

One step cassette style HBV test

INTRODUCTION

The one step Cassette Style HBV test is a rapid test based on the principle of immunoassay combined with conjugated colloid gold technology. The HBV test is a diagnostic device to detect the 5 markers associated with Hepatitis B infection

SPECIMEN COLLECTION

- For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.
- If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Bring the specimens to room temperature before testing .Do not freeze and thaw the specimen repeatedly.

TEST PROCEDURE

1. Remove the test kit from the pouch and place it horizontally on the desk.
2. Pipette 2 to 3 drops of serum in each sample well, read results after 15 minutes.

Note: For weak positive, read results after 25 minutes but no longer than 30 minutes (Diagram 1)

INTERPRETATION OF RESULTS

For HBsAg, HBsAb, HBeAg (Diagram 2)

Positive: Colored bands appearing in both control (C) and Test Region (T).

Negative: only one colored band appears in control Region (C).

Invalid: No band appearing in the control region (C) is an indicator of procedural error and/or the test reagent has been deteriorated. Specimen should be re-tested again. If problem persists, stop using products from this lot.

For HBeAb, HBcAb (Diagram 3)

Positive: A Distinct colored band appearing in the control Region (C).

Weak Positive: Colored band appearing in control Region (C) together with a faint colored band in Test Region (T).

Negative: Two colored bands appearing in both control (C) and Test Region (T).

Invalid: No band appearing in the control region (C) is an indicator of procedural error and/or the test reagent has been deteriorated. Specimen should be re-tested again. If problem persists, stop using products from this lot.

STORAGE AND STABILITY

The test kit can be stored at temperatures from 4°C to 30°C in the sealed pouch up to date of expiration . The test kit should be kept away from direct sunlight and moisture .Do not freeze the test kit.

PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond the expiry date.
3. The test device should not be reused.
4. Urine specimens may be infectious; insure proper handling and dispose of all used reaction devices into a biohazard container.

