Anti-HCV Rapid Test (Colloidal Gold)

Package Insert

For professional *in vitro* diagnostic use only.

INTENDED USE

The Anti-HCV Rapid Test (Colloidal Gold) 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.

INTRODUCTION

Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus.
HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens. Compared to the first-generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests.

PRINCIPLE

The Anti-HCV Rapid Test (Colloidal Gold) 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.

KIT COMPONENTS

Test Device	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
Assay Buffer	Phosphate buffered saline and preservative
Package Insert	For operation instruction.

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimens' collection use.
Lancets	for fingerstick whole blood only
Disposable heparinized capillary tubes and dispensing bulb	for fingerstick whole blood only
Timer	For timing use.
Centrifuge	For preparation of clear specimens
Disposable pipettes	For adding specimens use.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure 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.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The Anti-HCV Rapid Test (Colloidal Gold) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
- To collect Fingerstick Whole Blood specimens:
  Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingersitck Whole Blood specimen to the test device by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to approximately 50 μl. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood onto the specimen well (S) of the test device.
  - Add the Fingersitck Whole Blood specimen to the test device by using hanging drop:
    - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
    - Allow 2 hanging drops of fingerstick whole blood to fall onto the specimen well (S) of the test device, or move the patient's finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick 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 regulations covering the transportation of etiologic agents.

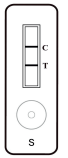
PROCEDURE

Bring tests, specimens, assay buffer and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.
2. For **Serum or Plasma** specimen: Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50~60μ L) to the specimen well (S), then add 1 drop of assay buffer (approximately 30~40μ L), and start the timer.
   For **Whole Blood** specimen: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 25~30 μ L) to the specimen well (S), then add 2 drops of assay buffer (approximately 60~80 μL), and start the timer.
3. Wait for the red line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

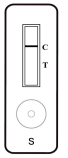
INTERPRETATION OF RESULTS

POSITIVE RESULT:



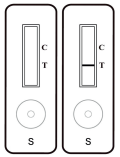
* A colored band appears in the control band region (C) and another colored band appears in the T band region.

NEGATIVE RESULT:



One colored band appears in the control band region (C). No band appears in the test band region (T).

INVALID RESULT:



Control band fails to appear. Results from any test which has not produced a control band at the specified reading 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 the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The Anti-HCV Rapid Test (Colloidal Gold) is for professional *in vitro* diagnostic use, and should be used for the qualitative detection of antibodies to HCV only.
2. 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.
3. 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.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Clinical Performance

A total of 550 patient samples from susceptible subjects were tested by the Anti-HCV Rapid Test and by a commercial EIA. Comparison for all subjects is showed in the following table:

Clinical results of Whole blood specimens

Method	HCV Rapid Test (Chemiluminescence Immunoassay, Bioscience)	Total

Anti-HCV Rapid Test(Colloidal Gold)	Results	Positive	Negative	Results
	Positive	148	3	151
	Negative	2	397	399
Total Results		150	400	550

Relative Sensitivity: 148/150	98.67% (98.38%～99.16%)
Relative Specificity: 397/400	99.25% (98.85%～99.55%)
Accuracy: 545/550	99.09% (98.62%～99.33%)

*** 95% Confidence Interval**

Clinical results of Serum specimens

Method		HCV Rapid Test (Chemiluminescence Immunoassay, Bioscience)		Total Results
Anti-HCV Rapid Test(Colloidal Gold)	Results	Positive	Negative	
	Positive	148	3	151
	Negative	2	397	399
Total Results		150	400	550

Relative Sensitivity: 148/150	98.67% (98.38%～99.16%)
Relative Specificity: 397/400	99.25% (98.85%～99.55%)
Accuracy: 545/550	99.09% (98.62%～99.33%)

*** 95% Confidence Interval**

Clinical results of Plasma specimens

Method		HCV Rapid Test (Chemiluminescence Immunoassay, Bioscience)		Total Results
Anti-HCV Rapid Test(Colloidal Gold)	Results	Positive	Negative	
	Positive	148	2	150
	Negative	2	298	400
Total Results		150	400	550

Relative Sensitivity: 148/150	98.67% (98.38%～99.16%)
Relative Specificity: 398/400	99.50% (98.85%～99.53%)
Accuracy: 546/550	99.27% (98.74%～99.63%)

*** 95% Confidence Interval**

Precision

Intra Assay

Within- run precision has been determined by using 10 replicates of twelve specimens containing negative, low positive and high positive samples. The negative and positive values were correctly identified >99% of the time.

Inter Assay

Between- run precision has been determined by using the same twelve specimens of negative, low positive and high positive of 10 independent assays and with three different lots of the Anti-HCV Rapid Test. The negative and positive values were correctly identified >99% of the time.

Cross-reaction

The following substances will not affect the detection and will not cause cross-reaction when tested under the concentration conditions shown in the table.

Substances	Result	Substances	Result	Substances	Result
Human cytomegalovirus	Negative	EB virus	Negative	HIV	Negative
HBV	Negative	HAV	Negative	syphilis	Negative
Herpes simplex virus	Negative	Influenza A virus	Negative	Influenza B virus	Negative

Interfering substances

The following potential interfering substances are added to the negative and positive samples. They will not affect the test at the following concentrations.

Substances	Result	Substances	Result	Substances	Result
Human albumin	Negative	bilirubin	Negative	Free hemoglobin	Negative
Triglycerides	Negative	Blood in patients with systemic lupus erythematosus	Negative	Antinuclear antibodies	Negative
Rheumatoid factor	Negative	Total immunoglobulin type G	Negative	IFNα	Negative
PegIFN	Negative	lamivudine	Negative	adefovir dipivoxil	Negative

LITERATURE REFERENCES

1. Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, and M. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 1989; 244:359
2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis. Science 1989; 244:362
3. van der Poel, C. L., H.T.M. Cuypers, H.W. Reesink, and P.N.Lelie. Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay.
4. Lancet 1991; 337:317Wilber, J.C. Development and use of laboratory tests for hepatitis C infection: a review. J. Clin. Immunoassay 1993; 16:204

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INSTRUCTIONS OF SYMBOL

	Consult instruction for use		Keep dry
	Store between	LOT	Batch number
	For single use		Date of manufacture
	Expire date		Contains sufficient for <n> tests
EC REP	European representative		