

JN-QC- Rapid TB Test Device

Whole Blood, Plasma or Serum

TEST INSTRUCTIONS



1. Remove the test device from the foil pouch, and place it on a flat, dry surface.



2. Add 5ul of sample to the sample well. If you're using the included micro-capillary tube to measure the sample size, simply pinch the sides of the tube between your fingers and place the tip into the sample, slowly release your fingers to draw the sample into the tube up to the black line printed on the end.



3. Touch the end of the microcapillary tube to the sample pad and pinch the tube once again to release the sample. Make sure that you do not use more than 5ul of sample. If using whole blood, allow sample to absorb for 1-2 minutes before adding the diluent.



4. Slowly add 5 drops of TB sample diluent to the sample well allowing each drop to fully absorb before adding the next drop. If required, add one more drop to fully clear the test window.
NOTE: full absorption of each drop is necessary to allow the sample to flow through the special filter in the sample well.



5. Start the timer.



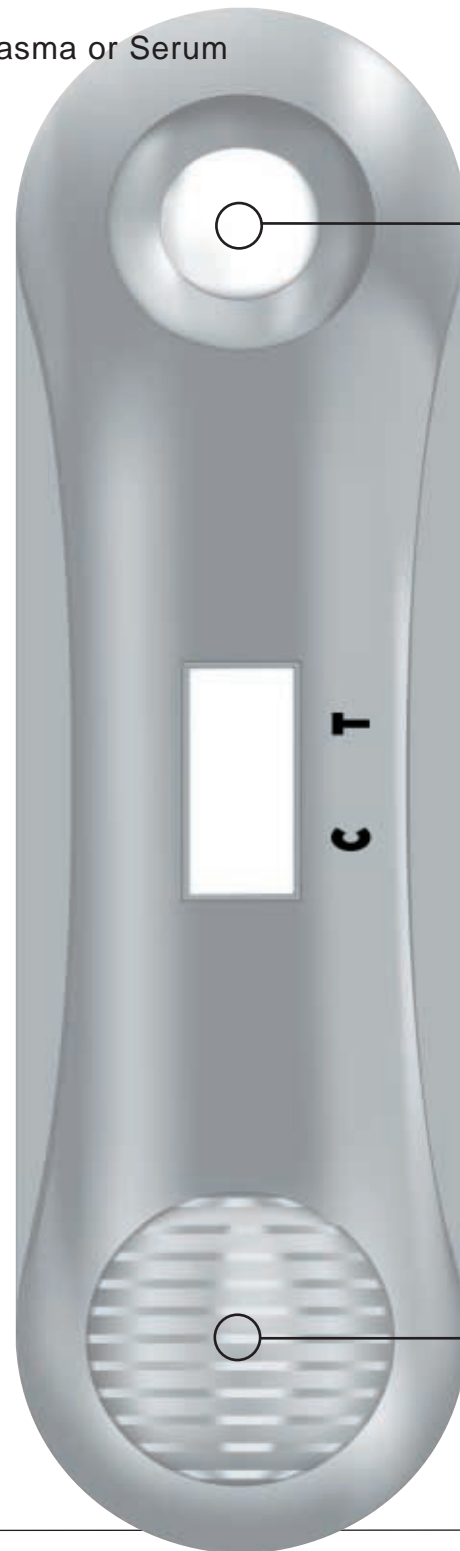
6. As the test begins to work, you will see purple color move across the Result Window in the center of the Test Device.

7. While results can often be seen within 2-3 minutes, interpret the test results at 7 to 8 minutes. Very weak samples may appear at 15 minutes. **Do not interpret test result after 20 minutes.**

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

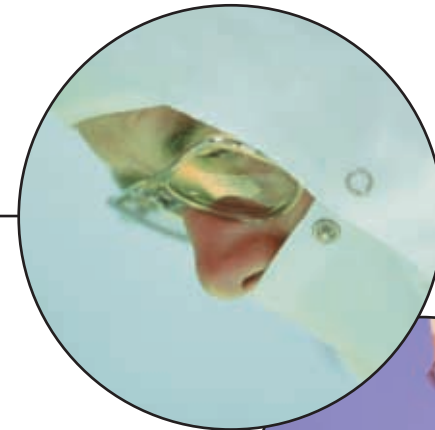
INTERPRETATION OF THE TEST

Positive	Invalid
C T	C T
Negative	Invalid
C T	C T



ASSAY INNOVATION

JN-QC Rapid TB Test Device



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ISO 9001

ISO 13485

EN 46001

GMP

QSR

EXPLANATION OF THE TEST

TB, or tuberculosis, is a disease caused by bacteria called *Mycobacterium tuberculosis*. The bacteria can attack any part of your body, but they usually attack the lungs. TB disease was once the leading cause of death in the United States. In the 1940s, scientists discovered the first of several drugs now used to treat TB. As a result, TB slowly began to disappear in the United States. But TB has come back. After 1984, the number of TB cases reported in the United States began to increase. More than 25,000 cases were reported in 1993. TB is spread through the air from one person to another. The bacteria are put into the air when a person with TB disease of the lungs or throat coughs or sneezes. People nearby may breathe in these bacteria and become infected. People who are infected with TB do not feel sick, do not have any symptoms, and cannot spread TB. But they may develop TB disease at some time in the future. People with TB disease can be treated and cured if they seek medical help. Even better, people who have TB infection but are not yet sick can take medicine so that they will never develop TB disease (1).

The JN-QC™ TB test utilizes a highly purified, specially produced, recombinant TB protein to detect antibodies against TB. The JN-QC™ TB test cassette has the letters T and C as “Test Line” and “Control Line” on the surface of the case. The Control Line should always appear if the test procedure is performed properly and the test reagents of the Control Line are working. A purple “Test Line” will be visible in the Result Window if the test is working properly. If antibodies against TB are not present, or are present at very low levels in the sample, then no color appears in the “Test Line”.

The JN-QC™ TB test is a solid phase immunochromatographic assay for the qualitative detection of antibodies against TB. This test is intended for professional use as an aid for the diagnosis TB infections.

MATERIALS PROVIDED

- 1- TB test device
- 1-Instruction sheet
- 1-Bottle of TB diluent
- 1-Disposable 5ul micro-capillary pipette

MATERIALS REQUIRED BUT NOT PROVIDED

- 1-Timer

PRECAUTIONS

The JN-QC™ TB test devices should be stored at room temperature. The test device is sensitive to humidity and to heat. Perform the test immediately after removing the test device from the foil pouch. **Do not use it beyond the expiration date.**

SPECIMEN COLLECTION AND STORAGE

Whole Blood specimen collection: Collect an anticoagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be used immediately or stored at 2-8 degrees C.

PLASMA/SERUM SPECIMEN COLLECTION:

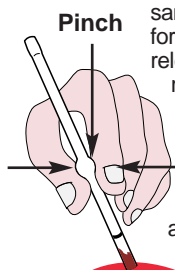
1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested they should be refrigerated at 2-8 degrees C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use.
3. Specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS

1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

TEST PROCEDURE

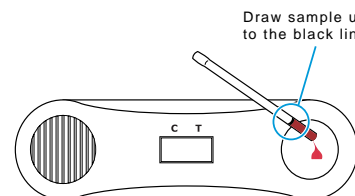
1. Remove the test device from the foil pouch, and place it on a flat, dry surface.
2. Add 5ul of sample to the sample well. If using a micro-capillary tube to measure the sample, squeeze the tube with the thumb and forefinger, touch to the sample and carefully release the tube drawing enough sample to reach the bottom of the black mark. Dispense the 5 micro-liters of material by touching the end of the device to the sample pad of the device and squeezing the tube to release the sample. **Do not use more than 5ul of sample.** (Figure 1) If using whole blood, allow sample to absorb for 1-2 minutes before adding the TB diluent.



3. Slowly add 5 drops of TB sample diluent to the sample well (Figure 1) allowing each drop to fully absorb before adding the next drop. If required, add one more drop to fully clear the test window. **NOTE: full absorption of each drop is necessary to allow the sample to flow through a special filter in the sample well. Start the timer.**

4. As the test begins to work, you will see purple color move across the Result Window in the center of the Test Device.
5. While results can often be seen within 2-3 minutes, interpret the test results 7 to 8 minutes. Very weak samples may appear at 15 minutes. **Do not interpret test result after 20 minutes.**

FIGURE 1



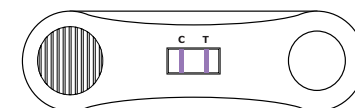
CAUTION: The above interpreting time is based on reading the test results at room temperature of 15 to 30 degrees C. If your room temperature is significantly lower than 15 degrees C, then the interpreting time should be properly increased.

INTERPRETATION OF THE TEST

1. A purple band will appear at the upper section of the Result Window to show that the test is working properly. This band is the Control Band.
2. The lower section of the Result Window indicates the test results. If another purple band appears at the lower section of the Result Window, this band is the Test Band.

POSITIVE RESULT: TWO PURPLE BANDS

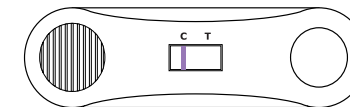
FIGURE 2



The presence of two purple bands (“T” band and “C” band) within the Result Window, no matter which band appears first, indicates that antibodies against TB are detected (Figure 2). Note: Generally, the higher the analyte level in the specimen, the stronger the “T” band color will be. When the specimen analyte 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: ONE PURPLE BAND

FIGURE 3



The presence of only one purple control line within the Result Window indicates that antibodies against TB are not detected (Figure 3).

INVALID RESULT:

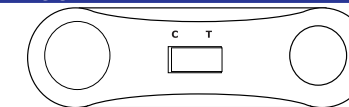


FIGURE 4

If after performing the test, no purple Control Line is visible within the Result Window, the result is considered invalid (Figure 4). Causes for invalid results may include not following the directions correctly or using the test beyond the expiration date. It is recommended that the specimen be re-tested using a new test device.

LIMITATIONS OF THE TEST

Although a positive result may indicate infection with TB, a diagnosis of TB can only be made on clinical grounds, if an individual meets the case definition for TB established by the Centers for Disease Control. For samples repeatedly tested positive, more specific supplemental tests must be performed. A single immunochromatographic test alone cannot be used to diagnose TB, even if the antibodies against TB are present in a patient specimen. A negative result at any time does not preclude the possibility of TB infection.

PERFORMANCE CHARACTERISTICS

No standards for performance have yet been established for TB rapid assays. Results of in-house testing using samples from around the world are as follows:

Test	Positives	Negatives	Spec%	Sen%
JN-QC™	102/104	64/16	97.04%	98.08%
TB-1	36/36			100%

While the number of samples tested was limited, the JN's rapid assay detected most positive samples used in this panel.

REFERENCES

1. <http://www.cdc.gov/nchstp/tb/faqs/qa.htm>