

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.



4. Slowly add 5 drops of HCV 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.



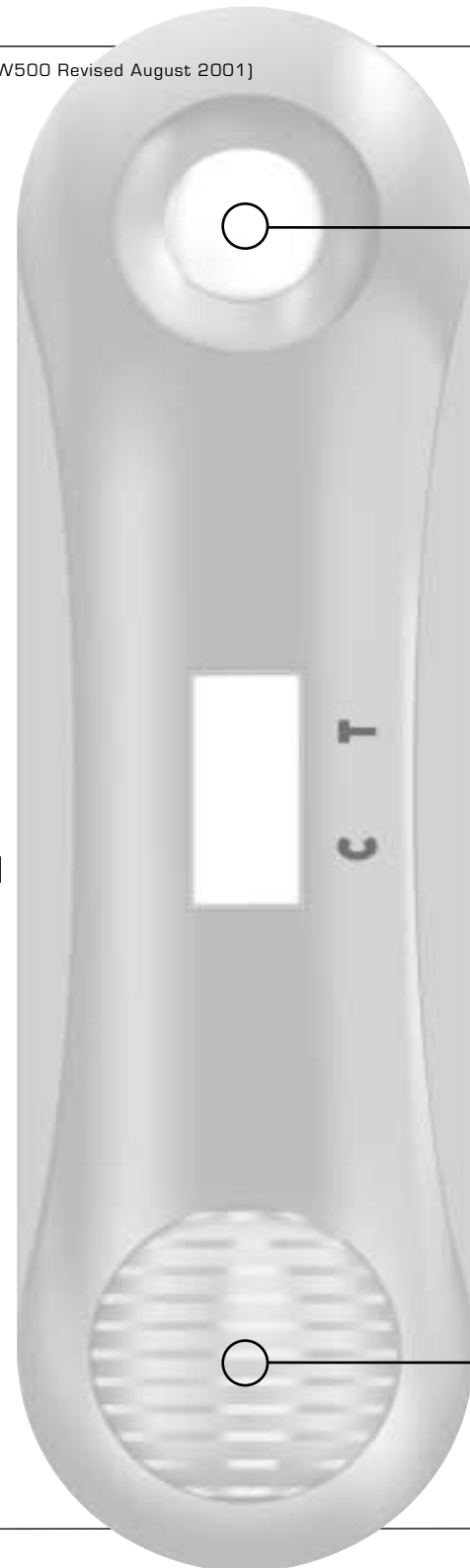
6. As the test begins to work, you will see purple color move across the Result Window in the center of the Test Device.

7. While results can often be seen within 2-3 minutes, interpret the test results at 7 to 8 minutes. 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.

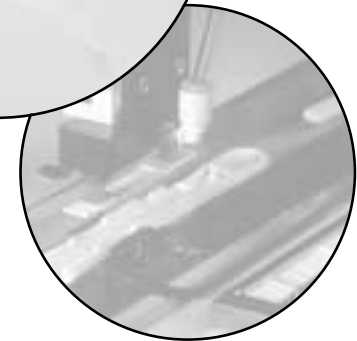
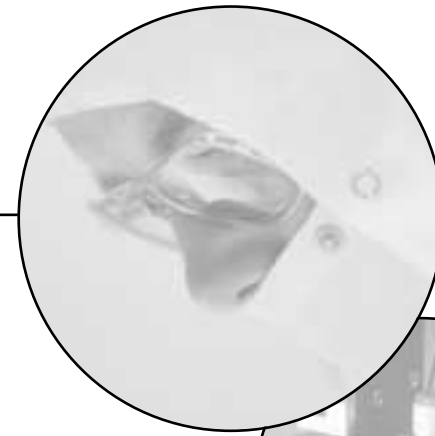
INTERPRETATION OF THE TEST

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



JN-QC-SPOT

One Step HCV Test Device 4.12



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 Not for sale in the United States.

EXPLANATION OF THE TEST

Hepatitis C Virus (HCV) is a widespread, serious liver disease. Millions of people, most of them in regions with poor medical care, are chronically infected with the virus, therefore facing an elevated risk of acquiring liver cancer. HCV is a single strand RNA virus. An antibody to HCV is found in most patients who are infected with the virus (1). The One Step HCV Test is a chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, IgA, etc.) against HCV in serum, plasma or whole blood.

The HCV test cassette has the letters T and C as "Test Line" and "Control Line" on the surface of the case. The "Control Line" is used for procedural control. 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 there are enough antibodies against HCV in the sample. If antibodies against HCV are not present or are present at very low levels in the sample, then no color appears in the "Test Line".

This test is intended for professional use as an aid in the detection of antibodies against HCV. Four specially selected HCV recombinant proteins are used in testing. This enables the One Step HCV Test to identify antibodies to HCV in plasma, serum or whole blood specimens with a high degree of accuracy.

MATERIALS PROVIDED

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

MATERIALS REQUIRED BUT NOT PROVIDED

- 1-Specimen collection container
- 1-Clock or timer

PRECAUTIONS

The One Step HCV test devices should be stored at room temperature. 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.

SPECIMEN COLLECTION AND STORAGE

Whole Blood specimen collection: Collect an anti-coagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested within 24 hours of drawing. Finger prick samples should be used immediately.

PLASMA/SERUM SPECIMEN COLLECTION:

- 1. Centrifuge whole blood to get plasma/serum specimen.

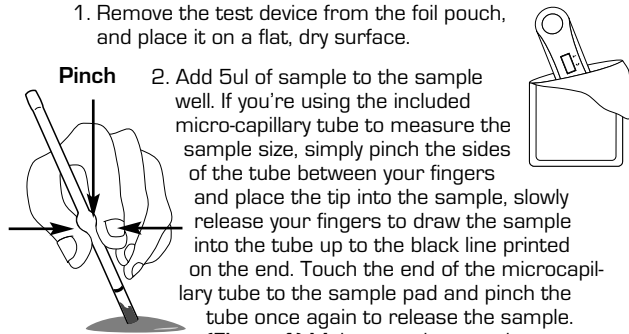
- 2. If specimens are not immediately tested they should be refrigerated at 2-8 degrees C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use.
- 3. Specimens containing a precipitate may yield inconsistent test results. Such specimens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

WARNINGS

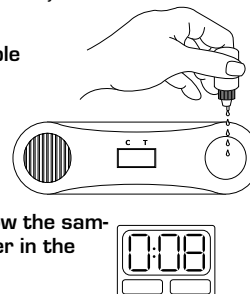
- 1. For in vitro diagnostic use only.
- 2. Do not eat or smoke while handling specimens.
- 3. Wear latex gloves while handling specimens. Wash hands thoroughly afterwards.
- 4. Avoid splashing or aerosol formation.
- 5. Clean up spills thoroughly using an appropriate disinfectant.
- 6. Decontaminate 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 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. Touch the end of the microcapillary tube to the sample pad and pinch the tube once again to release the sample. **(Figure 1)** Make sure that you do not use more than 5ul of sample.



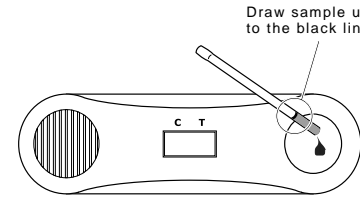
- 3. Slowly add 5 drops of HCV sample diluent 4.12 to the sample well allowing each drop to fully absorb before adding the next drop. If required, add one more drop to fully clear the test window. **NOTE:** full absorption of each drop is necessary to allow the sample to flow through a special filter 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 3-5 minutes, interpret the test results at 15 to 20 minutes. Do not interpret test result after 30 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.

FIGURE 1



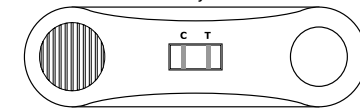
INTERPRETATION OF THE TEST

- 1. As the sample begins to migrate through the result window, the 2 soluble dye lines will disappear and a purple band will begin to 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:

The presence of two purple bands ("T" band and "C" band) within the Result Window, no matter which band appears first, indicates a positive result **(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.

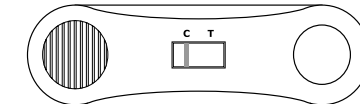
FIGURE 2



NEGATIVE RESULT:

The presence of only one band within the Result Window indicates a negative result **(Figure 3)**.

FIGURE 3

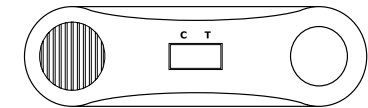


INVALID RESULTS

After performing the test and no purple band is visible within the Result Window, this result is considered invalid. **(Figure 4)** Causes of invalid results are: not following the directions correctly or the test is beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

NOTE: A positive result will not change once it has been established at 10 to 15 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 15 minutes.

FIGURE 4



LIMITATIONS

A negative result does not preclude the possibility of infection with HCV. 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 a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

No standards for performance have yet been established for HCV rapid assays. The One Step HCV Test was tested with a world-wide HCV performance panel (BBI) representing HCV types 1-4 plus untypable specimens in comparison with commercially available ELISA HCV assays, PCR, and RIBA 3.0 assays:

Test	Positive	Negative	Sen%	Spec%
JN-QC-SPOT	18/18	14/14	100%	100%

RESULTS:

The number of panel samples tested were limited, but included several samples considered indeterminate (low antibody levels below the threshold of the tests employed). However, the test successfully detected all positive samples and was non-reactive to all negative samples tested. These results demonstrate the HCV test performed favorably.

REFERENCES

- 1. Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR 1998;47[No. RR-19].