



2. Do not use the SMARTube™ beyond the labeled expiration date.
3. Do not use the SMARTube™ if it exhibits any signs of deterioration. A change in color from pink, a large white precipitate on the bottom of the SMARTube™, or clouding of the supernatant are indications of deterioration.
4. Use a separate disposable pipette for each sample to avoid cross contamination. Cross contamination between samples will invalidate test results.
5. Do not pipette samples by mouth.
6. Do not smoke, eat, or drink in areas in which the SMARTube™ is handled.

**Intended Use:**

The SMARTube™ (HIV-HCV) is intended to be used as a pretreatment for blood samples which are to be tested using currently licensed tests for anti-HIV or anti HCV. The tube is designed to improve the serological detection of antibodies to HIV and/or HCV virus.

Pretreatment in the SMARTube™ (HIV-HCV) increases the sensitivity of current tests for HIV or HCV without decreasing the specificity of the test kit. The solution enables the activation of the lymphocytes in the blood sample leading to proliferation of the cells and production of antibodies. This cell activation leads to improved diagnosis of HIV or HCV using HIV or HCV specific antibodies as the indicator for exposure/infection.

**Principle of the Method**

One ml of whole blood, collected in heparin is introduced into the SMARTube™. The SMARTube™, with the blood sample inside it, is then incubated at 37°C in a humidified CO<sub>2</sub> incubator for three to five days. After incubation, a sample of the supernatant, separated from the rest of the blood elements by gravity during the incubation period, is removed for testing using any currently available ELISA test or any other method for the detection of HIV or HCV antibodies.

**Equipment and Materials Required**

- Disposable plastic Pasteur pipettes
- 4 ml plastic tubes with caps
- Test tube racks
- Disposable gloves
- 37°C, humidified 5% CO<sub>2</sub> incubator
- Refrigerator (2-8°C)
- Autoclave (optional)
- 5% Sodium Hypochlorite solution
- Appropriate biohazard waste containers for materials contaminated with potentially infectious agents
- Immunoassay antibody kits for HIV or HCV detection
- Sterile 1 ml pipettes, or equivalent
- Laminar air flow hood

**Warnings and Precautions**

1. Bring the tube to room temperature before use.

7. Use disposable latex or polyethylene gloves and handle all materials used in the collection of samples, manipulations of the SMARTube™, pipettes used for transfer, and supernatants resulting from incubation cautiously as though capable of transmitting infectious agents. Consult a physician immediately in the event that contaminated materials are ingested or come in contact with open lacerations, lesions, or other breaks in the skin.
8. Immediately clean up spillage of blood-containing material with a 1:10 dilution of 5% sodium Hypochlorite solution and treat the cleaning material by an acceptable disposal method.
9. Treatment prior to disposal:
  - a. Autoclave for 60 minutes at 121°C or
  - b. Incinerate disposable materials or
  - c. Mix liquid waste with 5% sodium hypochlorite solution so that the final concentration is approximately 1% sodium hypochlorite. Allow 30 minutes before disposal.

**Storage Instructions**

Store the SMARTube™ at 2-8°C when not in use. Expiration date printed on the tube indicates latest recommended date of use.

**Collection and Handling of Specimens**

The SMARTube™ requires fresh blood samples. No special preparation or fasting of the patient is necessary. Collect blood samples for transfer into Heparin containing tubes. Send samples to the laboratory.

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 Alcohol before use.
  3. Collect aseptically 3-5 ml of blood, by puncture of the vein with G21 sterile needle, using standard venipuncture technique.
- After collection, gently mix the blood specimen in the collection tube (by turning the tube up side down gently at least five times). Aseptically transfer the blood into the SMARTube™ using either a sterile pipette or syringe as follows:

Transfer by sterile pipette: Under laminar air flow hood, open the stopper of the SMARTube™. Add 1 ml of whole blood (mix the blood well prior to

withdrawing from it the 1 ml) and cap the SMARTube™ tightly.

Transfer by syringe: using a sterile transfer 1 ml of whole blood into the SMARTube™.

**Note:** *Freshly collected specimens may be stored at room temperature (18-25°C) for several hours before transfer into a SMARTube™.*

4. Immediately before placing the SMARTube™ in the incubator, loosen the stopper of the tube so that it sits lightly on top of the tube, thus enabling gas exchange.
5. Place immediately in a humidified 5% CO<sub>2</sub> incubator at 36-38°C for 3 to 5 days (best at 37°C.)
6. At the end of incubation, transfer the supernatant fluid from the SMARTube™, using a Pasteur pipette into a 4 ml plastic tube. Be careful not to collect blood cells. Mix the fluid gently.

**Shipment:** SMARTubes™ containing blood specimens, and tightly closed, may be shipped at room temperature for several hours, when packaged in compliance with federal regulations governing the transport of etiologic agents.

#### **Testing Procedure**

1. The SMARTube™ fluid can be tested using any licensed tests for anti-HIV or anti-HCV. Testing should be performed in accordance with the package insert provided with the test kit.
2. All reagents should be handled in accordance with the instructions provided by the manufacturer of the test kit. To achieve a final plasma concentration as recommended in the kit, fluids taken from the SMARTube™ should be loaded at 5 times the volume of plasma recommended to be used and diluent's volume should be adjusted accordingly to the same final volume.
3. After testing, the remaining supernatant fluid 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 supernatant fluid can be stored at 2-8°C, for several days).

#### **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.

#### **Limitations of the Test**

The SMARTube™ requires freshly drawn blood samples.