

HIV / HBsAg / TP Serum Test Panel

INTRODUCTION

This test panel is a rapid direct binding test device for the visual detection of the antibody to human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAg) and anti-syphilis antibodies in serum specimens, as an aid in the diagnosis of HIV, hepatitis B and syphilis infection. Infection of any of the three viruses can be detected with a single test panel.

The test is based on the principle of sandwich immunoassay. Monoclonal and polyclonal antibodies are employed to identify HIV antibody, HBsAg and Syphilis antibody specifically.

This one step test is very sensitive and only takes about 10-20 minutes. Test results are to be read visually without the need of any special instrument.

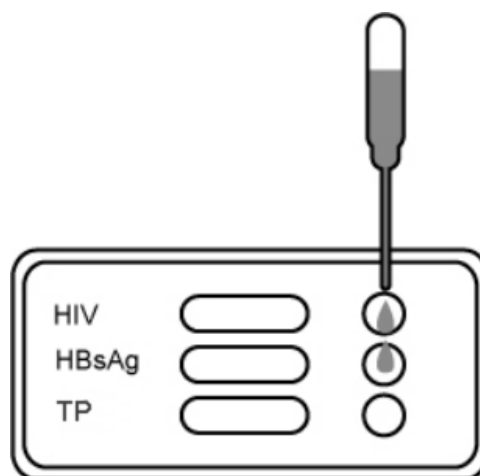
SPECIMEN COLLECTION

The test works best on fresh samples. Collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE

- Let the sealed pouch and the specimen come to room temperature before testing.
- When you are ready to begin testing, open the sealed pouch by tearing along the notch on the pouch. Remove the test panel from the pouch.
- Holding the samples dropper vertically and drop the specimen without air bubbles into the sample well.
 - For HIV and syphilis, draw 120µl (about 3 drops) of specimen into sample wells.
 - For HBsAg (about 4 drops) of specimen into sample well.
- Wait 10-20 minutes and read the results. Do not read results after 30 minutes.



INTERPRETATION OF RESULTS

Read the results for HIV, HBsAg and Syphilis in the corresponding result window. Interpret the test results separately according to the illustration as shown below:

- **Negative:** Only one colored band appears on the control (C) region. No apparent band on the test (T) region. This indicates a negative result.
- **Positive:** In addition to a pink coloured control (C) line, a distinct pink colored line also appears in the test (T) region. This indicates a positive result. More specific testing method is recommended to reach a clinical conclusion.
- **Invalid:** A total absence of color in both control region and testing band region is an indication of procedure error and/or test reagent deterioration. Repeat the test with a new test panel.



STORAGE AND STABILITY

The test kit can be stored at room temperature (2 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

- For in vitro diagnostic use only.
- Do not use test kit beyond expiry date.
- The test device should not be reused.

MANUFACTURER

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