Hellenic Accreditation System

Annex G1/16 to the Certificate No. **687**-7

SCOPE of ACCREDITATION
of the
Clinical Laboratory
of
LIFE CODE MEDICAL Ltd.,
Private Diagnostic Laboratory
Aspasia Divane – Konstantinos Tyrosvoutis MEDICAL Ltd.
(LIFE CODE MEDICAL Ltd.)

Tested materials / Products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Molecular Oncology		
1. Fresh Tissue Biopsy, Paraffin-Embedded Tissue compared to Peripheral Blood	Detection of Microsatellite DNA Instability – **MSI**	In-house method (P.MOR.21) using fluorescent PCR on an Eppendorf Mastercycler Gradient S thermal cycler targeting five microsatellite loci (BAT25, BAT26, NR21, NR24, MONO27), followed by fragment analysis on an ABI 3130 Genetic Analyzer (Applied Biosystems)
2. Fresh Tissue Biopsy, Paraffin-Embedded Tissue	Detection of Microsatellite DNA Instability – **MSI**	Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.33), with Agilent Technologies probes and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). The MSI score is calculated using validated VarSome Clinical algorithms as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
3. Peripheral Blood, Saliva, Cytological Material, Buccal Swab, Fresh Tissue Biopsy, Paraffin-Embedded Tissue	Detection of variants large genomic rearrangements, verification and detection of familial mutations in ***BRCA1*** and ***BRCA2*** gene mutations	Next Generation Sequencing (NGS) using in-house method (P.MOR.26), with Agilent Technologies and Twist Bioscience probes and sequencing on the

Tested materials / Products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
		DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). Data processing is performed using SeqPilot (JSI Medical Systems) and VarSome Clinical software, as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
4. Peripheral Blood, Bone Marrow, Saliva, Buccal Swab, Cytological Material, Fresh Tissue Biopsy, Paraffin-Embedded Tissue	**Detection of somatic variants and large genomic rearrangements** in single genes, gene panels, and across the entire human genome, depending on the referral indication, including panels for hematological malignancies and cancers of the breast, ovary, endometrium, prostate, lung, colon, melanoma, gastrointestinal tract, pancreas, kidney, urinary bladder and glioma, as well as **Clinical Exome (CES), Whole Exome (WES)**, etc.	Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.26), with Agilent Technologies probes and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). Data processing is performed using SeqPilot (JSI Medical Systems), VarSome Clinical software, as well as an internally developed and validated bioinformatics analysis ipeline of the laboratory.
5. Peripheral Blood, Bone Marrow, Fresh Tissue Biopsy, Paraffin-Embedded Tissue	**Detection of somatic variants and large genomic rearrangements in genes of the somatic series using a 680-gene panel** *ABL1, ABL2, ABR, ACVR1, ACVR1B, ACVR2A, ADGRA2, AJUBA, AKAP9, AKT1, AKT2, AKT3, ALK, ALOX12B, ALOX15B, AMER1, ANKRD11, ANKRD26, APC, APLNR, AR, ARAF, ARFRP1, ARHGAP26, ARHGAP35, ARID1A, ARID1B, ARID2, ARID5B, ASXL1, ASXL2, ATM, ATR, ATRX, AURKA, AURKB, AURKC, AXIN1, AXIN2, AXL, B2M, BAP1, BARD1, BBC3, BCL10, BCL2, BCL2L1, BCL2L11, BCL2L2, BCL6, BCOR, BCORL1, BCR, BIRC2, BIRC3, BLM, BMPR1A, BRAF, BRCA1, BRCA2, BRD4, BRIP1, BTG1, BTG2, BTK, C11ORF30, CALR, CARD11, CASP8, CASR, CBFB, CBL, CBLB, CCND1, CCND2, CCND3, CCNE1, CD22, CD274, CD276, CD38, CD44, CD58, CD70, CD74, CD79A, CD79B, CDC73, CDH1, CDK12, CDK2, CDK4, CDK6, CDK7, CDK8, CDKN1A, CDKN1B, CDKN1C, CDKN2A, CDKN2B, CDKN2C, CEBPA, CENPA, CFTR, CHD2, CHD4, CHD8, CHEK1, CHEK2, CIC, CIITA, CKS1B, COL17A1, CPA1, CRBN, CREBBP, CRKL, CRLF2, CSAD, CSF1R, CSF3R, CSNK1A1, CTCF, CTLA4, CTNNA1, CTNNB1, CTRC, CUL3, CUL4A, CUL4B, CUX1, CXCR4, CYLD, CYP17A1, DAXX, DCUN1D1, DDR1, DDR2, DDX3X, DDX41, DDX5, DEFB134, DHX15, DHX9, DICER1, DIS3,*</td><td>Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.26), with Agilent Technologies probes and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). Data processing is performed using SeqPilot (JSI Medical Systems), VarSome Clinical, and SeqOne software, as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory.</td>

Tested materials / Products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
	DIS3L2, DLX1, DNAJB1, DNMT1, DNMT3A, DNMT3B, DOT1L, DPYD, E2F3, EED, EGFL7, EGFR, EIF1AX, EIF4A2, EIF4E, ELAC2, ELF3, EML4, EP300, EPCAM, EPHA2, EPHA3, EPHA5, EPHA7, EPHB1, EPHB2, EPHB4, ERBB2, ERBB3, ERBB4, ERCC1, ERCC2, ERCC3, ERCC4, ERCC5, ERG, ERRFI1, ESR1, ESR2, ETS1, ETV1, ETV4, ETV5, ETV6, EWSR1, EZH2, EZR, FAM175A, FAM46C, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FAS, FAT1, FBXO11, FBXW7, FGF1, FGF10, FGF12, FGF14, FGF19, FGF2, FGF23, FGF3, FGF4, FGF5, FGF6, FGF7, FGF8, FGF9, FGFR1, FGFR2, FGFR3, FGFR4, FH, FLCN, FLI1, FLT1, FLT3, FLT4, FOXA1, FOXA2, FOXL2, FOXO1, FOXP1, FRS2, FUBP1, FYN, GABRA6, GATA1, GATA2, GATA3, GATA4, GATA6, GEN1, GID4, GLI1, GNA11, GNA13, GNAI2, GNAQ, GNAS, GPC3, GPS2, GRB2, GREM1, GRIN2A, GRM3, GSK3B, H3F3A, H3F3B, H3F3C, HDAC1, HGF, HIF1A, HIST1H1C, HIST1H2BD, HIST1H3A, HIST1H3B, HIST1H3C, HIST1H3D, HIST1H3E, HIST1H3F, HIST1H3G, HIST1H3H, HIST1H3I, HIST1H3J, HIST2H3C, HIST2H3D, HIST3H3, HLA-A, HLA-B, HLA-C, HNF1A, HNRNPK, HOXB13, HOXC6, HRAS, HSD3B1, HSP90AA1, ICOSLG, ID3, IDH1, IDH2, IDO1, IDO2, IFNGR1, IFNGR2, IGF1, IGF1R, IGF2, IKBKE, IKZF1, IKZF3, IL10, IL6R, IL6ST, IL7R, ING1, INHA, INHBA, INPP4A, INPP4B, INSR, IRF1, IRF2, IRF4, IRS1, IRS2, JAK1, JAK2, JAK3, JUN, KAT6A, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KEL, KIAA1549, KIF5B, KIT, KLF2, KLF4, KLHL6, KMT2A, KMT2B, KMT2C, KMT2D, KRAS, LAMP1, LATS1, LATS2, LMO1, LRP1B, LTK, LYN, LZTR1, MAF, MAGEC3, MAGI2, MALT1, MAML2, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MAP3K13, MAP3K14, MAP3K4, MAP3K7, MAPK1, MAPK3, MAX, MC1R, MCL1, MDC1, MDM2, MDM4, MECOM, MED12, MEF2B, MEN1, MERTK, MET, MGA, MGMT, MITF, MKNK1, MLH1, MLLT3, MPL, MRE11A, MSH2, MSH3, MSH6, MST1, MST1R, MTAP, MTOR, MUTYH, MYB, MYC, MYCL, MYCN,	

Tested materials / Products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
	MYD88, MYH9, MYOD1, NAB2, NBN, NCOA2, NCOA3, NCOR1, NCOR2, NEGR1, NF1, NF2, NFE2L2, NFKB2, NFKBIA, NKX2-1, NKX3-1, NLRC5, NOTCH1, NOTCH2, NOTCH3, NOTCH4, NPM1, NR3C1, NRAS, NRG1, NSD1, NT5C2, NTHL1, NTRK1, NTRK2, NTRK3, NUP93, NUTM1, P2RY8, PAK1, PAK3, PAK7, PALB2, PARK2, PARP1, PARP2, PARP3, PAX3, PAX5, PAX7, PAX8, PBRM1, PCBP1, PDCD1, PDCD1LG2, PDGFRA, PDGFRB, PDK1, PDPK1, PGR, PHF6, PHOX2B, PIAS3, PIAS4, PIK3C2B, PIK3C2G, PIK3C3, PIK3CA, PIK3CB, PIK3CD, PIK3CG, PIK3R1, PIK3R2, PIK3R3, PIM1, PIM2, PIM3, PLCG1, PLCG2, PLK2, PMAIP1, PML, PMS1, PMS2, PNRC1, POLD1, POLE, POLQ, POT1, PPARG, PPM1D, PPP2R1A, PPP2R2A, PPP4R2, PPP6C, PRAME, PRC1, PRDM1, PREX2, PRKAR1A, PRKCI, PRKDC, PRSS1, PRSS8, PSIP1, PSMA1, PSMB5, PSMD1, PSMG2, PTCH1, PTEN, PTK2, PTPN11, PTPRD, PTPRO, PTPRS, PTPRT, QKI, QSER1, RAB35, RAC1, RAD21, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, RAF1, RANBP2, RARA, RASA1, RB1, RBM10, RECQL4, REL, REST, RET, RFWD2, RFX5, RFXAP, RHEB, RHOA, RICTOR, RIT1, RNASEL, RNF43, ROS1, RPL22, RPL5, RPS6KA4, RPS6KB1, RPS6KB2, RPTOR, RRM1, RSPO2, RUNX1, RUNX1T1, RXRA, RYBP, SDC4, SDHA, SDHAF2, SDHB, SDHC, SDHD, SERPINB3, SERPINB4, SETBP1, SETD2, SF3B1, SGK1, SH2B3, SH2D1A, SHQ1, SIN3A, SLC34A2, SLIT2, SLX4, SMAD2, SMAD3, SMAD4, SMARCA4, SMARCB1, SMARCD1, SMARCE1, SMC1A, SMC3, SMG1, SMO, SNCAIP, SOCS1, SOS1, SOX10, SOX17, SOX2, SOX9, SPEN, SPINK1, SPOP, SPTA1, SRC, SRSF2, STAG1, STAG2, STAT1, STAT3, STAT4, STAT5A, STAT5B, STAT6, STK11, STK40, SUFU, SUZ12, SYK, TAF1, TAF3, TAP1, TAP2, TAPBP, TBL1XR1, TBX3, TCEB1, TCF12, TCF3, TCF7L2, TEK, TERC, TERT, TET, TET1, TFE3, TFEB, TFRC, TGFBR1, TGFBR2, TIPARP, TLR4, TMEM127, TMPRSS2, TNFAIP3, TNFRSF14, TOP1, TOP2A, TP53,	

Tested materials / Products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
	TP53BP1, TP63, TP73, TRAF2, TRAF3, TRAF7, TSC1, TSC2, TSHR, TYR, TYRO3, U2AF1, UGT1A1, UVRAG, VEGFA, VHL, VTCN1, WHSC1, WHSC1L1, WISP3, WRN, WT1, XBP1, XIAP, XPO1, XRCC2, YAP1, YES1, ZBTB2, ZBTB7A, ZFHX3, ZFP36L1, ZMYM2, ZMYM3, ZNF217, ZNF703, ZNF750, ZRSR2	
6. Fresh Tissue Biopsy, Paraffin-Embedded Tissue	Calculation of Total Tumor Mutation Burden –**TMB score**	Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.35), with Agilent Technologies probes and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). The TMB score is calculated using validated VarSome Clinical algorithms as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
7. Fresh Tissue Biopsy, Paraffin-Embedded Tissue	Calculation of Homologous Recombination Deficiency – **HRD score**	Next Generation Sequencing (NGS) using in-house Method (P.MOR.34), with Agilent Technologies probes and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). The HRD score is calculated using validated SeqOne algorithms, Varsome Clinical as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
8. Fresh Tissue Biopsy, Paraffin-Embedded Tissue	Detection of variants in Homologous Recombination Repair - **HRR genes**	Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.26), with Agilent Technologies probes and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). Data processing is performed using SeqPilot (JSI Medical Systems), VarSome Clinical, and SeqOne software, as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
9. Fresh Tissue Biopsy, Paraffin-Embedded Tissue	**Detection of somatic gene fusion transcripts - (RNA)** *ALK, BRAF, EGFR, ERG, FGFR1, FGFR2, FGFR3, MET, NRG1, NTRK1, NTRK2, NTRK3, PBX1, PPARG, PRKACA, RAF1, RET, ROS1, TFE3*	Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.37), following the Pillar Biosciences protocol and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech) or MiSeq (Illumina). Data processing is performed using Pivat software as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
10. Peripheral Blood in Streck Tubes – **Liquid Biopsy**	**Detection of somatic genetic variants in oncogenes through analysis of circulating tumour DNA – ctDNA** *AKT1, ALK, APC, AR, ARAF, ARID1A, ARID2, ASXL1, ATM, ATRX,*	Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.32), following the Pillar Biosciences protocol and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI

Tested materials / Products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
	*AXIN2,AXL, B2M, BCOR, BRAF, CARD11, CCND1, CDH1, CDK4, CDK6, CDKN2A,CIC, CREBP, CTCF, CTNNB1, **EGFR**, EP300, ERBB2, ERBB3, ESR1, EZH2,FBXW7, FGFR1, FGFR2, FGFR3, FLCN, FOXL2, GATA3, GLI1, GNA11, GNAQ ,GNAS, HNF1A, HRAS, IDH1, IDH2, IKZF1, JAK1, KDM5A, KIT, KRAS, MAP2K1,MAP2K2, MAPK1, MED12, MET, MLH1, MLL2, MRE11A, MSH6, MTOR, MYC,MYOD1, NCOR1, NF1, NFE2L2, NOTCH1, NRAS, NTRK1, NTRK3, PAK7, PDCD1, PDGFRA, PIK3CA, PIK3R1, POLE, PPP2R1A, PTCH1, PTEN, PTPN11, PTPRD,PTPRS, RAC1, RAF1, RB1, RET, RHEB, RHOA, RNF43, ROS1, RUNX1, SF3B1,SMAD4, SMO, SOX9, SPOP, STAT5B, STK11, TCF7L2, TP53, TSC1, U2AF1, VHL*	Tech). Data processing is performed using Pivat software as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
11. Peripheral Blood in Streck Tubes – **Liquid Biopsy**	**Detection of somatic fusion transcripts through analysis of circulating tumour RNA - ctRNA** *ALK, BRAF, EGFR, ERG, FGFR1, FGFR2, FGFR3, MET, NRG1, NTRK1, NTRK2, NTRK3, PBX1, PPARG, PRKACA, RAF1, RET, ROS1, TFE3*	Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.32), following the Pillar Biosciences protocol and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). Data processing is performed using Pivat software as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
12. Fresh Tissue Biopsy, Paraffin-Embedded Tissue	**Detection of clinically significant variants (HotSpot) in somatic genes – DNA** *KRAS, EGFR, BRAF, PIK3CA, AKT1, ERBB2, PTEN, NRAS, STK11, MAP2K1, ALK, DDR2, CTNNB1, MET, SMAD4, FBXW7, FGFR3, NOTCH1, ERBB4, FGFR1, FGFR2, TP53*	Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.38), following the Illumina protocol and sequencing on the MiSeq next-generation genetic analyzer (Illumina). Data processing is performed using SeqPilot (JSI Medical Systems) and Illumina software, as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory.
13. Fresh Tissue Biopsy, Paraffin-Embedded Tissue	**Detection of somatic gene fusion transcripts – RNA** *ALK, ROS1, RET, NTRK1, NTRK2, NTRK3, MET* exon 14 skip	Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.38), following the Illumina protocol and sequencing on the MiSeq next-generation genetic analyzer (Illumina). Data processing is performed using Illumina software as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
14. Fresh Tissue Biopsy, Paraffin-Embedded Tissue, Peripheral Blood, Bone Marrow	1. Detection of ***KRAS*** variants (exons 2, 3, 4) 2. Detection of ***EGFR*** variants (exons 18, 19, 20, 21)	In-house Method (P.MOR.17_v3) using Sanger Sequencing on an Eppendorf Mastercycler Gradient S thermal cycler and analysis on an ABI 3130 Genetic Analyzer (Applied Biosystems)

Tested materials / Products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
	3. Detection of ***BRAF*** *variants* (exons 11, 15)	
	4. Detection of ***NRAS*** variants (exons 2, 3, 4)	
	5. Detection of ***cKIT*** *variants* (exons 9, 11, 13, 17)	
	6. Detection of ***PDGFRA*** *variants* (exons 12, 18)	
15. Peripheral Blood, Saliva, Cytological Material, Buccal Swab	Detection of large genomic rearrangements in the ***BRCA1*** and ***BRCA2*** genes	Multiplex Ligation-Dependent Probe Amplification (MLPA) method, with CE-IVD SALSA MLPA P002 BRCA1 probemix and CE-IVD SALSA MLPA P045 BRCA2 probemix kits (MRC-Holland), and data analysis performed using Coffalyser.Net software Manufacturer's kit method (П.МОР.36)
Molecular Heamatology		
1. Bone Marrow, Peripheral Blood	Detection of ITD and D835 variants of the ***FLT3*** gene	Manufacturer's kit method (P.MOR.08) Seqline FLT3 Mutation Analysis Kit Cat-Nr.: SL80396
2. Bone Marrow, Peripheral Blood	Detection and quantification of fusion transcripts (*BCR-ABL-p210, BCR-ABL-p190, AML1-ETO, TEL-AML1, PML-RARa*)	Manufacturer's kit method (AML1-ETO, TEL-AML1, PML-RARa bcr1, PML-RARa bcr3 FusionQuant Kits, Ipsogen, CE-IVD)* and AB Analytica SA BCR-ABL Mbcr (CE-IVD)* BCR-ABL mbcr (CE-IVD)* or gb ONCO BCR-ABL MAJOR / ABL, gb ONCO BCR-ABL MINOR / ABL using the Real-Time PCR technique on a RotorGene 6000 real-time thermal cycler (Corbett Research)
3. Bone Marrow, Peripheral Blood	Detection of the V617F point mutation in the ***JAK2*** gene	In-house Method (P.MOR.11_v3) using the PCR-ARMS technique on an Eppendorf Mastercycler Gradient S thermal cycler
4. Bone Marrow, Peripheral Blood	Detection of fusion transcripts BCR/ABL-p210, BCR/ABL-p190, BCR/ABL-p230	Manufacturer's methodology Biomol BCR/ABL t(9;22) one step RT-PCR qualitative determination (p210, p190, p230)
Molecular Microbiology		
1. Cervical Cell Suspension, Fresh Tissue Biopsy, Paraffin-Embedded Tissue	Detection and genotyping of Human Papillomavirus - **HPV** strains [subtypes:16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68 (a, b) , 73, 82	*Manufacturer's kit method (P.MOR.09_v7) HPV Chip 1.0, Zytovision, CE-IVD* using microarray technology*

Tested materials / Products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
	(IS39, MM4), 26, 53, 66, 6, 11, 40, 42, 43, 44, 54, 55, 57, 70, 69, 71, 34, 67, 73, 61, 62, 72, 81CP8304, 83MM7, 90, 91].	
2. Cervical Cell Suspension, Fresh Tissue Biopsy, Paraffin-Embedded Tissue	Detection and genotyping of high-risk Human Papillomavirus - **HPV** strains	Manufacturer's method (P.MOR.27) HPV PCR Diagnostics using RT-PCR on RotorGene 6000 and RotorGene 3000 real-time thermal cyclers (Corbett Research), BioQuant 96 (Biosan), and BioRad systems
3. Serum, Plasma EDTA	1. Detection and quantitative determination of **HBV** viral load 2. Detection and quantitative determination of **HCV** viral load 3. Detection and quantitative determination of **HIV** viral load	Manufacturer's kit method (P.MOR.20_v1) (AmpliSens HBV, HCV, or HIV-Monitor – FRT PCR kit) using the Real-Time qPCR technique on a RotorGene 6000 real-time thermal cycler (Corbett Research)
Molecular Genetics		
1. Peripheral Blood, Saliva, Cytological material, Buccal Swab, Amniotic Fluid, Chorionic Villi	Detection of variants and large genomic rearrangements of the ***CFTR*** gene	Next Generation Sequencing (NGS) using In-house Method (P.MOR.26), with Agilent Technologies probes and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech) and MiSeq (Illumina). Data processing is performed using SeqPilot (JSI Medical Systems) as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
2. Peripheral Blood, Cytological Material, Buccal Swab, Saliva, Fresh Tissue Biopsy, Paraffin-Embedded Tissue, Amniotic Fluid, Chorionic Villi	**Detection of germline variants and large genomic rearrangements** in single genes, gene panels, and across all genes of the human genome depending on the referral indication, e.g., gene panels for cardiovascular diseases, **Clinical Exome (CES)**, **Whole Exome (WES)**, etc.	Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.26), with Agilent Technologies probes and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). Data processing is performed using SeqPilot (JSI Medical Systems) and VarSome Clinical software, Franklin genoox as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory
3. Peripheral Blood, Cytological Material, Buccal Swab, Saliva	***Detection of germline variants*** *and large genomic rearrangements in genes associated with* ***hereditary cancer*** *ABRAXAS1, APC, ATM, AXIN2, BAP1, BARD1, BLM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, DICER1, DIS3L2, EPCAM, FANCC, FH, FLCN, GALNT12, HNF1A, HNF1B, HOXB13, KIT, MC1R, MEN1, MET,*	Next Generation Sequencing (NGS) using In-house Method (P.MOR.26), with Agilent Technologies and Twist Bioscience probes and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). Data processing is performed using SeqPilot (JSI Medical Systems), VarSome Clinical software, Franklin genoox as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory

Tested materials / Products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
	MITF, MLH1, MLH3, MRE11, MSH2, MSH3, MSH6, MUTYH, NBN, NF1, NTHL1, PALB2, PMS1, PMS2, POLD1, POLE, POT1, PRSS1, PTCH, PTEN, RAD50, RAD51C, RAD51D, RECQL, RET, RNF43, RPS20, SDHA ,SDHAF2, SDHB, SDHC, SDHD, SMAD4, SMARCA4, STK11, TGFBR2,TP53, TSC1, TSC2, VHL, WT1, XRCC2, XRCC3	
4. Peripheral Blood, Cytological Material, Buccal Swab, Saliva	Detection of large genomic rearrangements in selected genomic regions	Using the Multiplex Ligation-Dependent Probe Amplification (MLPA) method, with CE-IVD SALSA MLPA kits (MRC Holland), and data analysis performed using Coffalyser.Net software Manufacturer's kit method (П.МОР.36)
5. Amniotic Fluid, Chorionic Villi, Products of Conception	Molecular rapid detection of aneuploidies for chromosomes 13, 18, 21, X, and Y (QF-PCR)	Manufacturer's method (P.MOR.12_5) ChromoQuant® QF-PCR kit (QF-STaR kits, CE-IVD*) using the QF-PCR technique on an Eppendorf Mastercycler Gradient S thermal cycler, followed by fragment analysis on an ABI 3130 Genetic Analyzer (Applied Biosystems*)
6. Amniotic Fluid, Chorionic Villi, Peripheral Blood	Detection of the F508del variant of the ***CFTR*** gene	In-house Method (P.MOR.13_v3) using the PCR-ARMS technique on an Eppendorf Mastercycler Gradient S thermal cycler
7. Peripheral Blood, Cytological Material, Buccal Swab, Saliva	1. Detection of the G1691A mutation of the Factor V gene (***Factor V***) 2. Detection of the G20210A mutation of the Prothrombin gene (Prothrombin, ***FII*****)** 3. Detection of the C677T mutation of the ***MTHFR*** gene 4. Detection of the A1298C mutation of the ***MTHFR*** gene	In-house Method (P.MOR.18_v1) using the PCR-RFLP technique on an Eppendorf Mastercycler Gradient S thermal cycler.
8. Peripheral Blood, Cytological Material, Buccal Swab, Saliva	Detection of variants in genes associated with coagulation such as: *FV G1691A (Leiden), FV H1299R (R2), FXIII V34L, β-fibrinogen -455G>A, FII G20210A, PAI-1 4G/5G, HPA1 a/b, MTHFR C677T, MTHFR A1298C, ACE I/D, ApoB R3500Q, ApoE E2/E3/E4, GPIa C807T*	*a) Manufacturer's kit method (P.MOR.19_v1) (CVD StripAssay, Vienna Lab, CE-IVD) using PCR on an Eppendorf Mastercycler Gradient S thermal cycler followed by reverse hybridization.** b) Next Generation Sequencing (NGS) using Manufacturer's kit method (P.MOR.26), with Agilent Technologies probes and sequencing on the DNBSEQ-G400 next-generation genetic analyzer (MGI Tech). Data processing is performed using SeqPilot (JSI Medical Systems) and VarSome Clinical software, as well as an internally developed and validated bioinformatics analysis pipeline of the laboratory

Tested materials / Products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
9. Amniotic Fluid, Chorionic Villi, Peripheral Blood, Bone Marrow, Products of Conception	Detection of microdeletions and microduplications with CNV microarrays - **Molecular Karyotype**	Manufacturer's kit method Agilent GenetiSure 8x60K CGH kit (P.MOR.25_v2)
Cytogenetics		
1. Peripheral Blood	Karyotype / Detection of constitutional chromosomal abnormalities	In-house Method (P.KYT.01, P.KYT.02) using cell culture, microscopic analysis, and karyotyping
2. Bone Marrow, Peripheral Blood	Karyotype / Detection of acquired chromosomal abnormalities	
3. Amniotic Fluid	Karyotype / Detection of constitutional chromosomal abnormalities	In-house Method (P.KYT.7, P.KYT.6) using cell culture, microscopic analysis, and karyotyping
4. Chorionic Villi	Karyotype / Detection of constitutional chromosomal abnormalities	
Molecular Cytogenetics		
1. Bone Marrow, Peripheral Blood, Buccal Swab, Amniotic Fluid, Chorionic Villi	Detection of sex chromosome and autosomal aneuploidies	FISH (P.KYT.03, P.KYT.04, P.KYT.05) – In situ hybridization using DNA probes for specific or repetitive sequences (ZytoVision, CE-IVD)*
2. Peripheral Blood, Bone Marrow, Surgical Biopsy, Paraffin-Embedded Tissue Section	**1. Detection of fusion genes such as:** BCR-ABL, ETO-AML1, TEL-AML1, PBX1-TCF3, PML-RARA, IgH-CCND1 (BCL1), IgH-FGFR3, IgH-BCL2, API2-MALT1, IGH-MYC, IGH-MAF and other fusion genes detected using the same method	
	2. Gene rearrangments such as: IgH, MLL, CBFb, ALK, EWSR1, FKHR, SS18, FIP1/PDGFRA, C-MYC, TCRA/D, E2A and other gene translocations detected using the same method	
	3. Chromosomal/gene deletions such as: 5/5q, 7/7q, p16 (9p21), D13S319 (13q14.3), 13q34, P53 (17p13.1), ATM (11q22.3), RB1 (13q14), MYB (6q23), D20S108 (20q12), 1p36, 19p13 and other chromosomal regions and/or genes detected using the same method	
	4. Gene amplification/gain such as: EGFR, N-MYC, 1q21, 17q, HER2, ROS1 and other genes detected using the same method	

**The use of the genetic analyser's brand name or kit refers to a specific analytical method and the corresponding experimental protocol.*

Site of assessment: **Laboratory permanent premises: 6 Karistou str., 115 23, Athens, Greece.**
Approved signatories: **A. Divane, F. Ieremiadou, T. Hamos, A. Daraki, Z. Patramani, Ch. Meristoudis, I. Sanidopoulos, K. Aggelaina, E. Mavridou, M. Sigala, E. Manisali**

This scope of Accreditation replaces the previous one dated 16.05.2024.
The Accreditation Certificate No. **687-**7, to ELOT EN ISO 15189:2022, is valid until **29.06.2032.**

Athens, 10th June 2026

Konstantinou Evangelos Apostolos
CEO of ESYD