Hellenic Accreditation System

Annex G1/11 to the Certificate No. **1043**-3

SCOPE of ACCREDITATION

of the

Hospital Blood Transfusion Service

of the

Laboratories Division

of

General Hospital of Nea Ionia «Konstantopouleio-Patission»

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques to be used
Immunohematological testing		
Whole Blood (EDTA)	ABO and RhD groups	Hemagglutination via spherical beads acting as a filter. Column Agglutination Technology (C.A.T.) ORTHO: VISION Max, ORTHO VISION SWIFT, MANUAL technique O. AIM. 530.12, version 2, 16-06-25 O. AIM. 530.10, version 2, 05-08-20
Whole Blood (EDTA)	Rhesus Phenotype (C, c, E, e), Kell	Hemagglutination via spherical beads acting as a filter. Column Agglutination Technology. (C.A.T.) ORTHO: VISION Max, ORTHO VISION SWIFT, MANUAL technique O. AIM. 530.12, version 2, 16-06-25 O. AIM. 530.10, version 2, 05-08-20
Whole Blood (EDTA)	ABO and RhD groups	Hemagglutination via gel microcolumn. GRIFOLS: Eflexis, manual technique E.AIM.530-1, version 2, 14-10-2020 O. AIM. 530.10, version 2, 05-08-20
Whole Blood (EDTA)	Rhesus Phenotype (C, c, E, e), Kell	Hemagglutination via gel microcolumn. GRIFOLS: Eflexis, manual technique E.AIM.530-1, version 2, 14-10-2020 O. AIM. 530.10, version 2, 05-08-20
Whole Blood (EDTA)	Direct Antiglobulin Test (DAT)	Hemagglutination via spherical beads acting as a filter. Column Agglutination Technology (C.A.T.) ORTHO: VISION Max, ORTHO VISION SWIFT, MANUAL technique O. AIM. 530.12, version 2, 16-06-25 O. AIM. 530.03, version 2, 05-08-20

Whole Blood (EDTA)	Analytical DAT	Hemagglutination via spherical beads acting as a filter. Column Agglutination Technology (C.A.T.) ORTHO: VISION Max, ORTHO VISION SWIFT, MANUAL technique O. AIM. 530.04, version 2, 08-09-20
Whole Blood (EDTA)	Direct Antiglobulin Test (DAT)	Hemagglutination via gel microcolumn GRIFOLS: Eflexis, manual technique E.AIM.530-1, version 2, 14-10-2020 O. AIM. 530.03, version 2, 05-08-20
Whole Blood (EDTA)	Analytical DAT	Hemagglutination via gel microcolumn GRIFOLS: Eflexis, manual technique E.AIM.530-1, version 2, 14-10-2020 O. AIM. 530.04, version 2, 08-09-20
Serum	Indirect Antiglobulin test (IAT-antibody screening)	Hemagglutination via spherical beads acting as a filter. Column Agglutination Technology. (C.A.T.) ORTHO: VISION Max, ORTHO VISION SWIFT, MANUAL technique O. AIM. 530.12, version 2, 16-06-25 O.AIM.530.05, version 2, 05-08-20
Serum	Indirect Antiglobulin test (IAT-antibody screening)	Hemagglutination via gel microcolumn. GRIFOLS: Eflexis, manual technique E.AIM.530-1, version 2, 14-10-2020 O.AIM.530.05, version 2, 05-08-20
Serum	Indirect Antiglobulin test (IAT- antibody identification)	Hemagglutination via spherical beads acting as a filter. Column Agglutination Technology. (C.A.T.) with 11 cell lines untreated and enzyme-treated ORTHO: VISION Max, ORTHO VISION SWIFT, MANUAL technique O.AIM.530.06, version 2, 05-08-20
Serum	Indirect Antiglobulin test (IAT- antibody identification)	Hemagglutination via gel microcolumn with 11 cell lines untreated and enzyme-treated GRIFOLS: Eflexis, manual technique E.AIM.530-1, version 2, 14-10-2020 O.AIM.530.06, version 2, 05-08-20
Patient's serum and donor's red blood cells	Compatibility test	Hemagglutination via spherical beads acting as a filter. Column Agglutination Technology (C.A.T.) ORTHO: VISION Max, ORTHO VISION SWIFT, MANUAL technique O. AIM. 530.12, version 2, 16-06-25 O.AIM.530.07, version 2, 05-08-2020
Patient's serum and donor's red blood cells	Compatibility test	Hemagglutination via gel microcolumn. GRIFOLS: Eflexis, manual technique E.AIM.530-1, version 2, 14-10-2020 O.AIM.530.07, version 2, 05-08-2020

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

Site of assessment: **Laboratory permanent premises: 3-5 Agias Olgas str., 14233 N. Ionia, Greece.**

Primary Sample Collection Site: Laboratory permanent premises: 3-5 Aghias Olga str., 14233 N. Ionia, Greece

Approved signatories: **I .Dendrinou, E.Tzini, G. Mpardakis, I. Brouzos, E.Goumalatsou, D. Baltzi, P. Georgiou, A. Sotirakou, I. Kountouri, V. Athanasiadou, K. Lisandropoulou, F. Laopoulou, E. Emanouil**

This Scope of Accreditation replaces the previous one dated 28.02.2025.
The Accreditation Certificate No. **1043**-3, to ELOT EN ISO 15189:2022, is valid until 30.06.2029.

Athens, 20th of May 2026

Konstantinou Evangelos Apostolos
CEO of ESYD