Hellenic Accreditation System

Annex G1/7 to the Certificate No.**1198**-2

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

Institute of Applied Biosciences - INAB
Centre for Research and Technology Hellas – CERTH

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Molecular genetics		
1. Peripheral Blood, Bone Marrow, DNA, Surgical Biopsy	Detection of TP53 gene mutations	Method based on general recommendations from the European Initiative in CLL, ERIC published in 2018 'ERIC recommendations for TP53 mutation analysis in chronic lymphocytic leukemia—update on methodological approaches and results interpretation' Automated DNA extraction in QIAcube (QIAGEN) for the amplification of exons 4-10 of the *TP53* gene using polymerase chain reaction in the GeneAmp 9700, 9902, and ProFlex machines of Applied Biosystems and Sanger sequencing on the Sanger sequencer 3500 Genetic Analyzer (Applied-HITACHI). *OE05-01-09/2η, 16-06-2025: SOPs for mononuclear cell isolation, DNA and RNA extraction and cDNA synthesis* *OE05-01-05/1η, 18-02-2020: SOP for TP53_SS test*
2. Peripheral Blood, Bone Marrow, DNA, RNA, Surgical Biopsy	Determination of mutational status of the heavy chain immunoglobulin gene	Method based on general recommendations from the European Initiative in CLL, ERIC published in 2017 'Immunoglobulin gene sequence analysis in chronic lymphocytic leukemia: updated ERIC recommendations' Automated DNA extraction in QIAcube (QIAGEN) or non-automated DNA extraction, for the amplification of B cell receptor immunoglobulin gene rearrangements using polymerase chain reaction in the GeneAmp 9700, 9902, and ProFlex machines of Applied Biosystems and Sanger sequencing on the Sanger sequencer 3500 Genetic Analyzer (Applied-HITACHI). *OE05-01-09/2η, 16-06-2025: SOPs for mononuclear cell isolation, DNA and RNA extraction and cDNA*

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
		synthesis *OE05-01-04/1η, 18-02-2020: SOP for BCR_SS test*
3. Peripheral Blood, Bone Marrow, DNA, RNA, Surgical Biopsy	Determination of immunoglobulin heavy chain gene rearrangements	Method based on general recommendations form EuroClonality published in 2019'EuroClonality/BIOMED-2 guidelines for interpretation and reporting of Ig/TCR clonality testing in suspected lymphoproliferations' 'EuroClonality-NGS Working group Standard Operating Procedure (SOP) for Two-step IG/TR NGS-based marker identification for the Illumina MiSeq platform' Automated DNA extraction in QIAcube (QIAGEN) or non-automated DNA extraction, Apmlification of the rearrangements of the B-cell receptor immunoglobulin by the polymerase chain reaction method using the GeneAmp 9700, 9902, and ProFlex machines from Applied Biosystems, library construction using NEBNext® Ultra™ II DNA Library Prep kit (New England Biolabs)* as well as next generation sequencing on the MiSeq (Illumina) sequencer. Bioinformatics analysis using the tools Vidjil IMGT/High V-QUEST. *OE05-01-09/2η, 16-06-2025: SOPs for mononuclear cell isolation, DNA and RNA extraction and cDNA synthesis* *OE05-01-06/2η-15-04-2024: SOP for BCR_NGS test* *OE05-01-10/1η, 01-10-2020: SOP for data analysis of BCR_NGS, TCR_NGS tests*
4. Peripheral Blood, Bone Marrow, RNA, Surgical Biopsy	Determination of β chain T cell receptor gene rearrangements	Automated DNA extraction in QIAcube (QIAGEN) or non-automated DNA extraction, amplification of T cell receptor rearrangements using the Clonality Assay - Tube A (Invivoscribe Technologies)* in the GeneAmp 9700, 9902, and ProFlex machines of Applied Biosystems, library construction using NEBNext® Ultra™ II DNA Library Prep kit (New England Biolabs)* and next generation sequencing on the MiSeq (Illumina) sequencer. Bioinformatics analysis using the tools Vidjil IMGT/High V-QUEST. *OE05-01-09/2η, 16-06-2025: SOPs for mononuclear cell isolation, DNA and RNA extraction and cDNA synthesis OE05-01-07/1η, 18-02-2020: SOP for TCR_NGS test* *OE05-01-10/1η, 01-10-2020: SOP for data analysis of BCR_NGS, TCR_NGS tests*

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
6. Peripheral Blood, Bone Marrow, RNA, Surgical Biopsy	Detection of TP53 gene mutations by next-generation sequencing	Method based on general recommendations from ERIC, the European Initiative in CLL, published in 2018 'ERIC recommendations for TP53 mutation analysis in chronic lymphocytic leukemia—update on methodological approaches and results interpretation' Automated DNA extraction in QIAcube (QIAGEN), amplification of exons 2-11 of the *TP53 gene* using polymerase chain reaction in the GeneAmp 9700, 9902, and ProFlex machines of Applied Biosystems, library construction using NEBNext® Ultra™ II DNA Library Prep kit (New England Biolabs)* and next generation sequencing on the MiSeq (Illumina) sequencer. Bioinformatics analysis that includes the tools BWA, GATK4.1, and Annovar with the reference genome GRCh37 - hg19. For the evaluation of mutations, the IARC TP53 Database (v.2019) and ClinVar (v.2024) databases are used. *OE05-01-09/2η, 16-06-2025: SOPs for mononuclear cell isolation, DNA and RNA extraction and cDNA synthesis* *OE05-01-12/1η, 02-01-2023: SOPs for TP53_NGS test* *OE05-01-15/1η, 01-11-2021: SOP for data analysis of TP53_NGS,HaemaPMN_NGS_panel,OncoPMN_NGS _panel*
7. Peripheral Blood, Bone Marrow, DNA, Surgical Biopsy	Detection of mutations in Hematologic malignancies in the genes *ASXL1, CXCR4, IKZF 2,NPM1,SRSF2, ATM, DNMT3A, IKZF 3, NRAS, STAG2BRAF, ETV6, IKZF1, PAX5, TET2BTK, EZH2, JAK1, PLCG2, TP53, CALR, FBXW7,JAK2, RHOA, U2AF1, CBL, FLT3, MPL, RUNX1, ZRSR2, CEBPA, IDH1, MYD88, SETBP1, CSF3R, IDH2, NOTCH1, SF3B1*	Automated DNA extraction in QIAcube (QIAGEN),library construction using Ampliseq for Illumina Custom Panel)**(Illumina) in the GeneAmp 9700, 9902, and ProFlex machines of Applied Biosystems, and next generation sequencing on the NextSeq (Illumina) sequencer. Bioinformatics analysis that includes the tools BWA, GATK4.1, and Annovar with the reference genome GRCh37 - hg19. For the evaluation of mutations, the IARC TP53 Database (v.2019) and ClinVar (v.2024) databases are used. *OE05-01-09/2η, 16-06-2025: SOPs for mononuclear cell isolation, DNA and RNA extraction and cDNA synthesis* *OE05-01-11/0,01-07-2019:SOPs HAEMAPMN_NGS_PANEL L test* *OE05-01-15/1η, 01-11-2021: SOP for data analysis of TP53_NGS,HaemaPMN_NGS_panel,OncoPMN_NGS _panel*
8. Peripheral Blood, Bone Marrow, RNA, Surgical Biopsy	Detection of mutations of Solid tumor in the genes AKT1, CDKN2A, IDH2, MLH1, PTEN, ALK, CHEK1, JAK2, MSH2, RAD50 AR, CHEK2, JUN, MSH6, RAD51 ATM, CTNNB1, KDR, mTOR, RB1, BCL2, EGFR, KIT, MYC, RET, BRAF, ERBB2, KMT2C, NF1, ROS1, BRCA1, ERBB4, KRAS, NOTCH1, SMAD4, BRCA2, ESR1, MAP2K1,	Automated DNA extraction in QIAamp DNA FFPE Tissue Kit (QIAGEN),library construction using Ampliseq for Illumina Custom Panel)***(Illumina) in the GeneAmp 9700, 9902, and ProFlex machines of Applied Biosystems, and next generation sequencing on the NextSeq (Illumina) sequencer. Bioinformatics analysis that includes the tools BWA, GATK4.1, and Annovar with the reference genome GRCh37 - hg19. For the evaluation of mutations, the IARC TP53 Database (v.2019) and ClinVar (v.2024) databases are used. *OE05-01-09/2η, 16-06-2025*: SOPs for mononuclear cell isolation, DNA and RNA extraction and cDNA

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	NRAS, STAT3, CCND1, FGFR1, MDM2, PALB2, STK11, CCNE1, FGFR2, MDM4, PDGFRA, TP53, CDK4, FGFR3, MEN1, PIK3CA, CDK6, IDH1, MET, PIK3CB	synthesis *OE05-01-16/0, 01-07-2019:* SOPs for *DNA FFPE isolation* *OE05-01-14/0, 01-07-*2019:SOPs OncoPMN_NGS_PANEL L test *OE05-01-15/1η, 01-11-2021:* SOP for data analysis of TP53_NGS,HaemaPMN_NGS_panel,OncoPMN_NGS_panel
9. Nasopharyngeal swab	Molecular detection of RNA of novel corona virus SARS-CoV-2	i. RNA isolation from the SARS-CoV-2 virus from nasopharyngeal swabs using an automated nucleic acid isolation system (KingFisher Flex System) and the MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit. Manufacturer's Direct SARS-COV-2 Real Time PCR Kit for in vitro diagnostic use (Vircell Microbiologists). Using AriaMx Real-Time PCR System. The mixture targets a specific part of the N gene and the E gene. *OE05-01-13/1η, 16-06-2025*: SOPs SARs_CoV_2test ii. RNA isolation from the SARS-CoV-2 virus from nasopharyngeal swabs using an automated nucleic acid isolation system (KingFisher Flex System) and the MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit. In house Real Time PCR 'Real-time RT-PCR assays for the detection of SARS-CoV-2 Institut Pasteur, Paris' using AriaMx Real-Time PCR System and Rotor-Gene Q Real-Time. The mixture targets a specific part of the S gene and RdRP/nCov_IP4. *OE05-01-13/1η, 16-06-2025 SOPs SARs_CoV_2test*

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

Site of assessment: **Centre for Research and Technology Hellas – CERTH, 6th km Charilaou-Thermi Rd, GR 57001,Thermi, Thessaloniki.**
Approved signatories: **K. Stamatopoulos, A. Hadzidimitriou.**

This scope of Accreditation replaces the previous one dated 14.06.2024.
The Accreditation Certificate No.**1198-**2**,** to ELOT EN ISO 15189:2022, is valid until 02.02.2029.

Athens, 01.09.2025

Konstantinou Evangelos Apostolos
CEO of ESYD