Hellenic Accreditation System

Annex G1/7 to the Certificate No. **1232**-2

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

ELEFTHO

Private Practice - Medical Company

Diagnostic Laboratory for Molecular and Cytogenetic Analysis

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Total blood (EDTA)	Mutation detection of Factor V (V-Leiden), Prothrombin (Factor II-G20210A), MTHFR (C677T&A1298C)	THROMBOPHILIA SUSCEPTIBILITY (8SNPS) and FOLATE METABOLISM, DNA-TECHNOLOGY (*CE-IVD)* Gentier Real-time PCR System (TIANLONG). *Lab protocol: DIRECTIVE* O.520-3/v1 10-01-2022
Total blood (EDTA)	Detection of CF508del mutation of CFTR gene related to Cystic Fibrosis.	REAL FAST ASSAY CF508del, VIENNA LAB (*CE-IVD)* Gentier Real-time PCR System (TIANLONG). *Lab protocol: DIRECTIVE* O.520-5/v1 10-01-2022
Cervical smear, sperm, biopsy, urethral smear, annal smear, pharyngeal smear, smear from damaged area	Human Papilloma virus detection and typing (HPV) - 21 types (16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73 και 82, 6, 11 and 44)	24 Human Papillomavirus Typing Kit, Mole Bioscience (CE IVD) Gentier Real-time PCR System (TIANLONG). *Lab protocol: DIRECTIVE* O.520-7/v2 16-01-2023
Total blood (EDTA)	specific detection of the Human Leukocyte Antigen HLA-B27 alleles	HLA-B27 Real-Time PCR Genotyping kit, DNA-TECHNOLOGY (CE-IVD) Gentier Real-time PCR System (TIANLONG). Lab protocol: DIRECTIVE O.520-12/v1 16-01-2023

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

Site of assessment: **Laboratory permanent premises: 32, 8 Dekembriou str., Chania, 73100, Crete, Greece.**

Primary Sample Collection Site: Laboratory permanent premises: 32, 8 Dekembriou str., Chania, 73100, Crete, Greece

Approved signatures: **Batakis Emmanouil, Balantinou Eirini.**

This scope of Accreditation replaces the previous one dated 13.04.2025.
The Accreditation Certificate No. **1232-**2, to ELOT EN ISO 15189:2022, is valid until 13.01.2030.

Athens, 31st July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD