

Hellenic Accreditation System



Annex G1/2 to the Certificate No.1067

SCOPE of ACCREDITATION

of the

Cyto/Histopathology Department

of

“MICRODIAGNOSTICS Ltd”

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Cytology Tests		
1. Cervico-vaginal conventional Pap smear (PAP test)	Cytopathology Examination Handling of specimen through the analytical (macroscopic process flow – microscopic examination) and post-analytical phase (reporting, transcription, archiving) for the detection of lesions that deviate from the normal cellular structure, to allow early diagnosis of tumors and specific diseases	Specimen Processing <u>Papanicolaou staining protocol</u> Automatic Slide staining with Thermo Scientific Gemini AS <u>Automated Slide Coverslipping</u> with Thermo Scientific CTM6 Microscopic Evaluation & Interpretation Bethesda Classification TBS 2014 Papanicolaou Classification 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)	<p>Cytopathology Examination</p> <p>Handling of specimen through the analytical (macroscopic process flow – microscopic examination) and post-analytical phase (reporting, transcription, archiving) for the detection of lesions that deviate from the normal cellular structure, to allow early diagnosis of tumors and specific diseases</p>	<p>Specimen Processing</p> <p>Biodyne CELLPREP LBC platform</p> <p><u>Papanicolaou staining protocol</u></p> <p>Automatic Slide staining with Thermo Scientific Gemini AS</p> <p><u>Automated Slide Coverslipping</u> with Thermo Scientific CTM6</p> <p>Microscopic Evaluation & Interpretation</p> <p>Bethesda Classification TBS 2014</p> <p>Papanicolaou Classification</p> <p>Nikon Eclipse 80i with Digital area scan camera of high resolution</p> <p>Nikon Eclipse E200</p> <p>OLYMPUS BX45</p> <p>ZEISS AXIOLAB</p>
Histological Tests		

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
<p>1. Excisional & Incisional Biopsies, Surgical Resection Specimens from Human tissue Formalin Fixed Paraffin Embedded Tissue [FFPE]</p>	<p>Histopathology examination Handling of specimen through the analytical (macroscopic process flow – microscopic examination) and post-analytical phase (reporting, transcription, archiving) For the detection of lesions that deviate from the normal cellular & morphological structure, to allow early diagnosis of tumors and specific diseases</p>	<p>Macroscopic Examination Grossing platform <u>GTS Vacuum</u> <u>Milestone ProCut Series</u> - Special Cutting equipment for standardization of grossing techniques <u>Milestone MacroPath Pro X</u> digital camera and PC software for complete grossing documentation</p> <p>Tissue Processing <u>Milestone Logos One</u> Histoprocessor Leica EG1150H & Leica EG1150C <u>Embedding Station</u></p> <p>Sectioning Leica RM2255 (automatic) PFM 3005E (semi-automatic) Water baths Electrothermal (x2)</p> <p>Staining <u>H&E staining protocol</u> Automatic Slide staining with Thermo Scientific Gemini AS <u>Automated Slide Coverslipping</u> with Thermo Scientific CTM6</p> <p>Microscopic Evaluation Nikon Eclipse 80i with Digital area scan camera of high resolution Nikon Eclipse Si-L Nikon Eclipse E200 OLYMPUS BX45 ZEISS AXIOLAB</p> <p>Interpretation of Results WHO ICD-O classification of neoplastic diseases. AJCC Cancer Staging Manual (latest edition-8th)</p>

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
<p>2. Excisional & Incisional Biopsies, Surgical Resection Specimens from Human tissue Fresh non-fixed tissue Frozen tissue embedded in a cryo-block Frozen tissue sections applied on microscopic slide (superfrost)</p>	<p>Histopathology examination Gross handling of biopsies & surgical specimens by a qualified pathologist 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</p>	<p>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</p>
<p>Histochemical Tests</p>		

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Excisional & Incisional Biopsies, Surgical Resection Specimens from Human tissue Formalin Fixed Paraffin Embedded Tissue [FFPE]	<p>PAS/AlcianBlue: For demonstration of acid mucopolysaccharides, acetic mucins & carbohydrates</p> <p>PAS: To demonstrate normal and pathologic tissue components characterized by adjacent glycolic or aminohydroxylic groups for histology and cytology</p> <p>Masson trichrome stain: For differentiating collagen tissue from smooth muscle in tumors and for highlighting collagen in cirrhosis</p>	<p>Manual Histochemical staining technique based on CE IVD kits</p> <p>PAS/AlcianBlue PAS Masson Trichrome Stain</p> <p>Microscopic evaluation</p> <p>Nikon Eclipse 80i with Digital area scan camera of high resolution Nikon Eclipse Si-L Nikon Eclipse E200 OLYMPUS BX45 Zeiss AXIOLAB</p>
Immunohistochemistry (IHC) Tests		
Excisional & Incisional Biopsies, Surgical Resection Specimens & from Human tissue & Body Fluids Formalin Fixed Paraffin Embedded Tissue [FFPE] Liquid based Cytology Specimens – Cell Blocks	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	<p>Immunostain Processing</p> <p>DAKO Autostainer Link 48 Leica Bond Max Autostainer Usage of detection kits Automated Slide Coverslipping Thermo Scientific CTM6</p> <p>Microscopic Evaluation</p> <p>Nikon Eclipse 80i with Digital Area Scan high resolution camera Nikon Eclipse Si-L Nikon Eclipse E200 OLYMPUS BX45 ZEISS AXIOLAB</p> <p>Interpretation of Results</p> <p>Dabbs Diagnostic Immunohistochemistry – Theranostic & Genomic Applications Latest Edition</p>
IHC Antibodies Tests		

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Excisional & Incisional Biopsies, Surgical Resection Specimens & from Human tissue & Body Fluids Formalin Fixed Paraffin Embedded Tissue [FFPE] Liquid based Cytology Specimens – Cell Blocks	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
	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

**Reference to the commercial name of a specific analyzer/kit, refers to a specific analytical method and protocol*

Site of assessment: **Laboratory permanent premises, 88, Mitropoleos str, 54622, Thessaloniki, Greece**
Approved signatories: **D. Hatzibougias, I. Hatzibougias**

This scope of Accreditation replaces the previous one dated 14.11.2016.
The Accreditation Certificate No.1067, to ELOT EN ISO 15189:2012, is valid until 13.11.2020.

Athens, 09.01.2018

Konstantinos Voutsinas
Managing Director, ESYP