Hellenic Accreditation System

Annex G1/13 to the Certificate No. **847**-5

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

“Iatropolis Magnitiki Tomografia S.A.”

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Biochemical Testing		
Blood serum	**Determination of 25 parameters**	**Automated biochemical analyzers ALINITY AC03290, AC03291, AC04765 Abbott Laboratories** MT-24-01 «Exam Catalog », version 6, 20/03/2024
	1. GLUCOSE	HEXOKINASE/G-6-PDH
	2. UREA	UREASE
	3. CHOLESTEROL	ENZYMATIC
	4. HDL	ACCELERATOR SELECTIVE DETERGENT
	5. LDL	CALCULATED
	6. URIC ACID	URICASE
	7. TRIGLYCERIDES	GLYCEROPHOSPHATE OXIDASE
	8. CREATININE	PICRIC ACID IN ALCALINE SOLUTION
	9. TOTAL BILIRUBIN	DIAZONIUM SALT
	10. DIRECT BILIRUBIN	DIAZONIUM SALT
	11. TOTAL PROTEIN	BIURET
	12. ALBUMIN	BROMOCRESOL GREEN
	13. IRON	FERENE
	14. CALCIUM	PHOTOMETRIC DETERMINATION WITH ARSENAZO

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Blood serum (continued)	15. PHOSPORUS	PHOSPHOMOLYBDIC ACID
	16. SGOT/AST	NADH (without P-5'-P)
	17. SGPT/ALT	NADH (without P-5'-P)
	18. γGT	L-Gamma-glutamyl-3-carboxy-4-nitroanilide SUBSTRATE
	19. CPK	IFCC METHOD
	20. LACTATE DEHYDROGENASE (LDH)	Conversion of L-lactic acid to pyruvate acid, mediated by NAD+
	21. ALP	IFCC METHOD
	22. MAGNESIUM	ENZYMATIC
	23. POTASSIUM	ION SELECTIVE ELECTRODE
	24. SODIUM	ION SELECTIVE ELECTRODE
	25. CLORIDE	ION SELECTIVE ELECTRODE
Whole blood (EDTA)	1. Glycated hemoglobin (HBA1c (A1C-2)	Anosotholosimetria microparticle agglutination inhibition
Immunochemical Testing		
Blood serum	**Determination of 15 parameters**	**Automated immunochemical analyzers AI20317, AI20318, AI20319, AI03382 Abbott Laboratories** MT-24-01 «Exam Catalog », version 6, 20/03/2024
	1. Ferritin	CHEMILUMINESCENCE (CLIA)
	2. Triidothyronine total (T3)	CHEMILUMINESCENCE (CLIA)
	3. Thyroxin total (T4)	CHEMILUMINESCENCE (CLIA)
	4. Free Triidothyronine (FT3)	CHEMILUMINESCENCE (CLIA)
	5. Free Thyroxin (FT4)	CHEMILUMINESCENCE (CLIA)
	6. Thyrotropin Hormone (TSH)	CHEMILUMINESCENCE (CLIA)
	7. Anti-thyroid peroxidase antibodies (anti-TPO)	CHEMILUMINESCENCE (CLIA)
	8. Antithyroglobulin antibodies (anti-TG)	CHEMILUMINESCENCE (CLIA)
	9. Total prostate-specific antigen (PSA)	CHEMILUMINESCENCE (CLIA)
	10. Free prostate-specific antigen (Free PSA)	CHEMILUMINESCENCE (CLIA)
	11. VITAMIN D	CHEMILUMINESCENCE (CLIA)
	12. VITAMIN B12	CHEMILUMINESCENCE (CLIA)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	13. FOLATE	CHEMILUMINESCENCE (CLIA)
	14. Carcinoembryonic antigen (CEA)	CHEMILUMINESCENCE (CLIA)
	15. Beta human chorionic gonadotropin (HCG)	CHEMILUMINESCENCE (CLIA)
Hematology testing		
Whole blood (EDTA)	**Determination of 15 parameters**	**Automated analyzer ALINITY HQ0721, HQ1083 Abbott Laboratories** MT-24-01 «Exam Catalog», version 6, 20/03/2024
	1. Red Blood Cells (RBC)	Flow cytometry
	2. Hematocrit (HCT)	Calculated from RBC & MCV
	3. Mean Cell Volume (MCV)	Flow cytometry
	4. Platelets (PLTs)	Flow cytometry
	5. Mean corpuscular haemoglobin (MCH)	Calculated from HGB & RBC
	6. Mean cell haemoglobin concentration (MCHC)	Calculated from HGB & HCT
	7. Hemoglobin (HGB)	Colorimetric determination
	8. White Blood Cells (WBC)	Flow cytometry
	9. Red Distribution Width (RDW)	Calculated
	10. Mean Platelet Volume (MPV)	Calculated
	11. Lymphocytes (LYMPH)	Flow cytometry
	12. Basophils (BASO)	Flow cytometry
	13. Monocytes (MONO)	Flow cytometry
	14. Neutrophils (NEUT)	Flow cytometry
	15. Eosinophils (EO)	Flow cytometry
Blood films	Red Blood Cells' Morphology / Platelets' Morphology/ White Blood Cell Differential Count (absolute number and %)**:** Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Abnormal Cells	Microscopic examination

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Molecular Testing		
Tissue Formalin Fixed and Paraffin Embedded (FFPE)	Detection of mutation V600E/V600complex of BRAF gene	EasyPGX ready *BRAF* multiplex PCR assay DiaTech Pharmacogenetics
Tissue Formalin Fixed and Paraffin Embedded (FFPE)	Mutation detection on KRAS gene (Exons: 2, 3, 4)	EasyPGX ready *KRAS* multiplex PCR assay DiaTech Pharmacogenetics
Tissue Formalin Fixed and Paraffin Embedded (FFPE)	Mutation detection on NRAS gene (exons: 2, 3, 4)	EasyPGX ready *NRAS* multiplex PCR assay DiaTech Pharmacogenetics
Tissue Formalin Fixed and Paraffin Embedded (FFPE)	Mutation detection on EGFR gene (exons:18,19,20,21)	EasyPGX ready *EGFR* multiplex PCR assay DiaTech Pharmacogenetics
1)Cervical smear in PreservCyt Solution CE-IVD vial (ThinPrep PAP TEST) of HOLOGIC/ROCHE company or similar vial of cervical smear accepted by ROCHE, 2) Urine in Colli Pee device UCM CE-IVD of NOVOSANIS company	Qualitative detection and typing of high-risk subtypes 16 & 18 and detection of 12 additional high-risk subtypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) collectively without typing them under the name Other High	HPV DNA Cobas Assay ROCHE Diagnostics
Cervical smear in PreservCyt Solution CE-IVD vial (ThinPrep PAP TEST) of HOLOGIC/ROCHE	Qualitative detection and typing of high-risk subtypes 16 & 18 and detection of 12 additional high-risk subtypes (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) collectively without typing them under the name Other High	AllPlex HPV 28 detection kit Seegene IVD-CE
Whole blood EDTA (x2)	Mutation detection on BRCA1-2 gene	Myriapod NGS BRCA 1-2 panel IVD-CEA7:D7
Whole blood EDTA (x2)	Mutation detection on BRCA1-2 gene	BRaCA panel IVD-CE

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Histopathology		
Biopsies and Surgical Specimens from whole Human Body Organs and Systems Formalin Fixed Tissues in 10% neutral buffered Formalin Paraffin Embedded Tissues Biopsy Excisional or Incisional Surgically Resected Specimens	Grossing and Microscopic Examination of tissues, in order to identify or exclude morphological and cytological aberrations from normal, and to establish Histological Diagnosis	**Gross and Microscopic Examination** Dissection Performed in Bio-Optika Trimming Teck Hood 180 Grossing Station Gross Description According to International and Hellenic Society of Pathology Guidelines (*CAP, ADASP, AJCC, FIGO, RCP, TNM,WHO, ΕΕΠΑ,* AFIP *etc).* Tissue processing Automated processing dehydration, clearing and paraffin tissue infiltration in closed type tissue processor, τύπου Thermo Scientific EXCELSIOR AS or open type Epredia STP-120-2 Decalcification (mild) Paraffin Embedding System A complete system with a thermal unit, a dispenser unit and a cooling unit Epredia/Histostar Preparation of tissue section on glass slide Automated Microtome Thermo Scientific HM 355S Semi-automated Microtome Epredia HM 340E Semi-automated Microtome Slee-CUT 5062 Haematoxylin / Eosin stain and addition of cover slip on the tissue section Permanent sections with an Automated Slide Stainer Epredia/Gemini AS and an Automated Glass Coverslipper Epredia ClearVue. Rapid H&E, manually **Microscopic Diagnosis** Microscopes OLYMPUS Mod. BX53 (two) and Mod. BX46 **Microscopic Evaluation and Interpretation of Results.** In Neoplasms: grading of malignancy and staging of the disease according to the AJCC recommendations (Cancer Staging Manual 8thEd), classification according to theWHO [ICD-O code]
Histochemistry		

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Biopsies and Surgical Specimens from whole Human Body Organs and Systems Formalin Fixed Tissues in 10% neutral buffered Formalin Paraffin Embedded Tissues Biopsy Excisional or Incisional Surgically Resected Specimens	Identification of tissue components and microorganisms.	**<u>Special staining:</u>** Automated, ready to use kits Closed system, with Automated Slide Stainer and Glass Cover slipper Epredia Gemini AS, for **GIEMSA** staining **Manually** for specific stains: MASSON TRICHROME PAS-D PAS PERLS RETICULIN **Microscopic Evaluation – Interpretation of Results**
Immunohistochemistry		
Biopsies and Surgical Specimens from whole Human Body Organs and Systems Formalin Fixed Tissues in 10% neutral buffered Formalin Paraffin Embedded Tissues Biopsy Excisional or Incisional Surgically Resected Specimens	**Detection of Markers and Protein Expression** **Antibodies** 1) CD45 (LCA) 2) Chromogranin A 3) Cytokeratin AE1+AE3 4) Ki-67 5) p53	**<u>IMMUNOHISTOCHEMISTRY</u>** Automated device for immunohistochemistry and antigen retrieval: Thermo Scientific Autostainer 480S+PT, **VENTANA Benchmark GX, DAKO Autostainerlink 48** **Morphometric analysis of tumors with immunohistochemistry** Semiquantitative method for each antibody; manually (ASI System) **Interpretation of Results – Reporting** According to International Guidelines.

**Reference to the commercial name of a specific analyzer, refers to a specific analytical method and protocol*
***IFCC: International Federation of Clinical Chemistry*

Site of assessement : **Permanent Laboratory premises, Laboratory main premises, 1 Tatoiou str & Anagenniseos str, 14451 Metamorfosi, Athens, Greece.**

Company branches & Primary Sample Collection Sites:

1. **Chalandri premise, 56 Ethnikis Antistaseos str, 15231 Chalandri, Athens, Greece**
2. **Argyroupoli premise, 599 Vouliagmeni Avenue, 16452 Argyroupoli, Athens, Greece**
3. **Athens premise, 64 Vasilissis Sofias str, 11528 Athens, Greece**
4. **Keratsini premise, 549 Grigoriou Lambraki Avn & Sxistou- Skaramgka Avn, 18757 Keratsini, Athens, Greece**
5. **Peristeri premise, 105 Vas. Alexandrou str & Mesologgiou str, 12131 Peristeri, Athens, Greece**
6. **Patision premise, 290 Patision str, 11255 Athens, Greece**

7. **Iliou premise, 29 Iliou str & Chrisiidos str, 13122 Ilion, Athens, Greece**
8. **Metamorfosi premise, 1 Tatoiou str & Anagenniseos str, 14451 Metamorfosi, Athens, Greece.**
9. **Nea Smirni premise, 187 Andrea Syggrou Aven, Nea Smirni 17121, Athens, Greece**

Approved signatures: **A Vatopoulos, P. Mazarakou, A. Soumila, M. Verzamani, H. Danassi, B. Dedouli, M. Simenidou, I. Adamopoulos, I. Moustakas, A. Karameris, S. Psarogiorgou, N. Chaleplidis, and E. Tsitsopoulos.**

This scope of Accreditation replaces the previous one dated 27.02.2025.
The Accreditation Certificate No. **847**-5, to ELOT EN ISO 15189:2022, is valid until 03.12.2029

Athens, 16.04.2025

Konstantinou Evangelos Apostolos
CEO of ESYD