Hellenic Accreditation System

Annex G1/6 to the Certificate No.**1211-2**

SCOPE of ACCREDITATION

of

Departments of Transfusion and Hematology,
Medical Biopathology (Microbiology)-Clinical Biochemistry,
Immunology – Histocompatibility

of the

Division of Laboratory Medicine
and
Medical Genetics Unit

of the

1st Department of Obstetrics and Gynecology
of Aristotle University of Thessaloniki

at

"PAPAGEORGIOU" General Hospital

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
Biochemical Tests		
Blood serum	**Determination of 12 parameters**	**Automated Analyzers Alinity ci (x2), Alinity c (x1)*** **Work Instruction: O19-2-2_ΒΙΟΠΑΘ-BIOX (Version 1.3/19-04-2023) & D19-02-EN02 Inserts Βιοχημικό (Version 1.2/02-09-2024)**
	1. Glucose	Enzymatic hexokinase method / G-6-PDH
	2. Urea	Urease method
	3. Uric Acid	Enzymatic – colorimetric (Uricase)
	4. G-Glutamyl-Transferase (γ-GT)	Enzymatic
	5. Total bilirubin (TBIL)	Enzymatic - kinetic - colorimetric (Diazonium salt)
	6. Direct bilirubin (DBIL)	Enzymatic - kinetic - colorimetric (Diazo Reaction)
	7. Potassium (K)	Ion Selective Electrode (ISE)

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
	8. Sodium (Na)	Ion Selective Electrode (ISE)
	9. Total Protein (TP)	Colorimetric (Biuret)
	10. Albumin (ALB)	Colorimetric (Bromocresol Green)
	11. Phosphorus (PHOS)	Colorimetric (Phosphomolybdate)
	12. 12. Magnesium (MG)	Enzymatic
Hematological Tests		
Whole Blood (EDTA)	**Determination of 8 parameters**	**Automated analyzers Abbott Alinity hq 740 (x1), hq 749 (x1) and Alinity hq 329 (x1)*** **Work Instruction: O19-2-2_ΑΙΜΑΤΟΛΟΓΙΚΟ (Version 1.2/20-04-2023) & D19-02-EN02 Inserts Αιματολογικό (Version 1.1/02-09-2024)**
	1.White blood cells (WBC)	Flow cytometry with optical scattering and fluorescence
	2.Red blood cells (RBC)	Flow cytometry with optical scattering
	3.Hemoglobin (HGB)	Absorption spectrophotometry
	4.Hematocrit (HCT%)	Calculated
	5.Meancorpuscularvolume (MCV) (fL)	Flow cytometry with optical scattering
	6. Mean corpuscularhemoglobin (MCH) (pg)	Calculated
	7.Mean corpuscular hemoglobin concentration (MCHC) (g/dL)	Calculated
	8. Platelets (PLTs)	Flow cytometry with optical scattering
Immunological Tests		
Blood serum	**Determination of 4 parameters** Detection of autoantibodies for Autoimmune Bullous Diseases IgG class 1. Desmoglein 1 2. Desmoglein 3 3. BP 180 4. BP 230	**Enzyme Linked Immunosorbent Assay (ELISA) using ELISA Analyzer (Dynex DSX)*** **Work Instruction: O19-2-3_ΑΝΟΣΟΛΟΓΙΚΟ (Version 1/15-5-17) & D19-02-EN02 Inserts Ανοσολογικό (Version 1.2/02-09-2024)**

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
Blood serum	**Determination of 1 parameter** Detection of autoantibodies for Autoimmune Bullous Diseases 1. SKIN IgG	**Indirect immunofluorescence with biochip technology – microscope Zeiss, AxionLab*** **Work Instruction: O19-2-5_ΑΝΟΣΟΛΟΓΙΚΟ (Version 1.1/03-06-2024) & D19-02-EN02 Inserts Ανοσολογικό (Version 1.2/02-09-2024)**
Blood serum	**Determination of 2 parameters** 1. Antinuclear antibodies ANA 2. Antibodies against the double-stranded DNA (anti-dsDNA)	**Indirect immunofluorescence (Semi Automatic Method)- Using Dispenser AP22 speedy IF*** **Work Instruction: O19-2-7_ΑΝΟΣΟΛΟΓΙΚΟ (Version 1/12-5-2022) & D19-02-EN02 Inserts Ανοσολογικό (Version 1.2/02-09-2024)**
Blood serum	**Determination of 5 parameters** 1. Antibodies against RNP 2. Antibodies against Sm 3. Antibodies against SS-A/Ro 4. Antibodies against SS-B/La 5. Antibodies against Scl-70	**Enzyme Linked Immunosorbent Assay (ELISA) using ELISA Analyzer (Dynex DSX)*** **Work Instruction: O19-2-6_ΑΝΟΣΟΛΟΓΙΚΟ (Version 1/12-5-2022) & D19-02-EN02 Inserts Ανοσολογικό (Version 1.2/02-09-2024)**
Blood serum	**Determination of 2 parameters** 1. Total prostate-specific antigen (TPSA) 2. Ferritin	**Chemiluminescence Microparticle Immunoassay (CMIA)** – automatic analyser Alinity i (Abbott)* **Work Instruction: O19-2-8_ΑΝΟΣΟΛΟΓΙΚΟ (Version 1/28-6-2022) & D19-02-EN02 Inserts Ανοσολογικό (Version 1.2/02-09-2024)**
Blood serum	**Determination of 2 parameters** 1. Thyroid-stimulating hormone (TSH) 2. Total human chorionic gonadotropin (ThCG)	**Chemiluminescence immunoassay (CLIA)** – automatic analyser Atellica solution IM Analyzer (Siemens)* **Work Instruction: O19-2-9 (Version 1/28-6-2022) & D19-02-EN02 Inserts Ανοσολογικό (Version 1.2/02-09-2024)**
Blood serum	**Determination of 1 parameter** 1. C-Reactive Protein (CRP)	**Nephelometry**, with automatic analyzer Immage 800 (Beckman Coulter)* **Work Instruction: OE19-2-10 ΑΝΟΣΟΛ (Version 1.1/03-06-2024) & D19-02-EN02 Inserts Ανοσολογικό (Version 1.2/02-09-2024)**

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
Flow Cytometry		
Whole Blood (EDTA)	**Determination of 5 parameters** 1. Determination of CD3+ percentage on lymphocytes 2. Determination of CD3+CD4+ percentage on lymphocytes 3. Determination of CD3+CD8+ percentage on lymphocytes 4. Determination of CD19+ percentage on lymphocytes 5. Determination of CD3-CD16/56+ percentage on lymphocytes	**Flow Cytometry** with Flow cytometer Navios (Beckman Coulter)* **Work Instruction: ΟΕ19-2-11 ΑΝΟΣΟΛ (Version 1.2/01-07-2024) & D19-02-EN02 Inserts Ανοσολογικό (Version 1.2/02-09-2024)**
HLA DNA Typing		
Whole Blood (EDTA)	HLA class II DNA typing of two (2) HLA genes (Low resolution): 1. HLA-DRB 2. HLA-DQB	**PCR with Sequence Specific Primers (PCR-SSP)** **Work Instruction: ΟΕ19-2-12 ΑΝΟΣΟΛ (Version 1.1/10-07-2024) & D19-02-EN02 Inserts Ανοσολογικό (Version 1.2/02-09-2024)**
Molecular Tests		
Whole Blood (EDTA)	FMF, Familial Mediterranean Fever Detection of 12 genetic variations of the *MEFV* gene: 1. E148Q 2. P369S 3. F479L 4. M680I (G >C) 5. M680I (G >A) 6. I692 del 7. M694V 8. M694I 9. K695R 10. V726A 11. A744S, 12. R761H	**PCR Techne Prime και VIENNA LAB TEST KIT - FMF StripAssays® CE IVD kit από Vienna Lab Diagnostics:** **Work Instruction: Ο19-2_ΜΟΝΑΔΑ ΓΕΝΕΤΙΚΗΣ (Version 1.1/02-09-2024) & D19-02-EN02 Inserts Γενετική (Version 1.0/20-12-2021)**

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
Whole Blood (EDTA)	Qualitative detection of the V617F genetic variation of the *JAK2* gene	**NanoDrop 2000 spectrophotometer** **Qiagen- Rotor-Gene Q MDx** **JAK-2 REAL TIME PCR KIT**, SNP Biotechnology, Cat. No: 21R-10-01 **Work Instruction: O19-3_ΜΓ (Version 1.1/02-09-2024)**
Whole Blood (EDTA)	Detection of the ΔF508 genetic variation of the *CFTR* gene	**NanoDrop 2000 spectrophotometer** **Qiagen- Rotor-Gene Q MDx** **CYSTIC FIBROSIS (CF) DELTA F508 REAL TIME PCR KIT**, SNP Biotechnology, Cat. No: 14R-10-01 **Work Instruction: O19-4_ΜΓ (Version 1.1/02-09-2024)**
Blood coagulation Tests		
Blood plasma (Citrate)	**Determination of 3 parameters**	**Automatic Analyzers** **STAGO STAR MAX 3 (x1) and STA COMPACT (x1) *** **Work Instruction: O19-2-3_ΑΙΜΑΤΟΛΟΓΙΚΟ (Version 1.3/20-04-2023) & D19-02-EN02 Inserts Αιματολογικό (Version 1.1/02-09-2024)**
	1. Prothrombin Time (PT)/INR	Clotting assay (Chronometric)
	2. Activated partial thromboplastin time (APTT)	Clotting assay (Chronometric)
	3. D-Dimer	Immunosymmetric

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

Site of assessment: **Laboratory Permanent premises, Agiou Pavlou 76, Municipality of Pavlou Mela, Prefecture of N. Efkarpia, PC 56429, Thessaloniki, Greece.**
Site of primary sample collection: **Hospital premises, Agiou Pavlou 76, Municipality of Pavlou Mela, Prefecture of N. Efkarpia, PC 56429, Thessaloniki, Greece.**
Approved signatories:

- **For Transfusion and Hematology Department: Dr. Anna Kioumi, Maria Topalidou, Kiriaki Kokoviadou, Anastasia Banti, Chrisa Apostolou, Vasiliki Kalaitzidou, Athanasios Anastasiadis, Christiana Parisi, Maria-Eirini Efstratiadou, Georgia Papaioannou, Anna Xanthopoulou.**
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- **For Immunology – Histocompatibility Laboratory: Dr. Anastasia Giannakou, Maria Mpantadaki, Stiliani lliadou, Dr Panagiota Lazidou, Dr Alexandra Fleva.**
- **For Genetic Unit: Associate Prof. Anthoula Chatzikyriakidou, Dr Sokratis Katafigiotis.**

This scope of Accreditation replaces the previous one dated 08.07.2024.
The Accreditation Certificate No.**1211-2**, to ELOT EN ISO 15189:2022, is valid until 12.07.2029.

Athens, 13th December 2024

Konstantinos Kourtalis
Chairman of ESYD