Hellenic Accreditation System

Annex G1/5 to the Certificate No.**1267**-3

SCOPE of ACCREDITATION

of the

Diagnostic Genetics and Precision Medicine Unit (DIGENIA)

of

Institute of Molecular Biology and Biotechnology

of

Foundation of Research and Technology

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Molecular Oncology		
FFPE tissue sections from solid tumors	Detection of single nucleotide variants (SNVs) and small insertions/deletions (indels) in solid tumor samples with the use of a custom Ion AmpliSeq NGS panels of 58 genes: (AKT1, ALK, AR, ATM, BCL2, BRAF, BRCA1, BRCA2, CCND1, CCNE1, CDK4, CDK6, CDKN2A, CHEK1, CHEK2, CTNNB1, EGFR, ERBB2, ERBB4, ESR1, FGFR1, FGFR2, FGFR3, IDH1, IDH2, JAK2, JUN, KDR, KIT, KMT2C, KRAS, MAP2K1, MDM2, MDM4, MEN1, MET, MLH1, MSH2, MSH6, MTOR, MYC, NF1, NOTCH1, NRAS, PALB2, PDGFRA, PIK3CA, PIK3CB, PTEN, RAD50, RAD51, RB1, RET, ROS1, SMAD4, STAT3, STK11, TP53)	Lab developed method Next Generation Sequencing (NGS) with Ion ApliSeq primers in Ion S5 XL™ System (ThermoFisher Scientific) using the custom gene panel of 58 genes for solid tumors (ThermoFisher Scientific). Data analysis performed using Ion Reporter Software (ThermoFisher). Lab Protocols O.520-01 Nucleic Acid Extraction_v3, O.520-02_Nucleic Acid Quantification _v2, O.520-03_Library Preparation for Custom Panels (Somatic and Germline)_v3, O.520-06_ PLAN RUN CHEF,S5_v2, O.520-04 BIOINFORMATIC ANALYSIS for CUSTOM PANELS_v5
FFPE tissue sections from solid tumors	Detection of single nucleotide variants (SNVs) and small insertions/deletions (indels) in solid tumor samples in 500 cancer related genes	Next Generation Sequencing (NGS) with kit Oncomine Comprehensive Assay Plus (ThermoFisher Scientific) in Ion S5 XL™ System (ThermoFisher Scientific). Data analysis performed using Ion Reporter Software (ThermoFisher). Lab Protocols O.520-01 Nucleic Acid Extraction_v3, O.520-02_Nucleic Acid

		Quantification _v2, O.520-07_Library Preparation OCA Plus_v1, O.520-06_ PLAN RUN CHEF,S5_v2, O.520-09 BIOINFORMATICS ANALYSIS for OCA PLUS_v1
Molecular Genetics		
Peripheral Blood	Detection of single nucleotide variants (SNVs) and small insertions/deletions (indels) germline origin in individual genes	Lab developed method with Sanger Sequencing in PCR VerityPro (Applied Biosystems) and SeqStudio Genetic Analyzer (Applied Biosystems). Lab Protocols O.520-01 Nucleic Acid Extraction_v3, O.520-02_Nucleic Acid Quantification _v2, O.520-08_Sanger Sequencing_v1
Peripheral Blood	Detection of single nucleotide variants (SNVs) and small insertions/deletions (indels) germline origin in 50 genes related to endocrine tumor	Lab developed method Next Generation Sequencing (NGS) with Ion ApliSeq primers in Ion S5 XL™ System (ThermoFisher Scientific) using the custom gene panel of 50 genes related to hereditary endocrine tumor syndromes (Ion AmpliSeq™, ThermoFisher Scientific). Lab Protocols O.520-01 Nucleic Acid Extraction_v3, O.520-02_Nucleic Acid Quantification _v2, O.520-03_Library Preparation for Custom Panels (Somatic and Germline)_v3, O.520-06_PLAN RUN CHEF,S5_v2, O.520-04 BIOINFORMATIC ANALYSIS for CUSTOM PANELS_v5

Site of assessment: **Laboratory permanent premises: Nikolaou Plastira 95 GR-70013, Heraklion, Crete Greece.**
Approved signatories**: E. Linardaki, C. Stratakis.**

This Scope of Accreditation replaces the previous one dated 23.04.2025.
The Accreditation Certificate No. **1267**-3, to ELOT EN ISO 15189:2022, is extended until 20.03.2026.

Athens, 18.09.2025

Konstantinou Evangelos Apostolos
CEO of ESYD