Hellenic Accreditation System

Annex G1/11 to the Certificate No. **920**-5

SCOPE of ACCREDITATION

of the

Department of Microbiology

of

General Pediatric Hospital "Aghia Sophia"

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Immunological testing		
1. Blood serum	**Determination of 1 parameter**	**Automated analyzers Immage 800, Beckman Coulter (NEF1 and NEF2)***
	1. C-Reactive Protein (CRP)	Nephelometry E.MK.530-1/5/10-4-2023
2. Blood serum	**Determination of 1 parameter**	**Automated analyzer Immage 800, Beckman Coulter (NEF2)***
	1 Antistreptolysin O (ASTO)	Nephelometry E.MK.530-1/5/10-4-2023
3. Blood Serum	**Determination of 8 parameters**	**Automated analyzer ARCHITECT i2000SR Abbott***
	1. CMV IgM Abs	Chemiluminesced (CMIA) E.MK.530-1/5/10-4-2023
	2. CMV IgG Abs	Chemiluminesced (CMIA) E.MK.530-1/5/10-4-2023
	3. Toxo-IgM Abs	Chemiluminesced (CMIA) E.MK.530-1/5/10-4-2023
	4. Toxo-IgG Abs	Chemiluminesced (CMIA) E.MK.530-1/5/10-4-2023
	5. Rubella IgM Abs	Chemiluminesced (CMIA) E.MK.530-1/5/10-4-2023
	6. Rubella IgG Abs	Chemiluminesced (CMIA) E.MK.530-1/5/10-4-2023
	7. EBV VCA-IgM	Chemiluminesced (CMIA) E.MK.530-1/5/10-4-2023
	8. EBV VCA-IgG	Chemiluminesced (CMIA) E.MK.530-1/5/10-4-2023

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Microbiological testing		
1. Blood	1.Culture Blood	**BACTEC FX**, **Becton-Dinkinson*** O.MK.530.03/4/ 19-11-2019 O.MK.530.10/1/ 30-09-2012
2. Pharyngeal swab	1.Culture of pharyngeal swab for the isolation of group A beta-haemolytic streptococcus (GAS)	Laboratory Instruction O.MK.530.01, 2/25-09-2015
3. Urine	1.Quantitative Culture Urine	Laboratory Instruction O.MK.530.06, 4/06-03-2019
Urine tests		
1. Urine	**Determination of 10 parameters**	**Automated analyzers UC-Max Analyser* (A) and (B)** O.MK.530.05/7/10-04-2023
	1. Specific Gravity	Ion quantification O.MK.530.05/7/10-04-2023
	2. pH	Colour change detection O.MK.530.05/7/10-04-2023
	3. Leukocytes	Hydrolysis of esters O.MK.530.05/7/10-04-2023
	4. Nitrates	Griess diozotization reaction O.MK.530.05/7/10-04-2023
	5. Protein	Protein error of indicators O.MK.530.05/7/10-04-2023
	6. Glucose	Oxidase/peroxidase reaction O.MK.530.05/7/10-04-2023
	7. Ketones	Legal's – nitroprusside test O.MK.530.05/7/10-04-2023
	8. Urobilinogen	Elrich's aldehyde test O.MK.530.05/7/10-04-2023
	9. Bilirubin	Van Den Berch reaction O.MK.530.05/7/10-04-2023
	10. Erythrocytes (blood)	Oxidisation reaction O.MK.530.05/7/10-04-2023
2. Urine Sediment	Examination of the urine sediment for leucocytes, red blood cells and their morphology, squamous cells, epithelial cells of urine system, bacteria, fungi, casts, crystals, amorphous salts.	Microscopic examination O.MK.530.05/7/10-04-2023

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

Site of assessment: **Laboratory permanent premises:Department of Microbiology "Aghia Sophia" Children's Hospital, 11527 Athens, Greece.**
Approved signatories: **L. Zachariadou, E. Kirikou, E. Petridou, N. Petropoulou, M. Mika, A. Michelaki, A. Stathi, G. Paradeisis, K. Spyridopoulou, H. Kalogera.**

This scope of Accreditation replaces the previous one dated 17.05.2023.
The Accreditation Certificate No. **920**-5, to ELOT EN ISO 15189:2022, is valid until 19.06.2027.

Athens, 16th of July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD