HELLENIC ACCREDITATION SYSTEM

# Annex G1/12 to the Certificate No. **971**-4

# SCOPE of ACCREDITATION

of the

## Histopathology laboratory

of

## "ISTODIEREVNITIKI S.A."

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Histological examinations** | | |
| **Human Body Tissue**<br>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**<br>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**<br><br>BIOPTICA TRIMMING PATH<br>Aspirated hood for cutting and reduction of histological samples<br>*(OE 703A_1, OE-703A_2)*<br><br>Specimen Dissection<br>Depending upon specimen type and according to Laboratory Grossing Manual SOP<br><br>Cassette Printer<br>CASSETTE PRINTER LASER SurePrint C100 – DAKEWE<br>FATech NOVA Laser Cassette Printer<br>*(OE 703A_1, OE 703A_2, OE 503_1)* |
| | | Tissue processing<br><br>MILESTONE LOGOS<br>THERMO SCIENTIFIC Excelsior AS<br>Epredia – Shandon Excelsior AS<br>Tissue Processor<br>*(OE 703A_1, OE 703A_3)* |
| | | Paraffin Embedding System<br><br>MEDITE TES 99.250<br>HISOSTAR Thermo Scientific<br>*(OE 703A_4)* |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>Fresh, Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens (continued) | | <u>Microtomy</u><br>Thermo Scientific HM 340E<br>PFM medical ROTARY 3005E<br>*(OE 703A_5, OE 503_1, OE 703Δ_1)* |
| | | <u>Haematoxylin and Eosin stain</u><br><u>Automated and manual</u><br>Haematoxilyn & Eosin Staining<br>THERMO SCIENTIFIC Gemini AS Automated Slide Stainer<br>Tissue-Tek Prisma Plus Automated Slide Stainer<br>*(OE 703A_6, OE 703A_7, OE 503_1, OE 703Δ_1)*<br>Rapid H&E (frozen sections)<br>*(OE 703A_6, OE 703Δ_1, OE-703A_7)* |
| | | <u>Coverslipping</u><br>Automated Coverslipper<br>THERMO CLEARVUE<br>Tissue-Tek Film Automated Coverslipper<br>*(OE 703A_8, OE 503_1, OE 703Δ_1)* |
| | | <u>Slide Checking & Section Quality</u><br>Manual<br>*(OE 703A_9, OE 503_1, OE 703Δ_1)* |
| | | <u>Interpretive Microscopy</u><br>Microscopic Evaluation-Interpretation of Results<br>- CARL ZEISS AXIOLAB Microscope<br>- OLYMPUS BX40F4 Microscope<br>*(OE 703A_10, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)* |
| | | <u>Neoplastic Diseases</u><br>Staging AJCC Cancer Staging Manual 7th Ed.<br>Grading as appropriate<br>Classification WHO ICD-O-2<br>Reporting of Results<br>(*OE 704A_1, OE 704A_5*) |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>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><br><br>Histochemistry using kit<br><br>Manual<br><br>***Stains:***<br>- Silver Methenamine<br>- Periodic Acid Schiff<br>- Silver Impregnation (Gomori)<br>- Perl's<br>- Masson Trichrome<br>- Congo Red<br>- Ziehl Neelsen<br><br>Microscopic Evaluation – Interpretation of Results<br>*(OE 703A_10, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1, OE 703A_11)* |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Immunohistochemistry examinations** | | |
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens | **Detection of Markers and Protein Expression** | Special staining -<br>IMMUNOHISTOCHEMISTRY:<br>Automated<br>Immunohistochemistry using detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO *<br><br>And antibodies as appropriate: Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*(OE 703A_10, OE 703A_12, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)* |
| | Fetal liver cells – yolk sac tumor | AFP |
| | Anaplastic large cell lymphoma | ALK |
| | Positive in prostate adenocarcinoma neoplastic cells, renal tubular cells | AMACR |
| | Triple negative breast cancer - prostate cancer | AR |
| | Scattered T cells in germinal centres and mantle zone B cells – Many T-cells | bcl-2 |
| | Germinal centre cells in lymphoid follicles | bcl-6 |
| | Gastro-intestinal (gastric, pancreatic and colonic) adenocarcinoma | CA 19-9 |
| | Parafolicular C cells of the thyroid | Calcitonin |
| | Smooth muscle cells of blood vessels and of bowel wall | Caldesmon |
| | Peripheral nerve gaglion – mesothelial cells - mesothelioma | Calretinin |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens | **Detection of Markers and Protein Expression** | <u>Special staining -</u><br><u>IMMUNOHISTOCHEMISTRY:</u><br>Automated<br>Immunohistochemistry using detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO *<br><br>And antibodies as appropriate: Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*(OE 703A_10, OE 703A_12, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)* |
| | All germinal centre B cells of lymph follicles | CD10 |
| | Normal and malignant plasma cells and in lymphoplasmocytoid cells | CD138 |
| | Neutrophils, eosinophils, macrophages, R-S cell in Hodgkin lymphoma | CD15 |
| | Langerhans cells – Langerhans's cell histiocytosis | CD1a |
| | B lymphocytes | CD20cy |
| | Follicular dendritic cells and a subpopulation of B cells | CD23 |
| | T lymphocytes | CD3 |
| | Activated lymphocytes and plasma cells and R-S cells in Hodgkin lymphoma – Anaplastic large cell lymphoma | CD30 |
| | Endothelial cells and their tumors - megacaryocytes | CD31 |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
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| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens | **Detection of Markers and Protein Expression** | <u>Special staining -</u><br><u>IMMUNOHISTOCHEMISTRY:</u><br>Automated<br>Immunohistochemistry using detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO *<br>And antibodies as appropriate: Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*(OE 703A_10, OE 703A_12, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)* |
| | Endothelial cells – GISTs – solitary fibrous tumor | CD34 |
| | T helper cells | CD4 |
| | All leucocytes | CD45 (LCA) |
| | T cells and occasionally on a subset of B cells | CD5 |
| | Peripheral nerves, Neuroendocrine cells/tumors – NK cells – ovarian stromal tumors | CD56 |
| | Macrophages | CD68 |
| | B lymphocytes - plasma cells | CD79a |
| | T cells,cytotoxic/ suppressor cells | CD8 |
| | Some lymphocytes, cortical thymocytes, granulosa cells of the ovary, most pancreatic islets cells, sertoli cells and some endothelial cells – Ewing sarcoma/PNET – Synovial sarcoma | CD99 |
| | Positive in GIST tumors, mast cells, Cajal cells, and melanocytes | CD117 (c-KIT) |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens | **Detection of Markers and Protein Expression** | Special staining -<br>IMMUNOHISTOCHEMISTRY:<br>Automated<br>Immunohistochemistry using detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO *<br><br>And antibodies as appropriate: Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*(OE 703A_10, OE 703A_12, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)* |
| | Normal and neoplastic intestinal epithelial cells | CDX2 |
| | Most adenoCa cells | CEA |
| | Islets of Langerhan cells of the pancreas – many neuroendocrine cells/tumors | Chromogranin A |
| | Epithelial cells | CK (AE1/AE3) |
| | A wide variety of epithelial cells | CK 19 |
| | Umbrella cells of Urothelium – intestinal epithelium | CK 20 |
| | Squamous epithelium | CK 5/6 |
| | Urothelium – non squamous epithelium and carcinomas of respiratory system – epithelium and carcinomas of bile/pancreatic and mammary ducts | CK 7 |
| | Many epithelial cells | CK 8/18 |
| | Squamous epithelium | CK HMW (34bE12) |
| | Mast cells, GIST | c-kit |
| | Proliferative zone of epithelial tissues – mantle cell lymphoma | CyclinD1 |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
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| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens | **Detection of Markers and Protein Expression** | <u>Special staining -</u><br><u>IMMUNOHISTOCHEMISTRY:</u><br>Automated<br>Immunohistochemistry using detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO *<br><br>And antibodies as appropriate: Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*(OE 703A_10, OE 703A_12, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)* |
| | Smooth and striated muscle cells | Desmin |
| | Epithelial cells and tumors of mammary gland ducts | E-cadherin |
| | Many epithelial cells – synovial sarcoma | EMA |
| | Many epithelial cells/adenocarcinomas | ESA |
| | Breast carcinoma – urothelial carcinomas | GATA-3 |
| | Breast carcinoma | GCDFP15 |
| | Astrocytes | GFAP |
| | Erythroid cells | Glycophorin A |
| | Trophoblasts of placenta, secreting HCG | HCG (beta) |
| | Hepatocytes | Hepatocyte |
| | Melanoma cells | HMB45 |
| | Plasma cells and related lymphoid cells containing IgA | IgA |
| | Plasma cells and related lymphoid cells containing IgG | IgG |
| | Plasma cells and related lymphoid cells containing IgM | IgM |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens | **Detection of Markers and Protein Expression** | <u>Special staining -</u><br><u>IMMUNOHISTOCHEMISTRY:</u><br>Automated<br>Immunohistochemistry using detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO *<br><br>And antibodies as appropriate: Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*OE 703A_10, OE 703A_12, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)* |
| | Leydig and Sertoli cells in testis | Inhibin |
| | Positive in neuroendocrine tumors and neuroendocrine cells. | INSM1 |
| | Kappa positive plasma cells and cells that have absorbed exogenous immunoglobulins | Kappa light chain |
| | Mitotic cell marker | Ki-67 |
| | Lambda positive plasma cells and cells that have absorbed exogenous immunoglobulins | Lambda light chain |
| | Melanocytes | Melanoma Cocktail |
| | A wide variety of epithelial cells/adenocarcinomas | MOC-31 |
| | Myocardial, skeletal and smooth muscle cells as well as myoepithelial cells. Myofibroblasts in the stroma of certain tumours – myofibroblastic tumors | MSA |
| | Plasma cells, activated T cells, R-S cells in Hodgkin’s lymphoma, Anaplastic large cell lymphoma | MUM1 |
| | Neutrophil granulocytes and monocytes in blood and precursors of granulocytes in the bone marrow | Myeloperoxidase |
| | Rhabdomyosarcomas | MyoD1 |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens | **Detection of Markers and Protein Expression** | Special staining -<br>IMMUNOHISTOCHEMISTRY:<br>Automated<br>Immunohistochemistry using detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO *<br><br>And antibodies as appropriate: Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*(OE 703A_10, OE 703A_12, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)* |
| | Rhabdomyosarcomas | Myogenin |
| | Positive in lung adenocarcinomas, alveolar lung cells, and renal tubular epithelial cells. | Napsin A |
| | Normal prostate and prostate adenocarcinoma | NKX3.1 |
| | Neuroendocrine and neuronal cells | NSE |
| | Normal squamous epithelium, myoepithelial cells, and basal cells. | P40 |
| | Prostate adenocarcinoma | P504S |
| | Many malignant cells | p53 |
| | Squamous epithelium/tumors – urothelium/tumors | p63 |
| | Kidney, thyroid, epithelium and tumors of Mullerian origin | PAX8 |
| | Trophoblasts of placenta – seminoma | PLAP |
| | Prostate glands | PSA |
| | Prostate glands | PSAP |
| | Schwann cell, adipocytes, cartilage – Langerhans cells/tumors – melanocytic tumors | S100 |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
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| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens | **Detection of Markers and Protein Expression** | Special staining -<br>IMMUNOHISTOCHEMISTRY:<br>Automated<br>Immunohistochemistry using detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO *<br><br>And antibodies as appropriate: Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*(OE 703A_10, OE 703A_12, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)* |
| | Smooth muscle cells and myoepithelial cells | SMA |
| | Smooth muscle cells and myoepithelial cells | SMMHC |
| | Islets of Langerhans cells of pancreas – Neuroendocrine cells/tumors | Synaptophysin |
| | Cortical thymocytes and primitive lymphocytes | TdT |
| | Follicular epithelial cells as well as colloid of thyroid | Thyroglobulin |
| | Follicular epithelial thyroid cells, non squamous epithelium of the lower respiratory system, lung adenocarcinomas / Neuroendocrine carcinoma | TTF-1 |
| | Mesenchymal cells, some epithelial cells/tumors | Vimentin |
| | Mesothelial cells/mesotheliomas, serous ovarian tumors, stromal cells and stromal tumors of ovary and endometrium, leiomyomatous tumors of female genital system, Wilms tumor | WT1 |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], Excisional and Needle Biopsies and Surgical Resection Specimens with Breast Cancer | **Prognostic Marker Expression for Breast Cancer** | Special staining -<br>IMMUNOHISTOCHEMISTRY:<br>Automated<br>Immunohistochemistry using detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO *<br><br>And antibodies as appropriate:<br>Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*(OE 703A_10, OE 703A_12, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)*<br><br>Morphogenic analysis, tumor immunohistochemistry.<br>Semiquantitative, method each antibody; manual<br>Interpretation of Results – Reporting based on: CAP breast-carcinoma-biomarker-14protocol-1100 |
| | Breast carcinoma | ER (SP1) |
| | Breast carcinoma | PgR (16SAN27) |
| | Breast carcinoma | Her-2 (4B5) |
| | Breast carcinoma | Ki67 (MIB-1) |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], Excisional and Needle Biopsies and Surgical Resection Specimens. | Assessment of the presence or absence of markers and expression of biomarker proteins of the **MMR system (Mismatch Repair):** | <u>Special staining -</u><br><u>IMMUNOHISTOCHEMISTRY:</u><br>Automated<br>Immunohistochemistry using detection kits<br>- Ventana BenchMark ULTRA*<br>And antibodies as appropriate: Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*(OE 703A_10, OE 703A_12, OE 704A_1, OE 704A_5, OE 503_1, OE 703Δ_1)*<br>Immunohistochemical study analysis using VENTANA MMR RxDx Panel CE-IVD. |
| | MMR protein | MSH6 (SP93) |
| | MMR protein | PMS2 (A16-4) |
| | MMR protein | MLH1 (M1) |
| | MMR protein | MSH2 (G219-1129) |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], Excisional and Needle Biopsies and Surgical Resection Specimens with Lung Cancer, Metastatic Urothelial Carcinoma (mUC), Breast Cancer and Triple-Negative Breast Cancer (TNBC). | **Assessment of Predictive Biomarkers using IVD Assays** | Special staining -<br>IMMUNOHISTOCHEMISTRY & HYBRIDIZATION:<br>Automated<br>Immunohistochemistry using IVD detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO *<br>And antibodies as appropriate:<br>Microscopic Evaluation – Interpretation of Results. Each Antibody<br>*(OE 703A_15)* |
| | Non-Small Cell Lung Cancer | ***ALK D5F3 (NSCLC)***<br>***Interpretation Guide, 1011879EN Rev H***<br>***Scoring Criteria:***<br>***Positive - Negative*** |
| | Non-Small Cell Lung Cancer | ***PD-L1 SP263 (NSCLC)***<br>***Interpretation Guide, 1015317EN Rev E***<br>***Scoring Criteria:***<br>***Pembrolizumab***<br>***Cut off TPS ≥ 1% (1%-49%) Second Line***<br>***Cut off TPS ≥ 50% First Line***<br>***Durvalumab***<br>***Cut off TC > 1%***<br>***PD-L1 22C3 (NSCLC)***<br>***Interpretation Manual, 29158 2021APR06 27/4/21***<br>***Scoring Criteria:***<br>***No PD-L1 Expression Cut off TC < 1%***<br>***Pembrolizumab***<br>***PD-L1 Expression Cut off TPS ≥ 1% (1%-49%)***<br>***High PD-L1 Expression Cut off TPS ≥ 50%*** |
| | Triple-Negative Breast Cancer (TNBC) | ***PD-L1 SP142 (TNBC)***<br>***Interpretation Guide, 1018231EN Rev C***<br>***Scoring Criteria:***<br>***Atezolizumab - Cut off IC ≥ 1%***<br>***PD-L1 22C3 (TNBC)***<br>***Interpretation Guide, D67159_01.2 29440 2023JAN10***<br>***Scoring Criteria:***<br>***Pembrolizumab***<br>***Cut off CPS <10***<br>***CPS ≥ 10*** |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], Excisional and Needle Biopsies and Surgical Resection Specimens with Lung Cancer, Metastatic Urothelial Carcinoma (mUC), Breast Cancer and Triple-Negative Breast Cancer (TNBC). | **Assessment of Predictive Biomarkers using IVD Assays** | Special staining -<br>IMMUNOHISTOCHEMISTRY & HYBRIDIZATION:<br>Automated<br>Immunohistochemistry using IVD detection kits<br>- Ventana BenchMark ULTRA*<br>- AUTOSTAINER LINK48 DAKO * |
| | Metastatic Urothelial Carcinoma (mUC) | ***PD-L1 SP142 (mUC)***<br>***Interpretation Guide, 1014987US Rev F***<br>***Scoring Criteria:***<br>***Atezolizumab - Cut off IC ≥ 5%*** |
| | Determination of HER2 gene amplification status on Chr17 | ***HER2 Dual ISH DNA (DISH) Breast Cancer***<br>***Interpretation Guide, 1018383EL Rev A***<br>***Scoring Criteria:***<br>***Amplified – Non-Amplified*** |
| | Gastric Adenocarcinoma including Gastroesophageal Junction (GEJ) | ***CLDN18 (43-14A) Ventana Assay***<br>***Interpretation Guide: 1016391EL Rev A (07/10/2024)***<br>***Scoring Criteria:***<br>***Zolbetuximab***<br>***Positive:***<br>≥ 75% viable tumor cells demonstrating moderate to strong membrane CLDN18 staining<br>***Negative:***<br><75 viable tumor cells demonstrating moderate to strong membrane CLDN18 staining |
| | Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer | ***FOLR1 (FOLR 1-2.1) Ventana Assay***<br>***Interpretation Guide: 1015222EL Rev B (03/06/2025)***<br>***Scoring Criteria:***<br>***Mirvetuximab Soravtansine***<br>***Positive:***<br>≥ 75% of viable tumor cells with moderate (2+) and/or strong (3+) membrane staining<br>***Negative:***<br><75% of viable tumor cells with moderate (2+) and/or strong (3+) membrane staining |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Molecular Genetics** | | |
| **Human Body Tissue**<br>Formalin Fixed Paraffin Embedded Tissue [FFPE], Excisional and Needle Biopsies and Surgical Resection Specimens with Lung Cancer | **Assessment of Molecular Biomarkers using IVD Assays**<br><br>**Non-Small Cell Lung Cancer (NSCLC)** | <u>Special techniques -</u><br><u>MOLECULAR BIOLOGY &</u><br><u>GENETICS:</u><br>Automated<br>Molecular Assays using IVD method & kits<br>- Biocartis Idylla™ System*<br><br>Microscopic Evaluation – Automated Procedure – Automation Result Analysis<br>*(OE 703A_16)*<br><br>- NCCN Guidelines NSCLC<br>- ESMO Clinical Practice Guidelines (NSCLC) |
| | Qualitative Detection of EGFR mutations (Exon 18,19,20,21) | ***Idylla™ EGFR Mutation Test***<br>***IFU BCT014648*** |
| | Qualitative Detection of BRAF mutations (V600E, V600E2, V600D, V600K, V600R & V600M) | ***Idylla™ BRAF Mutation Test***<br>***IFU BCT005528*** |
| | Qualitative Detection of KRAS mutations Exon 2 (codon 12, 13), Exon 3 (codon 59, 61) & Exon 4 (codon 117, 146) | ***Idylla™ KRAS Mutation Test***<br>***IFU BCT007559*** |
| | Qualitative Detection of specific gene fusions for ALK, ROS1, RET as well as MET exon 14 skipping and expression imbalance for ALK, ROS1 and RET. | ***Idylla™ GeneFusion Panel***<br>***IFU BCT013450*** |
| **Histopathology** | | |

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Human Body Tissue**<br>Fresh and Frozen Tissue; Excisional and Incisional Biopsies and Surgical Resection Specimens | **Intraoperative Consultation**<br>Gross and Microscopic Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the scope of Intraoperative Consultation | **Gross and Microscopic Evaluation – Interpretation of Results**<br>MILESTONE PrestoCHILL<br>Frozen Sections<br>Thermo Scientific HM550 Cryostat<br>CryoStar NX50 OVP / EPREDIA<br>Intraoperative Consultation<br>*OE 703A_1, OE 703A_2, OE 703A_3, OE 703A_6, OE 703A_13, OE 703A_14, OE 703Δ_1, OE 704A_1, OE 704A_5, OE 705A_6)* |

** 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, Antoni Tritsi 15-17, Pilea, Thessaloniki, Greece**
**Intraoperative Consulation Instalation: Interbalkan Medical Center, Askliliou 10, Farm School Ave. Pilea, Thessaloniki, Greece.**

Approved signatories: **Eleftherios Eleftheriadis, Thomas Zaramboukas, Themis Konstantinidis, Theodoros Tzigkalidis, Sofia Lypiridou, Prokopios Vogiatzis, Nikoleta Pastelli, Katerina Zarampouka, Stea Eleni - Chiotopoula, Stylianos Malasidis**

This Scope of Accreditation replaces the previous one dated 17.06.2025.
The Accreditation Certificate No. **971**-4, to ELOT EN ISO 15189:2022, is valid until 30.03.2028.

Athens, 14th of July 2026

Konstantinou Evangelos Apostolos
*CEO of ESYD*