CYPRUS ORGANIZATION FOR THE PROMOTION OF QUALITY
CYPRUS ACCREDITATION BODY

ACCREDITATION CERTIFICATE no. L088-3

The Board of Governors
of the Cyprus Organization for the Promotion of Quality,
the National Accreditation Body,
in accordance with the Article 7 of the Law 156(I)/2002

GRANTS ACCREDITATION to

LABORATORIES of

THE KARAISKAKIO FOUNDATION

in Nicosia

The Departments/Laboratories shown in annexes were assessed according to the Accreditation Criteria for Medical Laboratories, as defined in the Standard

CYS EN ISO 15189:2022

and were found technically competent to carry out the **Tests** included in the Scope of Accreditation which is described in the **Annexes** to this Certificate and is an **integrated part of it. The Scope of Accreditation** can change only after approval from the Cyprus Accreditation Body.

CYS-CYSAB is a signatory of the European co-operation for Accreditation Multilateral Agreement (EA-MLA) for accreditation in this field.

The current Accreditation Certificate, no. **L088-3**, **is issued on the 25th May 2026 and is valid until the 19th September 2028.**

Accreditation was awarded for the first time on the 20th September 2016.

S Cleridou

Dr Stephanie Cleridou
Director

Date: **25th May 2026**

This laboratory is accredited in accordance with the recognised International Standard ISO 15189:2022. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management System (ISO-ILAC-IAF Communiqué, 08/11/2021).

Annex

to the Accreditation Certificate no. L088-3 (CG)

THE KARAISKAKIO FOUNDATION LABORATORIES CYTOGENOMICS (CG)

Valid as from the 20th September 2024 until the 19th September 2028.
As from 30th April 2025 the valid version of the Standard is ISO 15189:2022.

Materials/ Products	Types of Tests	Methods applied/ Technical fields
Peripheral Blood, Bone Marrow	Interphase Fluorescence in situ hybridization ("FISH")	Interphase FISH using enumeration, break apart and fusion probes (CE-IVD). Hybridization Detection and Analysis using ThermoBrite Hybridization Machine and GenASIs Scan and Analysis System.
Peripheral Blood, Bone Marrow or Tissue	Analysis for copy number changes	CGH array protocol by Agilent. DNA labeling, hybridization, scanning, interpretation. MS 200 NimbleGen Scanner Agilent Cytogenomics Software
Peripheral Blood, Bone Marrow	Optical genome mapping and structural variation detection - Molecular Karyotyping	Saphyr BioNano Genomics

Annex

to the Accreditation Certificate no. L088-3 (MH)

SCOPE OF ACCREDITATION

for

THE KARAISKAKIO FOUNDATION LABORATORIES MOLECULAR HAEMATOLOGY-ONCOLOGY (MH)

Valid as from the 20th September 2024 until the 19th September 2028.
* Valid as from the 30th April 2025 the until the 19th September 2028.
** Valid as from the 25th May 2026 until the 19th September 2028.

As from 30th April 2025 the valid version of the Standard is ISO 15189:2022.

Materials /Products	Types of examinations	Methods applied / Technical fields
Peripheral Blood, Bone Marrow or Tissue	1. "Sample Processing" for nucleic acid extraction and storage, storage of stabilized cells.	In House Protocol: FBC (Sysmex), Erythrocyte lysis, DNA and RNA extraction (QIAGEN QIAcube, MagCore), RNAlater (QIAGEN)
Peripheral Blood, Bone Marrow	2. Detection of fusion transcripts associated with different types of haematological malignancies. del1(p32) (STIL-TAL1), t(1;11) (p32;q23) (MLL-EPS15), (1;11) (q21;q23) (MLL-MLLT11), t(1;19) (q23;p13) (TCF3-PBX1), t(3;5) (q25;q34) (NPM1-MLF1), t(3;21) (q26;q22) (RUNX1-MECOM), t(4;11) (q21;q23) (MLL-AFF1), t(5;12) (q33;p13) (ETV6-PDGFRB), t(5;17) (q35;q21) (NPM1-RARA), t(6;9) (p23;q34) (DEK-NUP214), t(6;11) (q27;q23) (MLL-MLLT4), t(8;21) (q22;q22) (RUNX1-RUNX1T1), t(9;9) (q34;q34) (SET-NUP214), t(9;11) (p22;q23) (MLL-MLLT3), t(9;12) (q34;p13) (ETV6-ABL1), t(9,22) (q34;q11) (BCR-ABL1), t(10;11) (p12;q23) (MLL-MLLT10), t(11;17) (q23;q21) (MLL-MLLT6), t(11;17) (q23;q21) (ZBTB16-RARA), t(11;19) (q23;p13.1) (MLL-ELL), t(11;19) (q23;p13.3) (MLL-MLLT1), t(12;21) (p13;q22) (ETV6-RUNX1), t(12;22) (p13;q11) (ETV6-MN1), t(15;17) (q24;q21) (PML-RARA), inv(16) (p13;q22) (CBFB-MYH11), t(16;21) (p11;q22) (FUS-ERG), t(17;19) (q22;p13) (TCF3-HLF), t(X;11) (q13;q23) (MLL-FOXO4)	Hemavision Screen (CE-IVD): Tandem nested multiplex RT-PCR and electrophoresis
Peripheral Blood, Bone Marrow	3. Detection of Minimum Residual Disease by fusion gene transcripts: ratio to control gene transcript. (t(1;19)(q23;p13) E2A-PBX1, t(4;11)(q21;q23) MLL-AF4, t(12;21)(p13;q22) TEL-AML1, t(9;22)(q34;q11) BCR-ABL m-bcr, t(9;22)(q34;q11) BCR-ABL M-bcr, del(1)(p32p32) SIL-TAL1, t(15;17)(q22;q21) PML-RARA, inv(16)(p13q22) CBFB-MYH11, t(8;21)(q22;q22) AML1-ETO)	In House Protocol, according to EAC Protocol: RT-qPCR, BioRad CFX96 Real Time System *Cepheid's GeneXpert system (CE-IVD)

Peripheral Blood, Bone Marrow or Tissue	4. Mutation detection (JAK2 p.V617F, c-KIT p.D816V, BRAF p.V600E, MYD88 p.L265P)	In House Protocol: Single tube semi-nested PCR, Allele Specific Oligonucleotide (ASO) priming, gel electrophoresis
Peripheral Blood, Bone Marrow	5. Mutation Screening (JAK2 exon 12, BCR-ABL kinase domain, TP53, Hemoglobin Alpha and Beta gene)	In House Protocol: PCR amplification, Sanger DNA Sequencing 3500XL Sequencer
Peripheral Blood, Bone Marrow	6. Indel Detection for FLT3 (ITD), CALR exon9 and *FMR1	In House Protocol: PCR amplification, Agarose gel electrophoresis, (Confirmatory test: Fragment Separation and Analysis 3500XL Sequencer)
Peripheral Blood	7. Cardiovascular disease panel CVD FV G1691A (Leiden), FV H1299R (R2), Prothrombin G20210A, Factor XIII V34L, β-Fibrinogen -455 G-A, PAI-1 4G/5G, GPIIIa L33P (HPA-1), MTHFR C677T, MTHFR A1298C, ACE I/D, Apo B R3500Q, Apo E2/E3/E4	*In House Amplicon Genetic Panel Illumina Platform (NGS Sequencing NextSeq 1000 & NextSeq 2000
Peripheral Blood, Bone Marrow or Tissue	8. T Cell Receptor and Immunoglobulin Gene Rearrangement Assays to identifying clonal B-cell and T-cell populations	Invivoscribe Technologies' IdentiClone™ assays (CE-IVD), PCR Amplification, Fragment Separation and Analysis 3500XL Sequencer
Peripheral Blood, Bone Marrow	9. T Cell Receptor and Immunoglobulin rearrangements by NGS to identifying clonal B-cell and T-cell populations and IGHV somatic mutations	Invivoscribe LymphoTrack Dx (CE-IVD) Illumina Platform (NGS Sequencing, MiSeq 1 & 2) LymphoTrack Analysis Software
Peripheral Blood, Bone Marrow	10. MRD Detection in Lymphoid Malignancies using Patient Specific Immunoglobulin or T-Cell Receptor Allele Specific Oligonucleotide (ASO)-based Real-Time PCR	In house Protocol: ASO Primer Design, Real Time PCR BioRad CFX96 Real Time System
Peripheral Blood, Bone Marrow	11. Chimerism detection of donor DNA component percentage in post-transplant sample	Devyser Chimerism Kit (CE-IVD) and *In House Amplicon NGS method Illumina Platform (NGS Sequencing NextSeq 1000 & NextSeq 2000), DEVYSER for Chimerism software

Peripheral Blood, Bone Marrow or Tissue (Fresh or FFPE)	12. Detection of gene fusions, splicing or exon skipping in genes associated with Solid Tumors, Sarcomas, Thyroid and Lung Cancer, Myeloid Malignancies, Acute Lymphocytic Leukemia, Lymphomas and other Hematological Malignancies	Archer FusionPlex assay, **Automated library preparation using Hamilton Liquid Handler, Illumina Platform (RNA NGS Targeted Sequencing) NextSeq 1000 & NextSeq 2000, Archer Bioinformatics Analysis Software
Peripheral Blood, Bone Marrow Tissue (Fresh or FFPE) or cfDNA	13. Detection of single nucleotide variants (SNVs), copy number, variations (CNVs), insertions and deletions in genes associated with Solid Tumors, Thyroid and Lung Cancer, Myeloid and other Hematological Malignancies	Archer VariantPlex assay, **Automated library preparation using Hamilton Liquid Handler, ctDNA assay Illumina Platform (DNA NGS Targeted Sequencing) NextSeq 1000 & NextSeq 2000, Archer Bioinformatics Analysis Software
Peripheral Blood, Bone Marrow or Tissue (Fresh or FFPE)	14. Germline Mutation and Copy Number Aberrations Detection in genes associated with cancer predisposition and other inherited conditions.	Agilent SureSelect Enrichment, Agilent Magnis (Library Preparation) Illumina Platform (DNA NGS Exome or Targeted Sequencing) NextSeq 1000 & NextSeq 2000, Saphetor Clinical Varsome NGS (Data Analysis) and Franklin (Data Analysis). Reflex or Confirmatory Testing: MRC Holland MLPA, ABI 3500XL (Fragment separation), Sanger Sequencing, MRC Holland Digital MLPA, Coffalyser Software analysis *In House Amplicon NGS method; Illumina Platform NextSeq 1000 & NextSeq 2000
Peripheral Blood, Bone Marrow or Tissue (Fresh or FFPE)	15. Somatic Mutation, **Detection and Quantification, Copy Number Aberrations and Promoter Methylation Detection in genes associated with various malignancies	Agilent SureSelect Enrichment and Agilent OneSeq CNV Backbone, Agilent Magnis (Library Preparation) Illumina Platform (DNA NGS Exome or Targeted Sequencing) NextSeq 1000 & NextSeq 2000, Saphetor Clinical Varsome (Data Analysis), Agilent SureCall NGS (Data Analysis) and Franklin (Data Analysis). Reflex or Confirmatory Testing: MRC Holland MLPA, ABI 3500XL (Fragment separation), Coffalyser Software analysis *In House Amplicon NGS

		method; Illumina Platform NextSeq 1000 & NextSeq 2000
Tissue (FFPE)	16. Detection of gene fusions for ALK, ROS1, RET, MET Exon 14 skipping and expression imbalance for ALK, ROS1, RET and NTRK1/2/3	Biocartis Idylla GeneFusion Assay
Tissue or Liquid Biopsy	17. EGFR, KRAS, NRAS, BRAF Mutation detection	Idylla Biocardis BRAF (CE-IVD), KRAS (CE-IVD), NRAS-BRAF (CE-IVD), EGFR (CE-IVD), ctKRAS (CE-IVD), ctNRAS-BRAF (CE-IVD), NRAS-BRAF-EGFR S492R, ctBRAF, ctKRAS, ctNRAS-BRAF-EGFR S492R, ctEGFR
Tissue (FFPE)	18. Detection of and Microsatellite Instability (MSI) in colorectal cancer or in solid tumors	Idylla Biocardis (CE-IVD)

Annex

to the Accreditation Certificate no. L088-3 (IG)

SCOPE OF ACCREDITATION

for

THE KARAISKAKIO FOUNDATION LABORATORIES IMMUNOGENETICS (IG)

Valid as from the 20th September 2024 until the 19th September 2028.
As from 30th April 2025 the valid version of the Standard is ISO 15189:2022.

Materials /Products	Types of examinations	Methods applied / Technical fields
Peripheral Blood, Bone Marrow	Class I and Class II HLA Genotyping	1) Next generation sequencing using NGS MiSeq 1& 2 (Holotype, Omixon) or Next generation sequencing MinION Nanopore (Omixon) HLA Typing Protocol 2) RT-PCR BioRad CFX96 Real Time PCR System (BAG Diagnostics) (CE-IVD)
Peripheral Blood	HLA Antibody screening and identification	Luminex LABScan 3D LABScreen Mixed Class I & II (CE-IVD), LABScreen Single Antigen HLA Class I and ExPlex combination (CE-IVD), LABScreen Single Antigen HLA Class II and ExPlex combination (CE-IVD)

Annex

to the Accreditation Certificate no. L088-3 (FC)

SCOPE OF ACCREDITATION

for

THE KARAISKAKIO FOUNDATION LABORATORIES
FLOW CYTOMETRY (FC)

Valid as from the 20th September 2024 until the 19th September 2028.
*Valid as from the 30th April 2025 the until the 19th September 2028.
** Valid as from the 25th May 2026 until the 19th September 2028.

As from 30th April 2025 the valid version of the Standard is ISO 15189:2022.

Materials /Products	Types of examinations	Methods applied / Technical fields
Peripheral Blood, Bone Marrow, CSF	(1) General Bone Marrow Investigation (2) Basic acute leukemia immunophenotyping (3) Basic LPD immunophenotype (4) B-Acute lymphoblastic leukemia, Minimal Residual Disease (5) Plasma Cell Multiple Myeloma Minimal Residual Disease	Cytoplasmic and surface cellular marker staining, Flow Cytometry Analysis FACS Verse and *FACS Lyric Flow Cytometer
Peripheral Blood	T Lymphocyte Enumeration	BD Trucount Absolut Counting tubes (CE-IVD), CD3/ CD8/ CD45/ CD4 BD Multitest (CE-IVD) surface cellular marker staining, FACS Verse and *FACS Lyric Flow Cytometry Analysis
Peripheral Blood, Bone Marrow	Lymphocyte subpopulation analysis	FACS Verse and *FACS Lyric Flow Cytometry Analysis CD3/ CD4/ CD8/ CD19/ CD16+56
Peripheral Blood	Paroxysmal Nocturnal Hemoglobinuria (PNH)	In-house method Detection of glycophosphatidylinositol (GPI)-linked antigens on hematopoietic cells using monoclonal antibodies FACS Verse and *FACS Lyric
Peripheral Blood, Bone Marrow, Cord Blood and Apheresis Products	CD34+ stem cell enumeration	BD Stem Cell Enumeration assay (CE-IVD), BD FACS Verse and *FACS Lyric
Peripheral Blood, Bone Marrow	Full Blood Count of Blood Samples by an automated Haematology Analyser (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, RDW-SD, RDW-CV, PDW, MPV, P-LCR, PCT, NEUT, LYMPH, MONO, EO, BASO)	Sysmex XN550 (CE-IVD)

Peripheral Blood	*Flow Cytometry Crossmatch	In House Protocol, Cell staining. BD FACS Lyric Flow Cytometer
Peripheral Blood, Bone Marrow	*Multiple Myeloma MRD by Euroflow	EuroFlow™ SOP for bulk lysis in MRD panels BD FACS Verse & FACS Lyric Flow Cytometer, Infinicyt Flow Cytometry Software
Serum	**Soluble CD25 (IL-2Ra) quantification	Bio-Plex 200 Pro Human Cytokine Assay

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Primary Sample Collection		
Materials/ Products	**Types of Tests**	**Methods applied/ Technical fields**
Peripheral Blood	1. Primary Sample collection and handling 2. Sample reception 3. Patient registration/Request Form 4. Sample transportation 5. Result transmission	Guidelines SOP 5.4.1.0 Test Requisition and Sample Receiving

General Remarks

These Annexes refer **only to tests** carried out **in the premises of the Laboratory**, Address: 15, Nicandrou Papamina Avenue, 2032, Nicosia

Dr Stephanie Cleridou
Director

Date: **25th May 2026**