Hellenic Accreditation System

Annex G1/2 to the Certificate No. **1358**-2

SCOPE of ACCREDITATION

of the

Departments: Hematology, Immunology - Histocompatibility, Biopathlogy, Biochemistry - Laboratory of Biological Chemistry NKUA, Cytopathology, Hospital Blood Transfusion Service, 1st Department of Pathology NKUA

of the

Laboratories Division

and the

Laboratory of Thalassemia Unit (Prevention - Screening and Genetics-Cystic Fibrosis)

of the

Interdivisional Departments / Units

of the

General Hospital of Athens "LAIKO"

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
Biochemical Tests		
Blood serum	**Determination of 7 parameters**	**Automated Biochemistry Analyzers Roche Cobas c702 (Cobas 8000) 1 (s/n 16 H5 - 07), 2 (s/n 16 J1 - 02) & 3 (s/n 18 W4 - 07)***
	1. Glucose	Reference Enzymatic method with hexokinase (GLUC3 Glucose HK 3rd generation 0105168791190c701.V11)
	2. Urea	Kinetic test with urease and glutamate dehydrogenase (UREAL Urea/BUN 0105171873190c701.V11)
	3. Creatinine	Enzymatic method (CREP2 Method of determination

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
		Creatinine plus ver.2 0105168589190c701CE0123.V14)
	4. Aspartate Aminotransferase (AST)	IFCC method without pyridoxal phosphate activation (AST Aspartate Aminotransferase acc. to IFCC without pyridoxal phosphate activation 0005850819190c701.V9)
	5. Alanine Aminotransferase (ALT)	IFCC method without pyridoxal phosphate activation (ALT Alanine Aminotransferase acc. to IFCC without pyridoxal phosphate activation 05850797500.V10)
	6. γ-Glutamyltransferase (γGT)	Enzymatic colorimetric method (GGT-2 γ-Glutamyltransferase ver.2 - Standardized against IFCC / Szasz 0005168775190c701.V8)
	7. Uric Acid	Enzymatic colorimetric method (UA2 Uric Acid ver.2 05171857500.V13)
Immunochemical Microbiological Tests		
Blood serum	**Determination of 6 parameters**	**Automated Immunochemistry Analyzer DIASORIN LIAISON XL*** **Work Instruction: OE.M.05 (version 1.2 / 25.11.2022) & OE.M.-EN02 Biopathology Inserts (version 1.1/ 17.12.2024)**
	Determination of the antibodies against the herpesviruses Herpes simplex virus 1 και 2 (HSV-1/2) 1. IgM HSV-1/2 2. IgG HSV-1/2	Chemiluminescence (CLIA)
	Determination of the antibodies against the herpesvirus Human Herpes Virus-3 (HHV-3) ή Varicella-Zoster virus (VZV) 3. IgM VZV 4. IgG VZV	Chemiluminescence (CLIA)
	Determination of the antibodies against the Human Herpes Virus-4 or Epstein-Barr virus (Epstein-Barr virus, EBV ή Human Herpesvirus-4, HHV-4) 5. IgM VCA EBV 6. IgG VCA EBV	Chemiluminescence (CLIA)

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
Hematological Tests		
Whole Blood (EDTA)	**Determination of 22 parameters**	**Automated Hematology Analyzer Sysmex XN 10 (s/n 39021)*** **Work Instruction: OE.M.06 (version 1.3 / 10.06.2024) & OE.M.-EN02 Hematology Inserts (version 1.1 / 17.12.2024)**
	1. White blood cells (WBC)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	2. Red blood cells (RBC)	Flow cytometry with hydrodynamic focusing and impedance variation.
	3. Hemoglobin (HB)	Absorption Spectrophotometry
	4. Hematocrit (HCT)	Calculated method
	5. Mean corpuscular volume (MCV)	Flow cytometry with hydrodynamic focusing and impedance variation.
	6. Mean corpuscular hemoglobin (MCH)	Calculated method
	7. Mean corpuscular hemoglobin concentration (MCHC)	Calculated method
	8. Platelets (PLT)	Flow cytometry with hydrodynamic focusing and impedance variation.
	9. Neutrophils Polymorphonuclear % (NEUTR%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	10. Neutrophils Polymorphonuclear # (NEUTR#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	11. Lymphocytes % (LYMPH%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	12. Lymphocytes # (LYMPH#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	13. Monocytes % (MONO%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	14. Monocytes # (MONO#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	15. Eosinophils Polymorphonuclear % (EO%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	16. Eosinophils Polymorphonuclear # (EO#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	17. Basophils Polymorphonuclear % (BASO%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	18. Basophils Polymorphonuclear # (BASO#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	19. Immature Granulocytes % (IG%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
	20. Immature Granulocytes # (IG#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	21. Nucleated Red blood cells % (NRBC%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	22. Nucleated Red blood cells # (NRBC#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
Whole Blood (EDTA)	**Determination of 23 parameters**	**Automated Hematology Analyzers Sysmex XN 10 (s/n 39022) and Sysmex XN 20 (s/n 14566)*** **Work Instruction: OE.M.06 (version 1.3 / 10.06.2024) & OE.M.-EN02 Hematology Inserts (version 1.1 / 17.12.2024)**
	1. White blood cells (WBC)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	2. Red blood cells (RBC)	Flow cytometry with hydrodynamic focusing and impedance variation.
	3. Hemoglobin (HB)	Absorption Spectrophotometry
	4. Hematocrit (HCT)	Calculated method
	5. Mean corpuscular volume (MCV)	Flow cytometry with hydrodynamic focusing and impedance variation.
	6. Mean corpuscular hemoglobin (MCH)	Calculated method
	7. Mean corpuscular hemoglobin concentration (MCHC)	Calculated method
	8. Platelets (PLT)	Flow cytometry with hydrodynamic focusing and impedance variation.
	9. Reticulocytes (RET% and RET #)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	10. Neutrophils Polymorphonuclear % (NEUTR%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	11. Neutrophils Polymorphonuclear # (NEUTR#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	12. Lymphocytes % (LYMPH%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	13. Lymphocytes # (LYMPH#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	14. Monocytes % (MONO%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	15. Monocytes # (MONO#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	16. Eosinophils Polymorphonuclear % (EO%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	17. Eosinophils Polymorphonuclear # (EO#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
	18. Basophils Polymorphonuclear % (BASO%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	19. Basophils Polymorphonuclear # (BASO#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	20. Immature Granulocytes % (IG%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	21. Immature Granulocytes # (IG#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	22. Nucleated Red blood cells % (NRBC%)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
	23. Nucleated Red blood cells # (NRBC#)	Flow cytometry with hydrodynamic focusing using a semiconductor Laser
Whole Blood (EDTA)	**Determination of 1 parameter**	**Automated Analyzer Roche Cobas Integra 400*** **Work Instruction: OE.M.07 (version 1.3 / 10.06.2024) & OE.M.-EN02 Hematology Inserts (version 1.1 / 17.12.2024)**
	1. Glycated hemoglobin (HB A1C)	Turbidity Inhibition Immunoassay (TINIA)
Whole Blood (EDTA)	**Determination of 1 parameter**	**Automated Analyzer Bio-Rad VARIANT II Hemoglobin Testing System*** **Work Instruction: ΔΓΕ02 (version 1.2 / 14.10.2024) & OE.M.-EN02 MMA-Prevention Inserts (version 1.0 / 22.11.2022)**
	1. Hemoglobin electrophoresis (HbA2)	High Performance Liquid Chromatography HPLC
Whole Blood (EDTA)	**Determination of 9 parameters**	**Automated Hematology Analyzer Sysmex XN-1000 (s/n 47527)*** **Work Instruction: ΔΓΕ02 (version 1.2 / 14.10.2024) & OE.M.-EN02 MMA-Prevention Inserts (version 1.0 / 22.11.2022)**
	1. White blood cells (WBC)	Flow cytometry with light scatter and fluorescence
	2. Red blood cells (RBC)	Flow cytometry with hydrodynamic focusing and impedance variation.
	3. Hemoglobin (HB)	Absorption Spectrophotometry
	4. Hematocrit (HCT)	Calculated method
	5. Mean corpuscular volume (MCV)	Flow cytometry with hydrodynamic focusing and impedance variation.
	6. Mean corpuscular hemoglobin (MCH)	Calculated method
	7. Mean corpuscular hemoglobin concentration (MCHC)	Calculated method

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
	8. Platelets (PLT)	Flow cytometry with hydrodynamic focusing and impedance variation.
	9. Reticulocytes (RET% and RET #)	Flow cytometry with light scatter and fluorescence
Hemostasis Tests		
Blood plasma (Sodium Citrate)	**Determination of 2 parameters**	**Automated Coagulation Analyzers Siemens CS 2500 (s/n 23993 and s/n 23995)*** **Work Instruction: OE.M.08 (version 1.3 / 10.06.2024) & OE.M.-EN02 Hematology Inserts (version 1.1 / 17.12.2024)**
	1. Prothrombin time (PT sec)	Coagulometric (Measurement of fibrin clot formation time)
	2. Prothrombin time international normalized ratio (INR)	Coagulometric (Measurement of fibrin clot formation time)
Immunohematology Tests		
Whole Blood (EDTA)	1. Blood Group (ABO-RhD) (forward)	Column Agglutination Technology. (C.A.T.), Analyzers: ORTHO AutoVue Innova 1 (s/n 4572) & 2 (s/n 3524)* **Work Instruction: OE.M.13 (version 1.1 / 30.09.2022) & OE.M.-EN02 Blood Center - Blood Group Inserts (version 1.0 / 22.11.2022)**
	2. Blood Group (ABO-RhD) (forward)	Agglutination in spot plate with antisera Anti-A1/Anti-A/Anti-B/Anti-AB/Anti-D Immunodiagnostika Gmbh* and Anti-D/Anti-A BIOSCOT* (manual) **Work Instruction: OE.M.13-4 (version 1.0 / 24.08.2022) & OE.M.-EN02 Blood Center - Blood Group Inserts (version 1.0 / 22.11.2022)**
	3. Phenotype Rhesus (C, c, E, e), Kell	Column Agglutination Technology. (C.A.T.), Analyzers: ORTHO AutoVue Innova 1 (s/n 4572) & 2 (s/n 3524)* **Work Instruction: OE.M.13 (version 1.1 / 30.09.2022) & OE.M.-EN02 Blood Center - Blood Group Inserts (version 1.0 / 22.11.2022)**
	4. Phenotype Rhesus (C, c, E, e), Kell	Agglutination in spot plate with antisera Anti-C/Anti-c/Anti-E/Anti-e Immunodiagnostika Gmbh* (manual)

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
		Work Instruction: OE.M.13-4 (version 1.0 / 24.08.2022) & OE.M.-EN02 Blood Center - Blood Group Inserts (version 1.0 / 22.11.2022)
Whole Blood (EDTA), Serum or Blood plasma (EDTA)	5. Blood Group (ABO) (Reverse)	Column Agglutination Technology. (C.A.T.), Analyzers: ORTHO AutoVue Innova 1 (s/n 4572) & 2 (s/n 3524)* **Work Instruction: OE.M.13 (version 1.1 / 30.09.2022) & OE.M.-EN02 Blood Center - Blood Group Inserts (version 1.0 / 22.11.2022)**
	6. Blood Group (ABO) (Reverse)	Agglutination in spot plate with red cell suspension Affirmagen Ortho Clinical Diagnostics* or pooled red cells suspension from blood units group A and B (manual) **Work Instruction: OE.M.13-4 (version 1.0 / 24.08.2022) & OE.M.-EN02 Blood Center - Blood Group Inserts (version 1.0 / 22.11.2022)**
Humoral Immune Response Tests		
Blood serum	**Determination of 5 parameters**	**Automated Nephelometry Analyzer Siemens BNII (s/n 214694)*** **Work Instruction: OE.M.15 (version 1.0 / 11.03.2022) & OE.M.16 (version 1.0 / 11.03.2022) & OE.M.-EN02 Immunology Inserts (version 1.1 / 17.12.2024)**
	Quantitative determination of Immunoglobulins: 1. IgG 2. IgA 3. IgM	Nephelometry
	Quantitative determination of Complement Factors: 4. C3 5. C4	Nephelometry
Blood serum	**Determination of 1 parameter**	**The HelMed® System, AESCU SYSTEMS (s/n 09-03-0019)* and Fluorescence Microscope AXIOPLAN – Zeiss (s/n 451887)*** **Work Instruction: OE.M.18 (version 1.1 / 24.10.2022) & OE.M.-EN02 Immunology Inserts (version 1.1 / 17.12.2024)**

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
	1. Determination of Antinuclear Autoantibodies (ANA) with the use of Hep-2 Cells	Indirect Immunofluorescence
Blood serum and CSF	**Determination of 1 parameter**	**Electrophoresis instrument Hydrasys Focusing – SEBIA (s/n 5985)*** **Work Instruction: OE.M.19 (version 1.1 / 10.03.2024) & OE.M.-EN02 Immunology Inserts (version 1.1 / 17.12.2024)**
	1. Oligoclonal bands of IgG Immunoglobulins in serum and CSF	Isoelectrofocusing and Immunofixation
Immunohematology Flow Cytometry Tests		
Whole Blood (EDTA) or / and Apheresis product (EDTA)	**Determination of 1 parameter**	**Flow Cytometer BD Biosciences FACSCanto™ II (s/n V33896202327)*** **Work Instruction: OE.M.17 (version 1.2 / 25.11.2022) & OE.M.-EN02 Immunology Inserts (version 1.1 / 17.12.2024)**
	1. Determination of the absolute number and the percentage of viable CD34+ Hematopoetic Progenitor Cells	Flow Cytometry
Molecular Microbiology Tests		
Nasopharyngeal swab, Oropharyngeal swab	1. Quantitative detection of SARS-CoV-2 RNA, gene RdRp	Manufacturer's method, Quantitative Real Time Reverse Transcriptase Polymerase Chain Reaction (qRT-PCR) (SARS-CoV-2 ELITe MGB® Kit CE IVD) with the use of the automated thermal cycler instruments ELITe InGenius®, 500 TH SERIES (ELITech Group, Molecular Diagnostics, France) (s/n 2071906B0430E and s/n 2072011B0755E)* **Work Instruction: OE.M.04 (version 1.1 / 21.03.2022) & OE.M.-EN02 Biopathology Inserts (version 1.1 / 17.12.2024)**
Blood plasma (EDTA)	2. Quantitative detection of human herpesvirus-5 or human cytomegalovirus DNA (HCMV DNA).	Manufacturer's method, Quantitative Real Time Polymerase Chain Reaction (qPCR) (CMV ELITe MGB® Kit CE IVD) with the use of the automated thermal cycler instruments ELITe InGenius®, 500 TH SERIES (ELITech Group, Molecular Diagnostics, France) (s/n 2071906B0430E and s/n 2072011B0755E)* **Work Instruction: OE.M.02 (version 1.1 / 21.03.2022) & OE.M.-EN02 Biopathology Inserts (version 1.1 /**

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
		17.12.2024)
	3. Quantitative detection of human herpesvirus-4 or Epstein Barr virus DNA (EBV DNA).	Manufacturer's method, Quantitative Real Time Polymerase Chain Reaction (qPCR) (EBV ELITe MGB® Kit CE IVD) with the use of the automated thermal cycler instrument ELITe InGenius®, 500 TH SERIES (ELITech Group, Molecular Diagnostics, France) (s/n 2071906B0430E)* **Work Instruction: OE.M.03 (version 1.1 / 21.03.2022) & OE.M.-EN02 Biopathology Inserts (version 1.1 / 17.12.2024)**
Thrombophilia Molecular Screening Tests		
Whole blood (EDTA)	Detection of Thrombosis-related mutations within the following genes: 1. FV G1691 (Leiden), 2. FII 20210 3. MTHFR C677T, 4. MTHFR A1298C	Manufacturer's method, End Point Polymerase Chain Reaction (EP-PCR) (Kit: Thrombotype plusV.3 CE IVD) using the Labcycler Basic SensoQuest (s/n 1133210167)* and Hybridization procedure using the automated system GT-BLOT 48 (S/N 1862-3)*. Automated DNA extraction using the XTR1 MagLEAD 12GC System (s/n 12C010B0416)*. **Work Instruction: OE.M.14 (version 1.4/18.04.2024) & OE.M.-EN02 Blood Center-Thrombophilia Inserts (version 1.0 / 22.11.2022)**
Molecular Genetics Tests		
Whole blood (EDTA), Amniotic fluid, Chorionic villi	1. Identification of pathogenic variants of β globin gene: 1. CD6 A>T HbS (HBB:c.20A>T) 2. IVSI-110 G>A (HBB:c.93-21G>A) 3. CD39 C>T (HBB:c.118C>T) 4. IVSI-1 G>A (HBB:c.92+1G>A) 5. IVSI-6 T>C (HBB:c.92+6T>C) 6. IVSII-745 C>G (HBB:c.316-106C>G)	In House Method of Melting Curve Genotyping Analysis with labeled probes (LightCycler 480 Genotyping Master and LightSNiP Probes) using the Roche Light Cycler 480II Real Time thermal cycler (s/n 26293 & s/n 34997)*. Automated DNA extraction using the Maxwell RSC PROMEGA System (S/N 10002899)*. **Work Instruction: ΔΓΕ01-01 (version 1.3 / 17.12.2024) & ΔΓΕ01-02 (version 1.2 / 17.12.2024) & ΔΓΕ01-03 (version 1.2 / 17.12.2024) & ΔΓΕ01-04 (version 1.2 / 17.12.2024)**
	2. Detection of pathogenic variants of β globin gene. Indicatively, the following pathogenic variants which cover	In House Method of High Resolution Melting Analysis (LightCycler 480 High Resolution Melting Master and synthetic

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
	approximately 93% of the variants found in the Greek population, are mentioned: 1. IVSI-110 G>A (HBB:c.93-21G>A) 2. CD39 C>T (HBB:c.118C>T) 3. IVSI-1 G>A (HBB:c.92+1G>A) 4. IVSI-6 T>C (HBB:c.92+6T>C) 5. CD6 A>T HbS (HBB:c.20A>T) 6. IVSII-745 C>G (HBB:c.316-106C>G) 7. CD6(-A) (HBB:c.20delA) 8. PolyA A>G (HBB:c.*111A>G) 9. -101 C>T (HBB:c.-151C>T) 10. +1480 C>G (HBB:c.*6C>G)	oligonucleotides) using the Roche Light Cycler 480II Real Time thermal cycler (s/n 26293 & s/n 34997)*. Automated DNA extraction using the Maxwell RSC PROMEGA System (S/N 10002899)*. **Work Instruction: ΔΓΕ01-01 (version 1.3 / 17.12.2024) & ΔΓΕ01-02 (version 1.2 / 17.12.2024) & ΔΓΕ01-03 (version 1.2 / 17.12.2024) & ΔΓΕ01-04 (version 1.2 / 17.12.2024)**
	3. Detection of the pathogenic variant F508del, p.Phe508del [c.1521_1523delCTT] of CFTR gene	In House Method of Melting Curve Genotyping Analysis with labeled probe (LightCycler 480 Genotyping Master και LightSNiP Probe) using the Roche Light Cycler 480II Real Time thermal cycler (s/n 26293 & s/n 34997)*. Automated DNA extraction using the Maxwell RSC PROMEGA System (S/N 10002899)*. **Work Instruction: ΔΓΕ01-01 (version 1.3 / 17.12.2024) & ΔΓΕ01-02 (version 1.2 / 17.12.2024) & ΔΓΕ01-03 (version 1.2 / 17.12.2024) & ΔΓΕ01-04 (version 1.2 / 17.12.2024)**
	4. Detection of pathogenic variants located on exons 2, 3, 4, 5, 6a, 6b, 7, 10, 11, 12, 13, 14a, 14b, 15, 16, 17a, 17b, 19, 20, 21 (legacy name) of CFTR gene. Indicatively, the three most frequently pathogenic variants of Greek population are mentioned 1. 621+1G→T, c.489+1 G>T 2. N1303K, p.Asn1303Lys [c.3909C>G] 3. G542X, p.Gly542* [c.1624G>T]	In House Method of High Resolution Melting Analysis (LightCycler 480 High Resolution Melting Master and synthetic oligonucleotides) using the Roche Light Cycler 480II Real Time thermal cycler (s/n 26293 & s/n 34997)*. Automated DNA extraction using the Maxwell RSC PROMEGA System (S/N 10002899)*. **Work Instruction: ΔΓΕ01-01 (version 1.3 / 17.12.2024) & ΔΓΕ01-02 (version 1.2 / 17.12.2024) & ΔΓΕ01-03 (version 1.2 / 17.12.2024) & ΔΓΕ01-04 (version 1.2 / 17.12.2024)**
Cytology Tests		
Cervicovaginal smear (Pap test) by conventional cytology	1. Microscopic evaluation and assessment of cervicovaginal smear, in order to detect lesions with abnormal features, aiming to the early diagnosis of neoplastic and other special	Qualitative method 1. Papanicolaou stain (automated staining machine SLEE Cromatec)*

Tested materials / products	Types of tests / Properties to be measured	Applied Methods / Techniques to be used
	diseases.	2. Microscopic evaluation (microscopes ZEISS AXIOSKOP 2 PLUS, ZEISS AXIOSKOP 40, ZEISS AXIOLAB and two OLYMPUS BX)* 3. Classification according to BETHESDA 2014* **Work Instruction: OE.M.01 (version 1.2 / 23.05.2024) & OE.M.-EN02 Inserts Cytology (version 1.1 / 17.12.2024)**
Cervicovaginal smear (Pap test) by liquid phase cytology technique (Thinprep)	2. Microscopic evaluation and assessment of cervicovaginal smear, in order to detect lesions with abnormal features, aiming to the early diagnosis of neoplastic and other special diseases.	Qualitative method 1. Papanicolaou stain (automated staining machine SLEE Cromatec)* 2. Liquid based cytology preparation machine Thinprep2000, Hologic* 3. Microscopic evaluation (microscopes ZEISS AXIOSKOP 2 PLUS, ZEISS AXIOSKOP 40, ZEISS AXIOLAB and two OLYMPUS BX)* 4. Classification according to BETHESDA 2014* **Work Instruction: OE.M.01 (version 1.2 / 23.05.2024) & OE.M.-EN02 Inserts Cytology (version 1.1 / 17.12.2024)**
Pathology Tests		
Histological Tests		
Biopsies and surgical specimens from all organs and systems Fresh tissue, Formalin Fixed Paraffin Embedded Tissue (FFPE)	1. Tissue gross and microscopical examination for the detection or / and exclusion of possible morphological and cellular lesions.	**Gross and microscopical observation** *PROPATH* Table for tissue and organ gross examination and processing, as well as tissue sampling. *DIAPATH Donatello™ Series 2* Automatic tissue processor. *Epredia HistoStar* Paraffin embedding system. *SLEE CUT5062* Microtome for tissue sectioning. *Thermo Scientific Microm HM340E* Microtome for tissue sectioning. *DAKO COVERSTAINER (s/n CS100-11118)* Automated slide hematoxylin-eosin stainer.

<table>
<tr><th>Tested materials / products</th><th>Types of tests / Properties to be measured</th><th>Applied Methods / Techniques to be used</th></tr>
<tr><td></td><td></td><td><u>Epredia CTM6</u>
Automated coverslipper.
<u>NIKON ECLIPSE 50i, E200, 80i και OLYMPUS BX40, BH2, CX21, CX41, BX51</u>
Microscopes for the microscopical observation of slides stained with hematoxylin-eosin and immunohistochemical markers.
Work Instruction: OE.M.10 (version 1.3 / 11.06.2024)</td></tr>
<tr><td colspan="3">Histochemical Tests</td></tr>
<tr><td>Biopsies and surgical specimens from all organs and systems
Formalin Fixed Paraffin Embedded Tissue (FFPE)</td><td>2. Hematoxylin-eosin staining</td><td>Microscopical examination of tissue and cell morphology, followed by staining with hematoxylin (nuclei) and eosin (cytoplasm).
Hematoxylin H (BIOGNOST) Eosin-Y (BIOGNOST).
Work Instruction: OE.M.10 (version 1.3 / 11.06.2024)</td></tr>
<tr><td colspan="3">Immunohistochemical Tests</td></tr>
<tr><td>Biopsies and surgical specimens from all organs and systems
Formalin Fixed Paraffin Embedded Tissue (FFPE)</td><td>3. Nuclear, cytoplasmic or membranous expression of chromogen-labelled cellular antigens (proteins)
<table><tr><td>Cytokeratin 7</td><td>Urothelium – respiratory type epithelium and carcinomas of the respiratory system – epithelium and carcinomas of bile ducts/pancreas and ducts of the mammary gland</td></tr><tr><td>Cytokeratin 20</td><td>Urothelium (κύτταρα cells), intestinal epithelium</td></tr><tr><td>Calretinin</td><td>Mesothelial cells, malignant mesothelioma, nerve ganglia</td></tr><tr><td>ERG</td><td>Endothelial cells, lymphocytes and prostate cancer cells</td></tr><tr><td>PGR</td><td>Percentage of progesterone expression in breast</td></tr></table></td><td>Automated method.
Immunohistochemical method by using detection systems for:
- LEICA BIOSYSTEMS BOND-III* (BOND-01 s/n 3211666 & BOND-03 s/n 3211779)
- LEICA BOND-MAX* (s/n M496457)
- ASPlus DAKO* (s/n DC3400-7377R-03)
and specific antibodies.
Microscopical observation and evaluation – interpretation of the results.
ANTIBODIES
• Actin Smooth Muscle (clone 1A4 – DAKO)
• AMACR/p504s (clone 13H4 – DAKO)
• Bcl-2 (clone 124 – DAKO)
• Bcl-6 (clone LN22 – Leica)
• c-erbB-2/HER2 (polyclonal – DAKO)
• CD3 (clone LN10 – Leica)
• CD4 (clone 4B12 – DAKO)</td></tr>
</table>

Tested materials / products	Types of tests / Properties to be measured		Applied Methods / Techniques to be used
		carcinoma	• CD5 (clone 4C7 – DAKO) • CD8 (clone C8/144B – DAKO) • CD10 (clone 56C6 – DAKO) • CD15 (clone Carb-3 – DAKO) • CD20 (clone L26 – DAKO) • CD23 (clone 1B12 – Leica) • CD30 (clone Ber-H2 – DAKO) • CD31 (clone JC70 – Cell Marque) • CD34 (clone QBEnd10 – DAKO) • CD79a (clone JCB117 – DAKO) • CD138 (clone MI15 – DAKO) • Cytokeratin 7 (clone OV-TL 12/30 – DAKO) • Cytokeratin 20 (clone Ks20.8 – DAKO) • Desmin (clone D33 – DAKO) • E-Cadherin (clone NCH-38 – DAKO) • ERG (clone EP111 – DAKO) • Estrogen Receptor Alpha (clone EP1 – DAKO) • Glial Fibrillary Acidic Protein (clone 6F2 – DAKO) • Kappa Light Chains (clone L1C1 – Cell Marque) • Ki-67 (clone MIB-1 – DAKO) • Lambda Light Chains (clone Lamb14 – Cell Marque) • MDM2 (clone SMP14 – Zeta Corporation) • MUM1 (clone MUM1p – DAKO) • p53 Protein (clone DO-7 – DAKO) • p63 Protein (clone 4A4 – BIOCARE MEDICAL) • PAX-5 (clone DAK-PAX5 – DAKO) • Progesterone Receptor (clone PgR636 – DAKO) • S100 (clone 4C4.9 – Epredia) • WT1 Protein (clone 6F-H2 – DAKO)
	MUM-1 (Multiple Myeloma Oncogene 1)	Plasma cells, multiple myeloma	
	CD138	Plasma cellss, B-lymphocytes, lymphomas	
	HER2	Percentage of the ERBB2 receptor expression in breast carcinoma	
	Ki-67 (MIB-1)	Assessment of the mitotic activity percentage of the tumor under examination	
	CD4	T-lymphocytes, monocytes, macrophages. Specific lymphoma subtypes	
	CD8	Cytotoxic T-lymphocytes, lymphoma subtypes	
	CD30	Immunoblasts, centroblasts, Hodgkin disease, anaplastic lymphomas, neoplasms of stem cells	
	P63	Myoepithelial and basal cells	
	CD34	Normal endothelial cells, angiosarcoma, primary dermatofibrosarcoma	
	CD3	Normal T-lymphocytes, T-lymphomas	
	CD5	Normal T-lymphocytes, lymphomas of T-cell line, thymic carcinoma	
	CD20	Normal B lymphocytes, majority of B cell line lymphomas	
	PAX-5	Normal B lymphocytes, Reed-Sternberg cells in Hodgkin disease, lymphoplasmacytic	

Tested materials / products	Types of tests / Properties to be measured		Applied Methods / Techniques to be used
		lymphoma	• Cytokeratin (clone MNF116 – DAKO) • Calretinin (clone DAK-Calret – DAKO) **Work Instruction: OE.M.10 (version 1.3 / 11.06.2024)**
	Actin Smooth Muscle	Myofibroblasts and myoepithelium, leiomyomas	
	AMACR (p504s)	Prostate adenocarcinoma	
	Bcl 2	Follicular lymphoma	
	Bcl 6	Follicular lymphoma, diffuse large B cell lymphoma, Burkitt lymphoma	
	CD10	Acute lymphoblastic leukemia, follicular lymphoma, Burkitt lymphoma, differential diagnosis of endometrial stromal sarcoma from uterine leiomyoma and leiomyosarcoma	
	CD15	Reed-Sternberg cells, Hodgkin disease	
	CD23	EBV-infected B-lymphoblasts, chronic lymphocytic leukemia	
	CD31	Endothelial cells, vascular origin of neoplasms	
	CD79α	Acute leukemias derived from progenitor B-cells, B-cell lymphomas	
	Desmin	Smooth muscle cells, rabdomyomas, rabdomyosarcomas, leiomyomas, leiomyosarcomas	
	E-Cadherin	Distinction between lobular and ductal breast carcinoma	
	Estrogen Receptor Alpha	Percentage of estrogen receptor expression in breast carcinomas	
	GFAP (Glial Fibrillary Acidic	Astrocytomas and ependymal cells of	

Tested materials / products	Types of tests / Properties to be measured		Applied Methods / Techniques to be used
	Protein)	the central nervous system	
	Kappa Light Chains	Kappa light chain expressing plasma cells	
	Lambda Light Chains	Lambda light chain expressing plasma cells	
	MDM2	Soft tissue sarcomas, osteosarcomas, brain tumors	
	p53 Protein	Classification of tumors derived from every cell line	
	S100	Tumors derived from Schwann cells, melanomas	
	(WT1) Protein	Wilms tumors, mesotheliomas	
	Pankeratin (MNF116)	Classification of neoplasms derived from epithelial lineage	

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

Site of assessment: **Laboratory Permanent premises:**

1. **17, Aghiou Thoma Str., 115 27, Athens, Greece (Building K),**
2. **16, Sevastoupoleos Str., 115 26, Athens, Greece (Building Π)**
3. **75, Mikras Asias Str., 115 27, Athens, Greece (Building 10, Medical School NKUA).**

Primary Sample Collection: **Laboratory Permanent premises:**

1. **17, Aghiou Thoma Str., 115 27, Athens, Greece (Building K),**
2. **16, Sevastoupoleos Str., 115 26, Athens, Greece (Building Π)**

Approved signatories:

- **For the Haematology Department: Prof. Dr. Aggeliki Papapanagiotou, Maria Katerini, Dimitra-Theodora Adamou, Anastasia Rigatou, Aikaterini Kourioti, Antigoni Papantoniou, Zacharias Tsakris, Anastasios Vogiatzakis, Asimina Lymperi, Aikaterini Papaioannou, Alexandros Papanastasiou, Georgia Hasioti, Kalliopi Sdraka, Thomas Tsarouxis, Dimitroula Zioga, Euthalia Xenou.**
- **For the Immunology-Histocompatibility Department: Nikolitsa Kafasi, Aglaia Dimitrakopoulou, Kalliroi Tsalimalma, Polyxeni Gkasouka, Eleni Lekka, Dimitrios Chronopoulos.**
- **For the Biopathology Department: Stavroula Smilakou, Dr. Efstathios Bekris, Dr. Panagiota Tsioli, Nikolaos Kalabogias.**
- **For the Biochemistry Department - Laboratory of Biological Chemistry NKUA: Prof. Dr. Aggeliki Papapanagiotou, Dr. Panagiotis Kanellopoulos, Anastasia Evagelatou, Maria Malliarou, Anna Koutroubeli, Evaggelia Gelou, Minas Minaidis.**
- **For the Cytopathology Department: Dr. Panagiota Mikou, Panagiota Keramari.**
- **For the Hospital Blood Transfusion Service Department : O. Katsarou, M. Gavalaki, A. Kouramba, G. Kanellopoulou, Th. Adraktas, H. Kalfa, Ch. Frantzeskakis, A. Varaklioti, I.**

Anastasopoulou, E. Zoulia, Z. Moschidis, A. Chanos, Th. Pirpiri, S. Gkotsi, S. Louvrou, A. Papachronis, N. Stavropoulou, M. Pittara, M. Tsivola, M. Gkioka, A. Gkikas, L. Kelaidis, M. Papadimitriou, A. Mousti, A. Tsatsomoirou, Th. Katoglou, M. Polizoidou, E. Psachoulia, A. Sioka, E. Vlachothanasi.

- **For the 1st Department of Pathology NKUA: Prof. Dr. Nikolaos Kavantzas, Prof. Dr. Penelopi Korkolopoulou, Prof. Dr. Andreas Lazaris, Prof. Dr. Stamatios Theocharis, Prof. Dr. Aphroditi Nonni, Prof. Dr. Charikleia Gakiopoulou, Dr. Paraskevi Alexandrou, Evaggelia Louka, Dr. Georgios Liapis, Assist. Prof. Dr. Eirini Thymara, Assist. Prof. Dr. Stratigoula Sakellariou, Assist. Prof. Dr. Eleftheria Lakiotaki, Dr. Anastasios Stofas, Dimitra Karagianni, Assist. Prof. Dr. Athanasia Sepsa.**
- **For the Prevention-Screening Laboratory of the Thalassemia Unit: Maria Dimopoulou, Pagona Flevari, Sevastianos Hatzidavid.**
- **For the Laboratory of Genetics - Cystic Fibrosis of the Thalassemia Unit: Angeliki Balassopoulou, Dr. Effrossini Boutou, Evangelia-Eleni Delaki, Dr. Eleni Yfanti.**

This scope of Accreditation replaces the previous one dated 30.06.2023.
The Accreditation Certificate No.**1358**-2, to ELOT EN ISO 15189:2022, is valid until 29.06.2028.

Athens, 16th of April 2025

Konstantinou Evangelos Apostolos
CEO of ESYD