# Hellenic Accreditation System

Annex G1/7 to the Certificate No. **1124**-3

## SCOPE of ACCREDITATION

of the

## Histopathology laboratory

of

## "METROPOLITAN GENERAL S.A."

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Histopathology** | | |
| **Biopsies and Surgical Specimens from Human Body Organs and Systems**<br>Unfixed Specimen for special processing or frozen section biopsy.<br>Tissue specimen fixed in 10% neutral buffered formalin<br>10% neutral buffered Formalin Fixed, Paraffin Embedded Tissue [FFPE]<br>Histological slides or paraffin blocks for second opinion [*consultation*]<br>Biopsies<br>Surgically Resected Specimen | **Histopathological examination activities for the purposes of clinical diagnosis**<br>Gross and Microscopic Examination of tissues in order to identify or exclude morphologically and cytologically, aberrations from normal for the purpose of diagnosis | **Macroscopic and Microscopic examination:**<br><u>Gross Evaluation and Dissection</u><br>Performed in a Grossing Station [PROPATH N.V]<br>Block printer [ThermoScientific PrintMate AS]<br>[BiopsySoft Information System]<br>According to international and Hellenic guidelines [*CAP, AJCC, WHO, ΕΕΠΑ etc.*].<br><u>Dissection of fresh specimen for frozen section biopsy</u><br>[Cryotome SLEE MEV+]<br><u>Tissue processing</u><br>[SAKURA Histo-Tek VP1]<br>(Ο.Δ.ΠΑΘΕ.520.G.03, 2, 05-03-2019).<br>Paraffin Embedding System<br>[Amos Scientific PTY LTD TEC 2800]<br>[Sakura Tissue-Tek TEC-6]<br>[BiopsySoft Information System]<br>(Ο.Δ.ΠΑΘΕ.520.G.03, 2, 05-03-2019). |
| Unfixed Specimen for special processing or frozen section biopsy.<br>Tissue specimen fixed in 10% | Gross and Microscopic Examination of tissues in order to identify or exclude morphologically | <u>Microtomy</u><br>[Semiautomatic Thermo Scientific HM 340E Leica Rm2245 Microtomes] |

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|---|---|---|
| neutral buffered formalin<br>10% neutral buffered Formalin Fixed, Paraffin Embedded Tissue [FFPE]<br>Histological slides or paraffin blocks for second opinion [*consultation*]<br>Biopsies<br>Surgically Resected Specimen<br>(continued) | and cytologically, aberrations from normal for the purpose of diagnosis<br>(continued) | [Leica RM2245]<br>[SLEE CUT 5062]<br>Section water baths<br>[Leica HI 1210] (X2)<br>[THERMO A84600060]<br>[SLEE SLIDETEC WATER-S]<br>Slide printers<br>[Matsunami SlideMate AS]<br>[Matsunami ESPO] (X2)<br><br>[BiopsySoft Information System]<br><u>Deparaffinization Systems</u><br>Hot air autoclave [Heraeus UT6]<br><u>Haematoxylin and Eosin staining</u><br>Automated Stainer<br>EPREDIA Gemini AS<br>(Ο.Δ.ΠΑΘΕ.520.G.04, 3, 20-09-2019)<br><br><u>Coverslipping</u><br>Automated Coverslipper<br>EPREDIA Clearvue<br><u>Cross-checking between paraffin blocks and slides, checking of tissue representation on slides, checking of section quality</u><br>[BiopsySoft Information System]<br><br><u>Interpretive Microscopy</u><br>[Nikon Eclipse 50i microscope with co-observer]<br>[Nikon Eclipse 50i microscope]X2<br>[Zeiss Axiostar plus microscope]<br>[Leica M LB microscope]<br>[Nikon Ci-L (FN22) LED microscope]<br>Microscopic Evaluation-Interpretation of Results |
| Unfixed Specimen for special processing or frozen section biopsy.<br>Tissue specimen fixed in 10% | Gross and Microscopic Examination of tissues in order to identify or exclude morphologically | <u>Neoplastic Diseases</u><br>Grading of the neoplasm.<br>Staging according to AJCC Cancer |

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|---|---|---|
| neutral buffered formalin<br>10% neutral buffered Formalin Fixed, Paraffin Embedded Tissue [FFPE]<br>Histological slides or paraffin blocks for second opinion [*consultation*]<br>Biopsies<br>Surgically Resected Specimen<br>(continued) | and cytologically, aberrations from normal for the purpose of diagnosis<br>(continued) | Staging Manual 7th Ed.<br>Classification according to WHO (ICD-O) |
| **Immunohistochemistry** | | |
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE].<br>Tissue on positively charged slides without prior handeling (deparaffinization, staining). | **Detection of Markers and Protein Expression**<br>Non-small cell carcinoma of the lung | Special staining - IMMUNOHISTOCHEMISTRY-IMMUNOCYTOLOGY:<br>Automated Immunohistochemistry methods using detection kits:<br>Ventana BenchMark XT, Ventana BenchMark ULTRA Autostainer* and antibody as appropriate:<br>(Ο.Δ.ΠΑΘΕ.520.G.01, 2, 05-03-2019).<br>Morphometric evaluation of the immunohistechemical study of the tumor. Non-automated method, evaluation-interpretation of results based on International Guidelines, evaluation in comparison with internal or external control [*positive and negative*]<br>ALK EML4 (D5F3 Roche) |
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE].<br>Tissue on positively charged slides without prior handeling (deparaffinization, staining).<br>**Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE]. | **Prognostic Marker Expression for Breast Cancer**<br>1) ER<br>2) PR<br>3) Her-2 | Special staining - IMMUNOHISTOCHEMISTRY:<br>Automated Immunohistochemistry using detection kits<br>Ventana BenchMark XT, Ventana BenchMark ULTRA Autostainer* and antibodies as appropriate.<br>(Ο.Δ.ΠΑΘΕ.520.G.01, 2, 05-03-2019).<br>Morphometric evaluation of the immunohistechemical study of the tumor. Non-automated method, |

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|---|---|---|
| Tissue on positively charged slides without prior handeling (deparaffinization, staining).<br>(continued) | | evaluation-interpretation of results based on International Guidelines, evaluation in comparison with internal or external control [*positive and negative*]<br><br>**Special antibodies**: ER (Roche SP1), PR (Roche 1E2), HER2 (Roche 4B5) |
| **Human Body Tissue**<br>10% neutral buffered Formalin Fixed, Paraffin Embedded Tissue [FFPE]<br>Tissue on positively charged slides without prior handeling (deparaffinization, staining). | **Detection of Markers and Protein Expression**<br><br>Microsatellite instability: | Special staining - IMMUNOHISTOCHEMISTRY-IMMUNOCYTOLOGY:<br>Automated Immunohistochemistry methods using detection kits:<br>Ventana BenchMark XT Autostainer*<br>and antibody as appropriate:<br>(Ο.Δ.ΠΑΘΕ.520.G.01, 2, 05-03-2019).<br><br>Morphometric evaluation of the immunohistechemical study of the tumor. Non-automated method, evaluation-interpretation of results based on International Guidelines, evaluation in comparison with internal or external control [*positive and negative*]<br><br>MLH1 (M1 Roche)<br><br>MSH2 (G219-1129 Roche)<br><br>MSH6 (SP93 Roche)<br><br>PMS2 (A16-4 Roche) |
| **Human Body Tissue**<br>10% neutral buffered Formalin Fixed, Paraffin Embedded Tissue [FFPE]<br>Tissue on positively charged slides without prior handeling (deparaffinization, staining). | **Detection of Markers and Protein Expression:**<br><br>PD-L1 | Special staining - IMMUNOHISTOCHEMISTRY-IMMUNOCYTOLOGY:<br>Automated Immunohistochemistry methods using detection kits:<br>Ventana BenchMark XT, Ventana BenchMark ULTRA Autostainer*<br>and antibody as appropriate:<br>(Ο.Δ.ΠΑΘΕ.520.G.01, 2, 05-03-2019).<br><br>Morphometric evaluation of the immunohistechemical study of the tumor. Non-automated method, evaluation-interpretation of results based on International Guidelines, |

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| | | evaluation in comparison with external control [*positive and negative*]<br><br>PD-L1 (SP263 Roche)<br><br>PD-L1 (SP142 Roche) |
| **Human Body Tissue**<br>10% neutral buffered Formalin Fixed, Paraffin Embedded Tissue [FFPE]<br>Tissue on positively charged slides without prior handeling (deparaffinization, staining). | **Detection of Markers and Protein Expression:**<br><br>1) p40<br>2) synaptophysin<br>3) napsin-A<br>4) TTF-1<br>5) CD10<br>6) p53<br>7) P504S<br>8) PSA<br>9) calretinin<br>10) desmin<br>11) PAX-8<br>12) GATA-3<br>13) CK5<br>14) CD3<br>15) CK7<br>16) CK20<br>17) CDX2 | <u>Special staining - IMMUNOHISTOCHEMISTRY-IMMUNOCYTOLOGY:</u><br>Automated Immunohistochemistry methods using detection kits:<br>Ventana BenchMark XT, Ventana BenchMark ULTRA, BOND MAX Autostainer*<br>and antibody as appropriate:<br>(Ο.Δ.ΠΑΘΕ.520.G.01, 2, 05-03-2019).<br>(Ο.Δ.ΠΑΘΕ.520.G.02, 3, 05-03-2019).<br><br>Morphometric evaluation of the immunohistechemical study of the tumor. Non-automated method, evaluation-interpretation of results based on International Guidelines, evaluation in comparison with internal or external control [*positive and negative*]<br><br>p40 (BC28 Ventana)<br><br>Synaptophysin (SP11 Ventana)<br><br>Napsin-A (IP64 Leica)<br><br>TTF-1 (SP141 Ventana)<br><br>CD10 (SP67 Roche)<br><br>p53 (DO-7 Leica, Roche)<br><br>P504S (NCCL-L-AMACR Leica)<br><br>PSA (35H9 Leica)<br><br>Calretinin (SP65 Roche)<br><br>Desmin (DE-R-11 Leica)<br><br>PAX-8 (SP348 Abcam) |

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| | | GATA-3 (L50-823 Cell Marque, Roche)<br>CK5 (XM26 Leica)<br>CD3 (A0452 Dako)<br>CK7 (OV-TL 12/30 Dako)<br>CK20 (Ks20.8 Dako)<br>CD-X2 (EPR2764Y Roche) |
| **Histopathology** | | |
| Human Body Tissue<br>Unfixed Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens | Intraoperative Consultation (frozen section biopsy)<br>Gross and Microscopic Examination of tissues following appropriate handling (cryotome sectioning, rapid H+E staining, coverslipping) in order to identify or exclude morphological and cytological abnormalities for the scope of Intraoperative Consultation of the surgeon. | Frozen Sections<br>[Cryotome SLEE MEV+]<br>Rapid H&E staining (frozen sections)<br>Intraoperative Consultation<br>Gross and Microscopic Evaluation – Interpretation of Results |
| Conventional vaginal and cervical smears.<br>Body fluids.<br>Breast secretions.<br>Mucosal smears.<br>Cell blocks.<br>Imprints.<br>Fine needle aspirations of organs (FNA). | Gross and Microscopic Examination of tissues in order to identify or exclude morphologically and cytologically, aberrations from normal for the purpose of diagnosis | **Macroscopic and Microscopic examination:**<br>Gross Evaluation<br>Hood chamber (CRUMA FL-1)<br>Handling of fluids<br>CYTOSPIN 4 (THERMOSHANDON) SL8 (THERMO SCIENTIFIC)<br>Slide heater (nuova II, THERMOLYNE)<br>Manual Papanicolaou staining<br>Manual modified Giemsa staining<br>(Ο.Δ.ΠΑΘΕ.520.G.04, 3, 20-09-2019) |
| Conventional vaginal and cervical smears.<br>Body fluids.<br>Breast secretions. | Gross and Microscopic Examination of tissues in order to identify or exclude morphologically and cytologically, aberrations from | Embedding of precipitate in paraffin blocks<br>Grossing Station (PROPATH N.V)<br>Tissue processing |

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|---|---|---|
| Mucosal smears.<br>Cell blocks.<br>Imprints.<br>Fine needle aspirations of organs (FNA).<br>(continued) | normal for the purpose of diagnosis (continued) | SAKURA Histo-Tek VP1<br>(Ο.Δ.ΠΑΘΕ.520.G.03, 2, 05-03-2019).<br><br>Paraffin Embedding System<br>[Amos Scientific PTY LTD TEC 2800]<br>[Sakura Tissue-Tek TEC-6]<br>(Ο.Δ.ΠΑΘΕ.520.G.03, 2, 05-03-2019).<br>Microtomy<br>[Semiautomatic Thermo Scientific HM 340E Leica Rm2245 Microtomes]<br>Section water baths [Leica HI 1210]<br>Deparaffinization Systems<br>Hot air autoclave [Heraeus UT6]<br>Haematoxylin and Eosin staining<br>Automated Stainer<br>[EPREDIA Gemini AS]<br>(Ο.Δ.ΠΑΘΕ.520.G.04, 3, 20-09-2019)<br>Coverslipping<br>Automated Coverslipper<br>[EPREDIA Clearvue]<br>Cross-checking between paraffin blocks and slides, checking of tissue representation on slides, checking of section quality<br>Manually<br>Interpretive Microscopy<br>NIKON ECLIPSE 50i |

** 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 , Mesogion Ave., 264, Cholargos, Athens, Greece.**
Approved signatories: **Eleni Patsea, Lydia Abou-Asabeh, Maria Chantziara, Maria Sevastiadou, Despina Pouloudi.**

**Primary Sample Collection Point: Permanent laboratory premises , Mesogion Ave., 264, Cholargos, Athens, Greece**

This scope of Accreditation replaces the previous one dated 31.06.2024.
The Accreditation Certificate No. **1124**-3, to ELOT EN ISO 15189:2022, is extended until 16.11.2026, according to ESYD decision.

Athens, 12th of May 2026

Konstantinou Evangelos Apostolos
*CEO of ESYD*