Hellenic Accreditation System

Annex G1/2 to the Certificate No. **1356**-2

SCOPE of ACCREDITATION

of the

NATIONAL RETROVIRUS REFERENCE CENTER

of

THE DEPARTMENT OF HYGIENE, EPIDEMIOLOGY AND MEDICAL STATISTICS

of

THE SCHOOL OF MEDICINE

of

THE NATIONAL AND KAPODISTRIAN UNIVERSITY OF ATHENS

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques used
Molecular Biology		
Plasma samples in EDTA	Detection and quantitation of HIV-1 RNA	Fully automated method with the use of the Cobas HIV-1 (Roche) kit on Roche Cobas 5800 analyzer. Laboratory protocol: O.520-3, version 1, 1/9/2022
Plasma samples in EDTA	Detection and quantitation of HIV-1 RNA	Fully automated method with the use of the NeuMoDx HIV-1 Quant test Strip on the NeuMoDx™ 96 Molecular System Laboratory protocol: O.520-4, version 1, 1/9/2022
Whole blood samples collected in EDTA	Qualitative detection of the HLA-B 5701 allelle.	Real-time PCR method with the use of the HLA-B5701 Real Fast Assay (CE-IVD) kit, running on Rotor-Gene QMDX Laboratory protocol: O.520-6, version 1, 1/9/2022

Tested materials / products	Types of test / Properties to be measured	Applied Standards / Techniques used
Immunology		
Plasma and/or serum samples	Simultaneous qualitative detection of the HIV p24 antigen and antibodies to HIV1/2.	Fully automated method with the use of the Architect HIV Ag/Ab Combo Reagent Kit on Architect i2000SR ABBOTT analyzer. Laboratory protocol: O.520-2, version 1, 1/9/2022
Plasma and/or serum samples	Qualitative assay for the confirmation and differentiation of individual antibodies to HIV-1 and HIV-2.	Single use immunochromatographic test to be read automatically on Biorad Geenius Reader Laboratory protocol: O.520-1, version 1, 1/9/2022

Site of assessment: **National Retrovirus Reference Center, Department of Hygiene, Epidemiology and Medical Statistics, School of Medicine, National and Kapodistrian University of Athens, 75 M.Asias str, Goudi, Athens, GR-11527**
Approved signatories**: G. Magiorkinis**.

This Scope of Accreditation replaces the previous one dated 01.06.2023.
The Accreditation Certificate No. **1356-**2, to ELOT EN ISO 15189:2022, is valid until 31.05.2028.

Athens, 30th of September 2025

Konstantinou Evangelos Apostolos
CEO of ESYD