

# One Step Anti-HIV 1+2 (Serum/Plasma) Test (Cassette)

(For professional use)

## Interpretation of the symbols on the package



Symbol for "Do not reuse"



Symbol for "Caution, see instructions for use"



20030101 Symbol for "batch code"



20030101 Symbol for "Use by"

## INTRODUCTION

One Step Anti-HIV 1+2 Test is a rapid direct binding test for the qualitative detection of antibodies to Human Immunodeficiency Virus Type 1 and Type2 (HIV) in human serum/plasma as an aid in the clinical assessment of HIV infection.

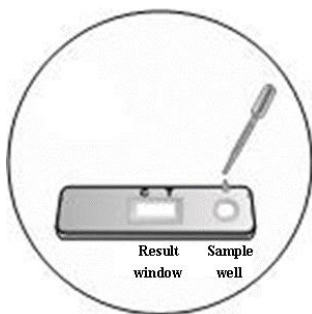
The test is based on the principle of double antigen sandwich immunoassay for the determination of anti-HIV antibodies in serum/plasma. Purified recombinant antigens are employed to identify antibodies specifically. This one step test is very sensitive and only takes about 10-15 minutes. Test results are read visually without any instrument.

## SPECIMEN COLLECTION

- 1) The test works best on fresh samples. It can be performed using either serum or plasma. Collect serum or plasma specimens following regular clinical laboratory procedures.
- 2) Only those specimens that are clean, clear and with good fluidity can be used for the assay. Avoid using hemolyzed, extremely thickened specimens.
- 3) If the specimen cannot be tested on the day of collection, store in a refrigerator or freezer. Bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

## TEST PROCEDURE

- 1) When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.
- 2) Add 50-60  $\mu$ l (1-2 drops) of sample into the sample well on the cassette.



- 3) Wait for 10-15 minutes and read results.
- 4) Do not read results after 20 minutes.

## INTERPRETATION OF RESULTS

### Negative:

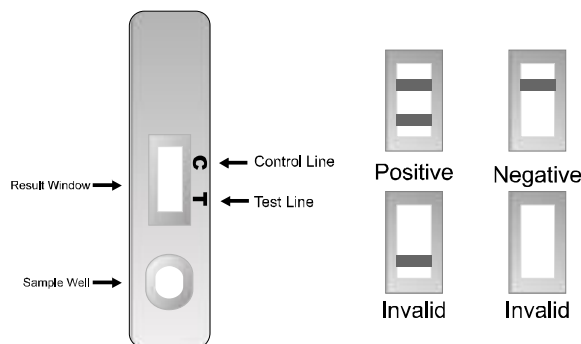
Only one colored band appears on the control (C) region. No apparent band on the test (T) region.

### Positive:

In addition to a pink colored control (C) band, a distinct pink colored band will also appear in the test (T) region.

### Invalid:

A total absence of color in either regions or only one color band appears on the test region indicate procedure error and/or the test reagent has deteriorated.



## STORAGE AND STABILITY

The test kit can be stored at 4 to 30° C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

## PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. For samples that are positive by this test, a more specific confirmatory test should be done. A clinical evaluation of the patient's information should be made before a final diagnosis is established. The use of a rapid test alone is not sufficient to diagnose AIDS. Also, a negative result does not preclude the possibility of infection.
5. The instructions for use and reading of the test must be followed exactly in order for the test to perform properly.