Hellenic Accreditation System

Annex G1/6 to the Certificate No. **1245**

SCOPE of ACCREDITATION

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 5, 10/05/2024***
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 6, 10/05/2024***
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 5, 10/05/2024***
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 5, 10/05/2024***

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
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 3, 10/05/2024***
Biochemical tests		
	Determination of 31 parameters	**Biochemical unit CH of automated analyzers ATELLICA 1 & ATELLICA 2 (SIEMENS)** ***Ε.Δ.ΕΡΓ.Ι.560-1, version 2, 10/06/2024***
Blood serum	1. Total Cholesterol (TC)	Enzymatic - Colorimetric (CHOD - PAP)
Blood serum	2. HDL Cholesterol (HDL-C)	Enzymatic - Colorimetric
Blood serum	3. Triglycerides (TGs)	Enzymatic - Colorimetric
Blood serum	4. VLDL Cholesterol (VLDL-C)	Calculated from TRIG (Enzymatic - Colorimetric)
Blood serum	5. Atherogenic index ((TC)/ (HDL-C))	Calculated from Total Cholesterol (TC) / HDL Cholesterol (HDL-C)
Blood serum	6. Total Lipids	Calculated from CHOL and TRIG (Enzymatic - Colorimetric)
Blood serum	7. Iron (Fe)	Colorimetric (Ferrozine)
Blood serum	8. Albumin (ALB)	Colorimetric (BCG)
Blood serum	9. Total Proteins (TP)	Colorimetric (Biuret)
Blood serum	10. Total Globin SF	Calculated from: Total Protein(TP) - Albumin (ALB)
Blood serum	11. Albumin/Globin ratio (ALB/SF)	Calculated from: TP - ALB
Blood serum	12. Calcium total (Ca)	Colorimetric (OCPC)
Blood serum	13. Magnesium (Mg)	Colorimetric (Xylidyl blue)
Blood serum	14. Phosphorus (P)	Colorimetric (Phosphomolybdate)
Blood serum	15. Glucose (GLU)	Enzymatic - Colorimetric (HK)
Blood serum	16. Creatinine (CREA)	Colorimetric (Jaffe)
Blood serum	17. Urea (UREA)	Enzymatic - Kinetic -Colorimetric (Urease)
Blood serum	18. Uric acid (UA)	Enzymatic - Colorimetric (Uricase -Peroxidase)
Blood serum	19. Aspartate aminotransferase (AST/SGOT)	Colorimetric
Blood serum	20. Alanine aminotransferase (ALT/SGPT)	Colorimetric

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Blood serum	21. Gamma-Glutamyl transferase Τρανσφεράση (γGT)	Enzymatic - Colorimetric γ-Glutamyl-3-carboxy-4nitroanillide
Blood serum	22. Alkaline Phosphatase (ALP)	Colorimetric
Blood serum	23. Creatine Kinase (CK/CPK)	Enzymatic - Colorimetric
Blood serum	24. Lactate Dehydrogenase (LDH)	Enzymatic - Colorimetric (L-P)
Blood serum	25. Total Bilirubin (TBIL)	Colorimetric DPD
Blood serum	26. Direct Bilirubin (DBIL)	Colorimetric DPD
Blood serum	27. Indirect Bilirubin (IBIL)	Calculated from TBIL and DBIL (Colorimetric)
Blood serum	28. Amylase (AMY)	Enzymatic - Colorimetric
Blood serum	29. Potassium (K)	Ion Selective Electrode (ISE)
Blood serum	30. Sodium (Na)	Ion Selective Electrode (ISE)
Blood serum	31. Chloride (Cl)	Ion Selective Electrode (ISE)
Immunochemical Tests		
	Determination of 5 parameters	**Immunology unit IM of automated analyzer ATELLICA 1 (SIEMENS)** ***Ε.Δ.ΕΡΓ.Ι.560-1, version 2, 10/06/2024***
Blood serum	1. Thyroid-stimulating hormone (TSH)	Chemiluminescence (CLIA) (non-competitive sandwich)
Blood serum	2. Total Thyroxine (TT4)	Chemiluminescence (CLIA) (Competitive)
Blood serum	3. Total Triidothyronine (TT3)	Chemiluminescence (CLIA) (Competitive)
Blood serum	4. Free Thyroxine (FT4)	Chemiluminescence (CLIA) (Competitive)
Blood serum	5. Free Triidothyronine (FT3)	Chemiluminescence (CLIA) (Competitive)
	Determination of 2 parameters	**Immunology unit IM of automated analyzer ATELLICA 2 (SIEMENS)** ***Ε.Δ.ΕΡΓ.Ι.560-1, version 2, 10/06/2024***
Blood serum	1. Thyroid-stimulating hormone (TSH))	Chemiluminescence (CLIA) (non-competitive sandwich)
Blood serum	2. Free Thyroxine (FT4)	Chemiluminescence (CLIA) (Competitive)
Hematological tests		
	Determination of 13 parameters	**Automated Hematology analyzers ADVIA 2120i 1 & ADVIA 2120i 2 (SIEMENS)** ***Ε.Δ.ΕΡΓ.Ι.560-1, version 2, 10/06/2024***
Whole Blood (EDTA)	1. Red blood cell (RBC)	Flow cytometry
Whole Blood (EDTA)	2. Hematocrit (HCT)	Calculated

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Whole Blood (EDTA)	3. Mean corpuscular volume (MCV)	Flow cytometry
Whole Blood (EDTA)	4. Platelets (PLT)	Flow cytometry
Whole Blood (EDTA)	5. Mean corpuscular Hemoglobin (MCH)	Calculated
Whole Blood (EDTA)	6. Mean corpuscular Hemoglobin concentration (MCHC)	Calculated
Whole Blood (EDTA)	7. Hemoglobin (HGB)	Photometric
Whole Blood (EDTA)	8. White blood cells (WBC)	Flow cytometry
Whole Blood (EDTA)	9. Neutrophils (number and %) (NEUT)	Flow cytometry
Whole Blood (EDTA)	10. Lymphocytes (LYMPH) (number and %)	Flow cytometry
Whole Blood (EDTA)	11. Monocytes (MONO) (number and %)	Flow cytometry
Whole Blood (EDTA)	12. Eosinophils (EOS) (number and %)	Flow cytometry
Whole Blood (EDTA)	13. Basophils (BASO) (number and %)	Flow cytometry
Blood films	1. White Blood Cell Differential Count	**Microscopy**
	2. RBC Morphology	
	3. PLT Morphology	

** 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,Aikaterini Foifa, Maragkou Efstathia, Dimitrios Manis,Zafeiropoulou Eleni, Giannakopoulou Konstantina, Ntalakou Konstantina.**

Prime sample collection site: 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.

The Accreditation Certificate No. **1245**, to ELOT EN ISO 15189:2022, has been extended until 07.04.2026, according to ESYD decison.

Athens, 25th of November 2025

Konstantinou Evangelos Apostolos
CEO *of ESYD*