# Hellenic Accreditation System

Annex G1/A20 to the Certificate No. **822**-8

# SCOPE of ACCREDITATION

of the

Clinical laboratory

of

**"GENEKOR Medical S.A."**

| Materials / Products tested | Types of test / Properties measured | Applied methods / Techniques used |
|---|---|---|
| **Molecular Genetics** | | |
| 1. Peripheral blood<br>Saliva | Mutation detection in *BRCA1* & *BRCA2* genes (Breast Cancer susceptibility genes 1 and 2)<br>(Full coding sequence, splice sites and 20bp flanking intronic sequences) | Target Enrichment Method based on capture approach KAPA HyperExplore MAX 3Mb T1 RUO (NimbleGen, Roche) *<br>(KAPA HyperCap workflow v3.0 07939493001 02/20)<br>(OE_MT_14, Version D.0, 01/09/2024)<br><br>Library preparation was carried out using the automated system MGISP-960.<br>(Automation version: V3.0)<br><br>For the above method sequencing was carried out using Next Generation Sequencing with DNBSEQ-G400, MGI<br>(User manual version: A10)<br><br>Data analysis was carried out using the analysis software SeqPilot (JSI Medical System).<br>(Version 5.4.1) |

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| 2. Peripheral blood<br>Saliva | Detection of large genomic rearrangements in *BRCA1* & *BRCA2* genes (Breast Cancer susceptibility genes 1 and 2) | 2A. Multiplex Ligation-Dependent Probe Amplification (MLPA) CE-IVD SALSA MLPA P002 *BRCA1* probemix and CE-IVD SALSA MLPA P045 *BRCA2/CHEK2* probemix (MRC-Holland)*<br><br>MDP- Version-010(21 May 2022)<br>(OE_MT _12, Version D.0, 01/09/2024) |
| | | 2B. Computational using the program SeqPilot (JSI Medical System) for test 1A and with the use of SeqPilot (JSI Medical System) and panelcn. MOPS (Hum Mutat. 2017, 38:889-897) for test 1B. Verification is carried out with the use of Multiplex Ligation-Dependent Probe Amplification (MLPA) CE-IVD SALSA MLPA P002 *BRCA1* probemix and CE-IVD SALSA MLPA P045 *BRCA2/CHEK2* probemix (MRC-Holland)*<br>(JSI Version 5.4.1)<br>MDP- Version-010 (21 May 2025) |
| 3. Peripheral blood<br>Saliva | Detection and analysis of known familial mutation in *BRCA1* & Analysis *BRCA2* genes (Breast Cancer susceptibility genes 1 and 2) | 3A. DNA sequencing by capillary electrophoresis with SeqStudio Genetic Analyzer (ThermoFisher)<br><br>(MAN0018646, Rev.B 2022) |
| | | 3B. Multiplex Ligation-Dependent Probe Amplification (MLPA) CE-IVD SALSA MLPA P002 *BRCA1* probemix and CE-IVD SALSA MLPA P045 *BRCA2/CHEK2* probemix (MRC-Holland)*<br>MDP- Version-010 (21 May 2025)<br>(OE_MT _05, Version D.0, 01/09/2024) |
| 4.Paraffin-embedded tissue, cytology specimens | 1. Somatic mutation-analysis in exons 18, 19, 20, 21 of *EGFR* gene | *In-house method* with Ion AmpliSeq™ Panel primers |

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| | 2. Somatic mutation analysis in exons 2, 3, 4 of *KRAS* and *NRAS* genes | (Thermo Fisher Scientific) and Next Generation Sequencing (NGS) with Ion Proton (Thermo Fisher Scientific) (Ion Ampliseq Library kit, MAN0006735, Revision H.0, 2025) (OE_MT_08, Version D.0, 01/09/2024) |
| | 3. Somatic mutation analysis in exons 11 and 15 of *BRAF* gene | |
| | 4. Somatic mutation analysis in exons 9, 11, 13 and 17 of *KIT* gene | |
| | 5. Somatic mutation analysis in exons 12, 14 and 18 of *PDGFRA* gene | |
| | 6. Somatic mutation analysis in exons 2 and 3 of *HRAS* gene | |
| 5A. Paraffin embedded tissue, peripheral blood, buccal swab | Analysis of DNA Microsatellite Instability (MSI) | 1A *In-house multiplex fluorescent PCR method* in five microsatellite loci and fragment analysis by capillary electrophoresis with SeqStudio Genetic Analyzer (ThermoFisher) (MAN0018646, Rev.B 2022) |
| 5B. Paraffin embedded tissue | | 1B *In-house method* with Ion AmpliSeq™ Panel primers (Thermo Fisher Scientific) and Next Generation Sequencing (NGS) with Ion Proton (Thermo Fisher Scientific) (Ion Ampliseq Library kit, MAN0006735, Revision H.0, 2025) (OE_MT_15, Version D.0, 01/09/2024) |
| 6. Paraffin embedded tissue | Detection and quantification of the *ALK* gene rearrangements | Fluorescent in situ hybridization (FISH) with ZytoVision CE-IVD kit (ZytoLight SPEC ALK Dual Color Break Apart Probe and ZytoLight FISH Tissue Implementation Kit)* (Version 2.1.1 EN, 2022-11-02) (O3_MT_10, Version D.0, 01/09/2024) |

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| 7. Paraffin embedded tissue | Detection and quantification of the overexpression of the *HER2/NEU* gene | Fluorescent in situ hybridization (FISH) with ZytoVision CE-IVD kit (ZytoLight SPEC ERBB2/CEN17 Dual Color Probe and ZytoLight FISH Tissue Implementation Kit)* (Version 2.1.1 EN, 2023-07-07) (OE_MT_11 Version D.0, 01/09/2024) |
| 8. Paraffin-embedded tissue, cytology specimens | Somatic mutation-analysis in exons 7, 9, 13, and 20 of *PIK3CA* gene | *In-house method* with Ion AmpliSeq™ Panel primers (Thermo Fisher Scientific) and Next Generation Sequencing (NGS) with Ion Proton (Thermo Fisher Scientific) (Ion Ampliseq Library kit, MAN0006735, Revision H.0, 2025) (OE_MT_16, Version D.0, 01/09/2024) |
| 9. Paraffin embedded tissue | Analysis of somatic mutations in *BRCA1 & BRCA2* genes | *In-house method* with the Oncomine BRCA Research Assay (Thermo Fisher Scientific) and Next Generation Sequencing (NGS) with Ion Proton (Thermo Fisher Scientific) (Oncomine BRCA Research Assay, MAN0014634, Revision B.0) (OE_MT_17, Version D.0, 01/09/2024) |
| 10. Paraffin embedded tissue | Analysis of somatic mutations in the *EGFR, BRAF, KRAS, NRAS, HRAS, KIT, PIK3CA, PDGFRA genes* (GenePlus) | CE-IVD methodology using the Oncology Multi-Gene Variant Assay (GenePlus) kit and next generation platform DNBSEQ-G400 (MGI) (DNBSEQ-G400 Instruction for Use:V10.0) (GenePlus V1.5) (OE_MT_06, Version D.0, 01/09/2024) |

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| 11. Liquid Biopsy | Analysis of mutations in the *ESR1 gene* (GenePlus) | CE-IVD methodology using the Circulating Tumor DNA 1021 Assay (GenePlus) kit and next generation platform DNBSEQ-G400 (MGI) (DNBSEQ-G400 Instruction for Use:V10.0)<br>(GenePlus V1.4)<br>(OE_MT_01, Version D.0, 01/09/2024) |
| 12. Paraffin embedded tissue | Tumor Mutation Burden (TMB) calculation (GenePlus) | CE-IVD methodology using the Oncology Multi-Gene Variant Assay (GenePlus) kit and next generation platform DNBSEQ-G400 (MGI) (DNBSEQ-G400 Instruction for Use:V10.0)<br>(GenePlus V1.5)<br>(OE_MT_07, Version D.0, 01/09/2024) |
| 13. Paraffin embedded tissue | Analysis of somatic mutations in *BRCA1 & BRCA2* genes (GenePlus) | *In-house* methodology using the KAPA HyperExplore MAX 3Mb T1 (Roche) and next generation platform DNBSEQ-G400 (MGI) (DNBSEQ-G400 Instruction for Use:V10.0)<br>(OE_MT_02, Version D.0, 01/09/2024) |
| 14. Paraffin embedded tissue | Genomic Instability Score (LOH, TAI, LST) | *In-house* methodology using the Oncoscan CNV FFPE assay, (ThermoFisher Scientific) and analysis with the Chromosome Analysis Suite (ChAS) and bioinformatics pipelines.<br>(P/N 703302 Rev. 1)<br>(OE_MT_13, Version D.0, 01/09/2024) |

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| 15. Paraffin embedded tissue | Analysis of somatic mutations and fusion in *FGFR1, FGFR2 & FGFR3* genes (GenePlus) | CE-IVD methodology using the Oncology Multi-Gene Variant Assay (GenePlus) kit and next generation platform DNBSEQ-G400 (MGI)<br>(DNBSEQ-G400 Instruction for Use:V10.0)<br>(GenePlus V1.5)<br>(OE_MT_09, Version D.0, 01/09/2024) |

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

Site of assessment: **Permanent Molecular Biology Laboratory premises, 52 Spaton Avenue, 15344, Gerakas, Attiki, Greece.**

Approved signatories: **G. Nasioulas, V. Mariatou-Metaxa, I. Papadopoulou, K. Tsantikidi, T. Bourkoula, G.Pepe, D. Bouzarelou, N. Katseli, S. Maxouri, C. Chatzigiannidou, A. Meintani, G. Tsigaridas, K. Potska, C. Dogka, E.Thanou, D. Fotiou, N. Tsoulos, M. Vlachou, A. Michala.**

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*