

# Health-Chem Diagnostics, LLC

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## ONE STEP™ TB TEST CASSETTE FOR FINGER STICK WHOLE BLOOD

### Explanation of the Test:

Tuberculosis (TB) is spread primarily via airborne transmission of aerosolized droplets developed by coughing, sneezing and talking.

**The One Step™ TB Cassette Test** is a chromatographic immunoassay for the qualitative detection of all human anti-TB (*M. tuberculosis*, *M. bovis* and *M. africanum*) antibodies (IgG, IgM, IgA, etc.). This test is intended for use as an aid in the diagnosis of TB.

**The One Step™ TB Cassette Test** is a chromatographic immunoassay for the qualitative detection of antibodies against TB in serum, plasma or whole blood.

### Materials Provided—

The TB Cassette Test kit contains the following items to perform the test:

1. TB cassette
2. Alcohol pad
3. Lancet
4. Buffer
5. Instructions

### Precautions—

**The One Step™ TB Cassette Test** kit should be stored at room temperature 4-30°C (40-86°F). **The test device is sensitive to humidity as well as to heat.** Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

### Procedure of the Test—

1. Remove the test cassette from the foil pouch, and place it on a flat, dry surface. Note: Once the test cassette is removed from the pouch, it should be used as soon as possible.
2. Push the lancet cap into the lancet body until it clicks (Figure 1).
3. Twist off the lancet cap (Figure 2) and discard it.

4. Clean the second or third finger by rubbing it with an alcohol pad.
5. Place platform end of lancet firmly against finger and press top firing pad (Figure 3).
6. Massage near the site to obtain blood flow. The lancet needle will retract safely after use. Dispose of the lancet in a suitable container.
7. Place the tip of the blood collection tube into the blood sample and make sure the tube is slightly lower than the blood sample so that the blood will automatically flow into the tube. Fill the tube with blood sample until it reaches the black line (Figure 4). If there is insufficient blood sample, massage near the site again to obtain more blood flow and fill the collection tube to the black line.
8. Then place the tip of the collection tube vertically into the Sample Well of the test device. Place two fingers over the vent hole of the tube (blocking air flow) and squeeze the top of the tube to expel the blood sample (about 50 µl) into the Sample Well (Figure 5). Note: if the vent hole is not completely blocked, the blood sample will not be completely expelled from the tube.
9. Open the buffer bottle and hold it upside down. Be sure to hold the bottle vertically (Note: drops may contain air-bubbles if the buffer bottle is not held vertically), add 1 hanging drop of buffer into the sample well. After the first drop is absorbed into the sample well, add another hanging drop of buffer.
10. As the test begins to work, you will see purple color dyes move across the Result Window in the center of the test cassette.
11. Interpret test results at 10 to 20 minutes. Do not interpret test results after 20 minutes.

**Caution:** The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than °C, then the interpretation time should be properly increased.

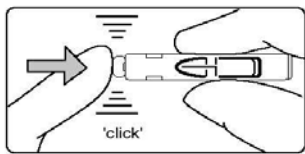


Figure 1

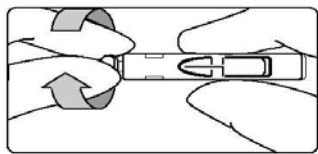


Figure 2

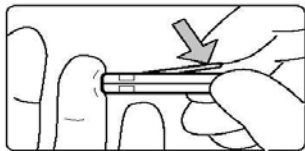


Figure 3

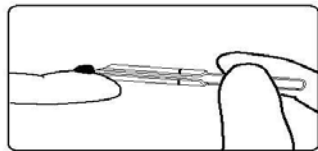


Figure 4

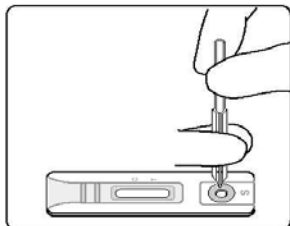


Figure 5



Figure 6

### Interpretation of the Test—

1. A color band will appear at the left section of the Result Window to show that the test is working properly. This band is the Control Band (“C” band).
2. The right section of the Result Window indicates the test results. If another color band appears at the right section of the Result Window it is the Test Band (“T” band).

**Positive Result:** The presence of two color bands (“T” band and “C” band) within the result window regardless of which band appears first indicates a positive result (Figure 6). Note: Generally, the higher the anti-TB antibody level in the specimen, the stronger the “T” band color will be. When the specimen anti-TB antibody level is close to but still within the sensitivity limit of the test, the color of the “T” band will be very faint.

**Negative Result:** The presence of only one purple color band (“C” band), within the Result Window, indicates a negative result (Figure 6).

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**Invalid:** If after performing the test, no color band is visible within the Result Window, the result is considered invalid. Some causes of invalid results are not following the directions correctly or the test may have deteriorated beyond the expiration date (Figure 6).

*Note: A positive result will not change once it has been established at 20 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 20 minutes.*

### Limitations of the Test

A negative result does not preclude the possibility of infection with TB. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

### Warnings

1. The same lancet needle should be used for one person only and should not be shared with another person, because the used needle is a biohazard.
2. Decontaminate and dispose of all specimens, reaction kits, lancet needle and potentially contaminated materials, as if they were infectious wastes, in a biohazard container.
3. Do not use the kit after the expiration date.
4. For in vitro diagnostic use only.

### References

1. Dixon RE: Symposium on nosocomial infections (Parts I,II and III). Am J Med 70:379-473, 631-744, 899-986, 1981.
2. Green GM, Daniel TM, and Ball WC: Koch Centennial Memorial. Am Rev Resp Dis 125:1-31 (Suppl), 1982.
3. Pennington JE: Respiratory Infections: Diagnosis and management. New York, Raven Press, 1983.

Manufactured in the USA by:  
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