Hellenic Accreditation System

Annex G1/26 to the Certificate No. **350**-8

SCOPE of ACCREDITATION

of the

Clinical Laboratory

Genotypos

Private Diagnostic Laboratory for Molecular and Cytogenetic Analysis M.S.A.

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Cytogenetics		
Peripheral Blood	1. Karyotype /Detection of congenital chromosome abnormalities	Cell Cultures, Karyotyping/ Chromosome analysis (ECA General Guidelines and Quality Assurance for Cytogenetics 2012, Acquired Cytogenetics 2013 and Cytogenetic Investigations in Tumors 2014)* with CytoVision (LUCIA) * or Lucia Cytogenetics (LUCIA)* *Lab protocols: ΠΚ-01/3/30.06.22, ΠΚ-02/3/30.06.22, ΠΚ-03/3/30.06.22, ΠΚ-04/4/30.06.22, ΠΚ-07/4/30.06.22, ΠΚ-08/3/30.06.22, ΠΚ-09/3/30.06.22, ΠΚ-22/4/30.06.22, ΠΚ-23/2/30.06.22, ΠΚ-24/3/30.06.22, ΠΚ-25/4/30.06.22, ΠΚ-27/2/30.06.22*
Bone Marrow, Peripheral Blood, Surgical Biopsy	1. Karyotype /Detection of acquired chromosome abnormalities	
Molecular Genetics		
Bone Marrow, Peripheral Blood	1. Qualitative detection of fusion gene transcripts: BCR/ABL	Real-Time PCR with the Ipsogen/QIAgen (CE-IVD) kits (BCR-ABL Mbcr, BCR-ABL mbcr, FusionQuant Kits)* on the Rotorgene Q-5Plex* (110). *Lab protocol: ΠΜ-45/08/30.06.25*
	2. Detection of the point mutation V617F in the JAK 2 gene	Real-Time PCR with SNP Biotechnology JAK-2 Real-Time PCR Kit (CE-IVD, SNP Biotechnology) on

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		Rotorgene Q-5Plex* (110, 198) Lab protocol: ΠΜ-111*/04/30.06.25*
Surgical Biopsy, Paraffin-embedded tissues (section), Peripheral Blood	1. Detection of 29 mutations in *EGFR* gene, exons 18-21: exon 18 (G719A, G719C, G719S), exon 19 [E746_A750del (1), E746_A750del (2), L747_P753>S, E746_T751>I, E746_T751del, E746_T751>A, E746_S752>A, E746_S752>V, E746_S752>D, L747_A750>P, L747_T751>Q, L747_E749del, L747_T751del, L747_S752del, L747_A750>P, L747_P753>Q, L747_T751>S, L747_T751del, L747_T751>P], exon 20 (T790M, H773_V774insH, D770_N771insG, V769_D770insASV, S768I), exon 21 (L858R, L861Q)	1. Real-Time PCR with AmoyDx® *EGFR* 29 Mutation Detection Kit (CE-IVD, Amoy Diagnostics Co., Ltd)* on Rotorgene Q-5Plex (198) *Lab protocol: ΠΜ-110/03/30.06.25*
Bone Marrow, Peripheral Blood, Surgical Biopsy	1. Quantitative measurement of transcripts: BCR-ABL-p210	Real-Time PCR with the geneMAP BCR-ABL1 p210 (Mbcr) IS-MMR Detection Kit (CE-IVD, geneMAP) with Real-Time PCR on RotorGene Q-5Plex* (110) *Lab protocol: ΠΜ-45/08/30.06.25*
Peripheral Blood	1. HLA-B27 haplotype detection	In-house method PCR System TC-512 (98, Techne)* *Lab protocol: ΠΜ-75/05/30.06.25*
Paraffin-embedded tissues (section), Surgical Biopsy	1. MSI (Microsatellite Instability) detection	In-house method at PCR ABI| Veriti (126, Applied Biosystems)*, or TC-512 (98, Techne)* CEQ 8000 Genetic Analyzer (Beckman Coulter)* *Lab protocol:* ΠΜ-77/*05/30.06.25*
Peripheral Blood, Buccal Swabs	1. Mutation detection of Factor V (V-Leiden), Prothrombin (Factor II-G20210A), MTHFR (C677T)	Vienna Labs FV-PTH- MTHFR StripAssay *CE-IVD** on PCR GeneAmp 9700 (151, ABI)* or PCR TC-512 (98, Techne)* and hybridization on DynaBlot heat (Dynex)* *Lab protocol: ΠΜ-57/05/30.06.25*
	2. Detection of genetic variants: Prothrombin (G20210A), Factor V (Leiden G1691A, R2 H1299R), MTHFR (C677T, A1298C) Factor XIII (V34L), PAI-1 4G/5G, ApoB (R3500Q), Apo E2/E3/E4, ACE I/D, GPIIIa L339	Vienna Labs CVD *CE-IVD** on PCR GeneAmp 9700 (151, ABI)* or PCR TC-512 (98, Techne)* and hybridization in DynaBlot heat (Dynex)* *Lab protocol: ΠΜ-78/05/30.06.25*

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	(HPA-1), β-Fibrinogen -455 G-A	
Peripheral Blood, Amniotic fluid, Chorionic Villus, Buccal Swabs	1.Mutation detection in the CFTR gene (Cystic Fibrosis)	Automated DNA extraction in QIAcube (QIAGEN)* or non-automated DNA extraction, Devyser CFTR (*CE-IVD)** on PCR TC-512 (247, Techne)* and Next Generation Sequencer (NGS) MiSeq (114, Illumina)*, software SOPHIA DDM* *Lab protocol: ΠΜ-73/03/30.06.25*
Surgical Biopsy, Paraffin-embedded tissues (section), Cell Free DNA	1. Detection of somatic mutations in the genes: *EGFR* (Exons 17-24 SNV/ Indels), *ALK* (Exon 20 SNV/ Indels/ Fusions), *ROS1* (Exon 32/34/35/36 SNV/Indels/ Fusions), *RET* (Exon 8/11/12 SNV/ Indels/Fusions), *KRAS* (Exon 2/3/4 SNV/Indels), *NRAS* (Exon 2/3/4 SNV/Indels), *PIK3CA* (Exon 10/14/21 SNV/Indels), *BRAF* (Exon 15 SNV/Indels), *HER2* (Exon 20 SNV/Indels), *MET* (Intron 14 SNV/Indels)	Non-automated DNA extraction, AmoyDx®Essential NGS Panel (AmoyDx, CE-IVD)* on PCR Biometra (analytikjena)* or Verity (125, Applied Biosystems)* and Next Generation Sequencer (NGS) NextSeq (233, Illumina)*, software SOPHIA DDM* *Lab protocol: ΠΜ-91/03/30.06.25*
Surgical Biopsy, Paraffin-embedded tissues (section), Cell Free DNA, Plasma	1. Detection of somatic and hereditary mutations in the BRCA1 και BRCA2 genes	Automated DNA extraction in QIAcube (QIAGEN)* or non-automated DNA extraction, AmoyDx®BRCA1 and BRCA2 ProPanel Gene Mutation Detection Kit (AmoyDx, CE-IVD)* on PCR Biometra (analytikjena)* or Verity (125, Applied Biosystems)* and Next Generation Sequencer (NGS) NextSeq (233, Illumina)*, software ANDAS* *Lab protocol: ΠΜ-90/03/30.06.25*
Surgical Biopsy, Paraffin-embedded tissues (section)	Detection of somatic gene mutations:: AKT1 (Exon 3,4 SNV/InDel), ALK (Exon 21-25 Fusion/SNV/InDel), BRAF (Exon 11,12, 15, 18 SNV/InDel), CDK4 (CNA), CTNNB1 (Exon 3 SNV/InDel), DDR2 (Exon 5, 8, 13-18 SNV/InDel), DPYD (rs3918290, rs55886062, rs67376798, rs75017182 SNPs), EGFR (Exon 3,7,12,14,18-22 SNV/InDel), ERBB2 (Exon 1-27 SNV/InDel/ CNA),	Non-automated method for isolating genetic material, manufacturer's method AmoyDx® HANDLE Classic NGS Panel (AmoyDx, CE-IVD)* on PCR Biometra (analytikjena)* or on PCR Verity (223, Applied Biosystems)* and a new generation genetic analyzer (NGS)* NextSeq (233, 196 Illumina)*, analysis with software ANDAS*

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	ESR1 (Exon 6,9 SNV/InDel), FGFR1 (Exon 5,6,13,15 Fusion/SNV/InDel), FGFR2 (Exon 3,5-9,12-16,18 Fusion/SNV/InDel), FGFR3 (Exon 3,7-15,17 Fusion/SNV/InDel), FGFR4 (Exon 3,6,9,10,12,13,15,16 SNV/InDel), HRAS (Exon 2-4 SNV/InDel), IDH1 (Exon 4 SNV/InDel), IDH2 (Exon 4 SNV/InDel), KEAP1 (Exon 2-6 SNV/InDel), KIT (Exon 9,11,13,14,17,18 SNV/InDel), KRAS (Exon 2-4 SNV/InDel), MAP2K1 (Exon 2,3,6 SNV/InDel), MET (Exon 3,9,12,14,15,20,21 SNV/InDel/ Exon 14 Skipping/ CNA), MYC (CNA), NFE2L2 (Exon 2 SNV/InDel), NKX2-1 (CNA), NRAS (Exon 2-4 SNV/InDel), NRG1 (Fusion), NTRK1 (Exon 14,15 Fusion/SNV/InDel), NTRK2 (Exon 18,19 Fusion/SNV/InDel), NTRK3 (Exon 16,17 Fusion/SNV/InDel), PDGFRA (Exon 12,14,18 SNV/InDel), PIK3CA (Exon 2,3,5,6,8-10,14,21 SNV/InDel), POLE (Exon 3-14,19 SNV/InDel), PTEN (Whole CDS SNV/InDel), RB1 (Exon 1-27 SNV/InDel), RET (Exon 5,6,8,10,11,13-16 Fusion/SNV/InDel), ROS1 (Exon 36-38,40,41 Fusion/SNV/InDel), STK11 (Exon 1-9 SNV/InDel), TP53 (Exon 2-11 SNV/InDel), UGT1A1 (rs10929302, rs8175347, rs4148323 SNPs), as well as Satellite Instability detection DNA (MSI)	*Lab protocol: ΠΜ-109/3/14.07.23*
Molecular Microbiology		
Peripheral Blood, Plasma, serum	1. Detection and quantification of Hepatitis B viral DNA	Real Time PCR with GeneProof HBV (*CE-IVD)** kit on RotorGene Q-5Plex* (198) *Lab protocol: ΠΜ-49/05/30.06.25*
	2. Detection and quantification of Hepatitis C viral RNA	Real Time RT-PCR with AmpliSens HCV-Monitor-FRT PCR kit (AmpliSens HCV, RUO)* on RotorGene Q-5Plex* (198) Lab protocol: ΠΜ-97/*03/30.06.25*
	3. Detection and quantification of Human Immunodeficiency virus type 1 RNA (HIV-1)	Real Time RT-PCR with AmpliSens HIV-Monitor-FRT PCR kit (AmpliSens HIV, RUO)* on RotorGene Q-5Plex*

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		(198) Lab protocol: ΠΜ-96*/03/30.06.25*
Surgical Biopsy, Cervicovaginal smears, Paraffin-embedded tissues (section), urethral swab, semen	Human papilloma virus (HPV) detection and genotyping [19 high-risk HPV DNA (HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 70, 73, and 82) and 2 low-risk HPV DNA (HPV 6 and 11)]	AmoyDx®Human Papillomavirus (HPV) Genotyping Detection Kit (AmoyDx, CE-IVD)* on CFX96TM Real-Time System (BIORAD 199)* Lab protocol: ΠΜ-88/*03/30.06.25*
Molecular Cytogenetics		
Bone Marrow and Peripheral Blood	Detection of sex and autosomal chromosome aneuploidies	Fluorescence in situ hybridization with DNA probes of unique or repetitive sequences (ECA General Guidelines and Quality Assurance for Cytogenetics 2012, Acquired Cytogenetics 2013 and Cytogenetic Investigations in Tumours 2014)* for localization of nucleic acid sequences in interphase/metaphase cells with Vysis HYBrite (Abbott Diagnostics), CytoVision (LUCIA)* or Lucia Cytogenetics (LUCIA)*. *Lab protocols: ΠΚ-04/4/30.06.22, ΠΚ-03/3/30.06.22, ΠΚ-02/3/30.06.22, ΠΚ-01/3/30.06.22, ΠΚ-05/30.06.22, ΠΚ-06/30.06.22, ΠΚ-07/4/30.06.22, , ΠΚ-08/3/30.06.22, ΠΚ-09/3/30.06.22, ΠΚ-10/3/30.06.22, ΠΚ-26/3/30.06.22, ΠΚ-27/2/30.06.22, ΠΚ-28/2/30.06.22, ΠΚ-29/3/30.06.22, ΠΚ-30/3/30.06.22, ΠΚ-31/2/30.06.22, ΠΚ-32/2/30.06.22, ΠΚ-47/2/30.06.22*
Peripheral Blood, Bone Marrow, Surgical Biopsy, Plasma Cells, Bone Marrow Biopsy, Formalin Fixed Paraffin Embedded tissue sections.	1. Fusion genes/specific translocations [BCR-ABL, ETO(CBFA2T1)-AML1(RUNX1 ή CBFA2), PBX-E2A(TCF3), IGH-CCND1(BCL1), IGH-FGFR3(MMSET), IGH-C-MAF, IGH-MAF-B, IGH-BCL2, IGH-CCND3, IGH-MYC, IGH-MALT1, API2/MALT1, COL1A1-PDGFB]	
	2. Gene rearrangements/translocations with variant partners [IGH, MLL, RARa, BCL6, EGFR1, FGFR1, CBFb, ALK, EWSR1, FKHR, CHOP, SYT, ETV6(TEL), ROS1, RET, FIP1+PDGFRA, PDGFRB, C-MYC]	
	3. Chromosome deletions/Gene losses [1p/19q, 5/5q, 6/6q, 7/7q, 9/9p(p16), 11q(ATM), 13q, 17p(P53), 20q]	
Surgical Biopsy, Formalin Fixed Paraffin Embedded tissue sections, Bone Marrow, Plasma Cells	Gene amplification [Her-2 neu (ERBB2), EGFR, FGFR1, MET, N-MYC, 1q21]	
Flow cytometry		
Bone Marrow and Peripheral Blood	1. Lymphocyte subpopulations analysis (CD3, CD4, CD8, CD16, CD19, CD45, CD56)	Stain-lyse-wash in house protocol (RUO) with BD fluorescent antibodies (CE-IVD) and analysis on a BD FACS CANTOII 8 color cytometer*Lab protocols: Π.ΚΡ-82, 83, 84/4/28.09.22*
Peripheral Blood	1. Erythrocyte, monocyte and neutrophils subpopulations lacking GPI-linked proteins analysis (CD59, CD14, CD24, FLAER) for Paroxysmal Nocturnal Haemoglobinuria diagnosis	Stain-lyse-wash in house protocol (RUO) with BD fluorescent antibodies (ICCS/ESCCA Consensus Guidelines, Cytometry B, 2018)* and analysis on a BD FACS CANTOII 8 color cytometer

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		Lab protocols: ΠΚΡ-86/3/28.09.22

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

Site of assessment: **Laboratory permanent premises: 493 Mesogion Ave., 153 43 Ag. Paraskevi, Athens, Greece (Cytogenetics, Molecular Genetics, Molecular Microbiology, Molecular Cytogenetics) and 4 Ilision Str., 115 28, Athens, Greece (Flow Cytometry).**

Primary Sample Collection: **Laboratory permanent premises: 493 Mesogion Ave., 153 43 Ag. Paraskevi, Athens, Greece.**

Approved signatures: **P. Constantoulakis, G. Christopoulou, K. Karypidis, D. Iakovaki, S. Bournazos, S. Samara, K. Oikonomaki, A. Spathis, P. Pollakis, I. Tsikari, S. Derdas, G. Paraskevopoulos, Ch. Malamaki, D. Avramopoulou, O. Dimou, A. Spring, L. Karantai, A. Vagena.**

This Scope of Accreditation replaces the previous one dated 12.09.2023.
The Accreditation Certificate No. **350**-8, to ELOT EN ISO 15189:2022, is valid until 10.05.2028.

Athens, 5th of August 2025

Konstantinou Evangelos Apostolos
CEO of ESYD