

I CONFIRM  
The Main Health  
Officer of the  
Russian Federation

*(Signed and sealed)*

**G.G. ONICHENKO**

“21” \_\_\_\_\_ 04 \_\_\_\_\_ 2010

№ 01-11/72-10

## **Instruction**

for use of medical device

**SMARTube™ HIV&HCV**

tube with reagent for blood sample pretreatment

for laboratory diagnostic *in vitro*

HIV-infection and hepatitis C.

Registration certificate № ФC32008/01615 from 18.04.2008

2010

## **I. Intended Use**

The SMARTube™ HIV&HCV, tube with reagent, is intended to be used as a pretreatment of human blood samples, for maximal activation, differentiation and proliferation of lymphocytes in tested sample, for specific antibodies to HIV and/or hepatitis C production, with following testing of plasma sample, which is obtained after incubation (36-38 C), during 3 – 5 days using ELISA test for anti-HIV or anti-HCV detection.

## **II. Medical Device Include**

Medical device (MD) SMARTube™ is sterile plastic tube .....

## **III. Principle of the Method**

One ml of whole blood, collected in heparin is introduced into the SMARTube™ (sterile pipette etc.). The SMARTube™, with the blood sample inside it, is then incubated at 36 - 38°C in a humidified CO<sub>2</sub> incubator for 5 days (3 days for blood banks). After incubation, a sample of the supernatant is used for testing using any currently available ELISA test or any other method for the detection of HIV or HCV antibodies.

## **III. Equipment and Materials Required**

1. Disposable gloves
2. 37°C, humidified 5% CO<sub>2</sub> incubator
3. Refrigerator (2-8°C)
4. Immunoassay antibody kits for HIV or HCV detection
5. semiautomatic pipettes with changed volume with sterile disposable types.
6. Laminar air flow hood, or other aseptic environment
7. Disposable tubes with Heparin.
8. SMARTubes™
9. Disinfectant solution, approved for using with potential HIV and/or HCV contaminated materials.

## **V. Testing Procedure**

### **Collection and Handling of Specimens**

The SMARTube™ requires fresh blood samples. No special preparation or fasting of the patient is necessary.

1. Check the blood collection tube to ensure that it is not cracked or broken.
2. Clean the top of the blood collection tube with 70% alcohol before use.
3. Collect the blood aseptically into a (full) small heparin containing tube, using standard venipuncture technique. After collection, gently mix the blood specimen with the heparin in the collection tube (by turning the test-tube up side down gently 8-10 times).

**Note:** *Freshly collected specimens may be stored and sent to the laboratory at room temperature (18-25°C) for up to 20 hours before transfer into a SMARTube™ and put into the incubator.*

4. Bring the SMARTube™ to room temperature prior to use.
5. Aseptically transfer the blood into the SMARTube™ using a sterile pipette, or tip, or syringe as follows:  
Transfer by sterile pipette or tip: under laminar air flow hood (or other aseptic conditions) open the cap of the SMARTube™. Add 1 ml of whole blood (mix the blood well prior to withdrawing from it) and cap the SMARTube™ tightly.  
Transfer by syringe: using a sterile (G21) needle transfer 1 ml of whole blood (after mixing the sample well) into the SMARTube™ and re-cap it.
6. Immediately before placing the SMARTube™ in the incubator, loosen the cap of the tube (one “click”) so that it sits loosely on top of the tube, thus enabling gas exchange.
7. Place immediately in a humidified 5% CO<sub>2</sub> incubator at 36-38°C (best at 37°C), for 3 to 5 days (optimal for diagnostics – 5 days).
8. At the end of incubation, use the supernatant fluid (SMART-plasma) as the sample on the diagnostic kit. For retesting, aseptically transfer the SMART-plasma from the SMARTube™, using a sterile pipette into a sterile test tube, and refrigerate; or freeze for long term storage. Be careful not to collect blood cells.
9. Some kits require the specimen to be centrifuged prior to testing. If so, the centrifugation can be done directly on the SMARTube™ prior to collecting the SMART-plasma to another sterile tube.
10. If the sample tubes are entered directly into the automatic analyzing equipment, follow the instructions of the manufacturer: spin if necessary, and then feed the SMARTube™ directly. Adjust the height of the collection tip so that the sample tested is collected from the supernatant fluid and it does not touch the red blood cells' layer.

### **Testing Procedure**

1. The SMART-plasma can be tested using any licensed antibody ELISA tests for anti-HIV or anti-HCV antibodies. Testing should be performed in accordance with the package insert provided with the test kit.
2. Use a separate disposable pipette for each sample to avoid cross contamination. Cross contamination between samples will invalidate test results.
3. All reagents should be handled in accordance with the instructions provided by the manufacturer of the test kit.  
Note: the SMART solution acts as a diluent and its volume should be taken into account when loading the wells with diluent and samples.
4. Since the SMART-plasma is a 1:5 dilution of the original plasma, to achieve a final plasma volume as recommended in the kit (for required final concentration), SMART-plasma should be loaded at 5 times the volume of plasma required for that kit. The diluent's volume should be adjusted accordingly to reach the required final volume.
5. After testing, the remaining SMART-plasma in the SMARTube™ can be divided into aliquots and frozen at -80°C for long term storage. However, until repeat testing, (for confirmation of a positive sample) the SMART-plasma can be stored at 2-8°C, for several days.

## **VI. Interpretation of Results**

Results of ELISA testing should be interpreted in accordance with the package insert instructions provided by the manufacturer of the test kit.

The SMART-solution has no effect on the readings of the negative and positive controls and leads to no change in the cut-off value.

## **VII. Waste Disposal**

- Blood containing SMARTube™ dispose of as biohazard waste according to the guidelines of your institution.
- Non used SMARTube™ (e.g. expired, cracked) dispose as regular house hold garbage.

## **VIII. Shipment and Storage**

1. Store the SMARTube™ refrigerated (2-8°C) when not in use.
1. Shelf life of a closed SMARTube™ unit (including after the opening of the primary container) is according to the expiration date printed on the label. Do not use the SMARTube™ beyond the labeled expiration date.
2. Do not use the SMARTube™ if it exhibits any signs of deterioration (e.g. a change in color from pink to yellow, a large white precipitate at the bottom of the SMARTube™ or clouding of the solution are indications of deterioration).

### **Shipment**

SMARTubes™ containing blood specimens, standing up-right and tightly closed, may be shipped at room temperature (18-25°C) for several hours, when packaged in compliance with federal regulations governing the transport of etiologic agents.

## **IX. Warring**

**X. Shelf life.** 9 months.

SMARTube™ reagent with expired date can not be used.

Manufacturing: “Smart Biotech LTD” Company, Israel.

Distributor: OAO “Biolife” Company, Russia.

Complains for the SMARTube™ HIV&HCV reagent quality should be sent to the distributor: 129226, Russia, Moscow, Dokunin str., 8/1; tel/fax (495) 784-6215; e-mail: [lap@biolife.su](mailto:lap@biolife.su) and to Standard Institute by name L.A.Tarasevich: 119002, Russia, Moscow, Sitcev Vrajek, 41; tel.: (499)241-3922, fax: (499) 241-9238; e-mail: [gisk@list.ru](mailto:gisk@list.ru)

General Director  
OAO “Biolife”

**A.P.Lapko**

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