

HEALTH-CHEM DIAGNOSTICS, LLC

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For the One-Step Detection of *Hepatitis B core Antibody (HBcAb)*

I. INTENDED USE

The HBcAb test is an immunochromatography based one step *in vitro* test. It is designed for qualitative determination of HBcAb in human serum specimens. This antibody is reported to be the first detectable antibody to appear after Hepatitis B infection.

II. PRINCIPLES OF THE TEST

HBcAb test is a sandwich immunoassay. When serum is added to the sample pad, it moves through the conjugate pad and mobilizes gold anti-HBcAb antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with HBcAb that is coated on the test region. If HBcAb is present, the result is the formation of a colored band in the test region. If there is no HBcAb in the sample, the area will remain colorless. 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.

III. MATERIALS PROVIDED

1. Test Device
2. Dropper
3. Instruction manual

IV. STORAGE AND STABILITY

HBcAb test device may be stored at ambient temperature of 20 - 30°C (50-85°F) in the original unopened foil pouches. Each Test Unit contains a desiccant. The test should be used immediately once the pouch has been opened. In case the temperature of the Test Unit is considerably below room temperature and the humidity of the air is high, it is advisable to let the Test Unit reach room temperature before opening the pouch. The shelf-life of HBcAb Test Unit is 18 months

from the date of manufacture. The expiration date is printed on the box.

V. SAMPLE COLLECTION AND STORAGE

1. The HBcAb test may be performed using human serum or plasma.
2. Specimens containing precipitate may yield 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. Decontaminate 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.

VI. 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 occur.
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.

VII. TEST PROCEDURE

1. Remove the “Test Device” from its foil wrapper by tearing along the “splice” and place it on a clean level surface.
2. Fill the disposable dropper with the sample.
3. Hold the disposable dropper in a vertical position and apply 4 free-falling drops of sample (one by one) into the sample well of the test device.

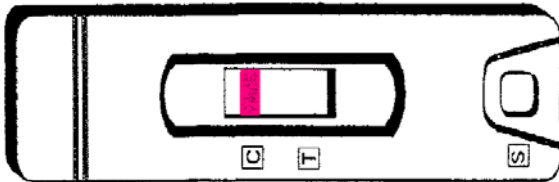
Allow each drop to soak in before adding the next one.

4. Read the results in 20 minutes.

VIII. INTERPRETATION

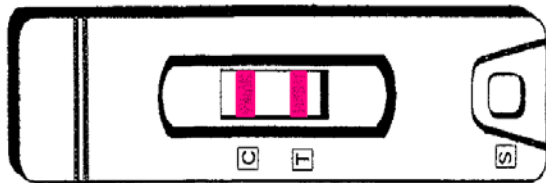
Positive Result:

The absence of a color band in the test region next to the letter “T” indicates that HBcAb is present and the specimen is positive.



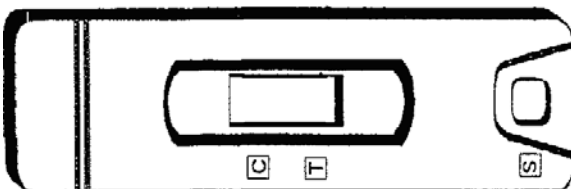
Negative Result:

If there is a rose-pink color band in the control region (marked with a “C”), and a rose-pink color band in the test region (marked with a “T”), there is no detectable HBcAb.



Invalid Result:

If a color band does not appear in the control region “C”, the test results are invalid. The sample may have been added to the wrong window, or the Test Device may have deteriorated. This specimen should be re-tested using a new Test Device.



IX. PERFORMANCE CHARACTERIZATION

Correlation between One-Step and ELISA

		One-Step	
		Pos.	Neg.
ELISA	Pos.	149	3
	Neg.	6	380

Sensitivity: 98.02%

Specificity: 98.44

External Controls:

Like any *in vitro* device, performance of HBcAb should be checked for accuracy and batch to batch variation by using known serum pools. These sera should be used in the same way as described in the assay procedure for serum samples. It is recommended that these control sera be used at least once with every batch or new shipment.

Internal Controls:

In addition to the external controls the test device has built-in controls. With each testing there should always be a rose-pink color band in the control region (“C”). If the color band does not appear in the control region, the result should be considered invalid. Also, after performing the test, the result window (“T”) should look clear white or uniform light pink. If the result window shows large red or purple streaks at the end of 10 minutes, the test should be considered invalid. Repeat the test using a fresh test device.

Manufactured in the USA by:
HEALTH-CHEM DIAGNOSTICS LLC,
US FDA & ISO Certified Facilities
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www.healthchemdiagnostics.com
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