Hellenic Accreditation System

Annex G1/2 to the Certificate No. 1273

SCOPE of ACCREDITATION

of the

Serology Laboratory

of the

Department of Microbiology

of

General Hospital "KORGIALENEIO-MPENAKEIO RED CROSS HOSPITAL"

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 BN Prospec (BN-02) καιAtellica NEPH630 (BN-01)***
	1. C-Reactive Protein (hsCRP)	Nephelometry E.530-1/1 23-11-2020
2. Blood Serum	**Determination of 8 parameters**	**Virological Immunological analyzer LIAISONDIASORIN (LI-03)*** E.530-1/1 23-11-2020
	1. CMV IgM Abs	Chemiluminesce (CMIA) E.530-1/1 23-11-2020
	2. CMV IgG Abs	Chemiluminesce (CMIA) E.530-1/1 23-11-2020
	3. Toxo-IgM Abs	Chemiluminesce (CMIA) E.530-1/1 23-11-2020
	4. Toxo-IgG Abs	Chemiluminesce (CMIA) E.530-1/1 23-11-2020
	5. EBV VCA-IgM	Chemiluminesce (CMIA) E.530-1/1 23-11-2020

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
	6. EBV VCA-IgG	Chemiluminesce (CMIA) E.530-1/1 23-11-2020
	7. HSV (1&2) IgM	Chemiluminesce (CMIA) E.530-1/1 23-11-2020
	8. HSV (1&2) IgG	Chemiluminesce (CMIA) E.530-1/1 23-11-2020
Microbiological testing		
1. Blood Serum	TPHA	Passive haemagglutination assay(BIORAD) E.530-1/1 23-11-2020
2. Blood Serum	RPR	Carbonlatex agglutination assay(LORNE, BIOREX) E.530-1/1 23-11-2020
Urine tests		
1. Urine	**Determination of 10 parameters**	**Automated analyzers AUTIONMAX -4280 (AU-04)andAUTIONMAX-4281 (AU-05)** E.530-1/1 23-11-2020
	1. Specific Gravity	Ion quantification E.530-1/1 23-11-2020
	2. pH	Colour change detection E.530-1/1 23-11-2020
	3. Leukocytes	Hydrolysis of esters E.530-1/1 23-11-2020
	4. Nitrates	Griess diozotization reaction E.530-1/1 23-11-2020
	5. Protein	Protein error of indicators E.530-1/1 23-11-2020
	6. Glucose	Oxidase/peroxidase reaction E.530-1/1 23-11-2020
	7. Ketones	Legal’s – nitroprusside test E.530-1/1 23-11-2020
	8. Urobilinogen	Elrich’s aldehyde test E.530-1/1 23-11-2020
	9. Bilirubin	Van Den Berch reaction E.530-1/1 23-11-2020
	10. Erythrocytes (blood)	Oxidisation reaction E.530-1/1 23-11-2020

Tested materials/ products	Types of test/ Properties to be measured	Applied Standards/ Techniques to be used
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 E.530-1/1 23-11-2020
3. Active Urine	1. Secondmorning urine for the detectionof abnormal red blood cells.	Microscopic examination E.530-1/1 23-11-2020

** 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 "Korgialeneio-Mpenakeio Red Cross Hospital", Athanasaki 2, Ampelokipoi 11526, Athens.**
Approved signatories: **P.Pantazi, K.Tsiveriotis, T. Nadeem. E. Papagrigoriou, S. Psallida, M. Afentoglou, T. Guajardo.**

This scope of Accreditation replaces the previous one dated 02.11.2021.

The Accreditation Certificate No.1273, to ELOT EN ISO 15189:2012, is valid until 01.11.2025.

Athens, 28th February 2023

Christos Nestoras
CEO of ESYD