Hellenic Accreditation System

Annex G1/3 to the Certificate No.1210

SCOPE of ACCREDITATION

of the

Clinical laboratory

of

«BIOEREYNA DIAGNOSTIC LABORATORIES»

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Molecular Genetics		
Whole blood/EDTA	Detection of the Human Leukocyte Antigen B27 alleles	Analyzer: Roche cobas z480 Method: REAL TIME PCR Roche DNA High Pure PCR Template Preparation Kit (ref.11796828001) HLA B27 LightMix kit TIB MOLBIOL, (Cat.No.40-0606-64, version180808) (OE04_Analysis methodology HLAB27_2.0/04-03-2021)
Molecular microbiology		
Nasopharyngeal, nasal, pharyngeal and / or oral sample in a special swab and virus transport material, sputum, bronchoalveolar lavage, intratracheal suction material	Detection of RNA of SARS CoV-2 virus / Qualitative	Real-time RT-PCR (LightMix Modular Sarbecovirus E-gene / LightMix Modular SARS-CoV-2 (COVID19) RdRP,) using the system cobas z480 (Roche). (OE04_2_Analysis methodology SARS Cov-2_1.0/02-11-2020)
Whole blood/EDTA	Detection of *CFTR*:c.1521_1523del (p.Phe508del) ΔF508 variant	Analyzer: Roche cobas z480 Method: REAL TIME PCR SNP Biotechnology Monoplex Cystic Fibrosis Delta F508 Rea| Time PcR Kit, CE IVD) (OE04_3_Analysis methodology CFTR ΔF508, 1.1/23.01.2023)

Site of assessment: **Permanent laboratory premises: 1 Selinou Str. Panellinio, 73131 Chania, Greece.**
Approved signatories: **M. Ntaoukakis, E. Sarchianaki.**

The Accreditation Certificate No. 1210, κατά ΕΛΟΤ EN ISO 15189:2012, is valid until 08.07.2024.

Athens, 11.04.2023

Christos Nestoras
CEO of ESYD