Hellenic Accreditation System

Annex G1/3 to the Certificate No. **1298**-2

SCOPE of ACCREDITATION

of the

Genetics - Genomics Center

of

MEDICON HELLAS SA

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Molecular Genetics Tests		
Nasopharyngeal smear, Oropharyngeal smear	Qualitative RNA detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in 3 genes RdRp, Egene, Ngene	Real-time reverse transcription polymerase chain reaction (RT-PCR) for SARS-CoV-2 coronavirus with 1copy ™ COVID-19 qPCR 4plex Kit CE IVD (1drop) in: Thermocyclers: BIOER QuantGene 9600 Real- Time PCR Detection System BIOER Line Gene 9600 Plus Real- Time PCR Detection System Extraction method: Automated Nucleic Acid Extraction System - Mole 32M (CE IVD) with Mole Nucleic Acid Extraction kit (CE, IVD) Automated Nucleic Acid Extraction System - MagCore® Plus II (CE IVD) with MagCore Viral NA 203 Extraction kit (CE, IVD) *Lab Protocol OE.M.01 (Version: 1.3 / 08.05.24)*

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Cell suspension (Colpotervical, Vaginal, Cervical smear), Semen, Urine	Detection and typing of human papillomavirus (HPV, Human Papilloma Virus) **24** subtypes**:** 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 26, 53, 66, 73, 82, 6, 11, 42, 43, 44, 81	Real-time polymerase chain reaction (RT-PCR) for human papillomavirus with Human Papillomavirus Nucleid Acid Amplification kit S014, CE IVD (Mole) <u>Thermocyclers</u> BIOER Line Gene 9600 Plus Real- Time PCR Detection System BIOER QuantGene 9600 Real- Time PCR Detection System <u>Extraction method</u>: Automated Nucleic Acid Extraction System - Mole 32M (CE IVD) with Mole Nucleic Acid Extraction kit (CE, IVD) Automated Nucleic Acid Extraction System - MagCore® Plus II (CE IVD) με MagCore Viral NA 203 Extraction kit (CE, IVD) Nucleid Acid Extraction Kit (Boiling method) P031(CE, IVD) (Mole) *Lab Protocol OE.M.03 (Version: 1.3 / 02.05.24)*

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

Site of assessment: **Laboratory premises: 5-7 Melitona Str, Gerakas, 15344, Greece**
Primary sample collection site**: 3, Melitona Str, Gerakas, 15344, Greece**
Approved Signatories: **Ioannis Kamatsos**

This scope of Accreditation replaces the previous one dated 23.02.2024.
The Accreditation Certificate No**1298**-2**,** to ELOT EN ISO/IEC 15189:2022, is valid until 02.06.2026.

Athens, 10th of April 2025

Konstantinou Evangelos Apostolos
CEO of ESYD