Hellenic Accreditation System

Annex G1/A5 to the Certificate No. **1294**-3

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

ANALYSI SA BIOPATHOLOGICAL DIAGNOSTIC RESEARCH LABORATORIES

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Biochemical testing		
Blood serum	**Determination of 12 parameters**	**Automated analyzer Atellica Solution Subsistem CH**
	1. Glucose (GLUC)	PHOTOMETRY Enzymatic (HEX-G6PDH) (Document number DP-20 2/4/2018/Version 1)
	2. Triglycerides (TRIG)	PHOTOMETRY Glycerol Phosphate Oxidase (Document number DP-20 2/4/2018/Version 1)
	3. Cholesterol Total (CHOL)	PHOTOMETRY Enzymatic – colorimetric (CHO-OEP-HBA) (Document number DP-20 2/4/2018/Version 1)
	4. Alanine Aminotransferase (ALT/SGPT)	PHOTOMETRY Enzymatic (NADH-without P-5'-P) (Document number DP-20 2/4/2018/Version 1)
	5. Aspartate Aminotransferase (AST/SGOT)	PHOTOMETRY Enzymatic (NADH-without P-5'-P) (Document number DP-20 2/4/2018/Version 1)
	6. Urea Nitrogen	PHOTOMETRY Enzymatic- enzyme glutamate dehydrogenase (GLDH) to reductively aminate α-ketoglutarate (Document number DP-20 2/4/2018/Version 1)
	7. Creatinine	PHOTOMETRY Enzymatic hydrolyzes creatinine to creatine. (Document number DP-20 2/4/2018/Version 1)
	8. G-gt	PHOTOMETRY substrate L-gamma-glutamyl 3-carboxy-4-nitranilide with glycylglycine.

Tested materials / products	Types of test / Properties	Applied standards / Techniques
		(Document number DP-20 2/4/2018/Version 1)
	9. Uric acid	PHOTOMETRY uricase method (Document number DP-20 2/4/2018/Version 1)
	10. Calcium	PHOTOMETRY Calcium reacts with OCPC to form a purple complex. (Document number DP-20 2/4/2018/Version 1)
	11. Alkaline phosphatase	PHOTOMETRY catalytic activity of alkaline phosphatase (Document number DP-20 2/4/2018/Version 1)
Whole Blood (EDTA)	12.Electrophoresis Hemoglobin	Electrophoresis Minicap Flex Piercing Sebia Capillarys 2 Document number DP-20 2/4/2018/Version 1)
Immunochemical Testing		
Blood serum	**Determination of 14 parameters**	**Automated analyzer Atellica Solution Subsistem IM**
	1. Follicle Stimulating Hormone (FSH)	
	2. Luteinizing Hormone (LH)	
	3. Estradiol (E2)	Chemiluminescent Microparticle Immunoassay (Document number DP-20 2/4/2018/Version 1))
	4. β-Human Chorionic Gonadotropin (β-hCG)	
	5. Thyroid-Stimulating Hormone (TSH)	
	6. Free Triiodothyronine (FT3)	
	7. Free Thyroxine (FT4)	
	8. Progesterone (PRG)	
	9. Vitamine B12	
	10. Ferritine	
	11. PSA Prostate Specific Antigen	
	12. CEA Carcinoembryonic Antigen	
	13. Papp-a	**Automated analyzer COBAS E-411** Electrochemiluminescence immunoassay “ECLIA” (Document number DP-20 2/4/2018/Version 1)
	14. FBhcg	**Automated analyzer COBAS E-411** Electrochemiluminescence immunoassay “ECLIA” (Document number DP-20 2/4/2018/Version 1)

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Immunological Tests		
Blood serum	**Determination of 4 parameters**	**Alegria, ORGENTEC Diagnostika GmbH**
	1.Anti-beta-2-Glycoprotein I IgG	ELISA Enzyme-linked Immunosorbent Assay Document number DP-54 15/06/2023 Version 1)
	2. Anti-beta-2-Glycoprotein I IgM	ELISA Enzyme-linked Immunosorbent Assay Document number DP-52 15/06/2023 Version 1)
	3. Anti-Cardiolipin IgG	ELISA Enzyme-linked Immunosorbent Assay Document number DP-55 15/06/2023 Version 1)
	4. Anti-Cardiolipin IgM	ELISA Enzyme-linked Immunosorbent Assay Document number DP-53 15/06/2023 Version 1)
Hematological Testing		
Whole Blood (EDTA)	**Determination of 8 parameters**	**Automated analyzer sysmex xn-550**
	1. Hemoglobin (HGB)	Hemoglobin concentration: colorimetric determination of hemoglobin. (Document number DP-20 2/4/2018/Version 1)
	2. Hematocrit (HCT)	The Hematocrit is the ratio of red blood cells to plasma and is expressed as a percentage of the whole blood volume. (Document number DP-20 2/4/2018/Version 1)
	3. Red Blood Cells (RBC)	Red Blood Cell concentration (Document number DP-20 2/4/2018/Version 1)
	4. Mean Corpuscular Volume (MCV)	Mean Cell Volume The MCV is derived from the RBC size distribution data on the 0°, 10°, and 90° histograms, and is expressed in femtoliters. (Document number DP-20 2/4/2018/Version 1)
	5. Mean Corpuscular Hemoglobin (MCH)	Mean Cell Hemoglobin The Mean Corpuscular Hemoglobin is the average amount of hemoglobin contained in the red blood cell expressed in picograms. (Document number DP-20 2/4/2018/Version 1)
	6. Mean Cell Hemoglobin Concentration (MCHC)	Mean Cell Hemoglobin Concentration, expressed in grams per deciliter. (Document number DP-20 2/4/2018/Version 1)
	7. White Blood Cells (WBC)	White Blood Cell concentration. Flow cytometry technology, with a Helium Neon Laser is as the light source. (Document number DP-20 2/4/2018/Version 1)
	8. Platelets (PLT)	Platelet concentration. The sample stream is then hydrodynamically focused to align the cells in single file as they pass through the Optical Flow Cell, which is an optically clear quartz chamber. (Document number DP-20 2/4/2018/Version 1)

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Coagulation Tests		
Bloodplasma (Citrate)	**Determination of 6 parameters**	**Automated analyzer BCS XP/ SIEMENS**
	1.D-Dimers	IMMUNOTURBIDITY Document number DP-20 2/4/2018/Version 1)
	2.Antithrombin III	CHROMOGENIC Document number DP-20 2/4/2018/Version 1)
	3. Protein –C Activity	CHROMOGENIC Document number DP-20 2/4/2018/Version 1)
	4. Activated partial prothrombine time (APTT)	CLOTTING Document number DP-20 2/4/2018/Version 1)
	5. Multifibren	CLAUS METHOD Document number DP-20 2/4/2018/Version 1)
	6. D-Dimers	IMMUNOTURBIDITY Document number DP-20 2/4/2018/Version 1)
Molecular Microbiology		
Serum, plasma	DNA detection and quantification of Hepatitis B virus	Real Time PCR technique with the use of QuantStudio5 instrument* (Applied Biosystems-Thermo Fisher Scientific) according to the kit manufacturer (artus HBV RG PCR kit- Qiagen* CE-IVD) (Document number DP-21 2/4/2018/Version 1)
Serum, plasma	RNA detection of Hepatitis C virus	Real Time PCR technique with the use of QuantStudio5 instrument* (Applied Biosystems-Thermo Fisher Scientific) according to the kit manufacturer (artus HCV RG PCR kit- Qiagen* CE-IVD) (Document number DP-22 2/4/2018/Version 1)
Upper and lower respiratory tract samples	RNA detection of SARS-CoV-2	Real Time PCR technique with the use of QuantStudio5 instrument according to the kit manufacturer TaqPath COVID19 Kit (ThermoFisher Scientific) (Document number DP-24 2/4/2022/Version 2)

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Cervical swabs, thin prep	Detection of human papilloma virus (HPV) high risk (HR)-14 types [14 types: 16,18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 και 68] and genotyping of HPV16 and HPV18.	Manufacturer's protocol; cobas® 6800 Human Papillomavirus (HPV) Test CE-IVD kit* (Roche Diagnostics GmbH), with automated sample processing and Realtime PCR using cobas® 6800 system (Roche Molecular Systems) * (Document number DP-23 16/10/2024/Version 2)
Molecular Oncology		
Formalin-fixed parafin-embedded tissue sample (FFPE sample)	1. Molecular detection of mutations in the KRAS, NRAS, BRAF and EGFR genes	Next generation sequencing technique (NGS – ION S5 Semiconductor Sequencer, by ThermoFisher Scientific) according to the kit manufacturer (COLON and LUNG V2 PANEL, by ThermoFisher Scientific) (Document number DP-39 12/1/2022/Version 1)
Peripheral blood	1. Molecular detection of mutations in the BRCA1,2 genes, detection of large genomic rearrangements in BRCA1,2 genes, complementary Sanger sequencing	Next generation sequencing technique (NGS – ION S5 Semiconductor Sequencer, by ThermoFisher Scientific) according to the kit manufacturer (BRCA1 and BRCA2 PANEL, by ThermoFisher Scientific), multiplex ligation-dependent probe amplification (MLPA) method using specially designed CE-IVD SALSA MLPA probemixes (SALSA MLPA P002 BRCA1 probemix and SALSA MLPA P045 BRCA2/CHEK2 probemix, MRC Holland) and the SALSA MLPA EK1 reagent kit – FAM (MRC Holland) reagent system, Sanger sequencing using specific primers for each possible pathological finding, after detection of mutations, and capillary electrophoresis for reaction products in the SeqStudio™ Genetic Analyzer System, of ThermoFisher Scientific
Molecular Genetics		
Peripheral blood	1. HLA-B27 haplotype detection	HLA-Ready Gene B27 kit manufacturer method of inno-train Diagnostik (CE-IVD) in Eppendorf Thermocycler PCR and agarose gel electrophoresis (Document number ΔΠ-51 20/5/2023/ Version 1)
Peripheral blood	1. Detection of thrombophilia predisposition mutations in Factor V (V-Leiden), Prothrombin (Factor II-G20210A), MTHFR (C677T, A1298C) genes	RHYMA TEST CVD STRIP TEST kit manufacturer method of CLONIT S.r.I (CE-IVD) in PCR Biometra Thermocycler and hybridization (Document number DP-48 20/5/2023/ Version 1)

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Peripheral blood	1. Cystic fibrosis transmembrane conductance regulator gene mutation detection F508del	In-house method using Biometra Thermocycler PCR and capillary electrophoresis for reaction products on the SeqStudio™ Genetic Analyzer System, ThermoFisher Scientific (Document number DP-49 20/5/2023/ Version 1)
Peripheral blood	1. Molecular detection of E2/E3/E4 alleles of the apolipoprotein E (APOE) gene	Selective amplification with real-time polymerase chain reaction (Real-Time PCR) and the use of the LightMix ApoE C112R R158C kit from TIBMOLBIOL (Document number DP-50 20/5/2023/ Version 1)
Cytogenetics		
Peripheral blood	Karyotyping / detection of chromosomal abnormalities	Cell Culture GTG banding Microscopic analysis Karyotyping (CaryoSystems image analysis software) (Document number DP-42 12/1/2022 Version 1)
Amniotic fluid, Chorionic Villus Sampling (CVS)	Karyotyping / detection of chromosomal abnormalities	Cell Culture GTG banding Microscopic analysis Karyotyping (CaryoSystems image analysis software) (Document number DP-41 12/1/2022 Version 1)
Peripheral Blood	High-resolution array-CGC analysis (CytoScan 750K Arrays, GeneScan 3000, ThermoFisher Scientific). Deletions or duplications as low as 150kb are detected and identified.	Array Comparative Genomic Hybridization (aCGH analysis) is completed with the use of CytoScan 750K Arrays Kit in the Affymetrix Genechip Scanner. Fluorescent labeling and hybridization of the extracted genomic DNA in the Genechip Hybridization Oven 645 (ThermoFisher Scientific) have been already performed. Finally, analysis of data is carried out with the use of Chromosome Analysis Suite (ChAS) Software. (Document number DP-44 12/1/2022 Version 1)
Amniotic Fluid, Chorionic Villi	Low-resolution array-CGC analysis (CytoScan® Optima Array, GeneScan 3000 (ThermoFisher Scientific). Deletions as low as 1MB or duplications as low as 2MB are detected and identified.	Array Comparative Genomic Hybridization (aCGH analysis) is completed with the use of CytoScan® Optima Array Kit in the Affymetrix Genechip Scanner. Fluorescent labeling and hybridization of the extracted genomic DNA in the Genechip Hybridization Oven 645 (ThermoFisher Scientific) have been already performed. Finally, analysis of data is carried out with the use of Chromosome Analysis Suite (ChAS) Software. (Document number DP-45 12/1/2022/Version 1)
Flow Cytometry		

Tested materials / products	Types of test / Properties	Applied standards / Techniques
Peripheral blood	Immunophenotype CD3+%, CD19+%, CD3+CD4+ %, CD3+CD8+%, CD3-CD16+56+%, CD3+CD16+56+ % CD3+, CD19+(absolute number), CD3+CD4+(absolute number), CD3+CD8+(absolute number), CD3-CD16+56+(absolute number), CD3+CD16+56+ (absolute number)	Flow Cytometry Flow Cytometer CYTEK NORTHERN LIGHTS CLC. (Document number DP-34 2/4/2018/Version 1)

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

Primary sample collection site: 51 Tsimiski str, 54623 Thessaloniki, Greece

Site of asseseement: **Permanent Laboratory premises, 51 Tsimiski str, 54623 Thessaloniki, Greece**

Approved signatories: **Spyridon Gerou, Vassiliki Pavlidou, Eleni Bella, Evrinomi Tsiargali, Peroulis Nikolaos, Kydonopoulou Kyriaki, Konstantinou Christina, Terzidou Maria.**

This Scope of Accreditation replaces the previous one dated 31.07.2025.
The Accreditation Certificate No. **1294-**3, to ELOT EN ISO 15189:2022, is extended until 23.11.2026, according to ESYD decision.

Athens, 22 May 2026

Konstantinou Evangelos Apostolos
CEO of ESYD