Hellenic Accreditation System

Annex G1/2 to the Certificate No.1171

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

BYLIS DC

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Biochemical Tests		
Blood Serum	**Determination of 12 parameters**	**Automated analyzer Cobas Integra 400^{+}-Roche *** P20-EK/00/02.05.2017
	1. Alanine Aminotransferase (ALT/GPT)	KINETICS-Alanine aminotransferase Liquid Reagent IFCC
	2. Aspartate Aminotransferase (AST/GOT)	KINETICS- Aspartate aminotransferase Liquid Reagent IFCC
	3. Glucose	END POINT-Hexokinase
	4. Urea	KINETIC-Urease
	5. Creatinine	KINETIC-Jaffe
	6. Cholesterol total	END POINT-Cholesterol
	7. Triglycerides	END POINT-Triglycerides
	8. Cholesterol HDL	END POINT -HDL-cholesterol
	9.Cholesterol LDL	END POINT- LDL-cholesterol
	10. Total Bilirubine	END POINT-Colorimetric Diazo
	11. Direct Bilirubine	END POINT-Diazo
Whole Blood	12. HbA1C	END POINT-HbA1C

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Immunochemical Tests		
Blood Serum	**Determination of 3 parameters**	**Automated analyzer Immulite One-Siemens*** P20-EK/00/02.05.2017
	1.Thyroid Stimulues Hormone (TSH)	Chemiluminescence
	2. Free Thyroxin (FT4)	Chemiluminescence
	3.Prostatic Specific Antigen (PSA)	Chemiluminescence
Hematology Tests		
Whole Blood (EDTA)	**Determination of 5 parameters**	**Automated analyzer XS-1000i Sysmex*** P20-EK/00/02.05.2017
	1. Hemoglobin (HB)	Method Photometry
	2. Haematocrit (HCT)	Method Numeric integration
	3. White Blood Cells (WBC)	DHSS Technology Cytometry & Cytochemical association
	4. Red Blood Cells (RBC)	Method Impedance
	5. Platelets (PTL)	Method Impedance
Urine Tests		
Urine	**Determination of 9 parameters**	**Strip analyser 500-Dialab *** P20-EK/00/02.05.2017
	1.Leucocytes	Urine Strip 11
	2.Nitrites	Urine Strip 11
	3.Urobilinogen	Urine Strip 11
	4.Protein	Urine Strip 11
	5.pH	Urine Strip 11

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
	6. SG (Specific Gravity)	Urine Strip 11
	7. Ketones	Urine Strip 11
	8. Bilirubine	Urine Strip 11
	9. Glucose	Urine Strip 11

**The use of the analyser's brand name refers to a specific analytical method and the corresponding experimental protocol*

Site of assessment: **Laboratory Permanent premises: FIER Lagjja 1 Maj, Rruga Jani Bakalli, Nd 7, Njesia 4, Albania.**
Approved signatories: **Elsa Shehu.**

This Scope of Accreditation replaces the previous one dated 21.06.2019.
The Accreditation Certificate No.1171, to ELOT EN ISO 15189:2012, is valid until 20.06.2023.

Athens, September 30, 2021

Spyridon Podaras
CEO of ESYD