HELLENIC ACCREDITATION SYSTEM

Annex G1/5 to the Certificate No. **1295**-2

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

“EUROGENETICA M.S.A.”

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Molecular Genetics		
Peripheral blood, Amniotic Fluid, Chorionic Villi	Mutation detection in the CFTR gene (Cystic Fibrosis)	Use of commercial kits by **Ampliseq (Thermo Fisher Scientific)** compatible with a **semiconductor sequencer**, according to the manufacturer’s instructions. Laboratory Protocol: MD_10 Protocol – **NGS_CFTR Method_01.09.2024**
Peripheral blood, Amniotic Fluid, Chorionic Villi, Product of Conception and samples of abortuses	Rapid aneuploidy detection for chromosomes 13, 18, 21, X, Y and detection of the ΔF508 mutation of the *CFTR* gene	In house method by QF-PCR using the PCR T1 Thermocycler Biometra and fragment analysis on Genetic Analyzer Applied Biosystems 3500* (SN: 29124-010) *Lab Protocol:* MΔ_02 Lab Protocol_QF-PCR_Ver.2.0_01.11.2021
Peripheral Blood	Multiplex PCR followed by capillary electrophoresis of the amplified products for the detection of 13 polymorphisms in 11 genes associated with cardiovascular diseases.	Genotyping of the 13 polymorphisms in 11 genes is performed using the CE-IVD Seqline CVD TOTAL PANEL kit. The procedure includes: Multiplex PCR, SNaPshot® mini-sequencing αvδ Fragment Analysis on Applied Biosystems 3500 with Seqline 110 Size Standard. Analysis and genotype calling are performed using GeneMapper™ 5 software. Laboratory Protocol: MD_11 Method – CVD_01.10.2025

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

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Peripheral blood, Amniotic Fluid, Chorionic Villi, Product of Conception and samples of abortuses	1. Detection of ΔF508 (c.1521_1523delCCT) in the CFTR gene (Cystic Fibrosis)	Use of RealFast™ Assay kit (CE-IVD, Vienna Lab) σε Rotor Gene Q (R00969)* *Lab Protocol:* MΔ_05 Method_ΔF508_01.11.2021
Peripheral blood	Mutation detection of BRCA1/2	Use of commercial kits from **Vanzyme**, compatible with the **semiconductor sequencer**, according to the manufacturer's instructions. Use of a commercial kit from **MRC Holland** for the detection of large genomic rearrangements in the **BRCA1** and **BRCA2** genes. Use of the **Applied Biosystems BigDye Terminator** commercial kit for the confirmation and familial testing of variants in the **BRCA1** and **BRCA2** genes. **Laboratory Protocols** • **MΔ_07** – *NGS Method for BRCA Analysis* – 31.08.2024 • **MΔ_08** – *MLPA Method for BRCA Analysis* • **MΔ_09** – *Sanger Sequencing Method for BRCA Analysis*
Molecular Microbiology		
Peripheral Blood, Plasma, serum	1. Detection of HBV, HCV, HIV viral NA	Use of Real -Time PCR Sacace Biotechnology HCV, HBV, HIV1/2 (CE, IVD) on Rotor Gene Q (R00969)* *Lab Protocol:* MΔ_04 Lab Protocol _VIRUSES_Ver.2.0_01.11.2021
Cytogenetics		
Peripheral Blood, Amniotic fluid, Chorionic villi sample (CVS), Product of Conception and samples of abortuses	1. Chromosomal analysis and karyotyping / Detection of chromosomal abnormalities	In-house method by cell culturing, cell collection (harvest), chromosome preparation and banding, karyotyping (Chromosome analysis). *Lab Protocol:* MΔ_01 _Lab Protocol _Ver.2.0_ 01.11.2021

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

**The mentioned commercial names are reffering to specific analytical method and laboratory work protocol.*

Site of assessment: **Permanent laboratory premises, Andrianoupoleos 7, 55133 Kalamaria, Thessaloniki**
Approved signaturies: **Xefteris A., Malamidou A., Sekerli E., Harisiou S.**
Primary Sample Collection Point: **Permanent Laboratory Facilities, Andrianoupoleos 7, Kalamaria 55133, Thessaloniki**
Branch, Tsimiski 77, 54622 Thessaloniki

This scope of Accreditation replaces the previous one dated 04.05.2026.
The Accreditation Certificate No. **1295**-2, to ELOT EN ISO 15189:2022, is extended until 04.05.2027, according to ESYD decision.

Athens, 26th of October 2026

Konstantinou Evangelos Apostolos
CEO of ESYD