Hellenic Accreditation System

Annex G1/9 to the Certificate No.**1065**-4

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

“BIOPATH INNOVATIONS S.A.”

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Molecular Genetics		
Paraffin Embedded Tissue, Cytology Specimens	Detection of somatic mutations within: 1. exons 18/19/20/21 of the *EGFR* gene	Real-time PCR Manufacturer's methods: 1. cobas® *EGFR* Mutation Test v2 (CE-IVD, Roche Molecular Diagnostics, F.362-2.1/v5 eff. date 01/08/25). Real-time PCR on COBAS z480™ Analyzer* (#409, Roche Molecular Diagnostics).
Paraffin Embedded Tissue, Cytology Specimens	Detection of somatic mutations within: 2. exons 18/19/20/21 of the *EGFR* gene 3. exons 2/3/4 of the *KRAS* gene 4. exons 2/3/4 of the *NRAS* gene 5. exons 11/15 of the *BRAF* gene 6. exons 8/10/14/21 of the *PIK3CA* gene	Next Generation Sequencing (NGS) with Ion Torrent™ technology (ThermoFisher Scientific) In house methods: 2. F.362-2.2/v7 eff. date 01/08/25 3. F.362-2.4/v7 eff. date 01/08/25 4. F.362-2.6/v7 eff. date 01/08/25 5. F.362-2.7/v6 eff. date 01/08/25 6. F.362-2.59/v4 eff. date 01/08/25 Target amplification with Ion AmpliSeq™ amplicons (Oncomine™, ThermoFisher Scientific), library preparation with Ion AmpliSeq™ Library kit 2.0 (ThermoFisher Scientific) and thermocyclers #26, #240, #456 or #488 (ThermoFisher Scientific), templating with Ion Torrent Ion Chef™* (#276, ThermoFisher Scientific), sequencing with Ion Torrent S5™* (#275, ThermoFisher Scientific) and analysis

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		with Ion Reporter software (ThermoFisher Scientific).
Paraffin Embedded Tissue, Cytology Specimens	7. Detection of Microsatellite Instability (MSI)	Next Generation Sequencing (NGS) with Ion Torrent™ technology (ThermoFisher Scientific) and in-house MiSuIte™ bioinformatics software. 7. In house method (F.362-2.67/v4 eff. date 01/08/25). Target amplification with custom Ion AmpliSeq™ amplicons (Thermo Fisher Scientific), library preparation with Ion AmpliSeq™ Library kit 2.0 (ThermoFisher Scientific) and thermocyclers #26, #240, #456 or #488 (Thermo Fisher Scientific), templating with Ion Torrent Ion Chef™*(#276, ThermoFisher Scientific), sequencing with Ion Torrent S5™* (#275, ThermoFisher Scientific) and analysis with in-house MiSuIte™ bioinformatics software (#406, BioMarker Solutions).
Paraffin Embedded Tissue, Cytology Specimens	8. Detection of somatic single-nucleotide variations (SNVs) and small insertions or deletions (InDels) within the coding regions, splice sites and flanking intronic regions of the *BRCA1* and *BRCA2* genes	Next Generation Sequencing (NGS) with Ion Torrent™ technology (ThermoFisher Scientific) 8. In house method (F.362-2.65/v4 eff. date 01/08/25). Target amplification with custom Ion AmpliSeq™ amplicons (ThermoFisher Scientific). Library preparation with Ion AmpliSeq™ Library kit 2.0 (ThermoFisher Scientific) and thermocyclers #26, #240, #456 or #488 (ThermoFisher Scientific), templating with Ion Torrent Ion Chef™*(#276, ThermoFisher Scientific), sequencing with Ion Torrent S5™* (#275, ThermoFisher Scientific) and analysis with Ion Reporter software (ThermoFisher Scientific).
Peripheral blood (cell-free DNA collection tubes, EDTA), Plasma Liquid Biopsies	9. Detection of somatic mutations within exons 18/19/20/21 of the *EGFR* gene	Real-time PCR 9. Manufacturer's method cobas® *EGFR* Mutation Test v2 kit (CE-IVD, Roche Molecular Diagnostics, F.362-2.21/v3 eff. date 01/08/25). Real-time PCR on the COBAS z480™ Analyzer* (#409, Roche Molecular Diagnostics).
Peripheral blood (cell-free DNA collection tubes, EDTA), Plasma Liquid Biopsies	Detection of somatic mutations within: 10. exons 18/19/20/21 of the	Next Generation Sequencing (NGS) with Ion Torrent™ technology (ThermoFisher Scientific) In house methods: 10. F.362-2.22/v7 eff. date 01/08/25.

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	EGFR gene 11. exons 2/3/4 of the *KRAS* gene	11. F.362-2.69/v4 eff. date 01/08/25. Target amplification with custom Ion AmpliSeq™ amplicons (Thermo Fisher Scientific). Library preparation with Ion AmpliSeq™ Library kit 2.0 (ThermoFisher Scientific) and thermocyclers #26, #240, #456 or #488 (ThermoFisher Scientific), templating with Ion Torrent Ion Chef™*(#276, ThermoFisher Scientific), sequencing with Ion Torrent S5™* (#275, ThermoFisher Scientific) and analysis with Ion Reporter software (ThermoFisher Scientific).
Peripheral blood (EDTA), Buccal swabs	12. Detection of germline single-nucleotide variations (SNVs) and small insertions or deletions (InDels) within the coding regions, splice sites and flanking intronic regions of the *BRCA1* and *BRCA2* genes	Next Generation Sequencing (NGS) with Ion Torrent™ technology (ThermoFisher Scientific) 12. In house method (F.362-2.64/v4 eff. date 01/08/25). Target amplification with custom Ion AmpliSeq™ amplicons (ThermoFisher Scientific). Library preparation with Ion AmpliSeq™ Library kit 2.0 (ThermoFisher Scientific) and thermocyclers #26, #240, #456 or #488 (ThermoFisher Scientific), templating with Ion Torrent Ion Chef™* (#276, ThermoFisher Scientific), sequencing with Ion Torrent S5™* (#275, ThermoFisher Scientific) and analysis with Ion Reporter software (ThermoFisher Scientific).
Peripheral blood (EDTA), Buccal swabs	13. Detection of germline single-nucleotide variations (SNVs) and small insertions or deletions (InDels) within the coding regions, splice sites and flanking intronic regions of the *ATM*, *BARD1*, *BRCA1*, *BRCA2* *BRIP1*, *CDH1*, *CHEK2*, *NBN*, *PALB2*, *PTEN*, *RAD51C*, *STK11* and *TP53* genes	Next Generation Sequencing (NGS) with Ion Torrent™ technology (ThermoFisher Scientific) 13. In house method (F.362-2.79/v3 eff. date 01/08/25). Target amplification with custom Ion AmpliSeq™ amplicons (ThermoFisher Scientific). Library preparation with Ion AmpliSeq™ Library kit 2.0 (ThermoFisher Scientific) and thermocyclers #26, #240, #456 or #488 (ThermoFisher Scientific), templating with Ion Torrent Ion Chef™*(#276, ThermoFisher Scientific), sequencing with Ion Torrent S5™* (#275, ThermoFisher Scientific) and analysis with Ion Reporter software (ThermoFisher Scientific).
Peripheral blood (EDTA)	14. Detection of germline large deletions / insertions in the coding regions of the *BRCA1* gene	Next Generation Sequencing (NGS) with Ion Torrent™ technology (ThermoFisher Scientific), QRS™ calibrators and in-house CNVSUITE™ bioinformatics software.

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		14. In house method (F.362-2.66/v4 eff. date 01/08/25). Target amplification with custom Ion AmpliSeq™ amplicons (Thermo Fisher Scientific) and custom QRS™ calibrators, library preparation with Ion AmpliSeq™ Library kit 2.0 (ThermoFisher Scientific) and thermocyclers #26, #240, #456 or #488 (ThermoFisher Scientific), templating with Ion Torrent Ion Chef™*(#276, ThermoFisher Scientific), sequencing with Ion Torrent S5™* (#275, ThermoFisher Scientific) and analysis with in-house CNVSUITE™ bioinformatics software (#407, BioMarker Solutions).
Pathology - Immunohistochemistry		
Paraffin Embedded Tissue, Cytology Specimens	Immunohistochemical detection of protein expression: 15: ALK (clone D5F3-Roche) 16: ALK (clone D5F3-CST) 17: PD-L1 (clone SP263) 18: PD-L1 (clone SP142) 19: HER2 (polyclonal antibody) 20: ER (clone EP1) 21: PR (clone PgR 636) 22: Ki67 (clone MIB-1)	Immunohistochemistry (IHC) 15. Manufacturer's Method Ventana® ALK (D5F3) assay (CE-IVD, Roche Molecular Diagnostics, F.362-2.30/v3 eff. date 01/08/25). 16. In house method using an anti-ALK D5F3 antibody (CST, F.362-2.62/v4 eff. date 01/08/25). 17. Manufacturer's Method Ventana® PD-L1 (SP263) assay (CE-IVD, Roche Molecular Diagnostics, F.362-2.31/v4 eff. date 01/08/25). Results expressed as TPS (Tumor Proportion Score) and/or CPS (Combined Proportion score). 18. Manufacturer's Method Ventana® PD-L1 (SP142) assay (CE-IVD, Roche Molecular Diagnostics, F.362-2.61/v3 eff. date 01/08/25). Results expressed as %IC (tumor-infiltrating immune cell score). 19. In house method using an anti-HER2 polyclonal antibody (Dako, F.362-2.80/v2 eff. date 01/08/25). 20. In house method using an anti-ER (EP1) antibody (Dako, F.362-2.81/v2 eff. date 01/08/25). 21. In house method using an anti-PR (PgR 636) antibody (Dako, F.362-2.82/v2 eff. date 01/08/25). 22. In house method using an anti-Ki67 (MIB-1) antibody (Dako, F.362-2.83/v2 eff. date 01/08/25). Staining performed on the BenchMark ULTRA™ Platform* (#120, Roche Molecular Diagnostics).

** The use of the genetic analyzer's brand name refers to a specific analytical method and the corresponding experimental protocol*

Site of assessment: **Laboratory permanent premises: 50 Agiou Konstantinou Street, 15124, Maroussi, Athens, Greece.**
Approved signatures: **S. Murray, T. Gavresea, C. Gouedard, E. Konstanta, S. Papadopoulou, S. Patera.**

This scope of Accreditation replaces the previous one dated 29.04.2024.
The Accreditation Certificate No. **1065**-4, to ELOT EN ISO 15189:2022, is valid until 30.10.2029.

Athens, 31st of July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD