# DRG® One Step Anti-HIV (1&2) (RAP-4577)

**Revised 17 June 2011 rm (Vers. 2.1)** **USA:RUO**

**This kit is intended for Research Use Only.**

**Not for use in diagnostic procedures.**

## INTENDED USE
The Rapid Test HIV1/2 test for detection of antibodies specific to human immunodeficiency of virus (HIV) in human serum, plasma or whole blood.

## PRINCIPLE
The Rapid Test HIV1/2 test has been designed to detect the HIV infection through visual interpretation of color development in the test device, which is a sandwich solid phase gold conjugate immunoassay. The test device contains membrane casstte that is pre-coated with HIV antigens on the test band region and goat-anti-rabbit polyclonal antibody on the control band region. The HIV antigens-colloid gold conjugate pad is placed at the end of the membrane. When the HIV specific antibodies are present in samples, the mixture of colloid gold conjugate, sample and developer buffer moves along the membrane chromatographically by a capillary action. This mixture then migrates to the test band region and forms a visible line as the antigen-antibody-antigen complex forms. Therefore, the formation of a visible precipitation in the test band region occurs when the sample is possible for the HIV specific antibodies. When the HIV specific antibodies are absent in the sample, no visible color band will form on the test line region. Therefore, the absence of the color band on the test line region indicates a negative result. A colored band will always appear at the control region. This control band serves as a procedural indicator for the proper performance of the test and the device.

## REAGENTS AND MATERIALS SUPPLIED
- 2 Test Device in each wrapped pouch: Each test cassette contains test strip with HIV antigen coated membrane.
- Each test cassette contains 1 bottle of sample dilution buffer.
- Each test cassette contains a disposable pipette.
- Instructions leaflet.

## MATERIALS REQUIRED BUT NOT SUPPLIED
- Specimen collection container
- Timer

## STORAGE AND STABILITY
The kit should be stored at room temperature (2-30°C) in the sealed pouch for the duration of the shelf life.

## PRECAUTIONS
- For Research Use Only
- Do not interchange reagents from different lots or use test kit beyond expiration date.
- There should be no smoking or eating where antigen containing materials are being handled.
- Wear disposable gloves and lab coat while handling specimens. Wash hands thoroughly afterwards. Use appropriate precautions in the collection, handling, storage and disposal of specimens, used pipette, and gloves. Discard used materials in a proper biohazard container.
- Do not open the foil pouch until you are ready to perform the test.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

## SPECIMEN COLLECTION AND STORAGE

**Fingerstick Specimens (Whole Blood)**

- Clean the area to be lanced with an alcohol swab. Squeeze the end of the fingertip and pierce it with a sterile lancet.
- Wipe away the first drop of blood with sterile gauze or cotton.
- Allow the second drop to flow directly into the sample well of the test device or use micropipet to withdraw fresh blood sample and dispense two drops (approximately 24 µl) into sample well.

**Plasma**

- Have a certified phlebotomist collect whole blood into a purple, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma for testing, or label and store it at 2-8°C for up to one week. Plasma may be frozen at -20°C for up to one year.

**Serum**

- Have a certified phlebotomist collect whole blood into a red top collection tube (containing no anticoagulants) by venipuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw the serum for testing, or label and store it at 2-8°C for up to one week. Serum may be frozen at -20°C for up to one year.

## TEST PROCEDURE

- Review specimen collection instruction.
- Test device together with Sample dilution buffer, test samples, be brought to room temperature (20°C to 30°C) prior to testing.
- Remove the test device from pouch when ready to perform the test. Label the device with sample identification.

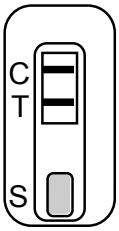
**Serum or Plasma Sample:**

- Use the pipette to withdraw serum or plasma from the specimen collection container and dispense one drop in a vertical position (approximately 35µl) into sample well first and then hold the sample dilution buffer bottle in a vertical position and immediately add one drop (approximately 35ul) of sample dilution buffer.
- Observe the result in 15 minutes. Strong positive results may be observed sooner. Do not interpret the results after 20 minutes.

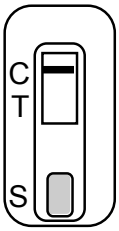
**Whole Blood Sample:**

- Use the pipette to withdraw whole blood sample and dispense one drop in a vertical position (approximately 35µl) into sample well or allow one drop of whole blood flow directly into sample well from finger. Wait until most of blood is absorbed, then hold the sample dilution buffer bottle in a vertical position and immediately add one drop (approximately 35µl) of count the time after addition of sample dilution buffer.
- Observe the result in 15 minutes. Strong positive results may be observed sooner. Do not interpret the results after 20 minutes.

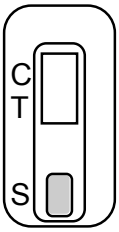
## INTERPRETATION OF RESULTS




Positive
Two colored lines should be observed in the viewing window. The line in the test region (T) is the probe line; the line in the control region (C) is the control line, which is used to indicate proper performance of the device. The color intensity of the test line may be weaker or stronger than that of the control line.




Negative
The control line appears in the test window, but the test line is not visible.




Invalid
No line appears in the control region.A positive sample should be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.

## LIMITATION OF PROCEDURE

- The assay is designed for human blood, serum or plasma use only.
- This test kit is to be used for the qualitative detection of antibodies to HIV.
- A negative result doesn't rule out infection by HIV because the antibodies to HIV may be absent or may not be present in sufficient quality to be detected at early stage of infection.

**Specificity**

- From the results of the sample tests, the Specificity of the test was calculated as follows :

$$\text{Specificity} = \frac{\text{true positive + true negative}}{\text{total cases}} \times 100\%$$

$$\text{Example: } = \frac{362+860}{364+861} = 99.7\%$$

**Precision**

- Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 99.5% of the time.

**Sensitivity**

- The test device passed the control serum evaluation panel issued from The National Institute for the Control of Pharmaceutical and Biological Products