Hellenic Accreditation System

Annex G1/B9 to the Certificate No. **988**-5

SCOPE of ACCREDITATION

of the

Blood Bank Unit

of the

University General Hospital «ATTIKON»

Tested materials / products	Types of tests / Properties to be measured	Applied Standards / Techniques to be used
Immunohematology Techniques		
Anticoagulated whole blood sample	1. ABO – RhD Type of Red Cells	Biovue Column Agglutination Technology (microcolumns with glass bead matrix as filter), Analyzers VISION MAX (ORTHO), VISION SWIFT (ORTHO) *O.560-5*
Anticoagulated whole blood sample	2. ABO – RhD Type of Red Cells	Direct hemagglutination technique. Analyzer NEO IRIS *Δ.560*
Anticoagulated whole blood sample	3. Rh Phenotype (C, c, E, e), Kell	Biovue Column Agglutination Technology (microcolumns with glass bead matrix as filter), Analyzers VISION MAX (ORTHO), VISION SWIFT (ORTHO) *O.560-5*
Anticoagulated whole blood sample	4. Rh Phenotype (C, c, E, e), Kell	Direct hemagglutination technique. Analyzer NEO IRIS *Δ.560*
Serum or plasma	5. Indirect Antiglobulin test (IAT)	Biovue Column Agglutination Technology (microcolumns with glass bead matrix as filter), Analyzers VISION MAX (ORTHO), VISION SWIFT (ORTHO) *O.560-5*
Serum or plasma	6. Indirect Antiglobulin test (IAT)	Solid phase in microplate (Capture R technique) Analyzer NEO IRIS *Δ.560*
Serum or plasma	7. Indirect Antiglobulin test (IAT)	Gel Column Agglutination Technology Analyzer BIORAD IH 500 O.410-18

Tested materials / products	Types of tests / Properties to be measured	Applied Standards / Techniques to be used
Serum	8. Investigation of a positive IAT-Antibody/dies identification	Gel column agglutination with the use of 11 control cells (panel) treated with enzyme and untreated *O.560-7*
Serum	9. Investigation of a positive IAT-Antibody/dies identification	Biovue Column Agglutination Technology (microcolumns with glass bead matrix as filter), Analyzers VISION MAX (ORTHO), VISION SWIFT (ORTHO) *O.560-5*
Red cells from an anticoagulated blood sample	10. Direct Antiglobulin Test (DAT)	Biovue Column Agglutination Technology (microcolumns with glass bead matrix as filter), Analyzers VISION MAX (ORTHO), VISION SWIFT (ORTHO) *O.560-5*
Red cells from an anticoagulated blood sample	11. Investigation of a positive DAT	Gel Column Agglutination Technology *O.560-3*
Patient serum or plasma samples and donor red cell suspension	12. Compatibility testing	Biovue Column Agglutination Technology (microcolumns with glass bead matrix as filter), Analyzer VISION SWIFT (ORTHO)*O.560-5*
Patient serum or plasma samples and donor red cell suspension	13.Compatibility testing	Gel Column Agglutination Technology, Analyzer BIORAD IH 500 *O.410-18*
Packed red cells or anticoagulated whole blood sample	14. Erythrocyte antigen phenotyping	Solid phase in microplate (technique Capture R) for antigens Fya, Fyb, S, s, cellano. Direct hemagglutination technique for antigens jka, jkb, M and N. Analyzer NEO IRIS *Δ.560*

**The trade name of the analyzer refers to a specific analytical method and work protocol.*

Site of assessment: **Laboratory permanent premises: 1 Rimini str, 12462 Haidari, Attiki, Greece**
Primary Sample Collection: **Laboratory permanent premises: 1 Rimini str., 124 62 Haidari, Attiki, Greece.**

Approved signatories: **Tsantes Argyrios, Douramani Panagiota, Kyriakou Elias, Kalantzis Dimitrios, Kokori Styliani, Kypraiou Athina, Katsadiotis George, Poulis Aristarchos, Gheorghe Loredana-Mariana (Medical Personnel).**
Approved signatories: **Loukopoulou Ilektra, Karagouni Maria, Antonopoulou Anthi, Gougoutsi Vasiliki Mamoureli Angeliki, Tsalas Stavros, Mandani Christina, Stasinou Ioulia, Iliana Tsampoula,Melissinou Maria (Nursing personnel), Papachristodoulou Maria, Makri Efstathia, Sympikou Ifigenia Ekaterini Kreatsoula, Petalari Nevila (Medical Laboratories Technicians), for all these tests except for cases requiring investigation which is made by the responsible physician.**

This Scope of Accreditation replaces the previous one dated 25.10.2023.
The Accreditation Certificate No**. 988-**5, to ELOT EN ISO 15189:2022, is valid until 23.06.2028.

Athens, 21st of July 2025

Konstantinou Evangelos Apostolos
CEO of ESYD