Hellenic Accreditation System

Annex G1/6 to the Certificate No.**1114**-3

SCOPE of ACCREDITATION

of the

Biochemistry–Hormonology Department, Microbiology Department, Hematology Department,

of

"P. & A. Kyriakou", Athens General Children's Hospital

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
Biochemical Tests		
Blood Serum, Urine	**Determination of ten (10) Analytes**	**Automated Biochemical Analyzers: Alinity A1 & A2, (Abbott*) KE.BIOX, version 4, 15/1/2025**
	1. Glucose	Enzymatic photometric endpoint method (UV) with hexokinase, G-6-PDH.
	2. Urea	Kinetic photometric (UV) with urease and glutamate dehydrogenase method.
	3. Creatinine	Enzymatic photometric endpoint method (creatinase/ sarcosine oxidase)
	4. Potassium	ISE
	5. Sodium	ISE
	6. Chloride	ISE
	7. Calcium	Arsenazo III - Photometric endpoint
	8. Phosphate (inorganic)	Photometric endpoint (UV) method with phosphomolybdate complex.
	9. Magnesium	Enzymatic (Isocitrate dehydrogenase), kinetic photometric (UV)
	10. Uric acid	Enzymatic calorimetric uricase endpoint method.

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
Blood Serum	**Determination of 19 Analytes**	**Automated Biochemical Analyzers: Alinity A1 & A2, (Abbott*)** **KE.BIOX, version 4, 15/1/2025**
	1. α-Amylase	Enzymatic kinetic colorimetric method, according to IFCC.
	2. Lipase	Calorimetric kinetic.
	3. Aspartate aminotransferase (SGOT/AST)	Enzymatic (malate dehydrogenase), kinetic photometric (UV)-NADH.
	4. Alanine aminotransferase (SGPT/ALT)	Enzymatic (lactate dehydrogenase), kinetic photometric (UV)-NADH.
	5. Gamma-glutamyltranferase (γ- GT)	Enzymatic kinetic colorimetric (L-gamma-glutamyl-3-carboxy-4-nitroanilide substrate).
	6. Alkaline Phosphatase	Colorimetric kinetic [Para-nitrophenyl phosphate (p-NPP)]
	7. Bilirubin total	Colorimetric endpoint / Diazonium Salt.
	8. Bilirubin direct	Colorimetric endpoint / Diazo Reaction.
	9. Bilirubin indirect	Calculated (from bilirubin total and direct)
	10. Total Protein	Colorimetric endpoint biuret method.
	11. Albumin	Colorimetric endpoint method with Bromocresol Green (BCG).
	12. Cholesterol	Enzymatic (cholesterol esterase) colorimetric endpoint method.
	13. Triglycerides	Enzymatic (Glycerol phosphate oxidase) colorimetric endpoint method.
	14. HDL-Cholesterol	Homogeneous enzymatic colorimetric endpoint method.
	15. LDL- Cholesterol	Homogeneous enzymatic colorimetric endpoint method.
	16. LDH	Kinetic photometric UV assay according to IFCC.
	17. CPK	Enzymatic (hexokinase / G-6-PDH) kinetic photometric UV -NADPH
	18. Iron	Endpoint colorimetric method. Ferene method.
	19. C-Reactive Protein	Endpoint immunoturbidimetric method with rabbit anti-CRP polyclonal antibodies (on latex)

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
Urine	**Determination of two (2) Analytes**	**Automated Biochemical Analyzers: Alinity A1 & A2, (Abbott*) KE.BIOX, version 4, 15/1/2025**
	1. Albumin (Urine)	Immunoturbidimetric endpoint method.
	2. Total Protein (Urine)	Turbidimetric endpoint method.
Blood Serum	**Determination of four (4) Drugs**	**Automated Biochemical Analyzers: Alinity A1 & A2, (Abbott*) KE.BIOX, version 4, 15/1/2025**
	1. Acetaminophen	Enzymatic colorimetric endpoint method.
	2. Amikacin	Homogeneous particle-enhanced turbidimetric inhibition immunoassay. Immunoturbidimetric kinetic method.
	3. Salicylate	Enzymatic (salicylate hydroxylase), kinetic photometric (UV)-NADH
	4. Tobramycin	Homogeneous particle-enhanced turbidimetric inhibition immunoassay. Immunoturbidimetric kinetic method.
Plasma	**Determination of one (1) Analyte**	**Automated Biochemical Analyzers: Alinity A1 & A2, (Abbott*) KE.BIOX, version 4, 15/1/2025**
	1. Ammonia NH_3	Enzymatic (glutamate dehydrogenase) kinetic photometric
Immunochemical Tests		
	Determination of two (2) Drugs	**Automated Biochemical Analyzer Architect i2000SR (Abbott)* KE.BIOX, version 4, 15/1/2025**
Blood Serum	1. Methotrexate	Competitive chemiluminescence microparticle immumoassay (CMIA)
Whole Blood (EDTA)	2. Cyclosporine	Competitive chemiluminescence microparticle immumoassay (CMIA)
Blood Serum	**Determination of 14 Hormones**	**Automated Immunoassay Analyzer pure e402, Roche* KE.BIOX, version 4, 15/1/2025**
	1. Thyrotropin (TSH)	Elecrtochemiluminescence (sandwich)
	2. Thyroxine (T4)	Elecrtochemiluminescence (competitive)
	3. Free Thyroxine (fT4)	Elecrtochemiluminescence (competitive)
	4. Triiodothyronine (T3)	Elecrtochemiluminescence (competitive)
	5. Free Triiodothyronine (fT3)	Elecrtochemiluminescence (competitive)
	6. Follicle Stimulating Hormone (FSH)	Elecrtochemiluminescence (sandwich)
	7. Luteinizing Hormone (LH)	Elecrtochemiluminescence (sandwich)

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
	8. Estradiol	Elecrtochemiluminescence (competitive)
	9. Testosterone	Elecrtochemiluminescence (competitive)
	10.Prolactin	Elecrtochemiluminescence (sandwich)
	11. Dehydroepiandrosterone sulfate (DHEA-S)	Elecrtochemiluminescence (competitive)
	12.Chorionic Gonadotropin+ beta subunit (hCG+β)	Elecrtochemiluminescence (sandwich)
	13. Cortisol	Elecrtochemiluminescence (competitive)
	14. Insulin	Elecrtochemiluminescence (sandwich)
	Determination of two (2) Hormones	**Automated Immunoassay Analyzer Cobas e411, Roche* KE.BIOX, version 4, 15/1/2025**
	1. Thyroglogulin	Elecrtochemiluminescence (sandwich)
	2. Progesterone	Elecrtochemiluminescence (competitive)
	Determination of two (2) Hormones	**Automated Analyzer Liaison XL, DiaSorin* KE.BIOX, version 4, 15/1/2025**
	1. Growth Hormone (hGH)	Chemiluminescence (sandwich)
	2. IGF-1	Chemiluminescence (sandwich)
	Determination of 1 Hormone	**Automated Analyzer microELISA MagoPlus KE.BIOX, version 4, 15/1/2025**
	1. 17α-OH-Progesterone	micro-ELISA, immunoassay competitive.
Blood Serum	**Quantitative Determination of Allergens**	**Immunoassay System IMMULITE 2000 SIEMENS* KE.MIK, version 4, 2-5-2025**
	1. Quantitative determination of Total IgE	Chemiluminescence
	2. Quantitative determination of Specific IgE to 61 allergens	Chemiluminescence
	Drugs	
	1. c1 Penicilloyl G	Chemiluminescence
	2. c2 Penicilloyl V	Chemiluminescence
	Mites	
	3. d1 Dermatophagoides pteronyssinus	Chemiluminescence
	4. d2 Dermatophagoides farinae	Chemiluminescence
	Animals	
	5. e1 Cat Dander Epithelium	Chemiluminescence

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
Blood Serum (continued)	6. e2 Dog Epithelium	Chemiluminescence
	7. e70 Goose Feathers	Chemiluminescence
	Grasses	
	8. g2 Bermuda grass	Chemiluminescence
	9. g6 Timothy grass	Chemiluminescence
	Venoms	
	10. i1 Honey bee	Chemiluminescence
	11. i2 White-faced hornet	Chemiluminescence
	12. i3 Yellow jacket	Chemiluminescence
	13. i4 Paper wasp	Chemiluminescence
	14. i5 Yellow hornet	Chemiluminescence
	15. i6 Cockroach	Chemiluminescence
	16. i71 Mosquito	Chemiluminescence
	17. i75 European hornet	Chemiluminescence
	Occupational	
	18. k82 Latex	Chemiluminescence
	Molds	
	19. m2 Cladosporium herbarum	Chemiluminescence
	20. m3 Aspergillus fumigatus	Chemiluminescence
	21. m4 Mucor racemosus	Chemiluminescence
	22. m6 Alternaria tenuis	Chemiluminescence
	Trees	
	23. t9 Olive	Chemiluminescence
	24. t16 White pine	Chemiluminescence
	25. t23 Italian cypress	Chemiluminescence
	Weeds	
	26. w19 Parietaria officialis	Chemiluminescence
	Foods	
	27. f1 Egg White	Chemiluminescence
	28. f2 Milk	Chemiluminescence
	29. f3 Codfish	Chemiluminescence
	30. f4 Wheat	Chemiluminescence
	31. f5 Rye	Chemiluminescence
	32. f8 Corn	Chemiluminescence
	33. f9 Rice	Chemiluminescence
	34. f10 Sesame seed	Chemiluminescence

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
Blood Serum (continued)	35. f12 Green pea	Chemiluminescence
	36. f13 Peanut	Chemiluminescence
	37. f14 Soybean	Chemiluminescence
	38. f17 Hazelnut	Chemiluminescence
	39. f18 Brasil nut	Chemiluminescence
	40. f20 Almond	Chemiluminescence
	41. f24 Shrimp	Chemiluminescence
	42. f33 Orange	Chemiluminescence
	43. f44 Strawberry	Chemiluminescence
	44. f49 Apple	Chemiluminescence
	45. f59 Octapus	Chemiluminescence
	46. f75 Egg yolk	Chemiluminescence
	47. f76 Alpha Lactalbumin	Chemiluminescence
	48. f77 Beta Lactoglobulin	Chemiluminescence
	49. f78 Casein	Chemiluminescence
	50. f79 Gluten	Chemiluminescence
	51. f83 Chicken meat	Chemiluminescence
	52. f84 Kiwi	Chemiluminescence
	53. f92 Banana	Chemiluminescence
	54. f93 Cacao	Chemiluminescence
	55. f95 Peach	Chemiluminescence
	56. f202 Cashew	Chemiluminescence
	57. f203 Pistachio	Chemiluminescence
	58. f214 Spinach	Chemiluminescence
	59. f235 Lentil	Chemiluminescence
	60. f256 Walnut	Chemiluminescence
	61. f259 Grape	Chemiluminescence
	Quantitative Determination of 3 Allergens Panels	**Immunoassay System IMMULITE 2000 SIEMENS* KE.MIK, version 4, 2-5-2025**
	1.GP2 (2,5,6,8,10,1 Grasses panel	Chemiluminescence
	2.MP1 (1,2,3,5,6) Mold panel	Chemiluminescence
	3.FP1 (13,17,18,20,36) Food panel	Chemiluminescence

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
Blood Serum (continued)	**Determination of nine (9) parameters**	**Immunoassay Analyzer Alinity *i* Abbott* KE.MIK, version 4, 2-5-2025**
	1. Cytomegalovirus IgG (CMV IgG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	2. Cytomegalovirus IgM (CMV IgM)	Chemiluminescent Microparticle Immunoassay (CMIA)
	3. Rubella virus IgG (Rubella IgG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	4. Rubella virus IgM (Rubella IgM)	Chemiluminescent Microparticle Immunoassay (CMIA)
	5. Toxoplasma IgG (TOXO IgG)	Chemiluminescent Microparticle Immunoassay (CMIA)
	6. Toxoplasma IgM (TOXO IgM)	Chemiluminescent Microparticle Immunoassay (CMIA)
	7. Anti-HBs	Chemiluminescent Microparticle Immunoassay (CMIA)
	8. HBsAg	Chemiluminescent Microparticle Immunoassay (CMIA)
	9. Anti-HCV	Chemiluminescent Microparticle Immunoassay (CMIA)
	Quantitative Determination of 1 Parameter	**Immunoassay Analyzer Alinity *i* Abbott* KE.MIK, version 4, 2-5-2025**
	1. alpha-fetoprotein (AFP)	Chemiluminescent Microparticle Immunoassay (CMIA)
Hematological Tests		
Whole Blood (EDTA)	**Determination of 10 Parameters**	**Automated Haematological Analyzers SYSMEX XN1000 (2), Roche* KE.AIM, version 3, 18-10-2024**
	1. White blood cells (WBC)	Fluorecent flow cytometry
	2. Red blood cells (RBC)	Hydrodynamic focusing. Fluorecent flow cytometry
	3. Hemoglobin (HGB)	SLS hemoglobin
Whole Blood (EDTA)	4. Hematocrit (HCT%)	Calculated by RBC and HGB
	5. Mean red corpuscular volume (MCV)	Flow cytometry with Hydrodynamic

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		focusing.
	6. Platelets (PLTs)	Electric conductivity with Hydrodynamic focusing.
	7. Mean corpuscular hemoglobin (MCH)	Calculated by RBC and HGB
	8. Mean corpuscular hemoglobin concetration (MCHC)	Calculated by HGB and HCT
	9. Red cell distribution width (RDW)	By calculation
	Leukocyte differential count	Fluorecent flow cytometry
	1.Neutrophils (number and %)	
	2.Lymphocytes (number and %)	
	3.Monocytes (number and %)	
	4. Eosinophils (number and %)	
	5.Baseophils (number and %)	
	Blood Smear	Optical microscopy
	1. Leukocyte differential count	
	2. Red cell morphology	
	3. Platelet morphology	
	Determination of one (1) Parameter	**Hb Next Menarini* KE.AIM, version 3, 18-10-2024**
	1. HbA1c	HPLC
Whole Blood, Bone Marrow	**Determination of five (5) Parameters**	**Flow cytometry Navios EX (BECKMAN COULTER*).**
	1. Immunophenotype B-ALL	*O.595.11, v4, 30-10-2019.*
	2. Immunophenotype T-ALL	

Tested Materials / products	Types of Test / Properties to be measured	Applied Standards Methods / Techniques to be used
	3. Minimal Residual disease (ALL)	
	4. Immunophenotype Acute Myeloid Leukemia	
	5. Immunophenotype Peripheral Blood	
Microbiological Tests		
Blood	Culture	Blood Culture System BACTEC FX (BECTON-DINKINSON)*- fluorescence method (SOP O.595.05) - positive specimens were inoculated onto culture media and were stained using GRAM stain (SOP O.595.09). Identification of organisms was carried out using VITEK® 2 COMPACT (BIOMERIEUX)* (SOP O.595.10)
Throat Specimen	Culture	Standard Operation Procedure O.595.07
Ear Specimen	Culture	Standard Operation Procedure O.595.08
Stool	Culture	Standard Operation Procedure O.595.06
Isolated microbial Strains	Identification	Automated instrument for bacterial identification VITEK® 2 COMPACT (BIOMERIEUX)* (SOP O.595.10)

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

Site of assessment: **Laboratory permanent premises: "P. & A. Kyriakou" Children's Hospital, Thivon & Lebadias st, 11527 Athens, Greece.**

Approved signatories: **Theodora Anastasiou-Grenzelia, Varvara Ntouna, Despina Hatzaki, Nikoleta Fildisi, Anastassios Doudoulakakis, Maria Papadimitriou, Evangelia-Eirini Vetouli, Georgios Kalogeras, Athina Dri, Maria Kafetzi, Stamatina Dimou, Adamantia Panagoulia, Stefanos Fakiolas, Sofia Zafiropoulou.**

This Scope of Accreditation replaces the previous one dated 11.01.2023.
The Accreditation Certificate No.**1114-**3, to ELOT EN ISO 15189:2022, is valid until 20.02.2027.

Athens, 1st of September 2025

Konstantinou Evangelos Apostolos
CEO of ESYD