Hellenic Accreditation System

Annex G1/2 to the Certificate No. 1245

SCOPE of ACCREDITATION

of the

Laboratory of Molecular Diagnostics

of the

Central Laboratories of Medical Biopathology

ΙΑΣΟ S.A.

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Molecular Microbiology		
Endocervical specimens received by endocervical brush device (broom protocol)	Molecular detection and typing of high-risk HPV types 16 and 18 and concurrent detection of the other 12 high-risk HPV types: 31, 33,35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.	CE-IVD method Cobas 4800 HPV test, carried out according to the manufacturer's instructions (Roche Diagnostics) with automated nucleic acid extraction method (COBAS x 480) and DNA amplification (COBAS z device). *Ο.Δ.ΜΟΡ.560.Ι.04, version 2, 01/07/2021*
Upper respiratory system specimens (rhinopharyngeal, nasal, oropharyngeal swabs and nasal wash) and lower respiratory specimens (sputum, tracheal and bronchial secretions)	Molecular detection of the SARS-CoV-2 RNA	Validated RUO method YOUSEQ SARS-CoV-2 Multiplex Real Time PCR for the concurrent detection of E and RdRp genes of the SARS-CoV-2. Test performed according to the instructions of the manufacturer (YouSeq Ltd) by the use of the AriaDx Real-Time PCR System thermal cycler for RNA amplification. *Ο.Δ.ΜΟΡ.560.Ι.03, version 2, 01/07/2021*
Whole blood and plasma, amniotic fluid, urine, biopsy specimens, specimens from the upper respiratory system (rhinopharyngeal and oropharyngeal swabs) and lower respiratory specimens (bronchial secretions).	Human cytomegalovirus (HCMV) DNA detection (all clinical specimens) and HCMV DNA quantification (whole blood, plasma, and amniotic fluid)	CE-IVD method, CMV R-GENE® kit. Test performed according to the manufacturer's (bioMérieux S.A.) instructions utilizing the AriaDx Real-Time PCR System thermal cycler for DNA amplification. *Ο.Δ.ΜΟΡ.560.Ι.01, version 2, 01/07/2021*

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Upper respiratory system specimens (rhinopharyngeal, nasal, oropharyngeal swabs, nasal wash) and lower respiratory specimens (sputum, tracheal and bronchial secretions)	RNA detection of influenza virus type A, type B and subtype A(H1N1) pdm09	CE-IVD method, RealStar® Influenza Screen & Type RT-PCR Kit 4.0. Test carried out according to the manufacturer's (Altona Diagnostics GmbH) instructions using the AriaDx Real-Time PCR System thermal cycler for RNA amplification. *Ο.Δ.ΜΟΡ.560.Ι.02, **version 2, 01/07/2021***
Endocervical specimens received by endocervical brush device (broom protocol)	Molecular detection and typing of high-risk HPV types 16 and 18/5 and concurrent detection of the other 11 high-risk HPV types: 31, 33,35, 39, 51, 52, 56, 58, 59, 66 and 68.	CE-IVD method Aptima HPV and Aptima HPV 16,18/45 Genotype Assay, carried out according to the manufacturers' instructions (HOLOGIC) with automated viral nucleic acid extraction and mRNA amplification using the PANTHER System Aptima Technology. *Ο.Δ.ΜΟΡ.560.Ι.05, **version 1, 10/05/2022***

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

Site of assessment: **Permanent laboratory premises, IASO. S.A. "IASO Private General, Obstetrics Gynaecological & Paediatrics Clinic, Diagnostic, Therapeutic & Research Center S.A.", 37-39 Kifisias Avenue, 15123, Marousi, Athens, Greece.**
Approved signatories: **Andreas F. Mentis, Tilemachos Skalidis, Christos Goumenopoulos, Lamprini Papalamprou, Dimitrios Manis.**

This Scope of Accreditation replaces the previous one dated 08.04.2021.
The Accreditation Certificate No.1245, to ELOT EN ISO 15189:2012, is valid until 07.04.2025.

Athens, August 01, 2022

Christos Nestoras
CEO of ESYD