

Hellenic Accreditation System



Annex G1/17 to the Certificate No. **822-6**

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		
<p>1. Peripheral blood Saliva</p>	<p>1. Mutation detection in BRCA1 & BRCA2 genes (Breast Cancer susceptibility genes 1 and 2) (Full coding sequence, splice sites and 20bp flanking intronic sequences)</p>	<p>Target Enrichment Method based on capture approach KAPA HyperExplore MAX 3Mb T1 RUO (NimbleGen, Roche) *</p> <p>(KAPA HyperCap workflow v3.0 07939493001 02/20) (OE_MD_14, Version D.0, 01/01/2022)</p> <p>Library preparation was carried out using the automated system MGISP-960. (Automation version: V2.0)</p> <p>For the above method sequencing was carried out using Next Generation Sequencing with MiSeq (Illumina) and DNBSEQ-G50, (MGI) genetic analyzers. (Document # 15039740 v10, 2019 Illumina, Inc.) (DNBSEQ-G50 User Manual version:A3)</p> <p>Data analysis was carried out using the analysis software SeqPilot (JSI Medical System).</p>

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
2. Peripheral blood Saliva	2. Detection of large genomic rearrangements in <i>BRCA1</i> & <i>BRCA2</i> genes (Breast Cancer susceptibility genes 1 and 2)	<p>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)*</p> <p>(MDP version-007; Issued on 01 March 2019 (MLPA)) (OE_MD _12, Version C.0, 01/08/2018)</p> <p>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)*</p> <p>(Version: 4.4.0 Build 505 (JSI), MDP version-007; Issued on 01 March 2019 (MLPA))</p>
3. Peripheral blood Saliva	3. Detection and analysis of known familial mutation in <i>BRCA1</i> & Analysis <i>BRCA2</i> genes (Breast Cancer susceptibility genes 1 and 2)	<p>3A. DNA sequencing by capillary electrophoresis with SeqStudio Genetic Analyzer (ThermoFisher)</p> <p>(MAN0017464, Rev.B 2019)</p> <p>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)*</p> <p>(MDP version-007; Issued on 01 March 2019 (MLPA)) (OE_MD _05, Version C.0, 01/08/2018)</p>

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
4.Paraffin-embedded tissue, cytology specimens	1. Somatic mutation-analysis in exons 18, 19, 20, 21 of EGFR gene 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	<i>In-house method</i> 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)
5A. Paraffin embedded tissue, peripheral blood, buccal swab	1. Analysis of DNA Microsatellite Instability (MSI)	1A <i>In-house multiplex fluorescent PCR method</i> in five microsatellite loci and fragment analysis by capillary electrophoresis with SeqStudio Genetic Analyzer (ThermoFisher) (MAN0017464, Rev.B 2019)
5B. Paraffin embedded tissue		1B <i>In-house method</i> 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)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
7. Paraffin embedded tissue	1. Detection and quantification of the overexpression of the HER2/NEU gene	<p>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)</p> <p>(OE_MD_11 Version C.0, 01/08/2018)</p>
8. Paraffin-embedded tissue, cytology specimens	1. Somatic mutation-analysis in exons 7, 9, 13, and 20 of <i>PIK3CA</i> gene	<p><i>In-house method</i> with Ion AmpliSeq™ Panel primers (Thermo Fisher Scientific) and Next Generation Sequencing (NGS) with Ion Proton (Thermo Fisher Scientific)</p> <p>(Ion Ampliseq Library kit, MAN0006735, Revision F.0, 2019)</p> <p>(OE_MD_16, Version C.0, 15/01/2020)</p>
9. Paraffin embedded tissue	1. Analysis of somatic mutations in <i>BRCA1</i> & <i>BRCA2</i> genes	<p><i>In-house method</i> with the Oncomine BRCA Research Assay (Thermo Fisher Scientific) and Next Generation Sequencing (NGS) with Ion Proton (Thermo Fisher Scientific)</p> <p>(Oncomine BRCA Research Assay, MAN0014634, Revision B.0)</p> <p>(OE_MD_17, Version C.0, 15/01/2020)</p>

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
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) Urothelial Cancer (UC) Gastric Cancer Head and Neck squamous cell carcinoma Cervical Cancer	<u>Special staining - IMMUNOHISTOCHEMISTRY</u> 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) Urothelial Cancer (UC)	<u>Special staining - IMMUNOHISTOCHEMISTRY</u> 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. Bourkoulas, G. Pepe, G. Kapetsis, E. Patsea, D. Apostolopoulou, D. Bouzarelou.**

This scope of Accreditation replaces the previous one dated 16.05.2022.

The Accreditation Certificate No. **822-6**, to ELOT EN ISO 15189:2012, is valid until 24.06.2024.

Athens, September 05, 2022

Christos Nestoras
CEO of ESYD