

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing. 1. Preparing Serum, Plasma, or Whole Blood Specimen:

a. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

b. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Specimens should not be frozen and thawed repeatedly.

c. Do not freeze whole blood specimens. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection.

i. Whole blood collected by fingerstick should be tested immediately.

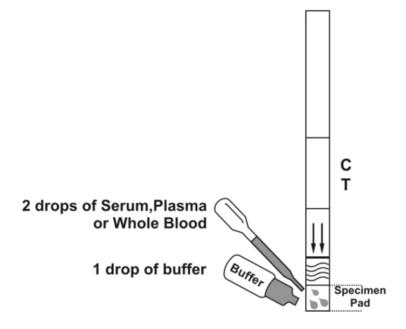
2. To Perform the Test:

- a. Remove the test strip from the foil pouch and use it as soon as possible.
- **b.** Place the test strip on a non-absorbent flat surface, with arrows pointing downwards as illustrated.

c. Hold the dropper vertically and transfer 2 drops of serum, plasma, or whole blood (approximately 50 μL) to the Specimen Pad of the test strip, then add 1 drop of buffer (approximately 40 μL) and start the timer. **i.** Avoid air bubbles.

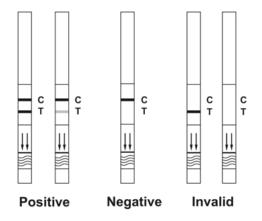
3. Interpreting Results:

- a. Wait for the colored line(s) to appear.
- b. Read results at 10 minutes.
- c. Do not interpret the result after 20 minutes.





Interpretation of Results



• **<u>POSITIVE</u>**: : Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

• The intensity of the color in the test line region (T) will vary depending on the concentration of antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

• **NEGATIVE:** One colored line appears in the control line region (C). No line appears in the test line region (T).

• **INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



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