HBc Ab Rapid Test (cassette) (RAP-4871)

Not for Sale in the USA

Revised 13 Jun 2008

INTENDED USE
FOR THE QUALITATIVE ASSESSMENT OF HBcAb IN HUMAN SERUM/PLASMA.
For *in vitro* Diagnostic Use. *Not for Sale in the United States.*

INTRODUCTION
The HBcAb test is an immunochromatography based one step *in vitro* test. It is designed for qualitative determination of HBcAb (anti-Hepatitis core antigen antibody) in human serum specimens.

TEST PRINCIPLE
HBcAb test is a competitive immunoassay. When serum is added to sample pad, it moves through the conjugate pad and dissolve the solid gold- anti-HbcAg antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and competed each other to bind to HBcAg (recombinant) that is coated on the test region. If anti-HBcAg antibody is present, the result is **No color band in T line**. If there is no anti-HBcAg antibody in the sample, the T line will show a color band. The sample continues to move to the control area and forms a pink to purple color, indicating the test is working and the result is valid.

MATERIALS PROVIDED
1. HBcAb Test device

MATERIALS REQUIRED BUT NOT SUPPLIED
1. Specimen collection containers
2. Clock or timer

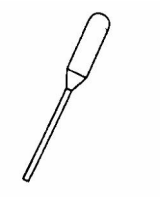
STORAGE
Store the test device at 2 to 30°C. Do not freeze.

PRECAUTIONS
1. Serum specimens can be collected at anytime of the day. Collect the specimen in a clean, dry plastic or glass container.
2 The sample can be refrigerated up to 72 hours prior to testing. A refrigerated sample must be allowed to warm to room temperature (8-30°C) and mixed well before testing.
3 Sodium azide can be added as a preservative up to 0.1% without effecting the test results.

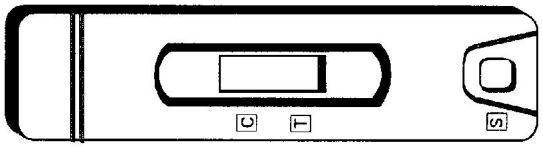
PROCEDURE

For Test Card:
1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 2-3 drops (80-120 µl) of sample into the sample well.
5. Read the result at 10 minutes.

(packaged together in foil pouch)



PIPETTE

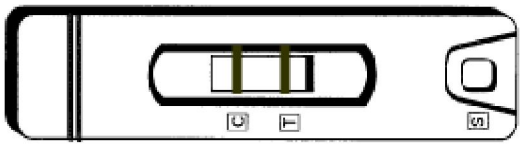


TEST DEVICE

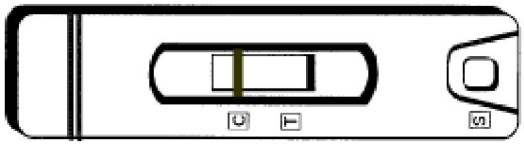
INTERPRETATION OF RESULTS

Positive: If there is no colored band visible in T line within 10 minutes, the test result is positive.
Negative: If test area has one color band and the control area displays another colored band, the result is negative.
Invalid result: The test result is invalid if a colored band does not form in the control region. The sample must be retested, using a new test device.

NEGATIVE RESULT



POSITIVE RESULT



Correlation between One-step and ELISA

		One-step	
		Pos.	*Neg.*
	Pos.	276	1
ELISA			
	Neg.	5	110

Sensitivity: **99.60%**
Specificity: **99.65%**

SAMPLE COLLECTION AND STORAGE

1. The HBcAb test may be performed using human serum or plasma.
2. If specimens are not immediately tested they should be refrigerated at 2-80C. For storage periods greater than 3 days, freezing is recommended.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS AND PRECAUTIONS

1. Wear disposable gloves while handling Specimens. Wash hands thoroughly afterwards.
2. Wipe up spills thoroughly using an appropriate intermediate to high level disinfectant.
3. Decotaminate and dispose of all specimens, reaction Kits and potentially contaminated materials, as if they were infectious, in a biohazard container.
4. Avoid splashing or aerosol formation.
5. Do not use the Kit after the expiration date.
6. For in vitro diagnostic use only.

LIMITATIONS OF THE TEST

1. HBcAb Kit is limited to the detection of Hepatitis B virus core antibody only.
2. Although the HBcAb Kit is very accurate in detect HBcAb, a very low incidence of false results might occure.
3. If negative or questionable results are obtained, and hepatitis B infection is suspected, the test should be repeated on a fresh serum specimen.
4. 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 evaluation of all clinical and laboratory findings.

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~sd 6/13/08