

Hellenic Accreditation System



ACCREDITATION CERTIFICATE

No. 822-8

The Hellenic Accreditation System (ESYD), as the national accreditation body of Greece in accordance with the Law 4468/2017,

ACCREDITS

the
Clinical Laboratory
of the
“GENEKOR Medical S.A.”
in Gerakas, Attika & in Thessaloniki, Greece

under the terms of the ELOT EN ISO 15189:2022 Standard and the ESYD Criteria, to carry out tests, as specified in the attached Scope of the Accreditation, which may be revised by decisions of ESYD.

The initial assessment was issued on the 25th of June 2012. This Certificate renews the accreditation and is valid until the 24th of June 2029 provided that the accredited body will comply with the above Standard and the ESYD Criteria.

Athens, 12th of September 2025



Hellenic Accreditation System



Annex G1/A21 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 Saliva	Detection of alterations in the <i>BRCA1</i> & <i>BRCA2</i> genes (Breast Cancer susceptibility genes 1 and 2) (Full coding sequence, splice sites and 20bp flanking intronic sequences)	1A. Target Enrichment Method based on capture approach KAPA HyperExplore MAX 3Mb T1 RUO (NimbleGen, Roche) * (KAPA HyperCap workflow v3.0 07939493001 02/20) (OE_MT_14A, Version E.0, 01/11/2025) Library preparation was carried out using the automated system MGISP-960. (Automation version: V3.0) For the above method sequencing was carried out using Next Generation Sequencing with DNBSEQ-T7, MGI. (User Manual Version 9.0)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
1. Peripheral blood Saliva (continued)		Data analysis was carried out using the analysis software SeqPilot (JSI Medical System) (Version 5.4.1) 1B. CE-IVD methodology using the Common Hereditary Cancer Panel kit (G2M) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). Library preparation was carried out using the automated system MGISP-960. (Automation version: V3.0) Data analysis was carried out using the analysis software SeqPilot (JSI Medical System) (Version 5.4.1) (DNBSEQ-T7, User Manual Version 9.0) (G2M, EN/USM/00171, Rev.03, Dt.16/04/2025) (OE_MT_14B, Version E.0, 01/11/2025)
2. Peripheral blood Saliva	Detection of large genomic rearrangements in <i>BRCA1</i> & <i>BRCA2</i> genes (Breast Cancer susceptibility genes 1 and 2)	2A. Multiplex Ligation-Dependent Probe Amplification (MLPA) CE-IVD SALSA MLPA P002 <i>BRCA1</i> probemix and CE-IVD SALSA MLPA P045 <i>BRCA2/CHEK2</i> probemix (MRC-Holland)* MDP- Version-010(21 May 2022) (OE_MT_12, Version D.0, 01/09/2024)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
2. Peripheral blood Saliva (continued)		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 <i>BRCA1</i> probemix and CE-IVD SALSA MLPA P045 <i>BRCA2/CHEK2</i> probemix (MRC-Holland)* (JSI Version 5.4.1) MDP- Version-010 (21 May 2025)
3. Peripheral blood Saliva	Detection and analysis of known familial alterations in the <i>BRCA1</i> & <i>BRCA2</i> genes (Breast Cancer susceptibility genes 1 and 2)	3A. DNA sequencing by capillary electrophoresis with SeqStudio Genetic Analyzer (ThermoFisher) (MAN0018646, Rev.B 2022)
		3B. Multiplex Ligation-Dependent Probe Amplification (MLPA) CE-IVD SALSA MLPA P002 <i>BRCA1</i> probemix and CE-IVD SALSA MLPA P045 <i>BRCA2/CHEK2</i> probemix (MRC-Holland)* MDP- Version-010 (21 May 2025) (OE_MT_05, Version D.0, 01/09/2024)
4.Paraffin-embedded tissue, cytology specimens	4A. Analysis of somatic alterations in the <i>AKT1</i> , <i>EGFR</i> , <i>ERBB2</i> , <i>BRAF</i> , <i>KRAS</i> , <i>NRAS</i> , <i>METex14</i> skipping <i>HRAS</i> , <i>IDH1</i> , <i>IDH2</i> , <i>KIT</i> , <i>PIK3CA</i> , <i>PDGFRA</i> genes (G2M, PAN Cancer Assay)	4A. CE-IVD methodology with the PAN Cancer Assay kit (G2M) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (G2M, EN/USM/0019-1, Rev.06, Dt.15/05/2025) (OE_MT_08, Version E.0, 01/11/2025)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	4B. Analysis of somatic alterations in the <i>AKT1</i> , <i>EGFR</i> , <i>ERBB2</i> , <i>BRAF</i> , <i>KRAS</i> , <i>NRAS</i> , <i>MET</i> <i>ex14 skipping</i> <i>HRAS</i> , <i>IDH1</i> , <i>IDH2</i> , <i>KIT</i> , <i>PIK3CA</i> , <i>PDGFRA</i> genes (G2M, G2M, Solid Tumor Lung NGS Panel)	4A. RUO methodology with the Solid Tumor Lung NGS Panel (G2M) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (G2M, EN/RBUSM/0134, Rev.00, Dt.26/06/2025 5) (OE_MT_18, Version E.0, 01/11/2025)
5A. Paraffin embedded tissue, peripheral blood, buccal swab	Analysis of DNA Microsatellite Instability (MSI)	5A. <i>In-house multiplex fluorescent PCR method</i> in five microsatellite loci and fragment analysis by capillary electrophoresis with SeqStudio Genetic Analyzer (ThermoFisher) (MAN0018646, Rev.B 2022) (OE_MT_05, Version D.0, 01/09/2024)
6. Paraffin embedded tissue	Detection and quantification of the <i>ALK</i> 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)
7. Paraffin embedded tissue	Detection and quantification of the overexpression of the <i>HER2/NEU</i> 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)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
8. Paraffin-embedded tissue, cytology specimens	Analysis of somatic alterations in the <i>BRAF</i> , <i>EGFR</i> , <i>ERBB2</i> , <i>IDH1</i> , <i>KIT</i> , <i>KRAS</i> , <i>NRAS</i> , <i>PDGFRA</i> , <i>PIK3CA</i> genes (Atila Biosystems)	CE-IVD methodology with the Hotspot Cancer Panel kit (Atila Biosystems) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (Atila, ACPN-HT-100, V2.0) (OE_MT_15, Version E.0, 01/11/2025)
9. Paraffin embedded tissue	9A. Analysis of Microsatellite Instability (GenePlus)	9A. CE-IVD methodology with the Oncology188-Gene Variant Assay kit (GenePlus) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (GenePlus BE202508001 V1.0) (OE_MT_16, Version E.0, 01/11/2025)
	9B. Analysis of Microsatellite Instability (PentaBase)	9B. CE-IVD methodology with the MicroSight MSI kit (Penta Base) and analysis with the BaseTyper 48.4 Quiet HRM Real-Time PCR System (PentaBase) (MicroSight MSI, V3.4, June 2025) (OE_MT_05, Version E.0, 01/11/2025)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
10. Paraffin embedded tissue	Analysis of somatic alterations in the <i>AKT1</i> , <i>EGFR</i> , <i>ERBB2</i> , <i>BRAF</i> , <i>KRAS</i> , <i>NRAS</i> , <i>METex14 skipping</i> , <i>HRAS</i> , <i>IDH1</i> , <i>IDH2</i> , <i>KIT</i> , <i>PIK3CA</i> , <i>PDGFRA</i> genes (GenePlus)	CE-IVD methodology with the Oncology Multi-Gene Variant Assay kit (GenePlus) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (GenePlus V1.5) (OE_MT_06, Version E.0, 01/11/2025)
11. Liquid Biopsy	11A. Analysis of alterations in the <i>AKT1</i> , <i>BRAF</i> , <i>BRCA1</i> , <i>BRCA2</i> , <i>EGFR</i> , <i>ESR1</i> , <i>KRAS</i> , <i>PIK3CA</i> , <i>PTEN</i> genes (GenePlus)	11A. CE-IVD methodology with the Circulating Tumor DNA 1021 Assay kit (GenePlus) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (GenePlus V1.4) (OE_MT_01, Version E.0, 01/11/2025)
	11B. Analysis of alterations in the <i>ESR1</i> gene (GenePlus)	11B. CE-IVD methodology with the Oncology188-Gene Variant Assay kit (GenePlus) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (GenePlus BE202508001 V1.0) (OE_MT_19, Version E.0, 01/11/2025)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
12. Paraffin embedded tissue	Tumor Mutation Burden (TMB) calculation (GenePlus)	CE-IVD methodology with the Oncology Multi-Gene Variant Assay kit (GenePlus) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (GenePlus V1.5) (OE_MT_07, Version E.0, 01/11/2025)
13. Paraffin embedded tissue	Analysis of somatic mutations in <i>BRCA1</i> & <i>BRCA2</i> genes (GenePlus)	CE-IVD methodology with the Oncology188-Gene Variant Assay kit (GenePlus) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (GenePlus BE202508001 V1.0) (OE_MT_02, Version E.0, 01/11/2025)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
14. Paraffin embedded tissue	Genomic Instability Score (LOH, TAI, LST) (GenePlus)	In-house methodology using the Oncoscan CNV FFPE assay, (ThermoFisher Scientific) and analysis with the Chromosome Analysis Suite (ChAS) and bioinformatics pipelines. (P/N 703302 Rev. 1) (OE_MT_13, Version D.0, 01/09/2024) CE-IVD methodology with the Oncology Multi-Gene Variant Assay kit (GenePlus) in combination with the Homologous Recombination Deficiency Assay kit (GenePlus) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (GenePlus V1.5 & BE202312003 V1.0) (OE_MT_13, Version E.0, 01/11/2025)
15. Paraffin embedded tissue	Analysis of somatic alterations and fusions in <i>FGFR1</i> , <i>FGFR2</i> & <i>FGFR3</i> genes (GenePlus)	CE-IVD methodology with the Oncology Multi-Gene Variant Assay kit (GenePlus) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (GenePlus V1.5) (OE_MT_03, Version E.0, 01/11/2025 & OE_MT_06, Version E.0, 01/11/2025)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
16. Paraffin embedded tissue	16A. Fusion analysis in the <i>ALK</i> , <i>ROS1</i> , <i>RET</i> , <i>FGFR1,2,3</i> , <i>NTRK1,2,3</i> , gene and <i>METex14</i> skipping (GenePlus)	16A. CE-IVD methodology with the Oncology Multi-Gene Variant Assay kit (GenePlus) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (GenePlus V1.5) (OE_MT_03, Version E.0, 01/11/2025)
	16B. Fusion analysis in the <i>ALK</i> , <i>ROS1</i> , <i>RET</i> , <i>FGFR1,2,3</i> , <i>NTRK1,2,3</i> , gene and <i>METex14</i> skipping (G2M, PAN Cancer Assay)	16B. CE-IVD methodology with the PAN Cancer Assay kit (G2M) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (G2M, EN/USM/0019-1, Rev.06, Dt.15/05/2025) (OE_MT_04, Version E.0, 01/11/2025)
	16C. Fusion analysis in the <i>ALK</i> , <i>ROS1</i> , <i>RET</i> , <i>FGFR1,2,3</i> , <i>NTRK1,2,3</i> , gene and <i>METex14</i> skipping (G2M, PAN Cancer Assay)	16C. RUO methodology with the Oncology Multi-Gene Variant Assay (GenePlus) and sequencing performed with the next-generation sequencing (NGS) genetic analyzer DNBSEQ-T7 (MGI). (DNBSEQ-T7, User Manual Version 9.0) (GenePlus V1.5) (OE_MT_17, Version E.0, 01/11/2025)

*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, Attica, Greece.**

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This scope of Accreditation replaces the previous one dated 12.09.2025.

The Accreditation Certificate No. **822-8**, to ELOT EN ISO 15189:2022, is valid until 24.06.2029.

Athens, 12th of May 2026

Konstantinou Evangelos Apostolos
CEO of ESYD