Hellenic Accreditation System

Annex G1/9 to the Certificate No.**1041**-3

SCOPE of ACCREDITATION

of the

Histopathology laboratory

of

"FRAGKIA-TSIVOU KONSTANTINA S.A." - HistoBio Diagnosis

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Histopathology		
Biopsies and Surgical Specimens from whole Human Body Organs and Systems Unfixed Specimen Formalin Fixed Specimen 10% neutral buffered Formalin Fixed, Paraffin Embedded Tissue [FFPE] Histological slides with tissue sections for second opinion [*consultation*] Biopsy, Excisional, Incisional or punch Surgically Resected Specimen	Grossing and Microscopic Examination of tissues, in order to identify or exclude morphological and cytological aberrations from normal,in order to establish the Histological Diagnosis	**Gross Examination and Dissection/ Tissue Processing and Tissue Sections on Glass Slide Preparation / Microscopic examination:** **OE.20, 1.1, 01-09-2025** **OE.14, 1.1, 01-09-2025** **OE.15, 1.2, 01-09-2025** **OE.16, 1.2, 01-09-2025** **OE.17, 1.2, 01-09-2025** **OE.18, 2.1, 01-09-2025** **OE.19, 1.2, 01-09-2025** <u>Gross Examination and Dissection</u> Performed in a wall Grossing Station [PROPATHN.V*ModCT4WFT*] Depending on type of specimen and according to laboratory documented instruction for Gross Examination and Dissection (ΟΕ-ΜΔ-21)

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Biopsies and Surgical Specimens from whole Human Body Organs and Systems Unfixed Specimen Formalin Fixed Specimen 10% neutral buffered Formalin Fixed, Paraffin Embedded Tissue [FFPE] Histological slides with tissue sections for second opinion [*consultation*] Biopsy, Excisional, Incisional or punch Surgically Resected Specimen– (continued)	Grossing and Microscopic Examination of tissues, in order to identify or exclude morphological and cytological aberrations from normal,in order to establish the Histological Diagnosis (continued)	Gross Description According to international and Hellenic guidelines [*CAP, ADASP, AJCC, FIGO, RCP, TNM, WHO, ΕΕΠΑ, AFIP etc*]. Frozen sections from unfixed specimenMicrotome / cryostat [SAKURA FINETEK USA Inc. [*mod Tissue-Tek Cryo3 Basic (5803).*
		Tissue processing Automated processing dehydration, clearing and paraffin tissue infiltration with Vacuum Infiltration tissue processor [SAKURA FINETEK USA inc./ *mod Tissue-Tek VIP 6].*
		Paraffin Embedding System A complete 3-modular system is used [*MEDLITE GmbH*], with a Thermal Unit [*modTES 99.*600], a Dispenser Unit [*modTES 99.200*] and a Cooling Unit [*modTES 99.410*]
		Preparation of tissue section on glass slide Electronic Rotary Microtome [*THERMO Fisher Scientific / mod MICROM HM 340E2*] and a manual Rotary Microtome [*PFM MEDICAL / mod PFM 3004*] Slides dried in a Tissue Dry Oven [*MEDLITE GmbH / mod TDO 66*].
		Haematoxylin and Eosin stain and addition of cover slip in the tissue section **OE.19, 1.2, 01-09-2025** Permanent sections With an Automated Slide Stainer and an Automated Glass Coverslipper. [*SAKURA FINETEK USA Inc, / ASS-Mod Tissue TekPrisma E2S and AGC-Mod. Glas g2*]

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Biopsies and Surgical Specimens from whole Human Body Organs and Systems Unfixed Specimen Formalin Fixed Specimen 10% neutral buffered Formalin Fixed, Paraffin Embedded Tissue [FFPE] Histological slides with tissue sections for second opinion [*consultation*] Biopsy, Excisional, Incisional or punch Surgically Resected Specimen– (***continued)***	Grossing and Microscopic Examination of tissues, in order to identify or exclude morphological and cytological aberrations from normal,in order to establish the Histological Diagnosis (continued)	Frozen sections Rapid H&E, manually
		Checking of representation in the histological section of the tissue included in paraffin block Checking of Quality of histological section and the result of stain. Checked initially with a microscope [*OLYMPUS / Mod CX31*]
		Microscopic Diagnosis **OE.22, 1.1, 01-09-2025** Microscopes [*OLYMPUS, Mod. CX41RFand ModBX41TF*]., **Microscopic Evaluation and Interpretation of Results.** In Neoplasms: grading of malignancy and staging of the disease according the AJCC recommendations (Cancer Staging Manual 7thEd), classification according to theWHO [ICD-O code]
Histochemistry		
Biopsies and Surgical Specimens from whole Human Body Organs and Systems Formalin Fixed Specimen 10% neutral buffered Formalin	Identification of tissue components and enzymes	Special staining: HISTOCHEMISTRY **Automated kits used.** **OE.21, 1.5, 01-09-2025** **OE.22, 1.1, 01-09-2025**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Fixed, Paraffin Embedded Tissue [FFPE] Histological slides with tissue sections for second opinion [*consultation*] Biopsy, Excisional, Incisional or punch Surgically Resected Specimen		Closed system used, with Automated Slide Stainer and an Automated Glass Cover slipper [*SAKURA FINETEK USA Inc, / ASS-Mod Tissue TekPrisma E2Sand AGC-Mod. Glas g2*] **Manually,** in certain cases, for specific stains. **Stains** Haematoxyline- Eosin [H-E] Alcian Blue / PAS Microscopic Evaluation – Interpretation of Results
Immunohistochemistry		
Biopsies and Surgical Specimens from whole Human Body Organs and Systems Formalin Fixed Specimen 10% neutral buffered Formalin Fixed, ParaffinEmbeddedTissue [FFPE] Histological slides with tissue sections for second opinion [*consultation*] Biopsy, Excisional, Incisional, FNB or punch Surgically Resected Specimen	Detection of Markers and Protein Expression 1)E-Cadherin 2)Ki67 3) CK7 4) CK20	**Special staining: IMMUNOHISTOCHEMISTRY** **OE.21, 1.5, 01-09-2025** **OE.22, 1.1, 01-09-2025** **Method.**Manually, with manufacturer's kit EnVision™ Flex (DAKO) and DAB as a chromogen. PT LINK, an automated device is used for deparaffinization**,** hydration and antigen retrieval of the tissue. **Special antibodies:** Ki-67 (DAKO, MIB-1) E-Cadherin (DAKO, NCH-38), CK7 (CELL MARQUE, OV-TL12/30), CK20 (CELL MARQUE, Ks20.8) **Morphometric analysis, tumor immunohistochemistry.** Semiquantitative method for each antibody; manually. **Interpretation of Results - Reporting** Each Antibody is evaluated in comparison with internal or external control [*positive and negative*]
Human Breast Tissue Formalin Fixed Paraffin Embedded Tissue [FFPE] Excisional and Needle Biopsy	**Prognostic Marker Expression for Breast Cancer** 1)ER 2)PR	**Special staining: IMMUNOHISTOCHEMISTRY** **OE.21, 1.5, 01-09-2025** **OE.22, 1.1, 01-09-2025**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Surgical Resection Specimens with Breast Cancer	3)Her-2	**Method.** Manually, with manufacturer's kit EnVision™ Flex (DAKO) and DAB as a chromogen. PT LINK, an automated device is used for deparaffinization**,** hydration and antigen retrieval of the tissue. **Special antibodies**:ER (DAKO, EP1), PR (DAKO, 636), HER2 (DAKO, Polyclonal) **Morphometric analysis, tumor immunohistochemistry.** Semiquantitative method for each antibody; manually. **Interpretation of Results – Reporting.** Based on international guidelines [e.g. CAP breast carcinoma]. Each Antibody is evaluated in comparison with internal or external control [*positive and negative*]

International and Hellenic guidelines used for Gross Examination and Dissection and Histologic interpretation of biopsies and surgical specimens

WHO: World Health Organizationy
ICD-O: International Classification of Diseases for Oncology
AJCC: AmericanJointCommitteeonCancer
CAP: CollegeofAmericanPathologists

Site of assessment: **Permanent laboratory premises , 1-3 Papada Str, 3rd floor, Athens, zip code 115 26, Greece.**
Approved signatories: **Konstantina Frangia - Tsivou, Kalypso Barbati, Aikaterini Pavlakis, Antigoni Sourla, Despoina Mourtzoukou, Sofia Tsitsiou, Menelaos Tzikanoulas, Andriani Zaxaratou**

This scope of Accreditation replaces the previous one dated 27.11.2024.
The Accreditation Certificate No. **1041-**3, to ELOT EN ISO 15189:2022, is valid until 31.05.2029.

Athens, 12th of February 2026

Konstantinou Evangelos Apostolos
CEO of ESYD