INSTRUCTIONS FOR THE COLLECTION, STORAGE, AND TRANSPORT OF BLOOD SPECIMENS FOR HIV TESTING

The National Reference Confirmatory Laboratory for HIV performs HIV testing on whole blood, serum, or plasma.

Venous blood (up to 5 mL) is collected in a closed or other approved blood collection system containing a clot activator or the anticoagulants EDTA, heparin, or citrate.

Each blood specimen must be labeled with the following information:

1. Full name of the patient (first, middle, and last name), or an identification code in the case of anonymous testing;
2. Age;
3. Barcode, for donors of blood and blood components;
4. Date of specimen collection.

Each blood specimen must be accompanied by a laboratory test requisition form in accordance with Annex No. 4 to Ordinance No. 47 of December 11, 2009, on the Conditions and Procedure for Testing, Reporting, and Recording of Infection with the Human Immunodeficiency Virus, issued by the Ministry of Health (promulgated in State Gazette No. 103 of December 29, 2009; amended in State Gazette No. 5 of January 14, 2011).

The information on the label of the vacuum tube or test tube must match the information on the requisition form accompanying the specimen!

The collected blood specimen is placed in a closed transport container for blood specimens, to which the accompanying requisition forms are attached. The optimal transport temperature for specimens is 4–8 °C, unless otherwise specified below. Blood specimens must be delivered within 24 hours of collection. The triple packaging principle applies:

1. Primary receptacle – a watertight, leakproof container holding the specimen itself. The receptacle is labeled with information on its contents and is wrapped in sufficient absorbent material to absorb the entire liquid content should the receptacle be damaged.
2. Secondary packaging – durable, watertight, leakproof packaging enclosing the primary receptacle. Several primary receptacles may be placed in a single secondary package.
3. Outer packaging – encloses the secondary packaging and protects its contents from adverse external conditions during transport.

The outer packaging must bear the following information:

1. Name and address of the sending healthcare facility;
2. Telephone number of the responsible person who is familiar with the contents of the shipment;
3. Name and address of the receiving laboratory;
4. For shipment by courier – the UN 3373 mark and the label “Biological Substance, Category B.”

The container with the specimens and accompanying requisition forms must be transported in a manner that ensures their completeness and traceability, as well as the integrity of the packaging.

In the event of an indeterminate or positive confirmatory test result, a new blood specimen is collected from the individual for repeat testing. The second specimen is arranged by the physician who ordered the initial test or by the Regional Health Inspectorate, in accordance with Ordinance No. 47 of December 11, 2009, of the Minister of Health.

The second blood specimen is obtained by a new venipuncture into closed collection systems: one tube with heparin anticoagulant, two tubes with EDTA anticoagulant, and one serum separator tube.

The heparin tube is stored and transported at room temperature (18–22 °C), whereas the EDTA tubes and the serum separator tube are stored and transported, whenever possible, under refrigerated conditions (4–8 °C).

The enclosed HIV/AIDS case notification form must be completed. The form is provided in Annex No. 9 to Ordinance No. 47 of December 11, 2009, on the Conditions and Procedure for Testing, Reporting, and Recording of Infection with the Human Immunodeficiency Virus, issued by the Minister of Health (promulgated in State Gazette No. 103 of December 29, 2009; amended in State Gazette No. 5 of January 14, 2011).

For **neonates** born to mothers with HIV infection or of unknown HIV status, a tube containing EDTA anticoagulant should be submitted.

For further information or clarification, please contact the National Reference Confirmatory Laboratory for HIV: tel. +359 2 931 80 71, e-mail: hiv.lab@ncipd.org

Prepared by:
Head of the Department of Virology and the NRCL-HIV
Prof. Ivailo Alexiev, DSc