Hellenic Accreditation System

Annex G1/A12 to the Certificate No. **994**-3

SCOPE of ACCREDITATION

of the

Clinical Laboratory

of

Central Laboratories S.A.

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Biochemical Tests		
1. Blood serum	**Determination of 43 parameters**	**Automated biochemical analyzer ADVIA 1800, SIEMENS * O.650-8/12/06-02-2019 Π.650-1/11/01-12-2020**
	1. Glucose	Enzymatic Chromatometric Reaction
	2. Urea	Enzymatic Chromatometric Reaction
	3. Uric Acid	Enzymatic Chromatometric Reaction
	4. Creatinine	Kinetic / Chromatometric Reaction
	5. Serum glutamic-oxaloacetic transaminase (SGOT)	Enzymatic Chromatometric Reaction
	6. Serum glutamic-pyruvic transaminase (SGPT)	Enzymatic Chromatometric Reaction
	7. Gamma-glutamyl trasferase (γ-GT)	Enzymatic Chromatometric Reaction
	8. Total Cholesterol	Enzymatic Chromatometric Reaction
	9. HDL Cholesterol	Enzymatic Chromatometric Reaction
	10. LDL Cholesterol	Enzymatic Chromatometric Reaction
	11. LDL Cholesterol	Calculated
	12. Triglycerides	Enzymatic Chromatometric Reaction
	13. Iron	Chromatometric Reaction

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
Blood serum (continued)	14. Alkaline phosphatase (ALP)	Enzymatic Chromatometric Reaction
	15. Calcium	Chromatometric Reaction
	16. Inorganic Phosphate	Chromatometric Reaction
	17. Potassium	Indirect Potentiometric ISE
	18. Sodium	Indirect Potentiometric ISE
	19. Chloride	Indirect Potentiometric ISE
	20. Creatinine kinase (CK)	Enzymatic Chromatometric Reaction
	21. Lactate dehydrogenase (LDH)	Enzymatic Chromatometric Reaction
	22. Albumin	Chromatometric Reaction
	23. Total Protein	Chromatometric Reaction
	24. Magnesium	Chromatometric Reaction
	25. Aldolase	Chromatometric Reaction
	26. Amylase	Enzymatic Chromatometric Reaction
	27. Bilirubin Total	Chromatometric Reaction
	28. Bilirubin Direct	Chromatometric Reaction
	29. Bilirubin indirect	Calculated
	30. TIBC – Total iron-binding capacity	Ferene Direct – End Point Chromatometric Reaction
	31. Transferrin	Turbidimetric
	32. C Reactive Protein (CRP)	Turbidimetric
	33. Complement C3	Turbidimetric
	34. Complement C4	Turbidimetric
	35. Total Globulins	Calculated
	36. Total Lipids	Calculated
	37. VLDL Cholesterol	Calculated
	38. Atherogenic index	Calculated
	39. Albumin rate	Calculated
	40. Creatinine Clearance	Calculated
	41. Urea Clearance	Calculated

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	42. Transferrin saturation	Calculated
	43. Angiotensin Converting Enzyme (ACE)	Enzymatic Chromatometric Reaction
2. Blood serum	**Determination of 30 parameters**	**Automated biochemical analyzer ADVIA 2400, SIEMENS * O.650-8/12/06-02-2019 П.650-1/11/01-12-2020**
Blood serum (continued)	1. Glucose	Enzymatic Chromatometric Reaction
	2. Urea	Enzymatic Chromatometric Reaction
	3. Uric Acid	Enzymatic Chromatometric Reaction
	4. Creatinine	Kinetic / Chromatometric Reaction
	5. Serum glutamic-oxaloacetic transaminase (SGOT)	Enzymatic Chromatometric Reaction
	6. Serum glutamic-pyruvic transaminase (SGPT)	Enzymatic Chromatometric Reaction
	7. Gamma-glutamyl trasferase (γ-GT)	Enzymatic Chromatometric Reaction
	8. Total Cholesterol	Enzymatic Chromatometric Reaction
	9. HDL Cholesterol	Enzymatic Chromatometric Reaction
	10. LDL Cholesterol	Calculated
	11. Triglycerides	Enzymatic Chromatometric Reaction
	12. Iron	Chromatometric Reaction
	13. Alkaline phosphatase (ALP)	Enzymatic Chromatometric Reaction
	14. Calcium	Chromatometric Reaction
	15. Lipase	Chromatometric Reaction
	16. Cholisterase	Chromatometric Reaction
	17. Zink	Chromatometric Reaction
	18. Potassium	Indirect Potentiometric ISE
	19. Sodium	Indirect Potentiometric ISE
	20. Chloride	Indirect Potentiometric ISE
	21. Creatinine kinase (CK)	Enzymatic Chromatometric Reaction
	22. Lactate dehydrogenase (LDH)	Enzymatic Chromatometric Reaction
	23. C Reactive Protein (CRP)	Turbidimetric
	24. Anti-streptolysine O (ASTO)	Turbidimetric
	25. Immunoglobulin A (IGA)	Turbidimetric
	26. Immunoglobulin G (IGG)	Turbidimetric
	27. Immunoglobulin M (IGM)	Turbidimetric
	28. Total Lipids	Calculated

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	29. VLDL Cholesterol	Calculated
	30. Atherogenic index	Calculated
3. Urine	**Determination of 15 parameters**	**Automated biochemical analyzer ADVIA 1800, SIEMENS * Ο.650-8/12/06-02-2019 Π.650-1/11/01-12-2020**
	1. Glucose	Enzymatic Chromatometric Reaction
	2. Urea	Enzymatic Chromatometric Reaction
	3. Uric Acid	Enzymatic Chromatometric Reaction
	4. Creatinine	Kinetic / Chromatometric Reaction
Urine (continued)	5. Calcium	Chromatometric Reaction
	6. Phosphate Inorganic	Chromatometric Reaction
	7. Potassium	Indirect Potentiometric ISE
	8. Sodium	Indirect Potentiometric ISE
	9. Chloride	Indirect Potentiometric ISE
	10. Albumin	Immunoturbidimetric
	11. Total Protein	Chromatometric Reaction
	12. Magnesium	Chromatometric Reaction
	13. Amylase	Enzymatic Chromatometric Reaction
	14. Creatinine Clearance	Calculated
	15. Urea Clearance	Calculated
4. Whole Blood (EDTA)	**Determination of 1 parameter**	**Automated biochemical analyzer, ADVIA 1800, SIEMENS * Ο.650-8/12/06-02-2019 Π.650-1/11/01-12-2020**
	1. Glucose-6-Phosphate Dehydrogenase (G-6-PD)	Enzymatic Chromatometric Reaction
5. Blood serum	**Determination of 6 parameters**	**Nephelometer, BN II, SIEMENS * Ο.650-8/12/06-02-2019 Π.650-1/11/01-12-2020**
	1. Apolipoprotein A1 (APO A1)	Nephelometric
	2. Apolipoprotein B (APO B)	
	3. Lipoprotein (a) (Lp(a))	
	4. Rheumatoid Factor (RF)	
	5. B2-Microglobulin	
	6. Immunoglobulin E (IGE)	

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
6. Urine	**Determination of 1 parameter**	**Nephelometer, BN II, SIEMENS * Ο.650-8/12/06-02-2019 Π.650-1/11/01-12-2020**
	1. B2-Microglobulin	Nephelometric
7. Blood serum		Microcapillary Electrophoresis
8. Blood serum		Agarose gel Electrophoresis
Immunochemical Tests		
1. Blood serum		Fluoroenzymeimmunoassay (FEIA)
2. Blood serum	**Determination of 1 parameters**	**Automated biochemical analyzer ADVIA 2400, SIEMENS * Ο.650-8/12/06-02-2019 Π.650-1/11/01-12-2020**
	1 Lithium	Chromatometric Reaction
3. Blood serum	**Determination of 13 parameters**	**Automated analyzer, ADVIA CENTAUR XP (1), SIEMENS * Ο.650-8/12/06-02-2019 Π.650-1/11/01-12-2020**
	1. Vitamin D (25-OH)	Chemiluminescense (CLIA)
	2. Human Chorionic Gonadotropin (THCG)	
	3. Ferritin	
	4. Insulin	
	5. Triidothyronine Total (T3)	
	6. Thyroxin Total (T4)	
	7. Thyrotropin Hormone (TSH)	
	8. Free Triidothyronine (Free T3)	

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	9. Free Thyroxin (Free-T4)	
	10. Estradiol (E2)	
	11. Progesterone (PRG)	
	12. Testosterone	
	13. Sex Hormone Binding Globulin (SHBG)	
4. Blood serum	**Determination of 10 parameters**	**Automated analyzer, ADVIA CENTAUR XP (2), SIEMENS *** **Ο.650-8/12/06-02-2019** **Π.650-1/11/01-12-2020**
	1. Carcinoembryonic antigen (CEA)	Chemiluminescense (CLIA)
	2. α-Fetoprotein (AFP)	
	3. Cancer antigen CA 125	
	4. Cancer antigen CA 15.3	
	5. Cancer antigen CA 19.9	
	6. CK-MB mass	
	7. Troponin I	
	8. Myoglobin	
	9. Vitamin B12	
	10. Follate Acid	
5. Blood serum	**Determination of 15 parameters**	**Automated analyzer, ADVIA CENTAUR XP (3), SIEMENS *** **Ο.650-8/12/06-02-2019** **Π.650-1/11/01-12-2020**
	1. Prostate Specific Antigen (PSA)	Chemiluminescense (CLIA)
	2. Free Prostate Specific Antigen (FPSA)	
	3. Ferritin	
	4. Valproic Acid	
	5. Digoxin	
	6. Carbamazepine	
	7. Thyrotropin Hormone (TSH)	
	8. ANTI-TG	
	9. ANTI-TPO	
	10. Follicle Stimulating Hormone (FSH)	
	11. Luteinizing Hormone (LH)	
	12. Prolactin (PRL)	

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	13. Cortisol	
	14. Dehydroepiandrosterone sulfate (DHEA-S)	
	15. Anti CCP	
6. Blood serum	**Determination of 9 parameters**	**Automated analyzer, ADVIA IMMULITE 2000i, SIEMENS *** **O.650-8/12/06-02-2019** **П.650-1/11/01-12-2020**
	1. Thyroglobulin (TG)	Chemiluminescense (CLIA)
	2. Calsitonin	
	3. Osteocalcin	
	4. Androstenedione	
	5. Homocysteine	
	6. Thyroid-Stimulating Immunoglobulin (TSI)	
	7. Insulin-like Growth Factor (IGF1)	
	8. Growth hormone (GH)	
	9. Hepatitis B surface antigen (HBsAg)	
7. Blood serum		Electrochemiluminescense (ECLIA)
8. Blood serum		Chemiluminescense (CLIA)
9. Blood serum	**Determination of 7 parameters**	**Automated analyzer, ADVIA CENTAUR XP (2), SIEMENS *** **O.650-8/12/06-02-2019** **П.650-1/11/01-12-2020**
	1. Antibodies to Human Immunodeficiency Virus (HIV Ag (p24) / HIV 1&2 Ab)	Chemiluminescense (CLIA)
	2. Antibodies to hepatitis C virus (Anti-HCV)	
	3. Antibodies to Hepatitis B surface antigen (Anti-HBs)	
	4. Antibodies to Hepatitis B -e antigen (Anti-HBe)	

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	5. Total Antibodies to hepatitis A virus (Anti-HAV)	
	6. IgM Antibodies to hepatitis A virus (Anti-HAV-IgM)	
	7. Hepatitis B-e antigen (HBeAg)	
10. Blood serum	**Determination of 10 parameters**	**Automated analyzer, ADVIA IMMULITE XPi, SIEMENS *** **О.650-8/12/06-02-2019** **П.650-1/11/01-12-2020**
	1. Antibodies to Hepatitis B core antigen (Anti-HBc)	Chemiluminescense (CLIA)
	2. IgM Antibodies to Hepatitis B core antigen (Anti-HBc-IgM)	
	3. Antibodies to Rubella virus IgG Ab (Rubella IgG Ab)	
	4. Antibodies to Rubella virus IgM Ab (Rubella IgG Ab)	
	5. Toxoplasma Gondii IgG antibodies (TOXO IgG)	
	6. Toxoplasma Gondii IgM antibodies (TOXO IgM)	
	7. Cytomegalovirus IgG antibodies (CMV IgG)	
	8. Cytomegalovirus IgM antibodies (CMV IgM)	
	9. Epstein Barr IgG antibodies	
	10. Epstein Barr IgM antibodies	
11. Blood serum		Electrochemiluminescense (CLIA)
12. Blood serum		ELISA
13. Blood serum		Indirect Immunofuorescence on HEP 2 substrate
14. Blood serum		ELISA

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
1. Urine	**Determination of 1 parameter**	**Automated analyzer, ADVIA CENTAUR XP (3), SIEMENS*** **Ο.650-8/12/06-02-2019** **Π.650-1/11/01-12-2020**
	1. Cortisol	Chemiluminescense (CLIA)
1. Blood plasma (EDTA)	**Determination of 1 parameter**	**Automated analyzer, ADVIA CENTAUR XP (1), SIEMENS*** **Ο.650-8/12/06-02-2019** **Π.650-1/11/01-12-2020**
	1. Parathyroid Hormone (PTH)	Chemiluminescense (CLIA)
2. Blood plasma (EDTA)		Electrochemiluminescense (CLIA)
3. Blood plasma (EDTA)	**Determination of 1 parameter**	**Automated analyzer, ADVIA IMMULITE 2000i, SIEMENS *** **Ο.650-8/12/06-02-2019** **Π.650-1/11/01-12-2020**
	1. ACTH	Chemiluminescense (CLIA)
Hematological Tests		
1. Whole Blood (EDTA)	**Determination of 17 parameters**	**Automated analyzers, ADVIA 2120i (ADV1) & (ADV2), SIEMENS *** **Ο.650-8/12/06-02-2019** **Π.650-1/11/01-12-2020**
	1. Hemoglobin	Chromatometric Reaction (ICSH modified)
	2. Red Blood Cells (RBC)	Volume analysis combined with flow cytometry
	3. White Blood Cells (WBC)	Volume analysis combined with flow cytometry
	4. Platelets (PLTs)	Volume analysis combined with flow cytometry
	5. Hematocrit (HCT)	Calculated Based on Specific Equation
	6. Mean Red Cell Volume (MCV)	Volume analysis with flow cytometry
	7. Mean Cell Hemoglobin (MCH)	Calculated Based on Specific Equation
	8. Mean corpuscular hemoglobin concentration (MCHC)	Calculated Based on Specific Equation
	9. Red Cell Dist.Width -CV	Calculated Based on Specific Equation
	10. Plateletcrit	Calculated Based on Specific Equation
	11. Mean Platelet Volume (MPV)	Volume analysis with flow cytometry
	12. Neutrophil (number and %)	Staining combined with flow cytometry
	13. Lymphocyte (number and %)	
	14. Monocyte (number and %)	

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	15. Eosinophil (number and %)	
	16. Basophil (number and %)	
	17. Atypical- Large unstained cells (number and %)	
2. Whole Blood (EDTA)	**Determination of 2 parameters**	**Automated analyzers, ADVIA 2120i (ADV2), SIEMENS *** **Ο.650-8/12/06-02-2019** **Π.650-1/11/01-12-2020**
	1. Reticulocyte Count (%)	Staining combined with cytometry
	2. Reticulocyte Hemoglobin Concentration (CHr)	
3. Whole Blood (EDTA)		HPLC – High Performance Liquid Chromatography
4. Whole blood (EDTA)		HPLC – High Performance Liquid Chromatography
5. Whole blood (EDTA)		Gel Agglutination
1. Blood serum		Gel Agglutination
1. Blood plasma (sodium citrate)	**Determination of 11 parameters**	**Automated Coagulation analyzer CS-2000i, SIEMENS *** **Ο.650-8/12/06-02-2019** **Π.650-1/11/01-12-2020**
	1. Fibrinogen (FIB)	Clotting
	2. Activated Partial Thromboplastin time (APTT)	Clotting
	3. Prothrombin time (PT sec)	Clotting
	4. Prothrombin time (INR)	Calculated

Materials/Products tested	Types of test/Properties measured	Applied methods/Techniques used
	5. D-DIMERS	Immunoturbidimetric
	6. Anti-XA	Chromatometric Reaction
	7. Antithrombin III	Chromatometric Reaction
	8. Protein C (Activity)	Chromatometric Reaction
	9. Activated Protein C Resistance (APC-R)	Clotting
	10. Protein S (Antigen Activity)	Immunoturbidimetric
	11. Free Protein S Antigen	Immunoturbidimetric
Molecular Genetics tests		
1. Whole blood (EDTA)		**O.650-8/12/06-02-2019** **O.650-11/10/19-02-2021** **Π.650-2/10/15-02-2021** PCR with HAIN LIFESCIENCE * stipassay kit in SimpliAmp™ Thermal Cycler (Applied Biosystems™)
Molecular Biology tests		
1. Blood plasma (EDTA)		**O.650-8/12/06-02-2019** **O.650-11/10/19-02-2021** **Π.650-2/10/15-02-2021** RT- PCR with Sacace BIOTECHNOLOGIES * kit in Rotor-Gene® Q (QIAGEN)
		O.650-8/12/06-02-2019 **O.650-11/10/19-02-2021** **Π.650-2/10/15-02-2021** RT- PCR with Sacace BIOTECHNOLOGIES * kit in Rotor-Gene® Q (QIAGEN)
2. Nasopharyngeal smear	**Determination of 1 parameter**	**O.650-8/12/06-02-2019** **O.650-11/10/19-02-2021** **Π.650-2/10/15-02-2021** RT- PCR with Viasure by CerTest, CE-IVD * kit in Rotor-Gene® Q (QIAGEN) (QIAGEN)

**Reference to the commercial name of a specific analyzer/kit, refers to a specific analytical method and protocol*

Site of assessment: **Laboratory permanent premises, 146th Petrou Ralli Str., GR-184 54, Nikaia, Attiki, Greece.**

Approved signatories: **A. Kotsigianni, A. Lentari, K. Mpouza.**

This scope of Accreditation replaces the previous one dated 25.01.2024.

The Accreditation Certificate No. **994**-3, to ELOT EN ISO 15189:2012, is valid until 28.07.2028.

Athens, 26th February 2024

Christos Nestoras
CEO of ESYD