Hellenic Accreditation System

Annex G1/1 to the Certificate No. **1477**

SCOPE of ACCREDITATION

for the

Molecular Genetics Unit

of the

Laboratory of General Biology

of the

School of Medicine

of the

University of Patras

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Molecular Genetics		
1. Peripheral Blood	1. Molecular testing of germline pathogenic point variants in BRCA and HRR genes for breast, ovarian, prostate and pancreatic cancer in the context of PARPi. Genes tested *ATM, BARD1, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, FANCD2, FANCL, KRAS, MRE11, NBN, PALB2, PIK3CA, POLD1, POLE, PPP2R2A, PTEN, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, TP53, XRCC2*	Next Generation Sequencing (NGS) using the commercially available kit Oncomine tumor specific panel HRR Pathway (ThermoFisher, USA), on germline genomic DNA extracted from peripheral blood. Lab Protocol O.520.01, O.520.13 and O.520.14, 09/09/2024 This method detects point mutations and small insertions/deletions (indels) present in the germline in the coding regions of the following Homologous Recombination Repair (HRR) genes: ATM, BARD1, BRCA1, BRCA2, BRIP1, CDK12, CHEK1, CHEK2, FANCD2, FANCL, MRE11, NBN, PALB2, PIK3CA, POLD1, POLE, PPP2R2A, PTEN, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, TP53, XRCC2, and hotspots in KRAS. Covered are the coding sequences and splice sites (±10 bp) in 27 HRR genes (see above), small regions of the KRAS gene (hotspots), as well as some

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		non-coding regions in BRCA1 and BRCA2 where pathogenic variants have been found. It does not detect copy number variants (CNVs) or large genomic rearrangements.
2. Peripheral Blood	2. Targeted molecular testing of germline pathogenic point variants in genomic DNA	The method detects point mutations and small insertions/deletions (indels) in genomic DNA extracted from peripheral blood, by targeted Sanger Sequencing Lab Protocol O.520-1 to O.520.10 version 1, 09/09/2024

Site of assessment: **Laboratory permanent premises: University of Patras (Faculty of Medicine), Department of General Biology, *Molecular Genetics Unit,* Preclinical Research Building, 3rd Floor, 1 Asklepiou Str., University Campus (Panepistimioupolis), 26504 Rio, Greece**

Primary Sample Collection Site: **University General Hospital of Patras. 26504 Rio, Greece**
Approved signatories**: Z. Lygerou.**

The Accreditation Certificate No.**1477**, to ELOT EN ISO 15189:2022, is valid until 29.10.2030.

Athens, 30th of October 2025

Konstantinou Evangelos Apostolos
CEO of ESYD