Hellenic Accreditation System

Annex G1/A10 to the Certificate No. **973**-4

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

KARYO Ltd

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
	Molecular Genetics	
1. Sections from formalin-fixed paraffin-embedded (FFPET) human non-small cell lung cancer (NSCLC) tumor tissue	1. Qualitative detection and identification of mutations in exons 18, 19, 20 and 21 of the epidermal growth factor receptor (EGFR) gene	Multiplex PCR with the COBAS EGFR Mutation Test CE-IVD kit* (Roche Diagnostics GmbH) using the Real Time PCR instrument COBAS z 480 Roche* (QP-46) (Document number ΔΠ-46 Version 1)
2. Sections from formalin-fixed paraffin-embedded (FFPET) human melanoma tissue	1. Qualitative detection of the BRAF V600 (T1799A) mutations	LightMix kit TIB MolBiol using the Lightcycler 480 II instrument. (Document number ΔΠ- 58 Version 1)
3. Sections from formalin-fixed paraffin-embedded (FFPET) human tissue	1. Qualitative detection of mutations in exon 2 of the Kras gene with HRM-PCR, retesting and confirmation of the mutated samples with the Lightmix kit 12/13 TIB MolBiol. 2. Qualitative detection and identification of mutations in exons 3,4 of the Kras gene with the LightMix kit TIB MolBiol.	HRM-PCR and LightMix kit* 12/13 with use of LightCycler 480 II instrument. Multiplex Real Time PCR for the rest of the exons with use of the Cobas z 480 instrument* (QP-23) (Document number ΔΠ-23 Version 2)
4. Sections from formalin-fixed paraffin-embedded (FFPET) human tissue	1.Qualitative detection of mutations in exons 2.3.4 of the Nras gene	LightMix kit TIB MolBiol* Multiplex PCR with use of the Real Time PCR instrument Cobas z 480* (QP-23) (Document number ΔΠ-23 Version 2)
5. Sections from formalin-fixed paraffin-embedded (FFPET) human tissue and peripheral blood	1.Detection of DNA Microsatellite Instability (MSI) from FFPET with HRM	HRM-PCR with use of the Real Time PCR instrument Cobas z 480* (QP-22) (Document number ΔΠ-22 Version 2)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
6. Peripheral blood	1.Molecular genetic testing of mutations: (G1691A) FV gene & (G20210A) FII gene	In house PCR for detection of mutations in FV, FII genes using T100 Biorad thermocycler and analyzing pcr products in agarose gel (Document number ΔΠ-24 Version 2)
7. Peripheral blood	1.Molecular genetic testing of the polymorphisms C677T and A1298C of the MTHFR gene using HRM-PCR	HRM-PCR (QP-24) with use of the Lightcycler 480 II instrument (Document number ΔΠ-24 Version 2)
8. Peripheral blood	1.Molecular genetic testing of the polymorphism 4G/5G of the PAI-1 gene	Light Mix Kit* Real time PCR with use of the Lightcycler 480 II instrument (Document number ΔΠ-24 Version 2)
9. Peripheral blood	1. Qualitative detection of the mutation V617F for JAK2 gene.	HRM-PCR with use of the Lightcycler 480 II instrument (Document number ΔΠ-26 Version 1)
10.Peripheral blood	1. Molecular detection of the BCR-ABL fusion transcript	Lightmix kit bcr-abl t(9;22) RT-PCR with use of the Lightcycler 480 II instrument (Document number ΔΠ-25 Version 1)
11. Peripheral blood, plasma (EDTA) cell cultures	1. Detection of HBV virus DNA, detection of HCV Qualitative detection of HBV/HCV	Sacace Biotechnologies kit PCR with use of the Corbett 6000 instrument (Document number ΔΠ-28 Version 1)
12. Cytological samples, Sections from formalin-fixed paraffin-embedded (FFPET) human tissue	Detection and identification of 41 genotypes of HPV.	Vision Array HPV detection system (QP-29) (Document number ΔΠ-29 Version 1)
13. Serum, plasma (EDTA)	Detection of the CMV, EBV viruses	CMV/EBV/HHV6 QUANT Real-TM kit on the Corbett 6000 platform. (QP-27) (Document number ΔΠ-27 Version 1)
14. Nasopharyngeal or Oropharyngeal specimen Saliva specimen Bronchoalveolar lavage	Molecular detection of RNA of SARS-CoV-2	RT-PCR with the RealAccurate Quadruplex SARS-CoV-2 PCR kit from Pathofinder using the MIC platform (Document number ΔΠ-51 Version 1)
15. Cytological samples, Sections from formalin-fixed paraffin-embedded (FFPET) human tissue	Detection and identification of 35 genotypes of HPV.	Master Diagnostics HPV kit Hybrisoft 12 detection system (ΔΠ-53) (Document number ΔΠ-53 Version 1)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
16. Peripheral blood, Cytological samples, Sections from formalin-fixed paraffin-embedded (FFPET) human tissue	Detection of somatic and germline mutations BRCA1&2.	Ion AmpliSeq Library Kit PlusOncomine BRCA research using the ION GENESTUDIO S5 Plus Sequencer Thermo. Analysing using Ion reporter Thermo fisher. (Document number ΔΠ-54 Version 1)
17. Peripheral blood	Detection of sequence variants in the CFTR gene in genomic DNA.	CFTR research panel Thermo using the ION GENESTUDIO S5 Plus Sequencer Thermo . Analysing using Ion reporter Thermo fisher. (Document number ΔΠ-55 Version 1)
18. Cytological samples, Sections from formalin-fixed paraffin-embedded (FFPET) human tissue	Detection of somatic mutations KRAS, NRAS, EGFR, BRAF, PIK3CA, ALK, ROS, RET genes	VAHTS AmpSeq Library Prep Kit V3 (Ref. NA210-02, Vazyme). Colon & Lung using the ION GENESTUDIO S5 Plus Sequencer Thermo. Analysing using Ion reporter Thermo fisher. (Document number ΔΠ-57 Version 1)
19. Cytological samples	Detection and identification of High Risk genotypes of HPV.	Alinity M , HR AMP Kit kit HPV (_Ref. 09N15-090) (Document number ΔΠ-60 Version 1)
Cytogenetics		
1. Bone Marrow, peripheral blood	1.Karyotyping / detection of acquired chromosomal abnormalities	Cell Culture GTG banding Microscopic analysis Karyotyping Metafer Slide Scanning Platform -IKAROS (Metasystems) (Document number ΔΠ-34 & ΔΠ 35 Version 2)

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
2. Sections from formalin-fixed paraffin-embedded (FFPET) human tissue	Detection of amplification of the gene *HER2* or rearrangements of *ALK gene* using in situ fluorescent hybridization (FISH)	Microdissection of formalin-fixed paraffin-embedded (FFPET) human tissue Deparaffinization of FFPET In situ fluorescent hybridization (FISH) Analysis using fluorescent microscopy Analysis of fluorescent signals using the Q- capture Imaging system (QP-32, QP-33) (Document number ΔΠ-32 & ΔΠ 33 Version 2)

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

Site of assessment :**Permanent laboratory premises, 51 Ermou srt., GR-54623, Thessaloniki, Greece.**
Primary sample collection site: 51 Ermou srt., GR-54623, Thessaloniki, Greece.
Approved signatories: **Th. Papadopoulos, G. Timologos, F. Kostopoulou.**

This scope of Accreditation replaces the previous one dated 22.06.2023.
The Accreditation Certificate No. **973**-4, to ELOT EN ISO 15189:2022, is valid until **01.04.2028.**

Athens, 31st July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD

Hellenic Accreditation System

Annex G1/B2 to the Certificate No **973**-4

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

KARYO Ltd
THESSALONIKI BRANCH

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
Biochemical testing		
Blood serum	**Determination of 8 parameters**	**Automated analyzer Dimension rxl max***
	1.Glucose (GLUC)	Enzymatic (G-6-PDH) (Document number DP-52 17/05/2021Version 1)
	2.Potassium	Potentiometric ISE (Indirect) (Document number DP-52 17/05/2021Version 1)
	3.Sodium	Potentiometric ISE (Indirect) (Document number DP-52 17/05/2021Version 1)
	4.Alanine Aminotransferase (ALT/SGPT)	EnzymaticNADH-without P-5'-P (Document number DP-52 17/05/2021Version 1)
	5.Aspartate Aminotransferase (AST/SGOT)	Enzymatic NADH-without P-5'-P (Document number DP-52 17/05/2021Version 1)
	6.Urea Nitrogen	Urease (Document number DP-52 17/05/2021Version 1)
	7.Creatinine	KineticAlkalinePicrate (Document number DP-52 17/05/2021Version 1)

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
Blood serum (continued)	8.G-gt	Colorimetric (L γ-Glutamyl-3-carboxy-4-nitroanillide) (Document number DP-52 17/05/2021Version 1)
Immunochemical Testing		
Blood serum (continued)	**Determination of 5 parameters**	**Automated analyzer CENTAUR XT***
	1.Prostate Specific Antigen (PSA)	Chemiluminescent Microparticle Immunoassay (Document number DP-52 17/05/2021Version 1)
	2. β-Human Chorionic Gonadotropin (β-hCG)	
	3. Thyroid-Stimulating Hormone (TSH)	
	4. Ferritine	
	5. CEA Carcinoembryonic Antigen	
Hematological Testing		
Whole Blood (EDTA)	**Determination of 8 parameters**	**Automated analyzer Sysmex xs-800i***
	1. Hemoglobin (HGB)	Hemoglobin concentration :colorimetric determination of hemoglobin. The Hemoglobin is directly measured and is expressed in grams of hemoglobin per deciliter of whole blood. (Document number DP-52 17/05/2021Version 1)
	2. Hematocrit (HCT)	Hematocrit The Hematocrit is the ratio of red blood cells to plasma and is expressed as a percentage of the whole blood volume. The HCT is calculated from the red blood cell count and the mean cell volume as follows: HCT = (RBC x MCV)/10 (Document number DP-52 17/05/2021Version 1)
	3. Red Blood Cells (RBC)	Red Blood Cell concentration The Red Blood Cell Count is directly measured, and is expressed as follows: RBC = # x 10e6/µL (Document number DP-52 17/05/2021Version 1)
	4. Mean Corpuscular Volume (MCV)	Mean Cell Volume The MCV is derived from the RBC size distribution data on the 0°, 10°, and 90° histograms, and is expressed in femtoliters. (Document number DP-52 17/05/2021Version 1)
	5. Mean Corpuscular Hemoglobin (MCH)	Mean Cell Hemoglobin The Mean Corpuscular Hemoglobin is the average amount of hemoglobin contained in the red blood cell expressed in picograms. (Document number DP-52 17/05/2021Version 1)

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
Whole Blood (EDTA) **(continued)**	6. Mean Cell Hemoglobin Concentration (MCHC)	Mean Cell Hemoglobin Concentration, expressed in grams per deciliter. MCHC is calculated from the HGB and the HCT as follows: MCHC = (HGB/HCT) x Document number DP-52 17/05/2021Version 1)
	7. Red blood cell Distribution Width (RDW)	Red Cell Distribution Width. Red Cell Distribution Width is a statistic parameter and is a measure of the heterogeneity of the RBC population. The CELL-DYN Ruby reports a relative RDW equivalent to a CV in grams per deciliter. Document number DP-52 17/05/2021Version 1)
	8. White Blood Cells (WBC)	White Blood Cell concentration. Flow cytometry technology , with a Helium Neon Laser is as the light source. The instrument measures with the MAPSS (for Multi-Angle Polarized Scatter Separation) technology both types of forward light scatter , both types of orthogonal (side) light scatter The WBC count is determined by enumerating the number of occurrences above a hardware threshold in the 0° channel. The information from all four measurements is used to differentiate the WBC into five subpopulations: Neutrophils Lymphocytes Monocytes Eosinophils Basophils (absolute concentration and percentage of WBC) (Document number DP-52 17/05/2021Version 1)
	9. Platelets (PLT)	Platelet concentration .The sample stream is then hydrodynamically focused to align the cells in single file as they pass through the Optical Flow Cell, which is an optically clear quartz chamber. A vertically polarized Helium Neon Laser is the light source. PLT parameters are calculated using 0° and 10° sensor data. (Document number DP-52 17/05/2021Version 1)
	10. MeanPlateletVolume (MPV)	The Mean Platelet Volume is derived from the PLT histogram after the PLT count has been determined. The MPV is expressed in femtoliters. (Document number DP-52 17/05/2021Version 1)

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

Site of assessement : **Permanent Laboratory premises, 105 Mitropoleos Thessaloniki, Greece.**
Primary sample collection site: 105 Mitropoleos Thessaloniki, Greece.
Approved signatories: **Aikaterini Zafrana.**

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