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

Konstantinou Evangelos Apostolos
CEO of ESYD

ESYD is a signatory of the European co-operation for Accreditation (EA) Multilateral Agreement for the activities covered by this certificate.

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 Saliva	Mutation detection in *BRCA1* & *BRCA2* genes (Breast Cancer susceptibility genes 1 and 2) (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) * (KAPA HyperCap workflow v3.0 07939493001 02/20) (OE_MT_14, Version D.0, 01/09/2024) 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-G400, MGI (User manual version: A10) Data analysis was carried out using the analysis software SeqPilot (JSI Medical System). (Version 5.4.1)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
2. Peripheral blood 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)* MDP- Version-010(21 May 2022) (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)* (JSI Version 5.4.1) MDP- Version-010 (21 May 2025)
3. Peripheral blood 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) (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)* MDP- Version-010 (21 May 2025) (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

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
		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)* MDP- Version-008 (6 May 2022) (OE_MD _05, Version C.0, 01/08/2018)
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 (Thermo Fisher Scientific) and Next Generation Sequencing (NGS) with Ion Proton (Thermo Fisher Scientific) (Ion Ampliseq Library kit, MAN0006735, Revision F.0, 2019) (OE_MD_08, Version C.0, 01/08/2018)
	2. Somatic mutation analysis in exons 2, 3, 4 of *KRAS* and *NRAS* genes	
	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	1. 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)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
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)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
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) (GenePlus V1.4) (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) (GenePlus V1.5) (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) (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. (P/N 703302 Rev. 1) (OE_MT_13, Version D.0, 01/09/2024)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
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) (DNBSEQ-G400 Instruction for Use:V10.0) (GenePlus V1.5) (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

Certificate

Management system as per

ELOT EN ISO 9001 : 2015

The Certification Body TÜV HELLAS (TÜV NORD) S.A. hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization:

GENEKOR MEDICALSA ·
PRIVATE DIAGNOSTICLABORATORY
MEDICAL SA ·
52, Spaton Ave ·
153 44 Athens
Hellas

with the sites according to the annex and the subcertificates

operates a management system in accordance with the requirements of ELOT EN ISO 9001 : 2015 and will be assessed for conformity within the 3 year term of validity of the certificate.

Scope

Receipt and Handling of Biological Samples, Molecular Biology Testing and Quality Assessment of Results.

Certificate Registration No. 041 15 0049
Audit Report No. E-1026/2024

End of validity of previous certificate: 2024-04-15
Recertification Audit Date: 2024-04-11
Valid from 2024-04-29
Valid until 2027-04-15
Initial certification 2015

Athens, 29.04.2024

TÜV HELLAS (TÜV NORD) S.A. Certification Body

TÜV HELLAS (TÜV NORD) S.A.
282, Mesogeion Ave.
155 62 Athens, Greece
tuvhellas.gr

MS Certification
No of certificate 185

TÜV®

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TÜVNORD

Certificate

TÜVNORD
TÜV HELLAS S.A.
ISO 27001
tuvhellas.gr

Management system as per

ISO/IEC 27001 : 2022

The Certification Body TÜV HELLAS (TÜV NORD) S.A. hereby confirms as a result of the audit, assessment and certification decision according to ISO/IEC 17021-1:2015, that the organization:

GENEKOR MEDICALS.A.PRIVATEDIAGNOSTICLABORATORY
52, Spaton Ave.
153 44 Athens
Hellas
with the sites according to the annex and the subcertificates

Genekor
Committed to Biotechnological Innovation

operates a management system in accordance with the requirements of ISO/IEC 27001 : 2022 and will be assessed for conformity within the 3 year term of validity of the certificate.

Scope

Receipt and Handling of Biological Samples, Molecular Biology Testing and Quality Assessment of Results.

S.o.A.: Version 5.0, Dated from: 25.02.2025

Certificate Registration No. 048 19 0009
Audit Report No. IS-0134/2025

End of validity of previous certificate 2025-03-03
Recertification Audit Date 2025-04-29
Valid from 2025-06-04
Valid until 2028-03-03
Certified since 2019

Athens, 04.06.2025

TÜV HELLAS (TÜV NORD) S.A. Certification Body

TÜV HELLAS (TÜV NORD) S.A.
282, Mesogeion Ave.
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IAF
ESYD
MS Certification
No of certificate 185

COLLEGE of AMERICAN PATHOLOGISTS

Certificate of Accreditation

Genekor Medical SA
Laboratory
Athens, Greece
Eirini Papadopoulou, PhD

CAP#:7541642

The organization named above meets all applicable standards for accreditation and is hereby accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to February 10, 2027 to maintain accreditation.
Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Kathleen G. Beavis, MD
Chair, Accreditation Committee

Donald S. Karcher, MD, FCAP
President, College of American Pathologists