

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 G1/4 to the Certificate No.1000-2

SCOPE of ACCREDITATION of the Clinical Laboratories of DIAGNOSTIC AND THERAPEUTIC CENTER OF ATHENS HYGEIA 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 ADVIA 1800 1 & 2 (Siemens)*
	1. Glucose_3 (GLUH_3)	Hexokinase 10698787_EL Rev. F, 2016-06
	2. Urea (BUN)	Urease, UV 10494054_EL Rev. F, 2017-04
	3. Uric acid (UA)	Uricase, UV 10494051_EL Rev. G, 2016-07
	4. Creatinine_2 (CREA_2)	Alkaline picrate-kinetic 10493978_EL Rev. L, 2016-09
	5. Cholesterol_2 (CHOL_2)	Cholesterol oxidase, esterase, peroxidase 10493968_EL Rev. D, 2016-09
	6. Triglycerides_2 (TRIG_2)	Enzymatic end point 10494049 Rev. D, 2016-09
	7. Glutamic oxaloacetic transaminase (SGOT/AST)	UV without P5P IFCC Method 10493951_EL Rev. F, 2016-05
	8. Glutamic-pyruvic transaminase (SGPT/ALT)	UV without P5P IFCC Method 10493941_EL Rev. H, 2017-08
	9. Gamma glutamyl transferase (GGT)	G – glutamyl – carboxy – nitroanilide 10493990_EL Rev. F, 2016-05

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 I, 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)	Calculated Thromborel S OUHPG29C11 Rev. 10, 2018-08
	3. Activated Partial - Thromboplastin Time (APTT)	Coagulometric assay - Activation of coagulation cascade Pathromtin SL OQGS29E11 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 2 parameters	Automated immunochemical analyzers Centaur XPT 1 & 3 (Siemens)
	1. Ferritin	Sandwich immunoassay two-point -measurement technology that. uses direct chemiluminescence (CLIA) 10629858_EL Rev. P, 2015-02
	2. Troponin	Sandwich Immunoassay three-point measurement technology that uses direct chemiluminescence (CLIA)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Blood serum (continued)		11200076_EL Rev. A, 2017-03
	Determination of 3 parameters	Automated immunochemical analyzer Centaur XPT 3 (Siemens)
	1. Vit B12	Competitive immunoassay using, direct chemiluminescence (CLIA) technology 10629913_EL Rev. T, 2015-02
	2. CK-MB	Sandwich immunoassay two-point -measurement technology that. uses direct chemiluminescence (CLIA) 10629833_EL Rev. M, 2015-01
	3. Folate	Competitive immunoassay using, direct chemiluminescence (CLIA) technology 10629859_EL Rev. U, 2015-02
	Determination of 5 parameters	Automated immunochemical analyzer Centaur-XPT,2 (Siemens)*
	1. Free Triiodothyronine (Free T3)	Competitive immunoassay using, direct chemiluminescence (CLIA) technology 10629863_EL Rev. M, 2015-01
	2. Total Human Chorionic Gonadotropin (tHCG)	Sandwich immunoassay two-point -measurement technology that. uses direct chemiluminescence (CLIA) 10634917_EL Rev. J, 2015-02
	3. Prostate Specific Antigen- (PSA)	10629889_EL Rev. U, 2017-08
	4. Free Thyroxin (Free T4)	Competitive immunoassay using, direct chemiluminescence (CLIA) technology 10629864_EL Rev. H, 2015-02
	5. Thyroid-stimulating hormone (TSH)	Competitive immunoassay using, direct chemiluminescence (CLIA) technology 10629909_EL Rev. L, 2017-07
Cytological tests		
1. Conventional vaginal and cervical smears	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 ^{II} /01.06.2016

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
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 ⁿ /01.06.2016
Anatomic pathology tests		
Histological tests		
1.Biopsies and surgical specimens of all Organs and systems 1a.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 THERMO SCIENTIFIC EXCELSIOR ES: tissue processor 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 LEICA CM 1950 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, special histochemical and immunohistochemical). HYG_I37/2 ⁿ /01.06.2016
Histochemical tests		
1β. Fresh tissue, FFPE tissue	2. 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

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
		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_I44/27/01.06.2016
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_I40/27/01.06.2016
Immunohistochemical tests		
1.Biopsies and surgical specimens of all Organs and systems 1a.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_P351/37/01.03.2019 ANTIBODIES* • 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) • GATA-3 (L50-823-Ventana Roche IVD) • S100 (4C4-9-CELL MARQUE IVD) • MELANOMA (HMB45-NOVOCASTRA IVD) • MELAN-A/MART1 (A103- Ventana Roche

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
		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) HYG_P351/3^u/01.03.2019
2. Biopsies and surgical specimens 2α. Fresh tissue, FFPE tissue from needle core biopsies or surgical biopsies with carcinoma	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_P351/3^u/01.03.2019
	1. Breast Carcinoma Prognostic Markers	Microscopic examination of gene probes tagged with fluorochrome or chromogen. Use of specialized probe kits manually with hybridization method of FISH Her2/Neu. 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

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
		• PH-meter • Pipette HYG_P350/4th/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 according to the ASCO/CAP guidelines 2018

**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 27.06.2019.

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

Αθήνα, October 31, 2019

