HELLENIC ACCREDITATION SYSTEM

Annex G1/13 to the Certificate No.**1067**-4

SCOPE of ACCREDITATION

of the

Clinical laboratory

of

MICRODIAGNOSTICS MEDICAL S.A.
PRIVATE DIAGNOSTIC LABORATORY

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Cytology Tests		
1. Cervico-vaginal conventional Pap smear (PAP test)	**Microscopic Evaluation & Interpretation** of Pap test for the detection of lesions that deviate from the normal cellular structure, to allow early diagnosis of tumors and specific diseases.	**OE.430.02.a/2/02.02.2018** **Specimen Processing** Papanicolaou staining protocol Automatic Slide staining with Thermo Scientific Gemini AS Automated Slide Coverslipping with Epredia ClearVue Coverslipper **Microscopic Evaluation & Interpretation** **Bethesda Classification TBS 2014** **Papanicolaou Classification** **E.510-1/2/20.10.2017** Nikon Eclipse 80i with Digital area scan camera of high resolution Nikon Eclipse E200 OLYMPUS BX45 ZEISS AXIOLAB

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
2. Cervico-vaginal Liquid-based Cytology -LBC sample (PAP test)	**Microscopic Evaluation & Interpretation** of Pap test for the detection of lesions that deviate from the normal cellular structure, to allow early diagnosis of tumors and specific diseases	**OE.430.02.b/2/02.02.2018** **Specimen Processing** THIN PREP LBC platform Papanicolaou staining protocol Automatic Slide staining with Thermo Scientific Gemini AS Automated Slide Coverslipping with Epredia ClearVue Coverslipper **Microscopic Evaluation & Interpretation** **Bethesda Classification TBS 2014** **Papanicolaou Classification** **E.510-1/2/20.10.2017** Nikon Eclipse 80i with Digital area scan camera of high resolution Nikon Eclipse E200 OLYMPUS BX45 ZEISS AXIOLAB

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Histological Tests		
1.Excisional & Incisional Biopsies, Surgical Resection Specimens from Human tissue Formalin Fixed Paraffin Embedded Tissue [FFPE]	**Macroscopic Examination** Handling of formalin fixed tissue by a qualified pathologist Specimen Processing through the embedding station, sectioning, staining and cover slipping **Microscopic Evaluation** of H-E slides for the detection of lesions that deviate from the normal cellular & morphological structure, to allow early diagnosis of tumors and specific diseases	**Macroscopic Examination** **E.510-1/2/20.10.2017** Grossing platform GTS Vacuum Milestone ProCut Series - Special Cutting equipment for standardization of grossing techniques Milestone MacroPath Pro X digital camera and PC software for complete grossing documentation **Tissue Processing** Milestone Logos One Histoprocessor, Epredia HistoStar Embedding Workstation Embedding Station **Sectioning** Leica RM2255 (automatic) Leica Histo Core AUTOCUT (automatic) PFM 3005E (semi-automatic) Water baths Electrothermal (x2) **OE.430.03.b/2/02.02.2018** **Staining** H&E staining protocol Automatic Slide staining with Thermo Scientific Gemini AS Automated Slide Coverslipping with Epredia ClearVue Coverslipper **Microscopic Evaluation** Nikon Eclipse 80i with Digital area scan camera of high resolution Nikon Eclipse Si-L Nikon Eclipse E200 OLYMPUS BX45 ZEISS AXIOLAB **Interpretation of Results** WHO ICD-O classification of neoplastic diseases. AJCC Cancer Staging Manual (latest edition-8th)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
2.Excisional & Incisional Biopsies, Surgical Resection Specimens from Human tissue Fresh non-fixed tissue Frozen tissue embedded in a cryo-block	**Macroscopic Examination** Gross handling of biopsies & surgical specimens by a qualified pathologist for sectioning by frozen sections equipment (cryostat) **Rapid H&E staining** protocol **Rapid microscopic evaluation** for the detection of lesions that deviate from the normal cellular & morphological structure, to allow early diagnosis of tumors and specific diseases, providing guidance to the surgeon intraoperatively	**OE.430.03.a /2/02.02/2018** **Macroscopic Examination** Grossing platform GTS Vacuum. Frozen sections equipment Thermo Scientific CRYOSTAT HM525 NX **Microscopic slide evaluation** Nikon Eclipse 80i with Digital area scan camera of high resolution **Interpretation of Results** “Intraoperative Consultation” Foundations in Diagnostic Pathology, series Editor John R. Goldblum
Histochemical Tests		
1.Excisional & Incisional Biopsies, Surgical Resection Specimens from Human tissue 2.Formalin Fixed Paraffin Embedded Tissue [FFPE]	**PAS/AlsianBlue:** For demonstration of acid mucopolysaccharides, acetic mucins & carbohydrates that can define the final diagnosis **PAS:** To demonstrate normal and pathologic tissue components characterizied by adjacent glycolic or aminohydroxylic groups for histology and cytology **Masson trichrome stain:** For differentiating collagen tissue from smooth muscle in tumors and for highlighting collagen in cirrhosis **Iron:** Hemosiderin **Silver :** Reticular network **Pas d**: Mucins	**Manual Histochemical staining technique based on CE IVD kits** PAS/AlsianBlue OE.430.01.a /2/02.02.2018 PAS OE.430.01.c /2/02.02.2018 Masson Trichrome Stain OE.430.01/d /2/02.02.2018 IRON OE.430.01.g/2/02.02.2018 SILVER OE.430.01.h/2/02.02.2018 Pas-d OE.430.01.b/2/02.02.2018 **Microscopic evaluation** Nikon Eclipse 80i with Digital area scan camera of high resolution Nikon Eclipse Si-L Nikon Eclipse E200 OLYMPUS BX45 Zeiss AXIOLAB

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Immunohistochemistry (IHC) Tests		
1.Excisional & Incisional Biopsies, Surgical Resection Specimens & from Human tissue & Body Fluids 2.Formalin Fixed Paraffin Embedded Tissue [FFPE] 3.Liquid based Cytology Specimens – Cell Blocks	**Specimen Processing** of the Formalin Fixed Paraffin Embedded Tissue for the sectioning of unstained slides, staining and cover slipping Selectively imaging antigens (e.g. proteins) in cells of a tissue section by exploiting the principle of antibodies binding specifically to antigens in biological tissues	**Immunostain Processing** **E .510-1/2/20.10.2017** DAKO Autostainer Link 48 Leica Bond Max Autostainer Ventana BenchMark Ultra **Usage of detection kits** Automated Slide Coverslipping Epredia ClearVue Coverslipper **Microscopic Evaluation** Nikon Eclipse 80i with Digital Area Scan high resolution camera Nikon Eclipse Si-L Nikon Eclipse E200 OLYMPUS BX45 ZEISS AXIOLAB **Interpretation of Results** Dabbs Diagnostic Immunohistochemistry – Theranostic & Genomic Applications Latest Edition
	IHC Antibodies Tests	**OE.430.01.e-f/2/02.02.2018** **OE.430.01.i/2/02.02.2019** **OE.430.01.l/1/02.03.2022** **OE.430.01.m/1/02.06.2024** **OE.430.01.n/1/02.03.2025** **E.410-1/1/15.11.2020**
1.Excisional & Incisional Biopsies, Surgical Resection Specimens & from Human tissue & Body Fluids	TTF1	Follicular epithelial cells of thyroid, non-squamous epithelium of the lower respiratory tract. Lung adenocarcinomas & Neuroendocrine carcinoma
	Ber-Ep4	Epithelial (non-squamous, non-mesothelial cells) – for Differential diagnosis btw adenocarcinoma – mesothelioma

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
2.Formalin Fixed Paraffin Embedded Tissue [FFPE] 3.Liquid based Cytology Specimens – Cell Blocks	Cyt7	Urothelium – non squamous epithelium and carcinomas of respiratory system – epithelium and carcinomas of bile/pancreatic and mammary ducts
	Cyt20	Urothelial Umbrella cells– intestinal epithelium
	Calretinin	Mesothelial Cells, malignant mesothelioma
	ER	Estrogen expression in breast carcinoma
	PR	Progesterone expression in breast carcinoma
	HER2	ERBB2 receptor protein expression in breast carcinoma
	Ki67	Mitotic count of neoplastic cells
	CD4	T-lymphocytes, monocytes, T-cell lymphomas
	CD8	Cytotoxic T-lymphocytes, T-cell lymphomas
	MUM-1	Plasma cells, Plasmacytoma OE
	GATA-3	Normal urothelium, breast carcinoma and urothelial carcinoma
	CD45	Lymphoid tissue, T-cell and B-cell lymphomas
	CD138	Plasma cells, B- lymphocytes, lymphomas
	CD30	Immunoblasts, centroblasts, Hodgkin lymphoma, anaplastic large cell lymphoma, germ cell neoplasms
	CYCLIN D1	Endothelial cells, mantle cell lymphoma
	ALK	Anaplastic large cell lymphoma, myofibroblastic tumor
	ROS-1	Macrophages, type II pneumonocytes, non-small cell lung carcinoma
	PD-L1	Squamous epithelial cells, germ cells, lung carcinoma and urothelial carcinoma, placenta
	P63/CALDESMON	Myoepithelial cells, basal cells
	CD34	Normal endothelial cells, angiosarcoma, dermatofibrosarcoma protuberans

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	MELAN-A	Normal melanocytes, melanoma, phaechromocytoma, PEComa
	CEA	Normal glandular cells, adenocarcinoma, squamous cell carcinoma
	SYNAPTOPHYSIN	Normal neuroendocrine cells, neuroendocrine tumors
	CHROMOGRANIN	Normal neuroendocrine cells, neuroendocrine tumors, phaechromocytoma
	CD3	Normal T cells, T cell lymphomas
	CD5	Normal T cells, T cell lymphomas, thymic carcinoma
	CD20	Normal B cells, B cell lymphomas
	PAX-5	Normal B cells, Reed-Sternberg cells, lymphoplasmacytic lymphoma
	CD15	Immune cells, Reed-Sternberg cells, adnexal skin tumors
	KAPPA	Normal B cells, myeloma, b cell lymphomas
	LAMDA	Normal B cells, myeloma, B cell lymphomas
	CDX2	Normal epithelial cells of gastrointestinal tract, normal epithelial cells of pancreatobiliary tract, colon adenocarcinoma, enteric type adenocarcinoma
	WT1	Mesothelial cells, mesothelioma, ovarian carcinoma, gonadoblastoma, nephroblastoma, desmoplastic round cell tumor
	PSA	Normal prostatic epithelial cells, acinic cell adenocarcinoma of prostate gland
1.Excisional & Incisional Biopsies, Surgical Resection Specimens & from Human tissue & Body Fluids 2.Formalin Fixed Paraffin Embedded Tissue [FFPE]	MSH6 MSH2 MLH1 PMS2	Epithelial neoplasms, epithelial cells of gastrointestinal tract

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	PAX8	Papillary thyroid carcinoma Clear cell renal cell carcinoma Serous ovarian carcinoma
	P53	Serous ovarian carcinoma Triple-negative breast carcinoma Endometrioid endometrial carcinoma Certain pre-invasive lesions (dysplasia)
Molecular Genetics		
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	**<u>EGFR Gene Mutations</u>** **1a, 2)** Detection of **EGFR** exons 18, 19, 20, 21 mutations **1b)** Detection of **EGFR** exons 3, 7, 9, 18, 19, 20, 21 mutations	**1)** Manufacturer's method with Ion AmpliSeq™ **1a)** Colon and Lung Cancer Research Panel v2 (ThermoFisher Scientific) **1b)** Cancer Hotspot Panel v2 (ThermoFisher Scientific) and DNA sequencing with Next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher Scientific-ThermoFisher Scientific Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software, in combination with the Variant caller plugin, based on the ClinVar, COSMIC and Varsome databases. **OE430.4C1/2/01.03.2023** **2)** Manufacturer's method with Entrogen's CE-IVD kit EGFR Mutation Analysis Kit and analysis with the Real-Time PCR method in the 7500 Real-Time PCR System instrument, Applied Biosystems **OE430.4D1/1 /01.02.2020** Manual genomic DNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit. **OE430.04F/1/01.02.2020**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	**<u>KRAS – NRAS Gene Mutations</u>** **1a, 1b, 2)** Detection of **KRAS** exons 2, 3, 4 mutations Detection of **NRAS** exons2, 3, 4 mutations	**1)** Manufacturer's method with Ion AmpliSeq™ **1a)** Colon and Lung Cancer Research Panel v2 (ThermoFisher Scientific) **1b)** Cancer Hotspot Panel v2 (ThermoFisher Scientific) and DNA sequencing with Next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher Scientific-ThermoFisher Scientific Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software, in combination with the Variant caller plugin, based on the ClinVar, COSMIC and Varsome databases. **OE430.4C1/2/01.03.2023** **2)** Manufacturer's method with Entrogen's CE-IVD kit RAS Mutation Analysis Kit and analysis with the Real-Time PCR method in the 7500 Real-Time PCR System instrument, Applied Biosystems **OE430.4D1/1 /01.02.2020** Manual genomic DNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit. **OE430.04F/1/01.02.2020**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	**<u>BRAF Gene Mutation</u>** **1a, 1b)** Detection of **BRAF** exons 11, 15 mutations **2)** Detection of **BRAF** exon 15 codon 600 mutations	**1)** Manufacturer's method with Ion AmpliSeq™ **1a)** Colon and Lung Cancer Research Panel v2 (ThermoFisher Scientific) **1b)** Cancer Hotspot Panel v2 (ThermoFisher Scientific) and DNA sequencing with Next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher Scientific-ThermoFisher Scientific Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software, in combination with the Variant caller plugin, based on the ClinVar, COSMIC and Varsome databases. **OE430.4C1/2/01.03.2023** **2)** Manufacturer's method with Entrogen's CE-IVD kit BRAF Codon 600 Mutation Analysis Kit II and analysis with the Real-Time PCR method in the 7500 Real-Time PCR System instrument, Applied Biosystems **OE430.4D1/1 /01.02.2020** Manual genomic DNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit. **OE430.04F/1/01.02.2020**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	**PIK3CA Gene Mutations** **1a)** Detection of **PIK3CA** exons 10, 14, 21 mutations **1b)** Detection of **PIK3CA** exons 2, 5, 7, 8, 10, 14, 19, 21 mutations **2)** Detection of **PIK3CA** exons 10, 21 mutations	**1)** Manufacturer's method with Ion AmpliSeq™ **1a)** Colon and Lung Cancer Research Panel v2 (ThermoFisher Scientific) **1b)** Cancer Hotspot Panel v2 (ThermoFisher Scientific) and DNA sequencing with Next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher Scientific-ThermoFisher Scientific Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software, in combination with the Variant caller plugin, based on the ClinVar, COSMIC and Varsome databases. **OE430.4C1/2/01.03.2023** **2)** Manufacturer's method with Entrogen's CE-IVD kit PIK3CA Mutation Analysis Kit and analysis with the Real-Time PCR method in the 7500 Real-Time PCR System instrument, Applied Biosystems **OE430.4D1/1 /01.02.2020** Manual genomic DNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit. **OE430.04F/1/01.02.2020**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	**<u>IDH2 Gene Mutations</u>** **1, 2)** Detection of **IDH2** exon 4 mutation	Manufacturer's method with Ion AmpliSeq™ Cancer Hotspot Panel v2 (ThermoFisher Scientific) and DNA sequencing with Next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher Scientific-ThermoFisher Scientific Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software, in combination with the Variant caller plugin, based on the ClinVar, COSMIC and Varsome databases. **OE430.4C1/2/01.03.2023** **2)** Manufacturer's method with Diatech's CE-IVD kit EasyPGX ready IDH1/2 and analysis with the Real-Time PCR method in the AriaDx, Agilent instrument **OE430.4D4/1 /01.02.2020** Manual genomic DNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit. **OE430.04F/1/01.02.2020**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	**<u>KIT Gene Mutations</u>** **1)** Detection of **KIT** exons 2, 9, 10, 11, 13, 14, 15, 17, 18 mutations **2)** Detection of **KIT** exons 9, 11, 13, 17 του mutations	**1)** Manufacturer's method with Ion AmpliSeq™ Cancer Hotspot Panel v2 (ThermoFisher Scientific) and DNA sequencing with Next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher Scientific-ThermoFisher Scientific Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software, in combination with the Variant caller plugin, based on the ClinVar, COSMIC and Varsome databases. **OE430.4C1/2/01.03.2023** **2)** Manufacturer's method with Entrogen's CE-IVD kit GIST Mutation Detection Kit and analysis with the Real-Time PCR method in the 7500 Real-Time PCR System instrument, Applied Biosystems **OE430.4D1/1 /01.02.2020** Manual genomic DNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit. **OE430.04F/1/01.02.2020**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	Detection of **ERBB2** exon 19, 20, 21 mutations Detection of **HRAS** exon 2, 3 mutations Detection of **TP53** 2, 4, 5, 6, 7, 8 mutations Detection of **MET** 2, 11, 14, 16, 19 mutations	Manufacturer's method with Ion AmpliSeq™ Cancer Hotspot Panel v2 (ThermoFisher Scientific) and DNA sequencing with Next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher Scientific- ThermoFisher Scientific Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software, in combination with the Variant caller plugin, based on the ClinVar, COSMIC and Varsome databases. **OE430.4C1/2/01.03.2023** Manual genomic DNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit. **OE430.04F/1/01.02.2020**
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	Detection of somatic mutations / large genomic rearrangements in **BRCA1**, **BRCA2** genes and somatic mutations in other HRR genes (**ATM, BARD1, BRIP1, CDK12, CHEK2, FANCD2, MRE11, NBN, PALB2, PPP2R2A, RAD51B, RAD54L, TP53**)	Manufacturer's method with Oncomine™ Panel primers (ThermoFisher Scientific) and DNA sequencing with Next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher Scientific - ThermoFisher Scientific, Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software, in combination with the Variant caller plugin, based on the ClinVar, COSMIC and Varsome databases. **OE430.4C1/2/01.03.2023** Manual genomic DNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit. **OE430.04F/1/01.02.2020**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Peripheral blood	Detection of hereditary mutations / large genomic rearrangements in **BRCA1**, **BRCA2** genes and hereditary mutations in other HRR genes (**ATM, BARD1, BRIP1, CDK12, CHEK2, FANCD2, MRE11, NBN, PALB2, PPP2R2A, RAD51B, RAD54L, TP53**)	Manufacturer's method with Oncomine™ Panel primers (ThermoFisher Scientific) and DNA sequencing with Next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher, Scientific Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software, in combination with the Variant caller plugin, based on the ClinVar, COSMIC and Varsome databases. **OE430.4C1/2/01.03.2023** Manual genomic DNA isolation with the Purelink Genomic DNA Kit. **OE430.4 E/1/01.02.2020**
Peripheral blood	Detection of hereditary mutations in **MSH2, MSH6, PMS2, EPCAM, MLH1** genes	Manufacturer's method with Ampliseq Custom Panel (ThermoFisher Scientific) and DNA sequencing with Next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher, Scientific Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software, in combination with the Variant caller plugin, based on the ClinVar, COSMIC and Varsome databases. **OE430.4C1/2/01.03.2023** Manual genomic DNA isolation with the Purelink Genomic DNA Kit. **OE430.4 E/1/01.02.2020**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	DNA detection of Microsatellite Instability **(MSI)**	Manufacturer's method with Diatech's CE-IVD kit: EasyPGX ready MSI and analysis with the Real-Time PCR method in the AriaDx, Agilent instrument **OE430.04D4/1/15.05.2023** Manual genomic DNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit. **OE430.04F/1/01.02.2020**
Peripheral blood	Detection of mutations in **DPYD, UGT1A1** genes	Manufacturer's method with Diatech's pharmacogenetics CE-IVD kit: Easy PGX ready DPYD Easy PGXready UGT1A1 and analysis with the Real-Time PCR method in the AriaDx, Agilent instrument **OE430.04D1B/1/01.02.2024** Manual genomic DNA isolation with the QiAmp DNA Blood Mini Kit **OE430.04F/1/01.02.2020**
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	Detection of gene rearrangements (chimeric transcripts) in ALK, ROS1, RET, FGFR1, FGFR2, FGFR3, NTRK1, NTRK2, NTRK3	Manufacturer's method with primers: a) Ion AmpliSeq™ RNA Fusion Lung Cancer Research Panel (ThermoFisher Scientific) b) Oncomine™ Tumor Specific RNA Fusion Panel (ThermoFisher Scientific) RNA sequencing analysis was performed using next-generation sequencing (NGS) in the Ion GeneStudio S5 instrument, ThermoFisher, Scientific Library construction: SimpliAmp Thermal Cycler (x3) THERMO SCIENTIFIC LSG Bioinformatics analysis tools: Analysis according to Hg19 with the Ion Reporter Software. **OE430.4C1/3/10.10.2025** Manual genomic RNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit **OE430.04F/1/01.02.2020**

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Formalin-fixed paraffin-embedded tissue (FFPE)	Detection and genotyping of **21 types of HPV**	Manufacturer's method with Amoy's Diagnostics CE-IVD kit: Human Papillomavirus (HPV) Genotyping Detection Kit **OE430.4D1/1 /01.02.2020** Manual genomic DNA isolation with the RecoverAll™ Total Nucleic Acid Isolation Kit. **OE430.04F/1/01.02.2020**
Cervico-vaginal Liquid-based Cytology -LBC sample (PAP test)	Detection and genotyping of **41 types of HPV**	Manufacturer's method with ZytoVisions CE-IVD kit: VisionArray HPV Chip 1.0 Zytovision **OE430.04D5/1/18.03.2023** Manual genomic DNA isolation with the NucleoSpin® Tissue Kit (Macherey-Nagel).
Cervico-vaginal Liquid-based Cytology -LBC sample (PAP test)	Detection of **18 types of HPV** and genotyping types 16, 18	Manufacturer's method with Yaneng Bioscience CE-IVD kit: Human Papillomavirus Nucleic Acid Detection and HPV16/18 Genotyping Kit **OE430.4D1/1 /01.02.2020** Manual genomic DNA isolation with the NucleoSpin® Tissue Kit (Macherey-Nagel).
Peripheral blood-derived plasma (liquid biopsy)	Qualitative detection and identification of **EGFR** exon 18, 19, 20 (including T790M), 21 mutations	Manufacturer's method with Entrogen's CE-IVD kit: ctDNA EGFR Mutation Detection Kit and analysis with the Real-Time PCR method in the 7500 Real-Time PCR System instrument, Applied Biosystems **OE 430.4 E /1/01.02.2020** Manual genomic DNA isolation with the MagMAX™ Cell-Free Total **OE.430.4A 1/01.02.2020**
Formalin-fixed paraffin-embedded tissue (FFPE), cytologic material (in liquid form or in the form of cell block)	Detection of the **ALK** gene mutations (translocations) Detection of the **ROS-1** gene mutations (translocations) Detection of the **Her2** gene amplification	Fluorescent in situ hybridization - FISH With ZytoVision CE-IVD kit (ZytoLight FISH Tissue Implementation Kit and ZytoLight FISH Cytology Implementation Kit. **OE.430.4G/1/18.03.2019**

Site of assessment: **Laboratory permanent premises, 88, Mitropoleos str, 54622, Thessaloniki, Greece.**
Primary Sample Collection: **Laboratory permanent premises, 88, Mitropoleos str, 54622, Thessaloniki, Greece.**

Approved signatories: **D. Hatzibougias.**

This scope of Accreditation replaces the previous one dated 29.01.2025.
The Accreditation Certificate No.**1067**-4, to ELOT EN ISO 15189:2022, is valid until 13.11.2029.

Athens, 14th of July 2026

Konstantinou Evaggelos Apostolos
CEO of ESYD