Hellenic Accreditation System

Annex G1/2 to the Certificate No. **1186**

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

EUROMEDICA PRIVATE DIAGNOSTIC LABORATORY OF WESTERN THESSALONIKI

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
Biochemical testing		
Blood serum	**Determination of 33parameters**	**Automated analyzer Alinityci(1)**
	1. Glucose (GLUC)	Enzymatic (HEX-G6PDH) (Document number ΔΠ-19/ Version 2)
	2. Triglycerides (TRIG)	GlycerolPhosphateOxidase (Document number ΔΠ-19/ Version 2)
	3. CholesterolTotal (CHOL)	Enzymatic – colorimetric (CHO-OEP-HBA) (Document number ΔΠ-19/ Version 2)
	4. HDL Cholesterol(HDL-Chol)	ASD(AcceleratorSelectiveDetergent),. (Document number ΔΠ-19/ Version 2)
	5. LDL Cholesterol(LDL-Chol)	Enzymatic – colorimetric (Document number ΔΠ-19/ Version 2)
	6. VLDL Cholesterol(VLDL-Chol)	Calculatedfromtriglycerides (TRIG) (Document number ΔΠ-19/ Version 2)
	7. Atherogenicindex	Calculated from total cholesterol (CHOL) and HDL cholesterol (HDL-Chol) (Document number ΔΠ-19/ Version 2)
	8. Totallipids (LIPIDS)	Calculated from total cholesterol (CHOL) and triglycerides (TRIG) (Document number ΔΠ-19/ Version 2)

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
	9. Uricacid (UA)	Uricase (Document number ΔΠ-19/ Version 2)
	10. Urea (UREA)	Urease (Document number ΔΠ-19/ Version 2)
	11. Creatinine (CREA)	KineticAlkalinePicrate (Document number ΔΠ-19/ Version 2)
	12. BilirubinTotal (TBIL)	Diazonium Salt (Document number ΔΠ-19/ Version 2)
	13. Bilirubindirect (DBIL)	Diazo (Document number ΔΠ-19/ Version 2)
	14. Bilirubin indirect (IBIL)	Calculated from bilirubin total (TBIL) and bilirubin direct (DBIL) (Document number ΔΠ-19/ Version 2)
	15. Calcium (Ca)	Arsenazo III (Document number ΔΠ-19/ Version 2)
	16. Phosphorus (Phos)	Phosphomolybdate (Document number ΔΠ-19/ Version 2)
	17. Iron (Fe)	Ferene (Document number ΔΠ-19/ Version 2)
	18. Albumin (ALB)	Colorimetric (Bromcresol Green) (Document number ΔΠ-19/ Version 2)
	19. TotalProtein (TP)	Colorimetric (Biuret) (Document number ΔΠ-19/ Version 2)
	20. Totalglobulin	Calculated from total protein (TP) and albumin (ALB) (Document number ΔΠ-19/ Version 2)
	21. Albumin / Total globulin ratio	Calculated from total protein (TP) and albumin (ALB) (Document number ΔΠ-19/ Version 2)
	22. Potassium (K)	Ion Selective Electrodes (ISE) (Document number ΔΠ-19/ Version 2)
	23. Sodium (Na)	Ion Selective Electrodes (ISE) (Document number ΔΠ-19/ Version 2)
	24. AlanineAminotransferase (ALT/SGPT)	EnzymaticNADH-without P-5'-P (Document number ΔΠ-19/ Version 2)

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
	25. AspartateAminotransferase (AST/SGOT)	Enzymatic NADH-without P-5'-P (Document number ΔΠ-19/ Version 2)
	26. Gamma-Glytamyl Transferase (γ-GT)	Colorimetric (L γ-Glutamyl-3-carboxy-4-nitroanillide) (Document number ΔΠ-19/ Version 2)
	27. Alkaline Phosphatase (ALP)	Colorimetric (Para-nP) (Document number ΔΠ-19/ Version 2)
	28. Creatine Kinase (CK/CPK)	NAC(N acetyl-L-cysteine) (Document number ΔΠ-19/ Version 2)
	29. Lactate Dehydrogenase (LDH)	IFCC (Document number ΔΠ-19/ Version 2)
	30. Amylase (AMY)	GNPG3 (Document number ΔΠ-19/ Version 2)
	31. Magnesium (Mg)	Colorimetric (Arsenazo) (Document number ΔΠ-19/ Version 2)
	32. C-reactiveprotein	Turbidimetry (TA) / Immunoturbidimetry (ITA) (Document number ΔΠ-19/ Version 2)
	33. Total Iron Binding Capacity (TIBC)	Calculated from UIBC and iron (Fe) (Document number ΔΠ-19/ Version 2)
Blood serum	**Determination of7parameters**	**Automated analyzer Alinityci(2)**
	1. Rheumatoid factor RF	Immunoturbidimetric (Document number ΔΠ-19/ Version 2)
	2. ASTO	Turbidemetric/Immunoturbidimetric (Document number ΔΠ-19/ Version 2)
	3. Immunoglobulin E (IgE)	Immunoturbidimetry (ITA) (Document number ΔΠ-19/ Version 2)
	4. Amylase (AMY) Urine	CNPG3 (Document number ΔΠ-19/ Version 2)
	5. Creatinine (CREA) Urine	KineticAlkalinePicrate (Document number ΔΠ-19/ Version 2)
	6. Calcium (Ca) Urine	Arsenazo III (Document number ΔΠ-19/ Version 2)
	7. Urine/CSF Protein(U/CSF Protein)	Benzethonium Chloride (Document number ΔΠ-19/ Version 2)

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
Immunochemical Testing		
Blood serum	**Determination of25parameters**	**Automated analyzer Alinityci(1)**
	1. Ferritin (FERR)	Chemiluminescent Microparticle Immunoassay (CMIA) (Document number ΔΠ-19/ Version 2)
	2. FollicleStimulatingHormone (FSH)	
	3. LuteinizingHormone (LH)	
	4. Prolactin (PRL)	
	5. Alpha Fetoprotein (AFP)	
	6. Estradiol (E2)	
	7. Testosterone (TESTO)	
	8. β-Human Chorionic Gonadotropin (β-hCG)	
	9. Carcinoembryonicantigen (CEA)	
	10. Cancerantigen 125 (CA125)	
	11. Cancerantigen 15.3 (CA15.3)	
	12. Cancerantigen 19.9 (CA19.9)	
	13. Prostate-SpecificAntigen (PSA)	
	14. Free Prostate-Specific Antigen (free-PSA)	
	15. Thyroid-StimulatingHormone (TSH)	
	16. Free Triiodothyronine (FT3)	
	17. Free Thyroxine (FT4)	
	18. TotalTriiodothyronine (TT3)	
	19. TotalThyroxine (TT4)	
	20. Anti-Thyroglobulin antibodies (anti-TG)	
	21. Anti-Thyroid Peroxidase antibodies (anti-TPO)	
Blood, serum	22. Insoulin(INS)	Chemiluminescent Microparticle Immunoassay

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
	23. Cortisol (CORT)	(CMIA) (Document number ΔΠ-19/ Version 2)
	24. *Homocysteine*	
	25. intactParathyroidHormone (iPTH)	
Blood, serum	**Determination of3parameters**	**Automated analyzer Alinityci(2)**
	26. 25-OH Vitamin D	Chemiluminescent Microparticle Immunoassay (CMIA) (Document number ΔΠ-19/ Version 2)
	27. Folate acid(Folate)	
	28. Vitamin B12	
Immunochemical Testing		
Bloodserum	**Determination of 11 parameters**	**Automated analyzer Alinity i**
	1. Hepatitis B surface antigen (HBsAg)	Chemiluminescent Microparticle Immunoassay (CMIA) (Document number ΔΠ-19/ Version 2)
	2. Hepatitis B core antigen antibodies (anti-HBc)	
	3. Human immunodeficiency virus type 1/2 antigen/antibodies (HIV 1/2 Ag/Ab)	
	4. Hepatitis C antibodies (anti-HCV)	
	5. Toxoplasma IgG antibodies (Toxo IgG)	
	6. Toxoplasma IgM antibodies (Toxo IgM)	
	7. Rubella IgG antibodies (Rubella IgG)	
	8. Rubella IgM antibodies (Rubella IgM)	
	9. Cytomegalovirus IgG antibodies (CMV IgG)	
	10. Cytomegalovirus IgM antibodies (CMV IgM)	
	11. Anti-HBs	
Hematological Testing		
Whole Blood (EDTA)	1.Glycated Haemoglobin A_1c (HbA_1c)	Enzymatic (Document number ΔΠ-19/ Version 2)
	Determination of10parameters	**Automated analyzer CELL-DYNRUBY**

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
Whole Blood (EDTA)	1. Hemoglobin (HGB)	Hemoglobin concentration : colorimetric determination of hemoglobin. The Hemoglobin is directly measured and is expressed in grams of hemoglobin per deciliter of whole blood. (Document number ΔΠ-19/ Version 2)
	2. Hematocrit (HCT)	Hematocrit The Hematocrit is the ratio of red blood cells to plasma and is expressed as a percentage of the whole blood volume. The HCT is calculated from the red blood cell count and the mean cell volume as follows: HCT = (RBC x MCV)/10 (Document number ΔΠ-19/ Version 2)
	3. Red BloodCells (RBC)	Red Blood Cell concentration The Red Blood Cell Count is directly measured, and is expressed as follows: RBC = # x 10e6/μL (Document number ΔΠ-19/ Version 2)
	4. MeanCorpuscularVolume (MCV)	Mean Cell Volume The MCV is derived from the RBC size distribution data on the 0°, 10°, and 90° histograms, and is expressed in femtoliters. (Document number ΔΠ-19/ Version 2)
	5. MeanCorpuscularHemoglobin (MCH)	Mean Cell Hemoglobin The Mean Corpuscular Hemoglobin is the average amount of hemoglobin contained in the red blood cell expressed in picograms. The MCH is calculated from the RBC and the HGB as follows: MCH = (HGB/RBC) x 10 (Document number ΔΠ-19/ Version 2)
	6. Mean Cell Hemoglobin Concentration (MCHC)	Mean Cell Hemoglobin Concentration, expressed in grams per deciliter. MCHC is calculated from the HGB and the HCT as follows: MCHC = (HGB/HCT) x 100 (Document number ΔΠ-19/ Version 2)
	7. Red blood cell Distribution Width (RDW)	Red Cell Distribution Width. Red Cell Distribution Width is a statistic parameter and is a measure of the heterogeneity of the RBC population. The CELL-DYN Ruby reports a relative RDW equivalent to a CV in grams per deciliter. (Document number ΔΠ-19/ Version 2)
	8. WhiteBloodCells (WBC)	White Blood Cell concentration. Flow

Tested materials / Products	Types of test / Properties measured	Applied Standards / Techniques used
		cytometry technology , with a Helium Neon Laser is as the light source. The instrument measures with the MAPSS (for Multi-Angle Polarized Scatter Separation) technology both types of forward light scatter , both types of orthogonal (side) light scatter The WBC count is determined by enumerating the number of occurrences above a hardware threshold in the 0° channel. The information from all four measurements is used to differentiate the WBC into five subpopulations: Neutrophils Lymphocytes Monocytes Eosinophils Basophils (absolute concentration and percentage of WBC) (Document number ΔΠ-19/ Version 2)
	9. Platelets (PLT)	Platelet concentration .The sample stream is then hydrodynamically focused to align the cells in single file as they pass through the Optical Flow Cell, which is an optically clear quartz chamber. A vertically polarized Helium Neon Laser is the light source. PLT parameters are calculated using 0° and 10° sensor data. (Document number ΔΠ-19/ Version 2)
	10. MeanPlateletVolume (MPV)	The Mean Platelet Volume is derived from the PLT histogram after the PLT count has been determined. The MPV is expressed in femtoliters. (Document number ΔΠ-19/ Version 2)

Site of assessment : **Laboratory permanent premises, 37E, Iatrou Gogousi, 56430, Thessaloniki**
Approved signatories: **Nikolaos Malisiovas, Michail Adamidis, Ifigeneia Repana.**

The Accreditation Certificate No. 1186, to ELOT EN ISO 15189:2012, is valid until 20.11.2023.

Athens, February 3rd, 2023

Christos Nestoras
CEO of E.SY.D.