

Hellenic Accreditation System



ACCREDITATION CERTIFICATE

No. 1000-2

The Hellenic Accreditation System (ESYD), as the national accreditation body of Greece in accordance with the Law 4468/2017,

ACCREDITS

the
Clinical Laboratories
of
DIAGNOSTIC AND THERAPEUTIC CENTER OF ATHENS
HYGEIA S.A.

in Maroussi, Attiki, Greece

under the terms of the ELOT EN ISO 15189:2012 Standard and the ESYD Criteria, to carry out tests, as specified in the attached Scope of the Accreditation, which may be revised by decisions of ESYD.

The initial assessment was issued on September 17, 2015. This Certificate is valid until September 16, 2023, provided that the accredited body will comply with the above Standard and the ESYD Criteria.

Athens, October 31, 2019



Hellenic Accreditation System



Annex G1/7 to the Certificate No.1000-2

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 9 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

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 4 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
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 4 parameters	Automated immunochemical analyzers Automated immunochemical analyzer Atellica IM 1 (Siemens)*
	1. Ferritin	Sandwich immunoassay two-point -measurement technology that. uses direct chemiluminescence (CLIA) Atellica IM Ferritin (Fer) 10995569 Rev. 03, 2019-07

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	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
	2. Vit B12	Competitive immunoassay using, direct chemiluminescence (CLIA) technology Atellica IM Vitamin B12 (VB12) 10995714 Rev. 02, 2019-08
	3. CK-MB	Sandwich immunoassay two-point -measurement technology that. uses direct chemiluminescence (CLIA) Atellica IM Creatine Kinase MB (CKMB) 10995530 Rev. 02, 2019-07
	4. Folate	Competitive immunoassay using, direct chemiluminescence (CLIA) technology Atellica IM Folate (Fol) 10995572 Rev. 03, 2019-07
	Determination of 6 parameters	Automated immunochemical analyzer Atellica IM 2 (Siemens)*
	1. Free Triiodothyronine (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) Atellica IM High-Sensitivity Troponin I (TnIH) 10997840 Rev. 06, 2019-08

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
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 Shandon VARISTAIN 24-4) 2. Microscopic evaluation (Microscopes NIKON 80i, 50i) 3. The 2014 BETHESDA System for reporting cervical Cytology (BETHESDA CLASSIFICATION) HYG_I36/2 ^o /01.06.2016
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 Shandon VARISTAIN 24-4) 2. THIN PREP CYTYC 2000* 3. Microscopic evaluation (Microscopes NIKON 80i, 50i) 4. The 2014 BETHESDA System for reporting cervical Cytology (BETHESDA CLASSIFICATION) HYG_I36/2 ^o /01.06.2016
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 THERMO SCIENTIFIC EXCELSIOR ES: tissue processor BIO-OPTICA BEC 150: Paraffin embedding system MEDITE TBS88: Paraffin embedding system THERMO SCIENTIFIC HM340E & HM355s: microtomes for preparation of paraffin blocks THERMO SCIENTIFIC GEMINI AS: automated staining system from Hematoxylin - Eosin THERMO SCIENTIFIC CLEARVUE: automated cover-slipping system CRYOSTAR NX50 EPREDIA and MICROM HM550: cryostats for frozen section preparation Olympus BX61, BX60 BX43, BX41, BX40 and NIKON eclipse E200 and ZEISS Axiolab: Microscopes for microscopic examination of all the histological section slides (Hematoxylin – Eosin,

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
		special histochemical and immunohistochemical). HYG_P359/3 ⁿ /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_I44/2 ⁿ /01.06.2016
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_I40/2 ⁿ /01.06.2016
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 immunohistochemical staining results. REAGENTS* • DAB KIT OR OPTIVIEW KIT (Ventana-Roche IVD) • HEMATOXYLINE I (Ventana-Roche IVD) • BLUING (Ventana-Roche IVD) • PROTEASE I(Ventana-Roche IVD) • AMPLIFIER A/B (Ventana-Roche IVD) • BLOCK BIOTIN A/B (Ventana-Roche IVD) HYG_P351/3 ⁿ /01.03.2019 ANTIBODIES* • ER (SP1 –Ventana Roche IVD) • PgR (1E2-Ventana Roche IVD) • HER2 / Neu (4B5-Ventana-Roche 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)	• Ki67 (MIB-1-DAKO IVD) • E-CADHERIN (NCH-38-DAKO IVD) • GATA-3 (L50-823-Ventana Roche IVD) • S100 (4C4-9-CELL MARQUE 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
		HYG_P351/3ⁿ/01.03.2019 HYG_F1324/1ⁿ/15.10.2021
2. Biopsies and surgical specimens Fresh tissue, FFPE	1. Breast Carcinoma Prognostic Markers	Microscopic examination and interpretation by semi-quantitative method of the automated immunohistochemical staining performed with the VENTANA BENCHMARK ULTRA, according to the ASCO/CAP guidelines. Expression of chromogen tagged cellular antigens ER(SP1 –Ventana Roche IVD), PgR (1E2-Ventana Roche IVD), Her2/Neu (4B5-Ventana-Roche IVD), Ki67(MIB-1-DAKO IVD) & E-cadherin (NCH-38-DAKO IVD) in the nucleus, the cytoplasm or the cell membrane HYG_P351/3ⁿ/01.03.2019 HYG_F1324/1ⁿ/15.10.2021
	2. Breast Carcinoma Prognostic Markers	<u>IN SITU HYBRIDIZATION</u> Microscopic examination of gene probes tagged with fluorochrome or chromogen with silver ions. <u>HYBRIDIZATION METHOD OF FISH Her2/Neu.</u> Use of specialized probe kits manually. REAGENTS (KITS)* • Vysis Paraffin Pre-treatment Reagent Kit (Vysis Pre-treatment Solution, Vysis Protease Buffer, Vysis Wash Buffer, Vysis Protease) ABBOTT -for Laboratory Use. • PathVysion HER-2 DNA Probe Kit II (LSI HER-2/neu SO/CEP 17 SG, DAPI Counterstain, NP-40, 20XSSC) ABBOTT-IVD MACHINERY • Oven • Water bath • Thermobrite • Thermometer • PH-meter • Pipette HYG_P350/4ⁿ/01.03.2019 Examination and counting of the Her2/Neu & CEP 17 gene signals as well as the Her2/CEP ratio with the OLYMPUS BX61 fluorescence microscope fitted with DAPI, Orange, Green and Double Orange/Green filters

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Fresh tissue, FFPE (continued)	Breast Carcinoma Prognostic Markers (continued)	according to the ASCO/CAP guidelines 2018 HYG_P350/4ⁿ/01.03.2019 <u>HYBRIDIZATION METHOD OF SISH.</u> Automated method in situ hybridization it uses for Her2/Neu silver ions, which after enzymatic process are converted to metallic silver, that settles in the tissue for CEP17 chromogen. The result is interpreted in the common microscope. <u>REAGENTS (KITS)*</u> • VENTANA HER2 DUAL ISH DNA PROBE COCTAIL (VENTANA-ROCHE IVD) • PROTEASE 3 (VENTANA-ROCHE IVD) • VENTANA RED ISH DIG KIT (VENTANA-ROCHE IVD) • VENTANA SILVER ISH DNP KIT (VENTANA-ROCHE IVD) • HYBREADY SOLUTION (VENTANA –ROCHE IVD) • HEMATOXYLIN II (VENTANA-ROCHE IVD) • BLUING (VENTANA-ROCHE IVD) <u>MACHINERY</u> • OVEN • VENTANA BENCHMARK ULTRA Observation and measurement of gene signals Her2/Neu, CEP17 and Her2/CEP17. according to the ASCO/CAP guidelines 2018 HYG_P352/4ⁿ/01.03.2019

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

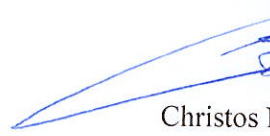
Site of assessment: **Permanent premises, Clinical Laboratories: 4, Erythrou Stavrou & Kifisias Ave., 15123, Maroussi, Athens, Greece.**

Approved signatories: **H. Papadogeorgaki, H. Salla, S. Papadopoulos.**

This Scope of Accreditation replaces the previous one dated 01.09.2021.

The Accreditation Certificate No **1000-2**, to ELOT EN ISO 15189:2012, is valid until 16.09.2023.

Athens, September 01, 2022


Christos Nestoras
CEO of ESYD

