

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 allele.	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