Hellenic Accreditation System

Annex G1/B1 to the Certificate No. **822**-8

SCOPE of ACCREDITATION

of the

Clinical laboratory

of

“GENEKOR Medical S.A. (Thessaloniki subdivision)”

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Histological Tests		
1.Fresh Tissue, Formalin - Fixed Paraffin -Embedded Tissue (FFPE)	Macroscopic and microscopic observation of tissues with the aim of recognizing or excluding morphological and cytological abnormalities.	**Macroscopic and Microscopic observation** *MILESTONE UltraGROSS ROSAI Edition* – Grossing Station *DAKEWE MEDICAL SUREPRINT C100* – Cassette Printer <u>Tissue Processing</u> *EPREDIA REVOS Tissue Processor* (OE_MTP_14, Version D.0, 1/9/2024)
		<u>Tissue Embedding</u> *MEDITE TES VALIDA* – Embedding Station (OE_MTP_04, Version D.0, 1/9/2024)
		<u>Microtomy</u> *EPREDIA HM 340E Rotary Microtome* – Semi-automatic Rotary Microtome (OE_MTP_02, Version D.0, 1/9/2024)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
		Hematoxylin and Eosin Stain and Manual Slide Cross-Checking *EPREDIA GEMINI AS Slide Stainer* – Automated Slide Stainer *EPREDIA CLEARVUE Coverslipper* – Automated Coverslipper Automated Staining Haematoxylin & Eosin Staining, (Gemini AS Automated Slide Stainer) (A81510100 Issue 10) (OE_MTP_03, Version D.0, 01/09/2024)
		Diagnostic Microscopy *NIKON Eclipse Ci-L Plus* – Light Microscope (OE_MTP_15, Version D.0, 1/9/2024)
Immunohistochemistry Tests		
1. Biopsies and Surgical Specimens Tissue Fixed in Formalin and Embedded in Paraffin (FFPE) originating from excisional or needle biopsies and surgically excised samples.	Immunohistochemical detection of the PD-L1 protein with the use of anti-PD-L1 antibody (Clone SP263) of Ventana – Roche. *Non-Small Cell Lung Cancer*	Special Stains - IMMUNOHISTOCHEMISTRY Automated Method Immunohistochemical method with the use of the CE-IVD detection kit: - Ventana BenchMark GX Autostainer (20656EN Rev K) Microscopic Evaluation and Interpretation of results. (OE_MTP_09, Version D.0, 01/09/2024) PD-L1 SP263 1015350EN Rev E
2. Biopsies and Surgical Specimens Tissue Fixed in Formalin and Embedded in Paraffin (FFPE) originating from excisional or needle biopsies and surgically excised samples.	Immunohistochemical detection of the PD-L1 protein with the use of anti-PD-L1 antibody (Clone SP142) of Ventana – Roche.	Special Stains - IMMUNOHISTOCHEMISTRY Automated Method Immunohistochemical method with the use of the CE-IVD detection kit: - Ventana BenchMark GX Autostainer (20656EN Rev K)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	Triple Negative Breast Carcinoma (TBNC) *Urothelial Carcinoma*	Microscopic Evaluation and Interpretation of results. (OE_MTP_09, Version D.0, 01/09/2024) PD-L1 SP142 1018834EN Rev B1
3. Biopsies and Surgical Specimens Tissue Fixed in Formalin and Embedded in Paraffin (FFPE) originating from excisional or needle biopsies and surgically excised samples.	Evaluation of Prognostic and Predictive Biomarkers for Breast Cancer. *Breast Cancer*	Special Stains - IMMUNOHISTOCHEMISTRY Automated Method Immunohistochemical method with the use of the CE-IVD detection kit: - Ventana BenchMark ULTRA Autostainer (1021470EL Version 1.0) Microscopic Evaluation and Interpretation of results. Each Antibody Separately (OE_MTP_06, Version D.0, 01/09/D024, OE_MTP_07, Version D.0, 01/09/2024, OE_MTP_10, Version D.0, 01/09/2024) ER (SP1) PgR (1E2) Her-2 (4B5)
4. Biopsies and Surgical Specimens Tissue Fixed in Formalin and Embedded in Paraffin (FFPE) originating from excisional or needle biopsies and surgically excised samples.	Identification of the amplification of the *HER2* gene on Chromosome 17	Special Stains - IMMUNOHISTOCHEMISTRY Automated Method Immunohistochemical method with the use of the CE-IVD detection kit: - Ventana BenchMark ULTRA Autostainer (1021470EL Version 1.0) Microscopic Evaluation and Interpretation of results. (OE_MTP_08, Version D.0, 01/09/2024)

Site of assessment: **Pathology Laboratory, E. Antistaseos 72 & Eantos, 55133, Kalamaria, Thessaloniki.**
Approved signatories: **D. Minotakis, P. Xirou, N. Vladika.**

This scope of Accreditation replaces the previous one dated 02.08.2024.
The Accreditation Certificate No. **822-**8, to ELOT EN ISO 15189:2022, is valid until 24.06.2029.

Athens, 12th of September 2025

Konstantinou Evangelos Apostolos
CEO of ESYD