Hellenic Accreditation System

Annex G1/2 to the Certificate No. 1180-2

SCOPE of ACCREDITATION

of the

Department of Immunology-Histocompatibility

of

"Aghia Sophia" Athens Children's Hospital

of the

1st Health District of Attica

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used / equipment
Immunological parameters		
1. Blood serum	**Determination of 13 parameters**	
	1.Immunoglobulin G (IgG)	Immunonephelometry Nephelometer BNII (Siemens) Method/Version: *OSARG09C34 Rev. 03 – EN, 2012-10**
	2. Immunoglobulin A (IgA)	Immunonephelometry Nephelometer BNII (Siemens) Method/Version: *OSARG09C34 Rev. 03 – EN, 2012-10**
	3. Immunoglobulin M (IgM)	Immunonephelometry Nephelometer BNII (Siemens) *Method/Version:* *OSARG09C34 Rev. 03 – EN, 2012-10**
	4. Immunoglobulin G_1 (IgG_1)	Immunonephelometry Nephelometer BNII (Siemens) Method/Version: *OQXIG09E34 Rev.05- EN, 2017- 10**
	5. Immunoglobulin G_2 (IgG_2)	Immunonephelometry Nephelometer BNII (Siemens) Method/Version: *OQXIG09E34 Rev.05- EN, 2017- 10**
Blood serum (continued)	6. Immunoglobulin G_3 (IgG_3)	Immunonephelometry

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used / equipment
		Nephelometer BNII (Siemens) Method/Version: *OPAVG03E34 Rev. 03-EN, 2012-04**
	7. Immunoglobulin G_4 (IgG_4)	Immunonephelometry Nephelometer BNII (Siemens) Method/Version: *OPAVG03E34 Rev. 03-EN, 2012-04**
	8.Complement component C3	Immunonephelometry Nephelometer BNII (Siemens) Method/Version: *OSAOG09E34 Rev. 04-EN, 2015-05**
	9. Complement component C4	Immunonephelometry Nephelometer BNII (Siemens) Method/Version: *OSAOG09E34 Rev. 04-EN, 2015-05**
	10.C1 esterase inhibitor (C1inh)	Immunonephelometry Nephelometer BNII (Siemens) Method/Version: *OQEYG09E34 Rev. 04-EN, 2015-05**
	11. Immunoglobulin E (IgE)	Fluoro Enzyme Immuno Assay (FEIA) / Immunocap 250 (Phadia) * Method/Version: *According to product catalogue 2018.*
	12.Specific Immunoglobulin E Allergens (RAST)	Fluoro Enzyme Immuno Assay (FEIA) / Immunocap 250 (Phadia) * Method/Version: *According to product catalogue 2018.*
	13.Tryptase	Fluoro Enzyme Immuno Assay (FEIA) / Immunocap 250 (Phadia)* Method/Version: *According to product catalogue 2018.*
2. Whole blood in EDTA	**Determination of 1 parameter**	
	Lymphocyte Immunophenotyping	Flow Cytometry FC-500 Flow Cytometer (Beckman Coulter), NAVIOS (3 LASER) Flow Cytometer (Beckman Coulter), DXFlex Flow Cytometer (Beckman Coulter) METHOD CODE: ME.010, VERSION:3 01/07/2023*, ME.015, VERSION:1, 01/07/2023*
3. Whole blood in EDTA, Apheresis product, Bone Marrow in EDTA	**Determination of 2 parameters**	
	1. CD34+ stem cell percentage on WBCs	Flow Cytometry FC-500 Flow Cytometer (Beckman Coulter), NAVIOS (3 LASER) Flow Cytometer (Beckman Coulter),

Materials / Products tested	Types of test / Properties measured	Applied methods / Techniques used / equipment
		DXFlex Flow Cytometer (Beckman Coulter) METHOD CODE: ME.011, VERSION:3, 01/07/2023*
	2. CD34+ stem cell absolute count (cells/μL)	Flow Cytometry FC-500 Flow Cytometer (Beckman Coulter), NAVIOS (3 LASER) Flow Cytometer (Beckman Coulter), DXFlex Flow Cytometer (Beckman Coulter) METHOD CODE: ME.011, VERSION:3, 01/07/2023*
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4. Whole blood in EDTA, Bone Marrow in EDTA, other Biological fluids	1. Minimal Residual Disease (%) measurement in Acute Lymphoblastic Leukemia	Flow Cytometry NAVIOS (3 LASER) Flow Cytometer (Beckman Coulter), DXFlex Flow Cytometer (Beckman Coulter) For B-MRD: METHOD CODE: ME.013, VERSION:3, 01/07/2023* For T-MRD: METHOD CODE: ME.014, VERSION:3, 01/07/2023*, ME.016, VERSION :1, 01/07/2023*
	2. Acute Leukemia Immunophenotyping	Flow Cytometry FC-500 Flow Cytometer (Beckman Coulter) NAVIOS (3 LASER) Flow Cytometer (Beckman Coulter) METHOD CODE: ME.012, VERSION:3, 01/07/2023*

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

Site of assessment: Permanent premises, "Aghia Sophia" Children's Hospital, Thivon and Papadiamantopoulou, Doxiadi building, ground floor, Athens.

Primary sample collection site: "Aghia Sophia" Children's Hospital, Thivon and Papadiamantopoulou, Athens

Approved Signatories: **Nikki Konstantinidou, Sofia Tantou, Marianna Tzanoudaki, Kleopatra Spanou, Evaggelia Pashali.**

This Scope of Accreditation replaces the previous one dated 16.09.2019.
The Accreditation Certificate No.1180-2, to ELOT EN ISO 15189:2012, is valid until 15.09.2028.

Athens, 8th July 2024

Christos Nestoras
CEO of ESYD