Hellenic Accreditation System

Annex G1/7 to the Certificate No.**1098**-2

SCOPE of ACCREDITATION

of the

PRIVATE DIAGNOSTIC AND PATHOLOGY LAB GOUTAS N. – VLACHODIMITROPOULOS D. MEDICAL O.E.- "ISTOMEDICA"

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: – O.520.01/1/09-02-2016, O.520.02/1/09-02-2016, O.520.04/1/09-02-2016, O.410/14/30-06-2016, O.520.05/1/09-02-2016** <u>Gross Examination and Dissection</u> Performed in a wall Grossing Station [Excelsior ES] Depending on type of specimen and according to laboratory documented instruction for Gross Examination and Dissection (0.520.01/1/09-02-2016) <u>Gross Description</u> According to international and Hellenic guidelines [*CAP, ADASP, AJCC, FIGO, RCP, TNM,WHO, ΕΕΠΑ, AFIP etc*]. <u>Frozen sections from unfixed specimen</u> cryostat [Shandon Cryotome E)

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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)	<u>Tissue processing</u> Automated processing dehydration, clearing and paraffin tissue infiltration with Vacuum Infiltration tissue processor [SHANDON EXCELSIOR ES*].*
		<u>Paraffin Embedding System</u> HistoStar
		<u>Preparation of tissue section on glass slide</u> Electronic Rotary Microtome [*Micro HM 355S*] and a manual Rotary Microtome [*SHANDON FINESSE ME+*]
		Haematoxylin and Eosin stain and addition of cover slip in the tissue section Permanent sections With an Automated Slide Stainer and an Automated Glass Coverslipper. [*THERMO SCIENTIFIC GEMINI AS*] 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*]

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Immunohistochemistry		
Human Breast Tissue Formalin Fixed Paraffin Embedded Tissue [FFPE] Excisional and Needle Biopsy Surgical Resection Specimens with Breast Cancer	**Prognostic Marker Expression for Breast Cancer** 1)ER 2)PgR 3)Her-2	**Special staining: IMMUNOHISTOCHEMISTRY O.520.03/1/09-02-2016, O.520.04/1/09-02-2016, O.420.01/6/12-04-2021** **Method:** Automated (Autostainer 480S LAB VISION) **Special antibodies**: : ER(sp1-Thermo), PgR (sp2- Thermo), Her-2 (sp3Thermo) **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*]

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
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) S-100-4c4.9 Thermo 2) Ki67-sp6-Thermo 3) CKHMW-34BETA E12-Thermo 4) E-cadherin- EP700Y-Thermo 5) HMB-45(melanoma)Thermo 6) P63-4A4- GENNOVA 7) P504S-13H4-Thermo 8) CD34-QBEnd/10-Thermo 9) CK7-OV-TL12130-Thermo 10) CK20-Ks20.B-Thermo 11) CK5/6-D5/16 B4-Thermo 12) CKPAN-AE1/AE2-Thermo 13) CDX2-EPR 2769Y-Thermo	**Special staining: IMMUNOHISTOCHEMISTRY O.520.03/1/09-02-2016, O.520.04/1/09-02-2016, O.420.01/6/12-04-2021** **Method:** Automated (Autostainer 480S LAB VISION) **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*]
Human Breast Tissue Formalin Fixed Paraffin Embedded Tissue [FFPE] Excisional and Needle Biopsy Surgical Resection Specimens with Breast Cancer	**Prognostic Marker Expression for Breast Cancer** 1)Her-2	**Special staining: IMMUNOHISTOCHEMISTRY O.520.03/1/09-02-2016, O.520.04/1/09-02-2016, O.420.01/6/12-04-2021** **Method:** Automated (BOND MAX Auto IHC/ISH stainer, LEICA) **Special antibodies**: Her-2 (LEICA) **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*]

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
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) P63 2) CK5/6 3) KI67 4) HMB-45	**Special staining: IMMUNOHISTOCHEMISTRY O.520.03/1/09-02-2016, O.520.04/1/09-02-2016, O.420.01/6/12-04-2021** **Method:** Automated (BOND MAX Auto IHC/ISH stainer, LEICA) **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 surgicalspecimens

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

Site of assessment: **Permanent laboratory premises, 92 Michalakopoulou Str., PC11528, Athens, Greece.**
Approved signatories: **Goutas Nikolaos, Vlachodimitropoulos Dimitrios, Mourtzoukou Eleni, Mourtzoukou Despoina,Tsitlidou Aliki, Vassilis Milionis.**

This scope of Accreditation replaces the previous one dated 27.08.2021.
The Accreditation Certificate No.**1098**-2, to ELOT EN ISO 15189:2012, is valid until 18.06.2025.

Athens, April 05, 2022

Christos Nestoras
CEO of ESYD