Hellenic Accreditation System

Annex **G1/A13** to the Certificate **No. 1085-4**

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

ACCESS TO GENOME

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Molecular Genetics / Molecular Cytogenetics		
1.Peripheral Blood, Amniotic Fluid, Chorionic Villi, Product of Conception	1.High resolution Array-CGH Analysis (backbone resolution of ~500kb in the entire genome and ~50kb in 240 regions associated with ~512 Genetic disorders).	Array Comparative Genomic Hybridization (aCGH) with the SurePrint 8x60k G3 ISCA V.3 kit* and the use of the Surescan following fluorescent labeling of genomic DNA and hybridization in the SurHyb chamber (Agilent Technologies). Analysis of the data is performed with the use of Agilent Cytogenomics 3.0.4.1 Software. (Document number ΔΠ-18-1/ Version 2)
2.Amniotic Fluid, Chorionic Villi, Product of Conception	1. Rapid detection of chromosomal aneu-ploidies for chromosomes 13, 18, 21, X, Y by QF-PCR and detection of the ΔF508 mutation in the *CFTR* gene.	*In-House method* Quantitative Fluorescent Polymerase Reaction (QF-PCR) for specific STRs of chromosomes 13, 18, 21, X, Y and part of exon 10 of the CFTR gene. Fragment analysis is performed using Genetic Analyzer ABI 3130xl followed by data analysis with the use of GeneMapper v4.0. (Document number ΔΠ-18-2/ Version 2)
3.Peripheral Blood, Amniotic Fluid, Chorionic Villi	1.Molecular detection of mutations in the *CFTR* (cystic fibrosis transmembrane	*In-House method* *CFTR* (cystic fibrosis

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	conductance regulator) gene: • Mutation analysis in exons 11,13,21 • Detection of the 621+1G→T mutation in intron 4 • Detection of the ΔF508 mutation in exon 10 • Detection of deletions/duplications in the 27 exons of the CFTR gene	transmembrane conductance regulator) gene analysis, by Denaturating Gradient Gel Electrophoresis (DGGE), Restriction Fragment Length Polymorphism (RFLP) and QF-PCR fragment analysis. Multiplex Ligation-dependent Probe Amplification (MLPA) is performed for the identification of deletions/duplications in the *CFTR* gene (SALSA MLPA P091 CFTR probemix, P091-100R (CE-IVD)*). In the case of unknown gel patterns DNA sequencing is performed using Genetic Analyzer ABI 3130xl (Applied Biosystems) (Document number ΔΠ-18-3/ Version 2)
4. Peripheral Blood	1.Molecular detection of mutations in the *MTHFR gene* (Methylene-tetrahydrofolate reductase gene): • - Detection of the A1298C mutation in exon 7 • Detection of the C677T mutation in exon 4	*In-House method* PCR amplification of the targeted regions and consequent processing by Restriction Fragment Length Polymorphism (RFLPs). Analysis of the digested PCR product by agarose gel electrophoresis. (Document number ΔΠ-18-4/ Version 1)
5. Cervicovaginal specimens, sperm specimens, urine specimens, oropharyngeal specimens**,** anal specimens**,** wart specimens, paraffin embedded specimens	1.Simultaneous screening and genotyping of 36 HPV types (High risk-HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66,68, 73and 82-, and low risk-HPV 6, 11, 40, 42,43,44, 54, 55,61,62, 67, 69, 70, 71, 72, 81, 84 and 89)	Simultaneous screening and genotyping of 36 HPV types (High risk-HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66,68, 73and 82-, and low risk-HPV 6, 11, 40, 42,43,44, 54, 55,61,62, 67, 69, 70, 71, 72, 81, 84 and 89) is performed with the use of the CE-IVD kit: HPV direct flow CHIP kit (Masterdiagnostica). With the specific CE IVD kit, direct amplification of the L1 HPV region is performed followed by reverse dot blot automatic hybridization, based on DNA-Flow Technology (e-BRID System®). Data analysis is performed with the use of hybriSoft 12. (Document number ΔΠ-18-5/ Version 1)
7. Cervicovaginal	The test utilizes amplification of target DNA by the Polymerase Chain Reaction	CE-IVD *Cobas 4800 HPV test*. Application of the protocol

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specimens	(PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV16 and HPV18 while concurrently detecting the rest of the high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).	according to manufacturer instructions (Roche Diagnostics) with automated nucleic acid isolation by the COBAS x 4800 system and real time PCR by the COBAS Z system. (Document number ΔΠ-18-6/ Version 1)
8. Peripheral blood Saliva	Mutation detection in BRCA1 & BRCA2 genes (Breast Cancer susceptibility genes 1 and 2) (coding regions, all splice sites and ± 8bp flanking intronic sequences) by Next Generation Sequencing	Sequencing by Next Generation Sequencing with the use of Ion Chef Instrument in combination with Ion GeneStudio™ S5 System (ThermoFisher), of all coding regions, all splice sites and ± 8bp flanking intronic sequences. Data analysis of the sequenced regions by Variant caller plugin with Ion Reporter 5.18, and Alamut®Visual. (Document number ΔΠ-18-6/ Version 1)
9. Peripheral blood Saliva	Detection of large genomic rearrangements (deletions/duplications) in *BRCA1* & *BRCA2* genes (Breast Cancer susceptibility genes 1 and 2) by Multiplex Ligation-Dependent Probe Amplification	Multiplex Ligation-Dependent Probe Amplification (MLPA) CE-IVD SALSA MLPA *BRCA1* probemix and CE-IVD SALSA MLPA *BRCA2* probemix (MRC-Holland) Data analysis of the genomic data with the use of Genetic analyser ABI 3130xl and analysis software GeneMapper v4.0. (Document number ΔΠ-18-6/ Version 1)
10. Peripheral blood Saliva	Detection and analysis/confirmation of known familial mutation in *BRCA1* & *BRCA2* genes (Breast Cancer susceptibility genes 1 and 2) by Sanger sequencing	Primer designing specific targeted regions of the *BRCA1* & *BRCA2* genes (Breast Cancer susceptibility genes 1 and 2) and sequence analysis by Sanger sequencing. Data analysis of the genomic data with the use of Genetic analyser ABI 3130xl and analysis software UGENE v1.31.1 (Document number ΔΠ-18-6/

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		Version 1)
10. Cervicovaginal specimens	Molecular qualitative assay for the detection of DNA from 14 high-risk human papillomavirus (HPV) genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 in clinical specimens. The assay specifically identifies HPV genotypes 16, 18, and 45 while reporting the concurrent detection of the other high-risk genotypes (31/ 33/ 52/ 58) and (35/ 39/ 51/ 56/ 59/ 66/ 68) at clinically relevant infection levels.	CE-IVD *Alinity m High Risk (HR) HPV*. Application of the protocol according to manufacturer instructions (Abbott Diagnostics) with automated nucleic acid isolation and real time PCR by the Alinity m System. (Document number ΔΠ-18-6/ Version 1)

**Reference to the commercial name of a specific kit, refers to a specific analytical method and protocol*

Site of assessment: **Laboratory permanent premises: 33A Ethnikis Antistaseos str., 55134, Kalamaria, Thessaloniki, Greece.**
Approved signatories: **Ioannis Papoulidis.**

This scope of Accreditation replaces the previous one dated 02.06.2025.
The Accreditation Certificate No.**1085-**4, to ELOT EN ISO 15189:2022, is valid until 12.03.2030.

Athens, 3rd of September 2025

Konstantinou Evangelos Apostolos
CEO of ESYD