Hellenic Accreditation System

Annex G1/11 to the Certificate No.**1000**-3

SCOPE of ACCREDITATION

of the

Clinical Laboratories

of

DIAGNOSTIC AND THERAPEUTIC CENTER OF ATHENS HYGEIA S.M.S.A.

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Biochemical tests		
1.Blood serum	**Determination of 10 parameters**	**Automated biochemical- analyzers Atellica CH 1 & 2 (Siemens)***
	1. Glucose_3 (GLUH_3)	Atellica CH Glucose Hexokinase_3 (GluH_3) 11097592 Rev. 03, 2019-05
	2. Urea (BUN)	Atellica CH Urea Nitrogen (UN_c) (Ουρεάση) 11097593 Rev. 02, 2019-07
	3. Uric acid (UA)	Atellica CH Uric Acid (UA) (Ουρικάση) 11097608 Rev. 03, 2019-05
	4. Creatinine_2 (CREA_2)	Atellica CH Creatinine_2 (Crea_2) 11097596 Rev. 04, 2019-07
	5. Cholesterol_2 (CHOL_2)	Atellica CH Cholesterol_2 (Chol_2) oxidase, esterase, peroxidase 11097609 Rev. 03, 2019-07
	6. Triglycerides_2 (TRIG_2)	Atellica CH Triglycerides (concentrated) (Trig) 11097591 Rev. 03, 2019-11
	7. Glutamic oxaloacetic transaminase (SGOT/AST)	Atellica CH Aspartate Aminotransferase (AST) 11097607 Rev. 02, 2019-07
	8. Glutamic-pyruvic transaminase (SGPT/ALT)	Atellica CH Alanine Aminotransferase (ALT) 11097605 Rev. 04, 2019-06
	9. Gamma glutamyl transferase (GGT)	Atellica CH Gamma-Glutamyl Transferase (GGT) 11097597 Rev. 02, 2019-07
	10. Reactive Protein_2 (CRP_2)	Atellica CH Reactive Protein_2 (CRP_2) Rev. 02.2019-10

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Hematological tests		
1. Whole blood (EDTA)	**Determination of 4 parameters**	**Automated hematology analyzers** **Advia 1, 2 & 3 (Siemens)***
	1. Complete Blood Count (CBC) - White Blood Cell Count (WBC)	Flow Cytometry & Light scatter analysis 00739500 /03/2019 T01-3621-52
	2. Complete Blood Count. (CBC)- Red Blood Cell Count (RBC)	Light scatter analysis 08008297 /03/2019 T01-3626-52
	3. Complete Blood Count (CBC)- Platelet Count (PLT)	Light scatter analysis 08008297 /03/2019 T01-3626-52
	4. Complete Count (CBC) - Hemoglobin (Hgb)	Photometric assay 08008297 /03/2019 T01-3626-52
Coagulation tests		
1. Whole blood (Sodium citrate)	**Determination of 5 parameters**	**Automated hemostasis- -analyzers** **SYSMEX CS-5100,** **SIEMENS BCS XP***
	1. Prothrombin Time (PT)	Coagulometric assay — Activation of coagulation cascade Thromborel S OUHPG29C11 Rev. 10, 2018-08
	2. International Normalized Ratio (INR)	Calibrated - Coagulometric assay - Activation of coagulation cascade Thromborel S OUHPG29C11 Rev. 10, 2018-08
	3. Activated Partial -Thromboplastin Time (APTT)	Coagulometric assay - Activation of coagulation cascade Pathromtin SL OQGSG29E11 Rev. 09, 2018-08
	4. Fibrinogen	Coagulometric assay — Activation of coagulation cascade Sysmex CS5100: Dade Thrombin Reagent B4233G25E11 Rev. 05, 2019-07 Siemens BCS-XP: Multifibren U OWZGG19E11 Rev04, 2018-01
	5. D-dimer	Immunoturbidity process, activation of aggregation. D-dimer Reagent: OPBPG03C34, Rev.05, 2013-01
NOTE: Each analyzer is a backup of the other, with equivalence in each parameter, with the exception of Fibrinogen, in which, due to different reagent used, there is no equivalence and is used only as an alternative backup methodology.		
Immunochemical tests		
1.Blood serum	**Determination of 5 parameters**	**Automated immünochemical analyzers** **Automated immünochemical analyzer Atellica IM 1 (Siemens)***
	1. Ferritin	Sandwich immunoassay two-point -measurement

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
		technology that. uses direct chemiluminescence (CLIA) Atellica IM Ferritin (Fer) 10995569 Rev. 03, 2019-07
	2. Troponin I high Sensitivity (TnIH)	Sandwich Immunoassay three-point measurement technology that uses direct chemiluminescence (CLIA) Atellica IM High-Sensitivity Troponin I (TnIH) 10997840 Rev. 06, 2019-08
	3. Vit B12	Competitive immunoassay using, direct chemiluminescence (CLIA) technology Atellica IM Vitamin B12 (VB12) 10995714 Rev. 02, 2019-08
	4. CK-MB	Sandwich immunoassay two-point -measurement technology that. uses direct chemiluminescence (CLIA) Atellica IM Creatine Kinase MB (CKMB) 10995530 Rev. 02, 2019-07
	5. Folate	Competitive immunoassay using, direct chemiluminescence (CLIA) technology Atellica IM Folate (Fol) 10995572 Rev. 03, 2019-07
	Determination of 6 parameters	**Automated immünochemical analyzer Atellica IM 2 (Siemens)***
	1. Free Triidothyronine (Free T3)	Competitive immunoassay using, direct chemiluminescence (CLIA) technology Atellica IM Free Triiodothyronine (FT3) 10995585 Rev. 02, 2020-02
	2. Total Human Chorionic Gonadotropin (t-HCG)	Sandwich immunoassay two-point -measurement technology that. uses direct chemiluminescence (CLIA) Atellica IM Total hCG (ThCG) 10995690 Rev. 03, 2020-02
	3. Prostate Specific Antigen-(PSA)	2-site sandwich immunoassay using direct chemiluminometric technology, which uses constant amounts of 2 antibodies Atellica IM Prostate-Specific Antigen (PSA) 10995662 Rev. 03, 2019-09
	4. Free Thyroxin (Free T4)	Competitive immunoassay using, direct chemiluminescence (CLIA) technology Atellica IM Free Thyroxine (FT4) 10995589 Rev. 03, 2019-07
	5. Thyroid-stimulating hormone (TSH)	Third-generation assay that employs anti-FITC monoclonal Antibody Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) 10995703 Rev. 03, 2019-08
	6. Troponin I high Sensitivity (TnIH)	Sandwich Immunoassay three-point measurement technology that uses direct chemiluminescence (CLIA)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
		Atellica IM High-Sensitivity Troponin I (TnIH) 10997840 Rev. 06, 2019-08
Cytological tests		
1.Conventional vaginal and cervical smears	1. Morphologic examination Detection of neoplasia and typing	**Qualitative and semi-quantitative method** 1. Pap stain (automatic stain machine Thermoscientific Gemini) 2. Microscopic evaluation (Microscopes NIKON 80i, 50i) 3. The 2014 BETHESDA System for reporting cervical Cytology (BETHESDA CLASSIFICATION) HYG_P367/3η/01.02.2023
2.Vaginal and cervical smears by liquid – based cytology (thin prep technique ©)	1. Morphologic examination. Detection of neoplasia and typing	**Qualitative and semi-quantitative method** 1. Pap stain (automatic stain machine Thermoscientific Gemini) 2. THIN PREP CYTYC 2000* 3. Microscopic evaluation (Microscopes NIKON 80i, 50i) 4. The 2014 BETHESDA System for reporting cervical Cytology (BETHESDA CLASSIFICATION) HYG_P367/3η/01.02.2023
Anatomic pathology tests		
Histological tests		
1.Biopsies and surgical specimens of all Organs and systems Fresh tissue, FFPE tissue	1.Macroscopic and microscopic examination of tissues for recognition and/or exclusion of morphologic and cytological abnormalities	**Macroscopic and microscopic examination** **PRO PATH**: gross dissection working station where tissue sampling is also performed **EXCELSIORE AS EPREDIA:** tissue processor **BIO-OPTICA BEC 150**: Paraffin embedding system **THERMO SCIENTIFIC EPREDIA HM340E && LEICA AS HistoCoreMuliant :** microtomes for preparation of paraffin blocks **GEMINI-SBTS-CLEARVUE (οίκου Epredia UK):** Automated staining system and cover-slipping system **LEICA CM1950 και CRYOSTAR NX50 EPREDIA**: cryostats for frozen section preparation **Olympus BX61, BX60 BX43, BX41, BX40 and NIKON eclipse E200 and ZEIZZ Axiolab:** Microscopes for microscopic examination of all the histological section slides (Hematoxylin – Eosin, special histochemical and immunohistochemical).

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
		HYG_P359/3η/16.11.2020
Histochemical tests		
1. Fresh tissue, FFPE tissue	1. Determination of tissue components and enzymes	**ESPECIAL HISTOCHEMICAL STAINS** Using special Kits, manually. GOMORI(silver impregnation, bio-optica), PAS (bio-optica), PAS D (bio-optica), PERL(neutral red-scharlau, Potassium hexacyanoferrate II-sigma), CONGO RED (sodium chloride-sigma, sodium hydroxide-sigma, mayers hematoxylin-merck , congo red-sigma) MASSON TRICHROME (with aniline blue-bio-optica) , ZIEHL NIELSEN (atom scientific) , GIEMSA(merck), ELASTICA (weigert van gieson –bio optica, MASSON FONTANA (silver nitrate-honeywell, sodium triosulphate-sigma, neutral red-scharlau), GROCOTT(bio-optica), GRAM(bio optica), ALCIAN BLUE PAS(bio optica) Microscopic examination and interpretation HYG_P360/5th /01.12.2023
2.FFPE tissue	1. Hematoxyline-Eosin stain	Microscopic examination of the morphology of tissues and cells stained with hematoxyline (nuclei) and eosin (cytoplasm) Hematoxyline) ,Gill III (Merck) Eosin-Y solution 0.5% alcoholic(Merck). HYG_P358/4η/01.12.2023
Immunohistochemical tests		
1.Biopsies and surgical specimens of all Organs and systems Fresh tissue, FFPE tissue	1.Expression of chromogen tagged cellular antigens (proteins) in the nucleus, the cytoplasm or the cell membrane	**VENTANA BENCHMARK ULTRA** Microscopic examination and interpretation using qualitatively or semi-quantitative methods of the automated immunochistochemical staining results. **REAGENTS*** • OPTIVIEW KIT (Ventana-Roche IVD) OR UNIVERSAL KIT (Ventana-Roche IVD) • HEMATOXYLINE I (Ventana-Roche IVD) • BLUING (Ventana-Roche IVD) • PROTEASE I(Ventana-Roche IVD) • AMPLIFIER A/B (Ventana-Roche IVD) HYG_P350/6η/01.12.2023 **ANTIBODIES*** • ER (SP1 –Ventana Roche IVD) • PgR (1E2-Ventana Roche IVD) • HER2 / Neu (4B5-Ventana-Roche IVD) • Ki67 (MIB-1-DAKO IVD)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Fresh tissue, FFPE tissue (continued)	Expression of chromogen tagged cellular antigens (proteins) in the nucleus, the cytoplasm or the cell membrane (continued)	•E-CADHERIN (NCH-38-DAKO IVD) •GATA-3 (L50-823-Ventana Roche IVD) •S100 (4C4-9-CELL MARQUE IVD) •SOX10 (SP267 -Ventana Roche IVD) •MELANOMA (HMB45-NOVOCASTRA IVD) •MELAN-A/MART1 (A103- Ventana Roche IVD) •TTF1 (8G7G3/1- CELL MARQUE IVD) •CHROMOGRANIN A (LK2H10 CELL MARQUE IVD) •SYNAPTOPHYSIN (27G12-NOVOCASTRA IVD) •CD30 (Ber-H2-DAKO IVD) •ALK (D5F3-Ventana Roche IVD) •PDL-1 (22C3-Ventana Roche IVD) •PDL-1 (SP263-Ventana Roche IVD) • PDL-1 (SP142- Ventana Roche IVD) • CK7 (OV-TL-12/30 DAKO IVD) • P63 (BC4A4 BIOCARE IVD) • PAX5 (SP34 CELL MARQUE IVD) • CD3 (2GV6 ROCHE IVD) • CD20 (L26 DAKO IVD) • CD5 (4C7 NOVOCASTRA IVD) • CD31 (JC70A DAKO IVD) • ERG (9FY BIOCARE IVD) • MDM2 (IF2 LIFE TECHNOLOGIES IVD) • DESMIN (D33 DAKO IVD) • IDH1 (R132H DIANOVA-DAKO IVD) • ATRX (POLYCLONAL SIGMA) • P53 (DO7 BIOGENEX IVD) • GFAP (GA-5 BIOGENEX IVD) • CD34 (QBEnd/10 CELL MARQUE IVD) • BCL2 (SP66 ROCHE IVD) • BCL6 (GI191 E/A8 CELL MARQUE IVD) • CD10 (SP67 ROCHE IVD) • CD23 (DAK-CD23 DAKO IVD) • KAPPA (POLYCLONAL DACO IVD) • LAMBDA (POLYCLONAL DACO IVD)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
		• MAMMAGLOBIN (31A5 CELL MARQUE IVD) • CALRETININ (SP65 ROCHE IVD) • CYCLIN D1 (SP4-R ROCHE VENTANA IVD) • MUM1 (MUM1p DAKO IVD) • WT1 (6F-H2 DAKO IVD) • PSA (431 LEICA IVD) • CDX2 (EPR2764Y CELL MARQUE IVD) • CD15 (MMA CELL MARQUE IVD) • CD79a (JCB117 DAKO IVD) • CD4 (SP35 ROCHE IVD) • CD8 (C8/144B DAKO IVD) • CK20 (NCL-L-CK20 LEICA IVD) • CD35 (EP197 ZETA IVD) • CD138 (B-A38 CELL MARQUE IVD) HYG_P350/6η/01.12.2023 HYG_F1324/1η/15.10.2021

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

Site of assessment: **Permanent premises, Clinical Laboratories: 4, Erythrou Stavrou & Kifisias Ave., 15123, Maroussi, Athens, Greece**.

Primary Sample Collection: **Permanent premises, Clinical Laboratories: 4, Erythrou Stavrou & Kifisias Ave., 15123, Marousi, Athens, Greece**

Approved signatories: **H. Papadogeorgaki, H. Salla, I. Klapsinou, K. Savvidou, S. Papadopoulos, D. Papaioannou, T. Georgiadis, A. Margariti, M. Sotiropoulou, M. Terzi, F. Mihalopoulou, G. Papias, A. Klimis, I. Themeli, C. Stamou, K. Paulou, A. Michail Strantzia.**

This Scope of Accreditation replaces the previous one dated 25.03.2024.

The Accreditation Certificate No **1000**-3, to ELOT EN ISO 15189:2022, is valid until **16.09.2028.**

Athens, 12.04.2024

Christos Nestoras
CEO of ESYD