HCV Rapid Test Device (Whole blood/Serum/Plasma)

INTENDED USE

The HCV Rapid Test Device (Whole blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of antibodies to HCV in human whole blood, serum or plasma specimens. This kit is intended to be used as an aid in the diagnosis of HCV infection.

PRINCIPLE

The HCV Rapid Test Device (Whole blood/Serum/Plasma) has been designed to detect antibodies to HCV through visual interpretation of color development in the internal strip. The membrane was immobilized with protein A on the test region. During the test, the specimen is allowed to react with colored recombinant HCV antigens colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interacts with reagents on the membrane. If there were enough HCV antibodies in specimens, a colored band will from at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use beyond expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precaution against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect test results.

COMPOSITION

Materials Provided

- Individually packed test device
- Dropper
- Package insert
- Buffer

Materials Required but Not provided

- Specimen collection container
- Centrifuge
- Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN

- The HCV Rapid Test Device (Whole blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid haemolysis.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum or plasma specimens may be stored at 2-8°C for up to 7 days. For long term storage, serum or plasma specimens should be kept below -20°C.Do not freeze whole blood specimens. Whole blood should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal, state or local regulations for the transportation of etiologic agents.

TEST PROCEDURE

Allow the test device, specimen, and buffer to equilibrate to room temperature (15 - 30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 2 drops of specimen (approximately 50 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer.
3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret results after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

PERFORMANCE CHARACTERISTICS

The HBsAg Rapid Test has been evaluated with a EIA test using clinical specimens. The results show that the sensitivity is 99.5%, the specificity is 100%, the specificity is 99.31% and the accuracy is 99.66% relative to the EIA test.

LIMITATIONS OF THE TEST

- The HCV Rapid Test Device (Whole blood/Serum/Plasma) is for professional in vitro diagnostic use, and should be used for the qualitative detection of antibodies to HCV only.
- The HCV Rapid Test Device (Whole blood/Serum/Plasma) will only indicate the presence of HCV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HCV viral infection.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the existence of HCV antibodies in blood, because antibodies may be absent or below the minimum detection level of the test.
- Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

INDEX OF SYMBOLS

	Do not reuse	IVD	For in vitro diagnostic use only
4°C 30°C	Stored between 4-30℃		Consult instruction for use
	Caution	LOT	Lot number
	Use by	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged

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