Hellenic Accreditation System

Annex G1/6 to the Certificate No. **1146**-2

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of the

BIOLAN S.A.

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Biochemical tests		
	Determination of 22 parameters	**Automated Biochemical Analyzer Alinity ci (ABBOTT) (Reagent kit Code)**
Blood serum	Albumin (ALB)	End point - photometric (Br-cresol gr) (G71151R02/B8P020)
	Alkaline phosphatase (ALP)	Enzymatic - photometric (Para-nP) (G71236R02/B8P200)
	Amylase (AMY)	Enzymatic - photometric (GNPG3) (G71201R02/B7P580)
	Calcium (Ca)	End point - photometric (Arsenazo III) (G71246R02/B7P570)
	Lactic dehydrogonase (LDH)	Enzymatic - photometric (IFCC) (G71205R03/B7P740)
	γ-Glutamyl-transferase (γ-GT)	Enzymatic - photometric (L-γG-3C-4N) (G71324R03/B7P730)
	Glucose (GLU)	Enzymatic - photometric (HEX-G6PDH) (G71245R04/B7P550)
	Creatine kinase (CK)	Enzymatic - photometric (NAC) (G71241R01/B8P420)
	Creatinine (CREA)	Kinetic - photometric (Jaffe) (G71243R04/B7P990)
	Magnesium (Mg)	End point - photometric (Arsenazo) (G71159R06/B8P190)
	Total proteins (TP)	End point - photometric (Biuret) (G71288R04/B7P520
	Total cholesterol (CHOL)	End point - photometric (CO-HBA) (G92076R01/B7P7T0)
	Urea (UREA)	Enzymatic - photometric (Urease) (G71148R03/B8P160)
	Uric acid (URIC)	Enzymatic - photometric (Uricase) (G71317R04/B8P560)
	Ferrum (Fe)	End point - photometric (Ferene) (G71300R03/B8P390)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	Alanine transaminase (ALT)	End point - photometric (NADH) (G71193R04/B7P980)
	Aspartate transaminase (AST)	End point - photometric (NADH) (G71194R06/B8P170)
	Triglycerides (TRIG)	Enzymatic - photometric (GPO) (G92077R01/B7P7S0)
	Phosphorus (Phos)	End point - photometric (p-molybdate) (G71301R02/B8P400)
	HDL Cholesterol (HDL)	Enzymatic - photometric (ASD) (G71192R03/B7P750)
	Sodium (Na)	Ion selective electrode (ISE) (G71456R02/B7P530)
	Potassium (K)	Ion selective electrode (ISE) (G71456R02/B7P530)
Immunochemical tests		
	Determination of 7 parameters	**Automated Biochemical Analyzer Alinity ci (ABBOTT) (Reagent kit Code)**
Blood serum	Immunoglobulin G (IgG)	Tholosimetry (G91782R02/B9P620)
	Immunoglobulin A (IgA)	Tholosimetry (G91780R01/B9P610)
	Immunoglobulin M (IgM)	Tholosimetry (G90663R01/B9P630)
	Complement protein C3	Tholosimetry (G90600R01/B9P560)
	Complement protein C4	Tholosimetry (G90602R01/B9P570)
	C reactive protein (CRP)	Tholosimetry (G71182R01/ B7P560)
	Pheumatoid factors (RF)	Tholosimetry (G90798R02/ B1R160)
Biochemical – Immunochemical tests		
	Determination of 1 parameter	**Automated Biochemical Analyzer Alinity ci (ABBOTT) (Reagent kit Code)**
Whole blood	Glucosyl-hemoglobin (HbA1C)	Photometric - Tholosimetry (G72097R070//B8P430)
Immunochemical analyses		
	Determination of 16 parameters	**Automated Immunochemical Analyzer: Alinity ci (ABBOTT) (Reagent kit Code)**
Blood serum	Creatin kinase MB (CKMB)	Chemiluminescence sandwich type (G91304R01/B4V380)
	Troponin I (TNI)	Chemiluminescence sandwich type (G75022R03/B7P65G)
	β-Chorionic gonadotrophin (BHCG)	Chemiluminescence sandwich type (G75022R03/B7P65G)
	Thyrotropin (TSH)	Chemiluminescence sandwich type (G71135R02/B7P510)
	Triiodothyronin (T3)	Competitive chemiluminescence (G71292R02/B7P480)
	Free Triiodothyronin (FT3)	Competitive chemiluminescence (G71277R04/B7P940)
	Thyroxin (T4)	Competitive chemiluminescence (G71299R02/B7P690)
	Free thyroxin (FT4)	Competitive chemiluminescence (G71331R03/B7P950)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	Antibodies TG (ATG)	Chemiluminescence sandwich type (G71158R03/B7P700)
	Antibodies TPO (ATPO)	Chemiluminescence sandwich type (G90639R04/B7P340)
	Toxoplasma IgG (TOXO-G)	Chemiluminescence sandwich type (G90622R03/B7P350)
	Toxoplasma IgM (TOXO-M)	Chemiluminescence sandwich type (G71279R02/B7P450)
	Rubella IgG (RUB-G)	Chemiluminescence sandwich type (G71285R04/B7P470)
	Rubella IgM (RUB-M)	Chemiluminescence sandwich type (G71305R01/B8P460)
	Cytomegalovirus IgG (CMV-G)	Chemiluminescence sandwich type (G71310R03/B8P470)
	Cytomegalovirus IgM (CMV-M)	Chemiluminescence sandwich type (G71168R05/B7P420)
Immunochemical tests		
	Determination of 8 parameters	**Automated Immunochemical Analyzer Alinity ii 1 (ABBOTT) (Reagent kit Code)**
Blood serum	Ferritin (FER)	Chemiluminescence sandwich type (G74986R04/B7P93G)
	Folic acid (FOL)	Competitive chemiluminescence (G83540R01/B8P14G)
	Hepatitis B antigen S (HBsAg)	Chemiluminescence sandwich type (G75093R04/B8P10G)
	Hepatitis B antibody S (HBsAb)	Chemiluminescence sandwich type (G83431R02/B7P89G)
	Hepatitis B antibody C (HBcAb)	Chemiluminescence sandwich type (G75005R02/B7P87G)
	Hepatitis C antibody (HCV)	Chemiluminescence sandwich type (G75040R03/B8P06G)
	Antibody for AIDS Virus (HIV)	Chemiluminescence sandwich type (G74987R03/B8P07G)
	25(OH) Vitamin D (25(OH)-Vit-D)	Competitive chemiluminescence (G75004R02/B8P45G)
Immunochemical tests		
	Determination of 14 parameters	**Automated Immunochemical Analyzer Alinity ii 2 (ABBOTT) (Reagent kit Code)**
Blood serum	Vitamin BI2 (B12)	Competitive chemiluminescence (G83568R01/B7P67G)
	Folicular hormone (FSH)	Chemiluminescence sandwich type (G71347R02/B7P490)
	Luteinizing hormone (LH)	Chemiluminescence sandwich type (G83553R02/B7P91G)
	Prolactin (PRL)	Chemiluminescence sandwich type (G74991R03/B7P66G)
	Progesterone (PRG)	Competitive chemiluminescence (G83558R03/B8P36G)
	Estradiol (E2)	Competitive chemiluminescence (G74927R06/B7P50G)
	Testosterone (TESTO)	Competitive chemiluminescence (G83437R03/B7P68G)
	Prostate antigen (PSA)	Chemiluminescence sandwich type (G83451R04/B7P92G)

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	Free prostate antigen (FPSA)	Chemiluminescence sandwich type (G97116R01/B8P1W0)
	Cancer embryonic antigen (CEA)	Chemiluminescence sandwich type (G75041R04/B7P62G)
	α-feto-protein (AFP)	Chemiluminescence sandwich type (G74903R02/B7P90G)
	Cancer antigen 125 (CA125)	Chemiluminescence sandwich type (G75060R04/B8P49G)
	Cancer antigen 19.9 (CA19.9)	Chemiluminescence sandwich type (G75062R03/B8P32G)
	Cancer antigen 15.3 (CA15.3)	Chemiluminescence sandwich type (G75059R02/B8P51G)

**The analyzer trade name / kit refers to a specific analytical method and the respective protocol*

Site of assessment: **Laboratory Permanent premises, Anthemiou 19 Patras, Creece.**
Approved signatories: **Helen Zisimopoulou**

This Scope of Accreditation replaces the previous one dated 12.01.2023.
The Accreditation Certificate No **1146**-2**,** to EN ISO 15189:2022, is valid until 06.11.2027.

Athens, 10.12.2024

Konstantinos Kourtalis
Chairman of ESYD