APPROVED BY:
DIRECTOR OF THE NCIPD
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INTERNAL RULES OF PROCEDURE
NATIONAL REFERENCE CONFIRMATORY LABORATORY FOR HIV, DEPARTMENT OF VIROLOGY, NCIPD

I. GENERAL PROVISIONS

The National Reference Confirmatory Laboratory for HIV (NRCL-HIV) is a reference, diagnostic, and research unit within the Department of Virology of the National Center of Infectious and Parasitic Diseases (NCIPD) and serves as a training base for doctoral students, medical residents, and healthcare professionals. It is located on the second floor of the building in the inner courtyard of the Department of Virology, 44A Gen. N. Stoletov Blvd.

These Rules govern the organization of work processes in the Laboratory.

II. SCOPE OF ACTIVITIES OF THE NRCL-HIV

1. Diagnostic and Reference Activities

1.1. By order of the Minister of Health, the Laboratory has been designated as the National Reference Confirmatory Laboratory within the Department of Virology. It is part of the NCIPD Laboratory Testing Complex (LTC), accredited by the Executive Agency "Bulgarian Accreditation Service" (EA BAS) in accordance with BDS EN ISO/IEC 17025:2018.

1.2. The NRCL-HIV performs definitive confirmatory diagnosis, confirms all cases of HIV infection in the country, and conducts virological monitoring of patients with HIV/AIDS in Bulgaria. It employs serological and molecular methods (Ag/Ab ELISA, a confirmatory line immunoassay [LIA], real-time PCR, sequencing, and rapid tests), including for antiretroviral drug resistance testing and virological monitoring of pregnant women and newborns.

1.3. Tests are charged according to the NCIPD fee schedule (Annex 1), approved by Council of Ministers Decree No. 255 of October 17, 2012 (promulgated in State Gazette No. 81 of October 23, 2012, as amended and supplemented).

1.4. Testing is carried out in compliance with good laboratory practice, according to the diagnostic kit manufacturers' protocols, and using certified technical equipment.

1.5. Specimens are received from healthcare facilities that have contracts with the NCIPD, as well as from patients whose blood is drawn in Room 6 of the building at 44A Gen. N. Stoletov Blvd.

1.6. Primary records are reviewed by the Head of the Laboratory and transferred to the official test reports. Reports for accredited methods are signed by the Head of the Department of Virology, and those for non-accredited methods by the Head of the Laboratory. All reports bear the signature and stamp of the NRCL-HIV; reports for accredited methods also bear the stamp of the LTC.

1.7. Results are released to the tested individuals or to their attending physicians. Confidentiality and personal data protection rules are observed in accordance with Regulation (EU) 2016/679 and the internal rules of the NCIPD.

1.8. The Laboratory participates annually in the external international quality assessment scheme of INSTAND, Germany.

1.9. The Anonymous and Free HIV/AIDS Counseling and Testing Office (KABKIS) operates under the auspices of the Laboratory.

1.10. The Laboratory annually submits epidemiological data to the EpiPulse system of the European Centre for Disease Prevention and Control, compiling data from HIV treatment centers across the country, as well as data on immune status at first testing, performed by the National Reference Laboratory of Immunology.

1.11. Laboratory specialists are members of the National Reference Center (NRC) for Sexually Transmitted Infections and Viral Hepatitis at the NCIPD and provide annual analyses and reports.

1.12. The Head of the NRCL-HIV participates in the National Reference Center for Antimicrobial Resistance and Antibiotic Consumption at the NCIPD.

2. Research Activities

2.1. Research is conducted according to an annual plan adopted by the Board of the Department of Virology and approved by the Head of the Department.

2.2. Securing research funding is a priority responsibility of the Head and the research staff, pursued through calls of the Bulgarian National Science Fund and through collaborations within European and other international programs.

2.3. Reporting takes place at the end of each year or funding period, in accordance with the contracts concluded. Interim and final reports are discussed by the Board of the Department.

2.4. Joint projects with other organizations are undertaken with the consent of the Director of the NCIPD and on the basis of a work program and budget approved in writing by both parties.

2.5. The Laboratory conducts sequencing and molecular epidemiological studies of HIV-1 transmission in the country, participates in national and international surveillance studies of HIV drug resistance and of the distribution of HIV subtypes in Bulgaria and Europe, and collaborates with laboratories and institutes in Bulgaria and abroad.

2.6. Results are presented annually at scientific meetings and published in international peer-reviewed journals with an impact factor and in Bulgarian journals included in the National Reference List of the National Center for Information and Documentation (NACID), including Problems of Infectious and Parasitic Diseases.

2.7. Once a year, the Laboratory organizes a national interlaboratory proficiency testing scheme for the laboratories in Bulgaria that perform HIV testing.

3. Educational Activities

3.1. The Laboratory serves as a base for the postgraduate training of doctoral students and medical residents from the healthcare system, offering theoretical and practical courses on the diagnosis and monitoring of HIV infection.

3.2. Training follows the NCIPD annual postgraduate education curriculum approved by the Director and the document management procedure of the Education Unit.

4. Organizational, Methodological, and Advisory Activities

4.1. The Head of the Laboratory serves on expert groups that prepare regulatory documents of the NCIPD and the Ministry of Health, including the Expert Council on AIDS at the Ministry of Health; contributes to the drafting of ordinances and guidelines on HIV testing and

notification and on the KABKIS; and serves on working groups concerned with the procurement of HIV diagnostic tests.

4.2. The Laboratory provides consultation to healthcare professionals across the country regarding specific epidemic situations, diagnostic challenges, and complicated clinical cases, and issues recommendations on the collection and shipment of clinical specimens. It also provides methodological guidance on matters related to the diagnosis and monitoring of HIV infection.

4.3. The Laboratory promptly submits rapid notifications to the Regional Health Inspectorates in accordance with Ordinance No. 21 of July 18, 2005, on the Procedure for Registration, Notification, and Reporting of Communicable Diseases.

4.4. The Laboratory trains staff of non-governmental organizations and Regional Health Inspectorates to provide voluntary HIV counseling and testing services in low-threshold health and social service centers, and participates in prevention campaigns on HIV and sexually transmitted infections.

III. ADMINISTRATIVE RELATIONS

1. The staff of the NRCL-HIV report to the Head of the Department of Virology and to the Director of the NCIPD. The Head of the Laboratory directs and is responsible for all of its activities. In the Head’s absence, his or her duties are temporarily assumed by the chief assistant professor or by another staff member designated by the Head.

2. Working hours are from 7:30 a.m. to 2:30 p.m.

3. Access to the Laboratory outside working hours and on non-working days is permitted only with the consent of the Director of the NCIPD and a written authorization signed by the Head of the NRCL-HIV and the Head of the Department.

4. All activities are carried out according to an annual plan adopted by the Board of the Department of Virology and approved by the Head of the Department. Changes to the plans may be made only with the consent and written approval of the Head of the Department.

5. Current tasks across all activities are assigned by the Head of the Laboratory, who reports on them weekly to the Head of the Department of Virology.

6. At the start of each working day, the Head of the Laboratory allocates the tasks for the day; at the end of each week, the Head reviews the plan for the following week with the staff.

7. The Head may assign additional duties not specified in the job description or the plan, related to ongoing tasks and epidemic situations, within the scope of the employee’s qualifications and in accordance with the Labor Code.

8. Annual paid leave is taken provided that adequate cover is ensured and the work process is not disrupted.

9. All staff members are familiar with and comply with the NCIPD Internal Labor Regulations.

IV. DUTIES OF STAFF

The rights and duties of each staff member are set out in a job description approved by the Director of the NCIPD and kept in the employee’s personnel file.

Upon commencement of employment, the employee is familiarized with the job description and complies with it. Upon a change of position or duties, the job description is updated and approved in accordance with the established procedure.

V. OCCUPATIONAL HEALTH AND SAFETY

1. All staff members are familiar with the sources of risk in the NRCL-HIV (biological and infectious materials) and comply with the rules for handling human blood and body fluids and with the Laboratory Safety Rules of the NRCL-HIV.
2. Staff wear laboratory clothing and personal protective equipment when handling biological materials.
3. The Head of the Laboratory is responsible for quarterly safety briefings and for the training of newly appointed staff, doctoral students, and medical residents.
4. Staff handling human blood and body fluids who lack immunity to HBV are vaccinated according to the recommended schedule (following assessment of virus-specific antibody titers).
5. At the end of each working day, the premises are checked to ensure that they are secured (windows and taps closed, electrical appliances switched off).
6. In the event of an incident, the rules and procedures established at the NCIPD are followed.
7. Any breach of these Rules, accident, or incident must be reported to the Head of the Laboratory, and the Head of the Department must be notified.

Annex 1

Fee Schedule for Tests Performed at the NRCL-HIV

Code	Laboratory Test	Price (EUR)	Turnaround Time (Including Issuance of Results)
301	Diagnosis of HIV infection by ELISA	9.20	7 business days
351	Detection of specific anti-HIV-1/2 antibodies by Western blot (LIA), per antibody	96.12	7 business days
352	Quantitation of HIV-1 RNA	74.65	14 business days

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