Hellenic Accreditation System

ACCREDITATION CERTIFICATE

No. 822-7

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, Attiki

under the terms of the ELOT EN ISO 15189:2012 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 June 25, 2012. This Certificate renews the accreditation and it is valid until June 24, 2029 provided that the accredited body will comply with the above Standard and the ESYD Criteria.

Athens, 02.08.2024

Christos Nestoras
CEO of ESYD

Hellenic Accreditation System

Annex G1/19 to the Certificate No. **822**-7

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	1.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_MD _14, Version D.0, 01/01/2022) Library preparation was carried out using the automated system MGISP-960. (Automation version: V2.0) For the above method sequencing was carried out using Next Generation Sequencing with DNBSEQ-G400, MGI (User manual version: A3) Data analysis was carried out using the analysis software SeqPilot (JSI Medical System).

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
2. Peripheral blood Saliva	2. 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-008 (6 May 2022) (OE_MD _12, Version C.0, 01/08/2018)
		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)* (Version: 5.3.0 Build 501(JSI), MDP- Version-008 (6 May 2022)
3. Peripheral blood Saliva	3. 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)

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
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 F.0, 2019) (OE_MD_15, Version C.0, 23/07/2019)
6. Paraffin embedded tissue	1. 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 1.3GB, 2019-01-28) (O3_MD_10, Version C.0, 01/08/2018)
7. Paraffin embedded tissue	1. 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 1.3GB, 2018-11-21) (OE_MD_11 Version C.0, 01/08/2018)
8. Paraffin-embedded tissue, cytology specimens	1. 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 F.0, 2019) (OE_MD_16, Version C.0, 15/01/2020)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
9. Paraffin embedded tissue	1.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_MD_17, Version C.0, 15/01/2020)
Immunohistochemistry examinations		
1. Paraffin embedded tissue	1. Immunohistochemical detection of the PD-L1 protein using the anti-PD-L1 monoclonal antibody (SP263, Ventana) Non Small Cells Lung Cancer (NSCLC) Urothilial Cancer (UC) Gastric Cancer Head and Neck squamous cell cancinoma Cervical Cancer	Special staining - IMMUNOHISTOCHEMISTRY Automated Immunohistochemistry using IVD detection kits - Ventana BenchMark GX Autostainer* Microscopic Evaluation – Interpretation of Results. (OE_MD_18, Version C.0, 15/01/2020) PD-L1 SP263 1015350EN Rev A
2. Paraffin embedded tissue	1. Immunohistochemical detection of the PD-L1 protein using the anti-PD-L1 monoclonal antibody (SP142, Ventana) Triple Negative Breast Cancer (TNBC) Urothilial Cancer (UC)	Special staining - IMMUNOHISTOCHEMISTRY Automated Immunohistochemistry using IVD detection kits - Ventana BenchMark GX Autostainer* Microscopic Evaluation – Interpretation of Results. (OE_MD_18, Version C.0, 15/01/2020) PD-L1 SP142 1018624EL Rev A

** 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 laboratory premises, 52 Spaton Avenue, 15344, Gerakas, Attiki, Greece.**

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

The Accreditation Certificate No. **822**-7, to ELOT EN ISO 15189:2012, is valid until **24.06.2029.**

Athens, 02.08.2024

Christos Nestoras
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 MEDICAL S.A.
PRIVATE DIAGNOSTIC LABORATORY
MEDICAL S.A.
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 ®

TÜVNORDGROUP

Certificate

Management system as per

ELOT ISO/IEC 27001 : 2013

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 MEDICAL S.A.
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operates a management system in accordance with the requirements of ELOT ISO/IEC 27001 : 2013 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.: ver. Γ.2, dated 17/02/2023

Certificate Registration No. 048 19 0009
Audit Report No. IS-0134/2024

End of validity of previous certificate: 2022-03-03
Recertification Audit Date: 2022-03-09
Valid from 2022-03-16
Valid until 2025-03-02
Initial certification 2019

Athens, 02.05.2024

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

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282, Mesogeion Ave.
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MS Certification
No of certificate 185