site: Sismanoglio - Amalia Fleming, General Hospital of Athens
Approved signatories:: **Nikoletta Maouni, Kalliopi Kotsaridi – Apergi, Lamprini Kioxou, Kleio Vrettou, Christina Kaprilian**

This scope of Accreditation replaces the previous one dated 09.07.2024.
The Accreditation Certificate No.**1201-**3, to ELOT EN ISO 15189:2022, is valid until 03.03.2029.

Athens, 10th of July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD