Hellenic Accreditation System

Annex G1/4 to the Certificate No.**1214**-2

SCOPE of ACCREDITATION

of the

Anatomic Pathology - Cytology Laboratory

of

251 Hellenic Air Force and Veterans General Hospital

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Histopathology		
Human Body Tissue Biopsies and Specimens. Fresh, Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens	**Histopathological examination activities for the purposes of clinical diagnosis** Gross and Microscopic Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	**Macroscopic and Microscopic examination, O.510.09,1,14-05-2019** Aspirated hood for cutting of histological samples EQUIP **Specimen Dissection** Depending upon specimen type and according to Laboratory Grossing
		Tissue processing Thermo Scientific Excelsior AS Leica TR1020.
		Paraffin Embedding System HISTOSTAR THERMO Bio-Optica BEC150-BEC170
		Microtomy LEICA RM2245 /2255
		Haematoxylin and Eosin stain Automated and manual Haematoxylin & Eosin Staining Thermo Scientific Gemini AS Automated Slide Stainer Rapid H&E (frozen sections)
		Coverslipping Automated Coverslipper CV5030 LEICA
		Slide Checking & Section Quality

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Human Body Tissue Biopsies and Specimens. Fresh, Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens (cont.)		Manual **<u>Interpretive Microscopy</u>** **Microscopes** CARL ZEISS AXIOLAB NIKON ECLIPSE 80 NIKON E200 LEICA DM 1000 OLYMPUS BX 45 Microscopic Evaluation-Interpretation of Results <u>Neoplastic Diseases</u> Staging according to AJCC Cancer Staging Manual 8th Ed. Grading as appropriate Classification WHO ICD-O-3 Reporting of Results
Histochemistry		
Human Body Tissue Biopsies and Specimens. Fresh, Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens	**Identification of tissue components and enzymes**	**<u>Special staining - HISTOCHEMISTRY</u>** Histochemistry using kits Manual <u>Stains</u> PAS/D (O.510.14,1,14-05-2019) GOMORI (O.510.12,1,14-05-2019) MASSON (O.510.13,1,14-05-2019) Microscopic Evaluation – Interpretation of Results
Immunohistochemistry		
Human Body Tissue Biopsies and Specimens. Fresh, Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens Cell block.	Detection of Markers and Protein Expression	<u>Special staining - IMMUNOHISTOCHEMISTRY:</u> (O.510.17,5,22-10-2024) Automated **<u>Immunohistochemistry using detection kits.</u>** ROCHE Ventana BenchMark ULTRA (s/n 322205 AN2 and s/n 322209 AN3) And antibodies as appropriate: Microscopic Evaluation – Interpretation of Results. Each Antibody

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	Normal and malignant plasma cells and in lymphoplasmocytoid cells	CD138
	T lymphocytes, NK lymphocytes, T- lymphomas and leukemias	CD3
	All lymphocytes	CD45 (LCA)
	B lymphocytes – plasmocytes , B-lymphomas and leukemias	CD79a
	Umbrella cells of Urothelium – intestinal epithelium	CK 20
	Urothelium – non squamous epithelium and carcinomas of respiratory system – epithelium and carcinomas of bile/pancreatic and mammary ducts	CK 7
	Proliferative zone of epithelial tissues – mantle cell lymphoma, hairy cell leukemia.	CyclinD1
	Smooth and striated muscle cells	Desmin
	Epithelial cells and tumors of mammary gland ducts	E-cadherin
	Breast carcinoma – urothelial carcinomas	GATA-3
	Cellular proliferation index	Ki-67
	Squamous epithelium/tumors – urothelium/tumors	p63
	T lymphocytes, activated B lymphocytes, lymphomas and leukemias.	CD43
	Epithelial cell marker. Healthy epithelia - Carcinomas	BerEP4
	Index of melanocytic line.	Melan A
Human Body Tissue Biopsies and Specimens.	**Prognostic BioMarker Expression for Breast Cancer**	Special staining - IMMUNOHISTOCHEMISTRY:

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Formalin Fixed Paraffin Embedded Tissue [FFPE], Excisional and Needle Biopsies and Surgical Resection Specimens with Breast Cancer		(O.510.17,5,22-10-2024) Automated Immunohistochemistry using detection kits ROCHE Ventana BenchMark ULTRA (s/n 322205 AN2 and s/n 322209 AN3) and antibodies Morphometric analysis, tumor immunohistochemistry. Semiquantitative, method each antibody; manual Interpretation of Results - Reporting based on:CAP, Breast Biomarkers Template 1.3.0.0, August 2019
	Breast carcinoma	ER
	Breast carcinoma	PgR
	Breast carcinoma	Her-2
Histolopathology		
Human Body Tissue Biopsies and Specimens. Fresh, and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens	**Intraoperative Consultation** Gross and Microscopic Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the scope of Intraoperative Consultation	**<u>Frozen Sections – Gross and microscopic examination - Interpretation of Results</u>** **O.510.09,1,14-05-2019** MILESTONE PrestoCHILL Thermo Shandon Cryotome E Cryostat LEICA CM1950
Cytopathology		
Biological specimens of cells from the superficial and deep organs of the human body (lymph nodes, breast, salivary glands, thyroid, liver, pancreas, lung, etc.) obtained by puncture or FNA (fine needle aspiration). Vaginal-cervical smears Specimen taken from the endocervical tube of the uterus. Mucosa (oral cavity, pharynx)	Cytological check, Cytological Examination Morphological examination - Detection and categorization of neoplasia Classification by internationally recognized systems	1. Centrifuge (centrifuge Model FN400 – BENCH-TOP) (in all liquid samples), O.510.30, 1, 14-05-2019 2. Coating of slides with a centrifuge (CytoSpin 4) or manually (in all liquid samples), O.510.30, 1, 14-05-2019 3. α) Papanicolaou stain with automated slide stainer O.510.32, 1, 14-05-2019 β) Diff-Quik Stain manually, O.510.31, 1, 14-05-2019 (in all samples_ except vaginal-cervical-endotracheal specimens)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Breast excretion Samples after special treatment (cerebrospinal fluid, bronchial wash or sputum secretion, urine) Fluids (pleural, ascites pericardial)		4. Interpretive Microscopy Microscopes Nikon ECLIPSE E200 OLYMPUS CX22 LEDRFS2 OLYMPUS CX23 LEDRFS2 ZEISS AXIOSKOP Nikon ECLIPSE Si 5. Classification according to: a) Bethesda system 2014 (for vaginal-cervical samples), b) Bethesda system 2017 (for FNA thyroid), c) Guidelines of the Hellenic Society of Clinical Cytology, the American Society of Cytopathology and the European Federation of Cytology Societies

** Commercial names mentioned are reffering to specific analytical method and laboratory work protocol.*

WHO: World Health Organizationy
ICD-O: International Classification of Diseases for Oncology
AJCC: American JointCommittee on Cancer
CAP: College of American Pathologists

Site of assessment: Permanent laboratory premises, 251 Hellenic Air Force and Veterans General Hospital, 3, P. Kanellopoulou Av., 11525 Athens

Approved signatories: **Dritsakos Konstantinos, Tsantopoulos Margaritis, Almpanis Zannis,, Chaleplidis Nikolaos, Spanou Kallirroi, Giovanitis Demetrios, Konstantinou Panagiotis, Dimopoulos Stavros, Zaharis Evangelos, Revelos Kyriakos.**

This Scope of Accreditation replaces the previous one dated 10.12.2024.
The Accreditation Certificate No. **1214-**2, to ELOT EN ISO 15189:2022, is valid until 17.06.2029.

Athens, 30th of January 2025

Konstantinou Evangelos Apostolos
CEO of ESYD