Hellenic Accreditation System

Annex G1/4 to the Certificate No. **1228**-2

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

AFFIDEA Private Diagnostic Laboratories and Multimodalities Medical Single Member S.A. AFFIDEA of KALLITHEA

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Biochemical Tests		
1. Blood serum	**Determination of 34 parameters**	**Automated biochemical analyzer Cobas 8000 PRO I, c-503, ROCHE***
	1. Glucose	Enzymatic Chromatometric method GOD-PAP OE 504-11, Version 4/22.10.2023
	2. Triglycerides	Enzymatic Chromatometric method GPO – PAP OE 504-11, Version 4/22.10.2023
	3. Total Cholesterol	Enzymatic method CHOD – PAP OE 504-11, Version 4/22.10.2023
	4. HDL-Cholesterol	Enzymatic Chromatometric method OE 504-11, Version 4/22.10.2023
	5. VLDL-Cholesterol	Calculated method OE 504-11, Version 4/22.10.2023
	6. LDL-Cholesterol	Enzymatic Chromatometric method OE 504-11, Version 4/22.10.2023
	7. Uric acid	Enzymatic Chromatometric method uricase/peroxidase OE 504-11, Version 4/22.10.2023
	8. Urea	Kinetic Enzymatic method / UV OE 504-11, Version 4/22.10.2023
	9. Creatinine	Kinetic Enzymatic method - JAFFE METHOD OE 504-11, Version 4/22.10.2023
	10. Total Bilirubin	Photometric method UV Liquid DPD OE 504-11, Version 4/22.10.2023
	11. Chlorides	ISE Indirect method OE 504-11, Version 4/22.10.2023
	12. Calcium	Photometric method -5NITRO-5METHYL-BAPTA OE 504-11, Version 4/22.10.2023

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood serum (continued)	13. Phosphorus	Photometric method end point PHOSPHOMOLYBDADE OE 504-11, Version-4/22.10.2023
	14. Iron	Colorimetric method /FERROZINE OE 504-11, Version 4/22.10.2023
	15.Total Protein	Colorimetric method BIURET OE 504-11, Version 4/22.10.2023
	16. Albumin	Photometric method BROMOCRESOL GREEN OE 504-11, Version 4/22.10.2023
	17. Serum glutamic-oxaloacetic transaminase (SGOT)	Photometric method UV / IFCC** without P-S-P OE 504-11, Version 4/22.10.2023
	18. Serum glutamic-pyruvic transaminase (SGPT)	Photometric method UV / IFCC** without P-S-P OE 504-11, Version 4/22.10.2023
	19. Gamma-glutamyl trasferase (γ-GT)	Enzymatic Colorimetric method GCNA-Liquid stand SZASZ OE 504-11, Version 4/22.10.2023
	20. Alkaline phosphatase (ALP)	Colorimetric method liquid acc to IFCC** OE 504-11, Version 4/22.10.2023
	21. Creatinine kinase (CPK)	Photometric method liquid acc to IFCC** OE 504-11, Version 4/22.10.2023
	22. Lactate dehydrogenase (LDH)	Photometric method UV/optimized (DGKC***) OE 504-11, Version 4/22.10.2023
	23. Amylase	Enzymatic colorimetric method liquid acc to IFCC** OE 504-11, Version 4/22.10.2023
	24. Magnesium	Chromatometric method / CPZ III OE 504-11, Version 4/22.10.2023
	25. Potassium	ISE method OE 504-11, Version 4/22.10.2023
	26. Sodium	ISE method OE 504-11, Version 4/22.10.2023
	27. Globulins	Calculated method OE 504-11, Version 4/22.10.2023
	28. Atheromatic index	Calculated method OE 504-11, Version 4/22.10.2023
	29. A/G ratio	Calculated method OE 504-11, Version 4/22.10.2023
	30. Total Iron Binding Capacity (TIBC)	Calculated method OE 504-11, Version 4/22.10.2023
	31. Total lipids	Calculated method OE 504-11, Version 4/22.10.2023
	32. Direct Bilirubin (D-BIL)	Interzonal method OE 504-11, Version 4/22.10.2023
	33. Indirect Bilirubin (I-BIL)	Calculated method OE 504-11, Version 4/22.10.2023
	34. Non-HDL Cholesterol (Non-HDL)	Calculated method OE 504-11, Version 4/22.10.2023

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Urine	**Determination of 11 parameters**	**Automated biochemical analyzer Cobas 8000 PRO I, c-503, ROCHE***
	1.Creatinine	Kinetic Enzymatic method - JAFFE METHOD OE 504-11, Version 4/22.10.2023
	2.Calcium	Photometric method -5NITRO-5METHYL-BAPTA OE 504-11, Version 4/22.10.2023
	3. Chlorides	ISE Indirect method OE 504-11, Version 4/22.10.2023
	4.Total Protein	Colorimetric method BIURET OE 504-11, Version 4/22.10.2023
	5.Phosphorus	Photometric method end point PHOSPHOMOLYBDADE OE 504-11, Version 4/22.10.2023
	6. Potassium	ISE method OE 504-11, Version 4/22.10.2023
	7. Sodium	ISE method OE 504-11, Version 4/22.10.2023
	8. Magnesium	Chromatometric method / CPZ III OE 504-11, Version 4/22.10.2023
	9. Glucose	Enzymatic Chromatometric method GOD-PAP OE 504-11, Version 4/22.10.2023
	10. Urea	Kinetic Enzymatic method / UV OE 504-11, Version 4/22.10.2023
	11. Uric acid	Enzymatic Chromatometric method uricase/peroxidase OE 504-11, Version 4/22.10.2023
Blood serum	**Determination of 32 parameters**	**Automated biochemical analyzer COBAS 8000 PRO II, c-503, ROCHE***
	1. Glucose	Enzymatic Chromatometric method GOD-PAP OE 504-11, Version 4/22.10.2023
	2. Triglycerides	Enzymatic Chromatometric method GPO – PAP OE 504-11, Version 4/22.10.2023
	3. Total Cholesterol	Enzymatic method CHOD – PAP OE 504-11, Version 4/22.10.2023
	4. HDL-Cholesterol	Enzymatic Chromatometric method OE 504-11, Version 4/22.10.2023
	5. VLDL-Cholesterol	Calculated method OE 504-11, Version 4/22.10.2023
	6. LDL-Cholesterol	Enzymatic Chromatometric method OE 504-11, Version 4/22.10.2023
	7. Uric acid	Enzymatic Chromatometric method uricase/peroxidase OE 504-11, Version 4/22.10.2023
	8. Urea	Kinetic Enzymatic method / UV OE 504-11, Version 4/22.10.2023
	9. Creatinine	Kinetic Enzymatic method - JAFFE METHOD OE 504-11, Version
	10.Total Bilirubin	Photometric method UV Liquid DPD OE 504-11, Version 4/22.10.2023

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood serum (continued)	11. Chlorides	ISE, Indirect method OE 504-11, Version 4/22.10.2023
	12. Calcium	Photometric method -5NITRO-5METHYL-BAPTA OE 504-11, Version 4/22.10.2023
	13. Phosphorus	Photometric method end point PHOSPHOMOLYBDADE OE 504-11, Version 4/22.10.2023
	14. Iron	Colorimetric method /FERROZINE OE 504-11, Version 4/22.10.2023
	15.Total Protein	Colorimetric method BIURET OE 504-11, Version 4/22.10.2023
	16. Albumin	Photometric method BROMOCRESOL GREEN OE 504-11, Version 4/22.10.2023
	17. Serum glutamic-oxaloacetic transaminase (SGOT)	Photometric method UV / IFCC** without P-S-P OE 504-11, Version 4/22.10.2023
	18. Serum glutamic-pyruvic transaminase (SGPT)	Photometric method UV / IFCC** without P-S-P OE 504-11, Version 4/22.10.2023
	19.Gamma-glutamyl trasferase (γ-GT)	Enzymatic Colorimetric method GCNA-Liquid stand SZASZ OE 504-11, Version 4/22.10.2023
	20. Alkaline phosphatase (ALP)	Colorimetric method liquid acc to IFCC** OE 504-11, Version 4/22.10.2023
	21. Creatinine kinase (CPK)	Photometric method liquid acc to IFCC** OE 504-11, Version 4/22.10.2023
	22. Lactate dehydrogenase (LDH)	Photometric method UV/optimized (DGKC***) OE 504-11, Version 4/22.10.2023
	23. Amylase	Enzymatic colorimetric method liquid acc to IFCC** OE 504-11, Version 4/22.10.2023
	24. Magnesium	Chromatometric method / CPZ III OE 504-11, Version 4/22.10.2023
	25. Potassium	ISE method OE 504-11, Version 4/22.10.2023
	26. Sodium	ISE method OE 504-11, Version 4/22.10.2023
	27. Urea/BUN (U-BUN)	Enzymatic Kinetic method OE 504-11, Version 4/22.10.2023
	28. Globulins	Calculated method OE 504-11, Version 4/22.10.2023
	29. Atheromatic index	Calculated method OE 504-11, Version 4/22.10.2023
	30. A/G ratio	Calculated method OE 504-11, Version 4/22.10.2023
	31. Total lipids	Calculated method OE 504-11, Version 4/22.10.2023
	32. Non-HDL Cholesterol (Non-HDL)	Calculated method OE 504-11, Version 4/22.10.2023
Urine	**Determination of 10 parameters**	**Automated biochemical analyzer COBAS 8000 PRO II, c-503, ROCHE***
	1.Creatinine	Kinetic Enzymatic method - JAFFE METHOD OE 504-11, Version 4/22.10.2023

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Urine (Continued)	2.Calcium	Photometric method -5NITRO-5METHYL-BAPTA OE 504-11, Version 4/22.10.2023
	3. Chlorides	ISE Indirect method OE 504-11, Version 4/22.10.2023
	4. Phosphorus	Photometric method end point PHOSPHOMOLYBDADE OE 504-11, Version 4/22.10.2023
	5. Potassium	ISE method OE 504-11, Version 4/22.10.2023
	6. Sodium	ISE method OE 504-11, Version 4/22.10.2023
	7. Magnesium	Chromatometric method / CPZ III OE 504-11, Version 4/22.10.2023
	8. Glucose	Enzymatic Chromatometric method GOD-PAP OE 504-11, Version 4/22.10.2023
	9. Urea	Kinetic Enzymatic method / UV OE 504-11, Version 4/22.10.2023
	10. Uric acid	Enzymatic Chromatometric method uricase/peroxidase OE 504-11, Version 4/22.10.2023
Blood serum	**Determination of 36 parameters**	**Automated biochemical analyzer COBAS 8000 PRO III, c-503, ROCHE***
	1. Glucose	Enzymatic Chromatometric method GOD-PAP OE 504-11, Version 4/22.10.2023
	2. Triglycerides	Enzymatic Chromatometric method GPO – PAP OE 504-11, Version 4/22.10.2023
	3. Total Cholesterol	Enzymatic method CHOD – PAP OE 504-11, Version 4/22.10.2023
	4. HDL-Cholesterol	Enzymatic Chromatometric method OE 504-11, Version 4/22.10.2023
	5. VLDL-Cholesterol	Calculated method OE 504-11, Version 4/22.10.2023
	6. LDL-Cholesterol	Enzymatic Chromatometric method OE 504-11, Version 4/22.10.2023
	7. Uric acid	Enzymatic Chromatometric method uricase/peroxidase OE 504-11, Version ~~3/20.11.~~2021 4/22.10.2023
	8. Urea	Kinetic Enzymatic method / UV OE 504-11, Version ~~3/20.11.~~2021 4/22.10.2023
	9. Creatinine	Kinetic Enzymatic method - JAFFE METHOD OE 504-11, Version
	10.Total Bilirubin	Photometric method UV Liquid DPD OE 504-11, Version 4/22.10.2023
	11. Direct Bilirubin (D-BIL)	Diazonal method, OE 504-11, Version 4/22.10.2023
	12. Indirect Bilirubin (I-BIL)	Calculated method, OE 504-11, Version 4/22.10.2023
	13. Chlorides	ISE, Indirect method OE 504-11, Version 4/22.10.2023

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood serum (continued)	14. Calcium	Photometric method -5NITRO-5METHYL-BAPTA OE 504-11, Version 4/22.10.2023
	15. Phosphorus	Photometric method end point PHOSPHOMOLYBDADE OE 504-11, Version 4/22.10.2023
	16. Iron	Colorimetric method /FERROZINE OE 504-11, Version 4/22.10.2023
	17.Total Protein	Colorimetric method BIURET OE 504-11, Version 4/22.10.2023
	18. Albumin	Photometric method BROMOCRESOL GREEN OE 504-11, Version 4/22.10.2023
	19. Serum glutamic-oxaloacetic transaminase (SGOT)	Photometric method UV / IFCC** without P-S-P OE 504-11, Version 4/22.10.2023
	20. Serum glutamic-pyruvic transaminase (SGPT)	Photometric method UV / IFCC** without P-S-P OE 504-11, Version 4/22.10.2023
	21.Gamma-glutamyl trasferase (γ-GT)	Enzymatic Colorimetric method GCNA-Liquid stand SZASZ OE 504-11, Version 4/22.10.2023
	22. Alkaline phosphatase (ALP)	Colorimetric method liquid acc to IFCC** OE 504-11, Version 4/22.10.2023
	23. Creatinine kinase (CPK)	Photometric method liquid acc to IFCC** OE 504-11, Version 4/22.10.2023
	24. Amylase	Enzymatic colorimetric method liquid acc to IFCC** OE 504-11, Version 4/22.10.2023
	25. Magnesium	Chromatometric method / CPZ III OE 504-11, Version 4/22.10.2023
	26. Potassium	ISE method OE 504-11, Version 4/22.10.2023
	27. Sodium	ISE method OE 504-11, Version 4/22.10.2023
	28. Urea/BUN (U-BUN)	Enzymatic Kinetic method OE 504-11, Version 4/22.10.2023
	29. Globulins	Calculated method OE 504-11, Version 4/22.10.2023
	30. Atheromatic index	Calculated method OE 504-11, Version 4/22.10.2023
	31. A/G ratio	Calculated method OE 504-11, Version 4/22.10.2023
	32. Total lipids	Calculated method OE 504-11, Version 4/22.10.2023
	33. UIBC	Photometric Method, OE 504-11, Version 4/22.10.2023
	34. TIBC	Calculated method OE 504-11, Version 4/22.10.2023
	35. Insulin Resistance (HOMA-IR Test)	Calculated method OE 504-11, Version 4/22.10.2023
	36. Non-HDL Cholesterol (Non-HDL)	Calculated method OE 504-11, Version 4/22.10.2023

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Hematological Tests		
Whole blood	**Determination of 11 parameters**	**Automated analyzers SYSMEX XN 550***
	1. White Blood Cells (WBC)	Flow Cytometry with fluorescence OE 504-11, Version 4/22.10.2023
	2. Red Blood Cells (RBC)	Hydrodynamic Focusing (DC Detection) OE 504-11, Version 4/22.10.2023
	3. Hemoglobin (HGB)	Photometry OE 504-11, Version 4/22.10.2023
	4. Hematocrit (HCT)	Hydrodynamic Focusing (DC Detection) OE 504-11, Version 4/22.10.2023
	5. Mean Cell Volume (MCV)	Calculated method (DC Detection) OE 504-11, Version 22.10.2023
	6. Mean Cell Hemoglobin (MCH)	Calculated method (DC Detection) OE 504-11, Version 4/22.10.2023
	7. Mean corpuscular hemoglobin concentration (MCHC)	Calculated method (DC Detection) OE 504-11, Version 4/22.10.2023
	8. Platelets (PLTs)	Hydrodynamic Focusing (DC Detection) OE 504-11, Version 4/22.10.2023
	9. Mean Platelet Volume (MPV)	Calculated method OE 504-11, Version 4/22.10.2023
	10. Red Cell Distribution Width (RDW)	Hydrodynamic Focusing (DC Detection) OE 504-11, Version 4/22.10.2023
	11. Red Cell Distribution Width (RDW-SD)	Calculated method OE 504-11, Version 4/22.10.2023
Immunochemical Tests		
1. Blood serum	**Determination of 26 parameters**	**Automated immunochemical analyzer COBAS 8000 PRO I, e-801, ROCHE***
	1. Prolactin (PRL)	Electrochemiluminescense (ECLIA) OE 504-11, Version 4/22.10.2023
	2. Follicle Stimulating Hormone (FSH)	
	3. Luteinizing Hormone (LH)	
	4. Cortisol	
	5. Thyrotropin Hormone (TSH)	
	6. Thyroxin total (T4)	
	7. Triidothyronine total (T3)	
	8. Free Triidothyronine total (Free T3)	
	9. Free Thyroxin (Free T4)	
	10. β-Human Chorionic Gonadotropin (β-HCG)	
	11. Estradiol (E2)	
	12. Carcinoembryonic antigen (CEA)	

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood serum (continued)	13. Cancer antigen CA 125	
	14. Cancer antigen CA 15-3	
	15. Cancer antigen CA 19-9	
	16. Prostate Specific Antigen (PSA)	
	17. Vitamin D, Total	
	18. Vitamin B12	
	19. Follate	
	20. Ferritin	
	21. Insulin	
	22. Parathyroid Hormone (PTH)	
	23. Progesterone	
	24. Testosterone	
	25. Dehydroepiandrosterone-sulfate (DHEA's)	
	26. Insulin Resistance (HOMA-IR Test)	Calculated method
	Determination of 12 parameters	**Automated immunochemical analyzer COBAS 8000 PRO II, e-801, ROCHE***
	1. Vitamin D, Total	Electrochemiluminescense (ECLIA) OE 504-11, Version 4/22.10.2023
	2. Vitamin B12	
	3. Ferritin	
	4. Folate	Electrochemiluminescense (ECLIA) OE 504-11, Version 4/22.10.2023
	5. Free Triidothyronine total (Free T3)	
	6. Free Thyroxin (Free T4)	
	7. Prostate Specific Antigen (PSA)	
	8. Thyrotropin Hormone (TSH)	
	9. Triidothyronine total (T3)	
	10. Thyroxin total (T4)	
	11. a-fetoprotein (AFP)	
	12. Sex Hormone Binding Globulin (SHBG)	
Blood serum	**Determination of 10 parameters**	**Automated immunochemical analyzer COBAS 8000 PRO III, e-801 (II), ROCHE***
	1. Progesterone	Electrochemiluminescense (ECLIA) OE 504-11, Version 4/22.10.2023
	2. Cortisol	
	3. Follicle Stimulating Hormone (FSH)	

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used
Blood serum (Continued)	4. Testosterone	
	5. a-fetoprotein (AFP)	
	7. Sex Hormone Binding Globulin (SHBG)	
	8. Dehydroepiandrosterone-sulfate (DHEA's)	
	9. Prolactin	
	10. Luteinizing Hormone (LH)	
	11. Estradiol	
Blood Serum	**Determination of 16 parameters**	**Automated immunochemical analyzer COBAS 8000 PRO III, e-801 (I), ROCHE***
	1. Folate	Electrochemiluminescense (ECLIA) OE 504-11, Version 4/22.10.2023
	2. Vitamin D3 (Vit D3)	
	3. Thyrotropin Hormone (TSH)	
	4. Cancer antigen CA 19-9	
	5. Cancer antigen Ca 15-3	
	6. Ferritin	
	7. Insulin	
	8. β-Human Chorionic Gonadotropin (β-HCG)	
	9. Free Thyroxin (Free T4)	
	10. Prostate Specific Antigen (PSA)	
	11. Triidothyronine total (T3)	
	12. Vitamin B12 (Vit B12)	
	13. Thyroxin total (T4)	
	14. Carcinoembryonic antigen (CEA)	
	15. Free Triidothyronine total (Free T3)	
	16. Insulin Resistance (HOMA-IR Test) (Υπολογιστική)	Calculated method
Whole blood	**Determination of 1 parameter**	**Automated analyzer VARIANT II TURBO LINK (I), BioRad***
	Glycated Hemoglobin A1c (HbA1c)	HPLC OE 504-11, Version ~~3/20.11.~~2021 4/22.10.2023
	Determination of 1 parameter	**Automated analyzer VARIANT II TURBO LINK (II), BioRad***
	Glycated Hemoglobin A1c (HbA1c)	HPLC OE 504-11, Version 4/22.10.2023

**Reference to the commercial name of a specific analyzer/kit, refers to a specific analytical method and protocol*
***IFCC: International Federation of Clinical Chemistry*
****DGKC: Deutsche Geselschaft fur Klinische Chemie*

Site of assessment: **Laboratory permanent premises, 260 Eleftheriou Venizelou Av., Kallithea, Attiki, Greece.**
Primary Collection Site: **260 Eleftheriou Venizelou Av., Kallithea, Attiki, Greece.**

Approved signatories: **Christina Economidou.**

This scope of Accreditation replaces the previous one dated 09.03.2022.
The Accreditation Certificate No.**1228**-2, to ELOT EN ISO 15189:2022, is valid until 22.11.2029.

Athens, 18th July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD