Hellenic Accreditation System

Annex G1/7 to the Certificate No. **951**-3

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

Intermedica Center

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Biochemical Testing		
1. Blood serum	**Determination of 23 parameters**	**Automated analyzer COBAS 6000 (C501 module) I & II***
	1. Glucose	Enzymatic reference method with hexokinase.
	2. Urea	KINETIC-urease and glutamate dehydrogenase
	3. Creatinine	KINETIC-Creatinine Jaffe Compensated Method for Serum &Plasma
	4. Total Protein	Colorimetric assay
	5. Albumin	Colorimetric assay
	6. Cholesterol	Enzymatic, colorimetric method.
	7. HDL- Cholesterol	Enzymatic colorimetric test.
	8. Triglycerides	Enzymatic colorimetric test.
	9. Uric Acid	Enzymatic colorimetric test.
	10. Total Bilirubin	Colorimetric assay
	11. Calcium	Measured photometrically
	12. Phosphorus	Molybdate UV.
	13. Magnesium	Colorimetric endpoint method.

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Blood serum (continued)	14. Iron	Colorimetric assay.
	15. SGOT (AST)	IFCC** without pyridoxal phosphate activation
	16. SGPT (ALT)	IFCC** without pyridoxal phosphate activation
	17. Bilirubin Direct (BIL-D)	Diazo method
	18. Alkaline Phosphatase	Colorimetric assay
	19. GGT	Enzymatic colorimetric assay
	20. Lactate Dehydrogenase	UV assay
	21 CKL	UV-test
	22.Amylase	Enzymatic colorimetric assay
	23. C-Reactive Protein	Enhanced immunoturbidimetric assay
Tumor Markers Tests		
Blood serum	**Determination of 7 parameters**	**Automated analyzer COBAS 6000 (e601 module) I & II***
	1. Tumor marker CA-125	ECLIA
	2. Tumor marker CA 15-3	ECLIA
	3. Tumor marker CA 19-9	ECLIA
	4. Carcinoembryonic antigen (CEA)	ECLIA
	5. Prostate Specific Antigen (PSA)	ECLIA
	6.Free-PSA	ECLIA
	7.Alpha –fetoprotein	ECLIA
Tests of Reproduction Hormones		
Blood serum	**Determination of 8 parameters**	**Automated analyzer COBAS 6000 (e601 module) I***
	1. Follicle Stimulating Hormone (FSH)	ECLIA
	2. Luteining Hormone (LH)	ECLIA
	3. Estradiol (E2)	ECLIA
	4. Prolactin	ECLIA
	5. Testosterone	ECLIA
	6. Human choriotic gonadotropin (hCG)	ECLIA

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Blood serum (continued)	7. Progesterone (PRG)	ECLIA
	8.Cortisol	ECLIA
Tests of Thyroid Hormones		
Blood serum	**Determination of 6 parameters**	**Automated analyzer COBAS 6000 (e 601 module) I & II***
	1. Thyrotropin (TSH)	ECLIA
	2. Free Triiodothyronine (FT3)	ECLIA
	3. Free Thyroxine (FT4)	ECLIA
	4. Anti-Thyroglobulin (A-TG)	ECLIA
	5.Anti- thyroid Peroksidase (Anti-TPO)	ECLIA
	6.Thyroxine (T_4)	ECLIA
Tests of TORCH		
Blood serum	**Determination of 10 parameters**	**Automated analyzer COBAS 6000 (e601 module) I***
	1. Citomegalovirus IgG	ECLIA
	2. Citomegalovirus IgM	ECLIA
	3. Rubella IgG	ECLIA
	4. Rubella IgM	ECLIA
	5. Toxoplasma IgG	ECLIA
	6. Toxoplasma IgM	ECLIA
	7. Herpes Simplex Type I IgG	ECLIA
	8. Herpes Simplex Type II IgG	ECLIA
	9. HBSAG	ECLIA
	10. Anti HCV	ECLIA
Tests of Cardiac Markers		
Blood serum	**Determination of 3 parameters**	**Automated analyzer COBAS 6000 (c501/e601 module) I & II ***
	1. Creatine Kinase-MB (CK-MB)	ECLIA - (c501 module)
	2. Cardiac Specific Troponine-T	ECLIA- (e601 module)

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Whole Blood (K3-EDTA)	3. Pro-BNP	ECLIA- (e601 module)
Hematology Testing		
Whole Blood (K3-EDTA)	**Determination of 9 parameters**	**1-Sysmex XN 550, SN: 16503* 2- Sysmex XN 550,SN :16504***
	1. Hemoglobim (HB)	Colorimetric (SLS Hemoglobin)
	2. Haematocrit (HCT%)	RBC Comulitative Pulse Height Detection
	3. Mean Corpuscular Haemoglobin Concentration (MCHC)	Automatic calculation from HGB and HCT
	4. Mean Corpuscular Volume (MCV)	Automatic calculation from HGB and HCT
	5. Mean Corpuscular Haemoglobin (MCH)	Automatic calculation from HGB and HCT
	6. White Blood Cells (WBC)	Flow Cytometry by Semiconductor Laser
	7. Red Blood Cells (RBC)	Deirect Current
	8. Platelets (PTLs)	Deirect Current
	9. REC	Microscopy
Specific Proteins		
Blood serum	**Determination of 12 parameters**	**Automated analyzer COBAS 6000 (c501 module) I */ (e601 module) I ***
	1. Transferine	Enhanced immunoturbidimetric assay
	2. IgA	Enhanced immunoturbidimetric assay
	3. IgG	Enhanced immunoturbidimetric assay
	4. IgM	Enhanced immunoturbidimetric assay
	5. IgE	ECLIA
	6. Complement C_3	Enhanced immunoturbidimetric assay

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
Blood serum (continued)	7. Complement C_4	Enhanced immunoturbidimetric assay
	8. RF	Enhanced immunoturbidimetric assay
	9. ASLO	Enhanced immunoturbidimetric assay
	10. Vitamin B_{12}	ECLIA (e601 module)
	11. Folic Acid	ECLIA (e601 module)
	12.Ferritine	ECLIA (e601 module)

**The use of the 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: Street: "JORDAN MISJA", AL 1001, Tirana, Albania.**
Approved signatories:
ANILA MITRE - Immunological testing , Hormonal testing, Viral testing and Biochemical testing
ANILA BEQJA- Hematology testing
PALMIRA DAJA- Hematology testing
ADILTA BEJKO- Hematology testing and Biochemical Testing

This scope of Accreditation replaces the previous one dated 14.09.2020.
The Accreditation Certificate No. **951**-3, to EN ISO 15189:2012, is valid until 01.12.2022.

Athens, November 02, 2021

Spyridon Podaras
CEO of ESYD