Hellenic Accreditation System

Annex G1/9 to the Certificate No.**1010**-4

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

Biocheck Diagnostic Center

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Biochemical testing		
1. Blood serum, blood plasma (EDTA)	**Determination of 21 parameters**	**Automated analyzer A/15 (BioSystems)***
	1. Alkaline Phosphatase (ALP)	DEA (I1-VM/01)
	2. Alanine Aminotranferase (ALT/SGPT)	IFCC (I1-VM/01)
	3.Amylase (AMYL)	CNPG3/BENZYLIDENE (I1-VM/01)
	4. Aspartate Aminotranferase (AST/SGOT)	IFCC (I1-VM/01)
	5.Calcium (Ca)	ARSENAZO III (I1-VM/01)
	6.Creatinine Kinase (CK NAK)	IFCC (I1-VM/01)
	7.Creatinine (CREA)	JAFFÈ MOD. (I1-VM/01)
	8. Gamma-glutamyltransferase (GGT)	IFCC (I1-VM/01)
	9.Glucose (GLU)	GOD POD (I1-VM/01)
	10.HDL Cholesterol (HDLC)	BI-REACTIVE LIQUID (I1-VM/01)
	11.Iron (Fe)	FERROZINE (I1-VM/01)
	12.LDL Cholesterol	ENZYMATIC DIRECT (I1-VM/01)

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Blood serum, blood plasma (continued)	13.Magnesium (Mg)	XYLIDYL BLUE (I1-VM/01)
	14.Phosphate (P)	PHOSPHOMOLYBDATE REDUCTION UV (I1-VM/01)
	15.Total Bilirubin (BILT)	DIAZO WITH SULPHANILIC ACID (I1-VM/01)
	16.Total Cholesterol (CHOL)	CHOD PAP (I1-VM/01)
	17.Total Proteins (TP)	BIURET REACTION (I1-VM/01)
	18.Triglycerides (TRIG)	LIPASE/GPO-PAP (I1-VM/01)
	19.Urea (UREA)	UREASE KINETIC (I1-VM/01)
	20.Uric Acid (UA)	UREASE PEROXIDASE (I1-VM/01)
	21.Albumin (ALB)	BROMOCRESOL GREEN/PURPLE (I1-VM/01)
Immunochemical testing		
1. Blood Serum, blood plasma (EDTA)	**Determination of 13 parameters**	**Automated analyzer Cobas e 411 (ROCHE)**
	1. α1-Fetoprotein (AFP)	FPIA (I1-VM/01)
	2. Carcinoembryonic Antigen (CEA)	FPIA (I1-VM/01)
	3. Estradiol (E2)	FPIA (I1-VM/01)
	4.Ferritin	FPIA (I1-VM/01)
	5. Triidothyronine Free (FT3)	FPIA (I1-VM/01)
	6. Thyroxin Free (FT4)	FPIA (I1-VM/01)
	7. Human Chorionic Gonadotropin (HCG)	FPIA (I1-VM/01)
	8. Immunoglobulin E (IgE)	FPIA (I1-VM/01)
	9. Luteinizing Hormone (LH)	FPIA (I1-VM/01)
	10. Progesterone (PRG)	FPIA (I1-VM/01)

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Blood Serum, blood plasma (continued)	11. Prolactin (PRL)	FPIA (I1-VM/01)
	12. Testosterone Total (TESTO)	FPIA (I1-VM/01)
	13. Thyrotropin Hormone (TSH)	FPIA (I1-VM/01)
	Determination of 6 parameters	**Automated analyzer Cobas -e 411 (ROCHE)**
	1. Cancer Antigen 125 (CA-125)	IMMUNOFLUORESCENCE; ELFA (I1-VM/01)
	2. Cancer Antigen 15-3 (CA-15.3)	IMMUNOFLUORESCENCE; ELFA (I1-VM/01)
	3. Follicle Stimulating Hormone (FSH)	IMMUNOFLUORESCENCE; ELFA (I1-VM/01)
	4. Prostate Specific Antigen Total	IMMUNOFLUORESCENCE; ELFA (I1-VM/01)
	5. Triidothyronine Total (T3)	IMMUNOFLUORESCENCE; ELFA (I1-VM/01)
	6. Thyroxin Total (T4)	IMMUNOFLUORESCENCE; ELFA (I1-VM/01)
Blood Coagulation testing		
1. Blood Plasma (sodium citrate)	**Determination of 3 parameters**	**Semi-automated analyzer BFT II (Siemens)***
	1. Prothrombin time (PT, ISI<= 1.4)	Siemens Thromborel S (I1-VM/01)
	2. Prothrombin time (PT/INR)	Calculated INR (I1-VM/01)
	3.Fibrinogen (FIB)	Immunoturbidimetric (I1-VM/01)
Hematology testing		
1.Whole Blood (EDTA)	**Determination of 12 parameters**	**Automated analyzer Mythic -22 (Orphee)***
	1. Haematocrit (HCT%)	Dedicated Reagent Calculated (I1-VM/01)
	2. Hemoglobim (HB)	Dedicated Reagent Photometric (I1-VM/01)
	3. Mean Corpuscular Haemoglobin (MCH)	Dedicated Reagent Calculated (I1-VM/01)
	4. Mean Corpuscular Haemoglobin Concentration (MCHC)	Dedicated Reagent Calculated (I1-VM/01)

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Whole Blood (EDTA) (continued)	5. Mean Corpuscular Volume (MCV)	Dedicated Reagent Electrical impedance (I1-VM/01)
	6.Platelets (PTLs)	Dedicated Reagent Electrical impedance (I1-VM/01)
	7.Red Blood Cells (RBC)	Dedicated Reagent Electrical impedance (I1-VM/01)
	8. White Blood Cells (WBC)	Dedicated Reagent Electrical impedance (I1-VM/01)
	9. RDW-SD	Calculated method
	10. RDW-CV	Calculated method
	11. MPV	Calculated method
	12. PDW	Calculated method
Urine testing		
1.Urine	**Determination of 10 parameters**	**Automated analyzer Clinitek 500 (Siemens)***
	1.Bilirubin	MULTISTIX 10 SG BAYER (I1-VM/01)
	2.Blood	MULTISTIX 10 SG BAYER (I1-VM/01)
	3.Glucose	MULTISTIX 10 SG BAYER (I1-VM/01)
	4.Ketones	MULTISTIX 10 SG BAYER (I1-VM/01)
	5.Leukocytes	MULTISTIX 10 SG BAYER (I1-VM/01)
	6.Nitrite	MULTISTIX 10 SG BAYER (I1-VM/01)
	7.Ph	MULTISTIX 10 SG BAYER (I1-VM/01)
	8.Protein	MULTISTIX 10 SG BAYER (I1-VM/01)
	9.Specific Gravity	MULTISTIX 10 SG BAYER (I1-VM/01)
	10.Urobilinogen	MULTISTIX 10 SG BAYER (I1-VM/01)

**The use of the genetic analyser's brand name refers to a specific analytical method and the corresponding experimental protocol*
*** IFCC: International Federation of Clinical Chemistry*

Site of assessment: **Laboratory Permanent premises: Bulevardi Zhan D'Ark, Pallati 15 katesh, Kati 3 prane Drejtorise se Policise, 1000, Tirana, Albania.**

Primary Sample Collection Site: Bulevardi Zhan D'Ark, Pallati 15 katesh, Kati 3 prane Drejtorise se Policise, 1000, Tirana, Albania.

Approved signatories: **Anjeza Tafaj and Jotilda Gjoka.**

This Scope of Accreditation replaces the previous one dated 15.05.2024.
The Accreditation Certificate No.**1010**-2, to EN ISO 15189:2022, is extended until 08.11.2028.

Athens, 28th November 2025

Konstantinou Evangelos Apostolos
CEO of ESYD