HELLENIC ACCREDITATION SYSTEM

Annex G1/9 to the Certificate No **1119**-4

SCOPE of ACCREDITATION

of the

Histopathology laboratory

of

"ISTOTIPOS S.A."

Materials / Products subjected to tests	Types of tests / Measured properties	Applied methods / Techniques used
Histological tests		
Biopsies and surgical specimens from all organs and systems Fresh tissue, formalin fixed and paraffin embedded (FFPE) tissue, and tissue from frozen sections, coming from excision biopsies, and surgically excised samples and organs	Macroscopic and microscopic observation of tissues in order to recognize or exclude morphological and cytological abnormalities.	**Macroscopic and microscopic observation** Dissecting table for macroscopic process of tissues, special order due to laboratory requirements. <u>Macroscopic Evaluation and Sampling</u> According to the type of the sample and following the relevant protocol (OE01, Version1.1/ 01.04.2024) <u>Process of specimens</u> Automated tissue processor: MILESTONE LOGOS ONE, REVOS EPREDIA Distributor of paraffin: BIOPTICA STATION, LEICA ARCADIA <u>Microtomy: MICROM HM340, THERMO HM340, LEICA RM2245</u> <u>Staining with Haematoxylin and Eosin</u> Automated staining with Haematoxylin and Eosin at LEICA AUTOSTAINER XL ST5010 Quick staining with Haematoxylin and Eosin (for frozen sections). Manual stain, cryo-section at LEICA CM1520, BRIGHT B4049, LEICA CM1510(genesis hospital) <u>Mounting</u> Automated machine for mounting of histological slides: LEICACV5030 with robotic arm TS5015

Biopsies and surgical specimens from all organs and systems Fresh tissue, formalin fixed and paraffin embedded (FFPE) tissue, and tissue from frozen sections, coming from excision biopsies, and surgically excised samples and organs (continued)		<u>Matching between tissue blocks and histological slides / Quality assessment of tissue sections</u> Manually. <u>Diagnostic Microscopy</u> Microscopy: 4* NIKON ECLIPSE E200, ZEISS AXIOSKOP, DIGITAL MICTOSCOPE VENTANA DP200. Microscopic evaluation – Interpretation of results. Neoplastic Diseases: Staging AJCC Cancer staging manual 7th ed. Grading as appropriate. Classification WHO ICD-O-2. Reporting of results
Histochemical tests		
Biopsies and surgical specimens from all organs and systems Fresh tissue, formalin fixed and paraffin embedded (FFPE) tissue, and tissue from frozen sections, coming from excision biopsies, and surgically excised samples and organs	Assessment of tissue constituents and enzymes.	<u>Special stains – Histochemistry.</u> Histochemical methods with the use of kits. Manually. Elastin / Van Gieson. Periodic Acid Schiff. Diastase Periodic Acid Schiff Silver Impregnation Perl's Giemsa AB-PAS ALCIAN BLUE MASSON ZIEHL NEELSEN CONGO RED Microscopic evaluation – Interpretation of results. (OE01, Version1.1/ 01.04.2024)
Immunohistochemical tests		
1. **Biopsies and surgical specimens from Human Breast** Formalin fixed and paraffin embedded (FFPE) tissue coming from needle or excision biopsies, and surgically excised samples with Breast Cancer	Assessment of Expression of Prognostic Biomarkers of Breast Cancer: Breast carcinoma Breast carcinoma Breast carcinoma	<u>Special stains – Immunohistochemistry.</u> Automated method. Immunohistochemical method with the use of detection kit and specialized antibodies as indicated.Ventana Bench Mark ULTRA, GX Autostainer. Morphometric analysis,tumor immunohistochemistry,semiquantitative,method each antibody: Manual. Interpretation of results-reporting based on: CAP breast carcinoma-biomarkers-14protocol-1100 ER PgR Her-2 (OE01, Version1.1/ 01.04.2024)

2. Assessment of the presence or absence of markers and protein expression	Peripheral nerve ganglia – mesothelial cells – mesothelioma	Calretinin
	Peripheral nerves, neuroendocrine cells/tumors – NK cells – ovarian stromal tumors	CD56
	Lower gastrointestinal tract-Neoplasms with osteoblastic differentiation-Merkel cell carcinoma -Neoplasms of soft tissue.	SATB2
	Smooth and striated muscle fibers.	DESMIN
	Kidney, thyroid gland, epithelium and tumors of Müllerian epithelial-type origin	PAX8
	Squamous epithelium	CK 5/6
	Malignant neoplastic cells	P53
	B lymphocytes – plasma cells	CD79a
	Breast carcinoma – urothelial carcinoma	GATA3
	T lymphocytes	CD3
	Germinal center B cells.	BCL6
	Langerhans pancreatic islets cells, neuroendocrine cells/tumors.	CHROMOGRANIN A
	Epithelial cells, mostly adeno carcinoma.	CK 8/18
	Epithelial cells, adenocarcinoma.	EP-CAM
	Prostate glands, prostate carcinoma.	PSA
	Plasma cells and plasma cell differentiation in benign and neoplastic conditions	CD 138
	T cells - subunit B cells.	CD 5

	B cells, endometrial stromal	CD 10
	pulmonary adenocarcinoma and pulmonary neuroendocrine malignancy, small cell lung carcinoma	TTF1
	B lymphocytes.	PAX 5
	Lung adenocarcinoma, clear cell carcinoma of the uterus/ovarian, follicular carcinoma of kidney	NAPSIN A
	Langerhans pancreatic islets cells, neuroendocrine cells/tumors.	SYNAPTOPHYSIN
	Squamous cell carcinoma, urothelial carcinoma	P40
	Th cells .	CD 4
	Reactive lymfocytes- R-S cells. Hodgkin lymphoma, anaplastic large cell lymphoma, testis embryonal carcinoma	CD 30
	Prostate cancer, clear cell carcinoma uterus/kidney	AMACR
	Programmed-death ligand 1	PDL-1
	Scattered T cells in germinal centres and mantle zone B cells – Many T-cells	BCL-2
	Mitotic cell marker	KI-67
	T cells,cytotoxic/ suppressor cells	CD 8
	Neuroendocrine malignancy	INSM1
	Mast cells, GIST	C-KIT

	B lymphocytes	CD 20
	Epithelial cells	CK-PAN
	Mesothelioma, nevus cells,melanoma	BAP-1
	Serus carcinoma, hpv related carcinoma and dysplasia	P16
	Deficiency in DNA mismatch repair	dMMR (MLH1-MSH2-MSH6-PMS2)

Site of assessment: **Permanent laboratory premises: Thalitos 6, Thessaloniki.**
Approved signatories: **Miliaras Dimosthenis, Goupou Eleni, Giannouli Angeliki, Mpotsfari Elli, Christoforidou Varvara, Venizelos Ioannis.**

This scope of Accreditation replaces the previous one dated 31.08.2026.
The Accreditation Certificate No.**1119-**4, to ELOT EN ISO 15189:2022, is valid until 08.09.2031.

Athens, 16th of September 2026

Konstantinou Evangelos Apostolos
CEO of ESYD