

TEST PROCEDURE

- Perform Positive and Negative Control tests prior to using the kit for patient samples (see package insert for details).
1. Transfer 100 µL of clinical sample to the **Reagent A - Lysis Buffer** vial and mix sample solution by gently shaking.
 2. After 5-10 minutes, add 25 µL of **Reagent B - Loading Buffer** to sample solution and mix components by pipetting up and down 5 times.
 3. Immediately add 100 µL of sample solution to **Reagent C - Detector** vial and mix by gently shaking for 5 seconds.
 4. Immediately transfer 100 µL of sample solution (the entire sample volume) into the **Test Cassette** sample well, with the cassette face-up on a flat horizontal surface.
 5. Read test results 30-45 minutes after sample application.

Consult Package Insert PN 1001100, Rev E for detailed instructions

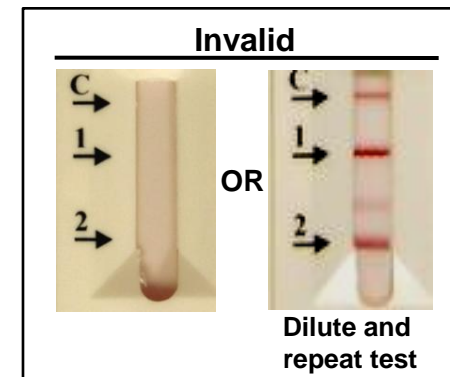
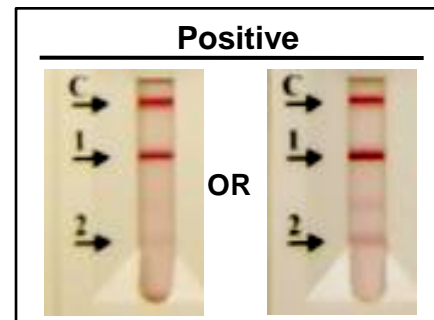
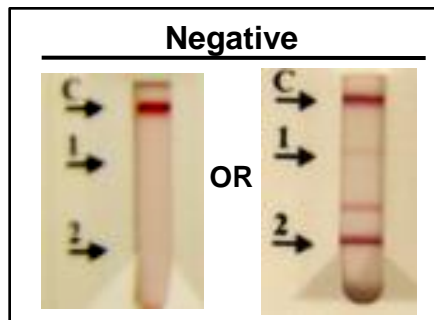
See Back for TEST INTERPRETATION



TEST INTERPRETATION

- Test is **NEGATIVE** if: Only control line (C) seen
- Test is **NEGATIVE** if: Control line (C) and Line 2 seen only **OR** Line 2 intensity is greater or equal to Line 1 intensity
- Test is **POSITIVE** if: Control line (C) and Line 1 seen only **OR** Line 1 intensity is greater than Line 2 intensity
- Test is **INVALID** if: No control line (C) seen **OR** both Line 1 and Line 2 intensities are greater than Control Line intensity
 - **IMPORTANT:** For an invalid test which shows both Line 1 and Line 2 intensities are greater than Control Line intensity, dilute sample 1:10 in M4 VTM and repeat test.

Test Results Examples



Consult Package Insert PN 1001100, Rev E for detailed instructions

