

Introduction

ANTI-TP Rapid Screen Test is a chromatographic immunoassay for the qualitative detection of antibodies to TP in human serum. Two Purified recombinant antigens of TP are used in test band as capture materials and gold conjugates. If the antibody of Anti-TP is present in the sample in concentration above the labeled, complex will be formed. This complex is then captured by antigens immobilized in the Test Zone of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of the anti-TP present in the sample. This one step test is very sensitive and only takes about 15 minutes. Test results are read visually without any instrument.

Materials And Components

Materials Provided

Individually sealed foil pouches containing:

- One cassette test device.
- One buffer
- One plastic dropper
- Lancet
- Alcohol Wipe
- One package insert (instruction for use)

Materials Required But Not Provided

- sample collection containers
- timer or clock

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.

Specimen Collection

For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. For plasma, collect whole blood into a purple, blue or green top collection tube (containing EDTA, citrate or heparin, respectively) by vein puncture, separate plasma from whole blood.

Use the specimen inside an hour. If the specimen can not be tested inside an hour, store the specimen in 4 °C cold closet or refrigerator but don't freeze. Bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

Test Procedure

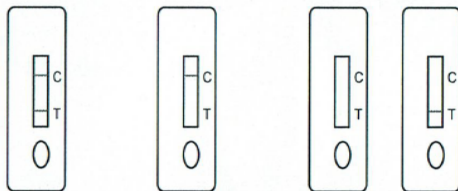
- Open a pouch containing a cassette, lay the cassette.
- Using the plastic dropper provided, draw two or three drops of sample into the sample well of the cassette.
- Read results within 15 minutes. Do not read results after 20 minutes.**

Interpretation Of Results

Negative: Only one pink band appears on test region of the Cassette. This indicates that there is no detectable anti-TP in the serum.

Positive: Two pink bands appear on test region of the Cassette. This indicates that the specimen contains detectable amount of anti-TP.

Invalid: If without colored band appears on test region of the Cassette, this is an indication of a possible error in performing the test. The test should be repeated using a new device.



(a) Positive

(b) Negative

(c) Invalid

Precaution

- Must use fresh specimen and avoid repetitive freezing, the result will be invalid
- Use it before expiry date.
- The package of kit should not be opened until it reaches the room temperature if it taken out from the refrigerator.
- Old Serum can not be used. If the serum is thick, it can be used only after being separated.

Limitation

- The test is for in-vitro diagnostic use only.
- The test is qualitative filter detection, it can not be used as the final test for blood donation.