Hellenic Accreditation System

Annex G1/15 to the Certificate No. **621**-6

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

LOCUS MEDICUS S.A.

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Molecular Microbiology		
1. Cervical swabs, thin prep, paraffin embedded tissues	1. Detection and genotyping of human papilloma virus (HPV) [41 types: 6, 11, 16, 18, 26, 31, 33, 34, 35, 39, 40, 42, 43, 44, 45, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 62, 66, 67, 68A, 68B, 69, 70, 72, 73, 81CP8304, 82IS39, 82MM4, 83MM7, 84MM8, 90, 91]	PCR and hybridization using microarray chips Vision Array HPV chip 1.0 CE, IVD (Zytovision). (P.640.46_v1_2023.07.01)
2. Cervical swabs, thin prep, paraffin embedded tissues	1. Detection and genotyping of HPV High Risk-14 types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)	Real Time PCR technique, on a SACACE-SaCycle-96 instrument, according to the kit manufacturer (Sacace Biotechnologies, HPV genotypes Real-TM Quant - CE-IVD) (P.640.31_v3_2019.10.01)
3. Serum, plasma	1. RNA detection of HIV-1 virus	Real Time PCR technique, following reverse transcription, on a SACACE -SaCycle-96 instrument, according to the kit manufacturer (HIV Real-TM Quant Dx, SACACE Biotechnologies) (P.640.25_v3_2019.08.30)
4. Serum, plasma	1. RNA quantification of HIV-1 virus	Real Time PCR technique, following reverse transcription, on a SACACE -SaCycle-96 instrument, according to the kit manufacturer (HIV Real-TM Quant Dx, SACACE Biotechnologies) (P.640.30_v2_2019.08.30)
5. Serum, plasma	1. DNA detection and quantification of Hepatitis B virus	Real Time PCR technique, on a SACACE-SaCycle-96 instrument,

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		according to the kit manufacturer (HBV Real-TM Qual, SACACE Biotechnologies) (P.640.21_v3_2018.03.01 & (P.640.27_v2_2018.03.01)
6. Serum, plasma	1. RNA detection of Hepatitis C virus	Real Time PCR technique, following reverse transcription, on a SACACE -SaCycle-96 instrument, according to the kit manufacturer (HCV Real-TM Qual, SACACE Biotechnologies) (P.640.20_v3_2018.03.01)
7. Serum, plasma	1. RNA quantification of Hepatitis C virus (HCV)	Real Time PCR technique, following reverse transcription, on a SACACE -SaCycle-96 instrument, according to the kit manufacturer (HCV Real-TM Qual, SACACE Biotechnologies) (P.640.29_v2_2018.03.01)
Molecular Genetics		
2. Peripheral blood	1. F508del mutation detection at CFTR gene (Cystic Fibrosis transmembrane conductance regulator)	Real Time PCR technique on a Light Cycler instrument. (LightSNiP CFTR Δ508F, TIB MOLBIOL). (P.640.32_v1_2017.09.01)
3. Peripheral Blood, Bone Marrow	Detection and quantification of mRNA BCR/ABL fusion transcripts	Reverse transcription and Real Time PCR assay according to manufacturer's instructions QIAGEN IPSOGEN BCR-ABL1 IS MMR (P.640.42_v1_2022.10.20)
4. Peripheral Blood, Bone Marrow	Detection of JAK2 gene mutation (V617F)	Real time PCR assay according to manufacturer's instructions kit BIOMOL V617F MUTATION OF THE JAK2 GENE (P.640.43_v1_2022.10.20)
Cytogenetics		
1.Peripheral Blood	1.Karyotype / Detection of constitutional chromosome abnormalities	*In house method* for Cell Culturing. Microscopic Analysis and Karyotyping (P.630.01_v5_2022.09.01)
2.Bone Marrow	1.Karyotype /Detection of acquired chromosome abnormalities	*In house method* for Cell Culturing. Microscopic Analysis and Karyotyping (P.630.03_v4_2022.09.01)
Molecular Cytogenetics		
1. Bone Marrow, Peripheral Blood, Ascetic fluid, Cellular swab	1. Detection of sex and autosomal chromosome aneuploidies	Fluorescence in situ hybridization with DNA probes of unique or repetitive sequences (CE-IVD)

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		according to the international guidelines (ECA Cytogenetic Guidelines and Quality Assurance, Version 2, 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 CytoVision (Applied Imaging). (P.630.06_v2_2022.09.01, P.630.14_v4_2022.09.01 P.630.15_v1_2022.09.01 P.630.16_v1_2022.09.01 P.630.17_v1_2022.09.01 P.630.18_v1_2022.09.01 P.630.19_v1_2023.07.01)
2. Bone Marrow, Peripheral blood, Surgical Biopsy, Formalin Fixed Paraffin Embedded tissue sections, Ascetic fluid, Cellular swab	1. Detection of fusion genes [BCR-ABL1, ETO-AML1, TEL-AML1, PBX1-TCF3, PML-RARA, IGH-CCND1 (BCL1), IGH-FGFR3, IGH-BCL2, BIRC3-MALT1, IGH-MYC, IGH-MAF, CBFB/MYH1, RPN1/MECOM, DEK/NUP214, FIP1L1/PDGFRA, COL1A1-PDGFB, PCM1-JAK2, IGH-MAFB]	Fluorescence in situ hybridization with DNA probes of unique or repetitive sequences (CE-IVD) according to the international guidelines (ECA Cytogenetic Guidelines and Quality Assurance, Version 2, 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 CytoVision (Applied Imaging). (P.630.06_v2_2022.09.01, P.630.08_v2_2022.09.01, P.630.14_v4_2022.09.01 P.630.15_v1_2022.09.01 P.630.16_v1_2022.09.01 P.630.17_v1_2022.09.01 P.630.18_v1_2022.09.01 P.630.19_v1_2023.07.01)
	2. Gene rearrangements/translocations (IGH, MLL, CBFB, ALK, EWSR1, FKHR, SS18, MYCBP, TCRA/D, E2A, TRA/D, BCL2, BCL6, IGL, IGK, PDGFRB, ETV6, MAML2, DDIT3, NR4A3, FGFR1, FUS, IRF4-DUSP22, JAK2, ABL1, ABL2, CRLF2, WWTR1, NUP98, FLT3)	
	3. Chromosome deletions/Gene losses/ Gene amplification [5/5q, 7/7q, D13S319 (13q14.3), 13q34, TP53(17p13.1), ATM (11q22.3), RB1(13q14), MYB (6q23), D20S108 (20q12), 1p36, 19p13, CDKN2C, SNPR/5qter, TUPLE/ARSA, AR/KAL, CDKN2A/D9Z1, 11q gain/loss, EGFR, N-MYC, 17q, HER-2, CKS1B, MDM2]	

** Commercial names mentioned are referring to specific analytical method and laboratory work protocol.*

Site of assessment:
Permanent laboratory premises, 246 Mesogeion Ave., GR-155 61, Cholargos-Athens, Greece.
Branch-Primary sample collection site: 68 Ag. Triados str, GR-153 43, Ag. Paraskevi-Athens, Greece.
Approved signatories: **Ch. Kyprianidou, E. Filiou, N. Georgakopoulos, A. Bitsakos, A. Tsirigoti, G. Boronikola, G. Georgoulias, M. Paschou, M. Papadimitropoulos.**

This scope of Accreditation replaces the previous one dated 12.04.2024.
The Accreditation Certificate No. **621**-6, to ELOT EN ISO 15189:2022, is valid until 15.10.2030.

Athens, 31st July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD