

One-Step HBsAb Cassette Test

THE ONE STEP HBSAB TEST IS A RAPID, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES AGAINST HEPATITIS B SURFACE ANTIGEN (HBSAB) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS INTENDED FOR HEALTHCARE PROFESSIONAL USE.

SUMMARY AND PRINCIPLE OF THE ASSAY

The One Step HBsAb Test uses the “sandwich principle”, a solid phase colloidal gold enhanced immunoassay technique for determination of HBsAb in human whole blood, serum or plasma. The nitrocellulose membrane is coated with HBsAg in the test region and anti-HBsAg antibody in the control region. During the assay the specimen is allowed to react with the colored conjugate (HBsAg colloid gold conjugate); the mixture then migrates chromatographically on the membrane by the capillary action.

An HBsAb positive specimen produces a distinct color band in the test region, formed by the specific antibody-HBsAg complex. Absence of this colored band in the test region suggests a negative result. A colored band always appears in the control region serving as procedural control regardless of the test result.

The sensitivity of the test is 10mIU/ml.

MATERIALS PROVIDED

Each Kit Contains:

- Test cards/ test strips individually foil pouched with a desiccant
- Package Insert
- Sample dispensing plastic dropper with each test pouch. (for card only)

MATERIALS REQUIRED BUT NOT PROVIDED:

- Lancet
- Pipette
- Heparinized capillary tubes and rubber bulb
- Positive and negative controls (optional)

STORAGE CONDITIONS

The test kits must be stored at 2-30 in the sealed pouch and under dry conditions.

WARNINGS AND PRECAUTIONS

It is recommended that all specimens be handled in accordance with Biosafety Level 2 practices as described in the CDC NIH Publication, Biosafety in Microbiological and Biomedical Laboratories or other equivalent guidelines.

1. For *in vitro* diagnostic use only.
2. Wear gloves to perform this procedure and treat all specimens and used devices as potentially infectious.
3. Clean and disinfect all spills of specimens and reagents using a suitable disinfectant, such as 1% Sodium Hypochlorite.
4. Sterilize all devices used in this assay prior to disposal.

5. Do not use test beyond the expiration date.
6. ALL positive results must be confirmed by an alternative method.
7. Do not interchange reagents from one kit lot to another.

SAMPLE COLLECTION

Whole Blood:

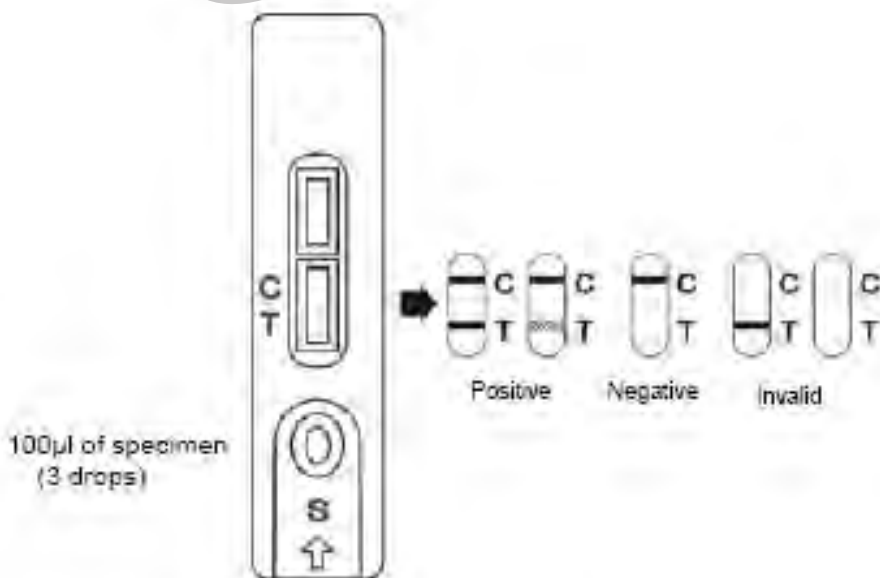
1. Collect whole blood specimens following regular clinical laboratory procedures.
2. Heparinized capillary tubes must be used for collecting whole blood samples. Do not use hemolyzed blood samples.
3. Whole blood specimens should be used immediately after collection.

Serum or Plasma

1. Collect serum or plasma specimens following regular clinical laboratory procedures.
2. Only those specimens that are clean, clear and with good fluidity can be used for the assay.
3. Those specimens that are apparently hemolyzed, extremely thickened or with very high fat level are NOT suitable for the assay.
4. Storage: A specimen should be refrigerated if not used the same day of collection. Specimens should be frozen if not used within 3 days of collecting. Avoid freezing and thawing the specimens more than 2-3 times before use. 0.1% of sodium azide can be added to specimen as preservative without affecting the results of the assay.

ASSAY PROCEDURES

1. Remove the test card from its foil pouch.
2. Identify the test card for each specimen or control on blank pad of the test card with a mark pen or sticker.
3. Dispense 100 μ l (3 drops) specimen or control to the sample well.
4. Interpret test results at 15 minutes.



READING THE TEST RESULTS

Do not interpret test results after 20 minutes

The presence or absence of HBsAb provides valuable information on the status of individuals with type B viral hepatitis. A positive test for anti-HBsAg antibody can be a useful adjunct for assessing immunity of clinical recovery of the patient. The quantitative measurement of HBsAb is valuable in assessing the level of the immune response to the HBV vaccine.

1. **Positive:** A pink test band appearing in the test region indicates a positive result. Lower the concentration, the longer it takes to produce a test band, and the weaker the test band may be.
2. **Negative:** The absence of a pink test band in the test region indicates a negative result.
3. **Invalid:** There should always be a pink control band in the control region regardless of test result. If control band is not seen, the test is considered invalid and should be repeated using a new test strip.

PERFORMANCE CHARACTERISTICS

The One Step HBsAb Test can detect antibodies against HBsAg (HBsAb) in human whole blood, serum, or plasma at concentration as low as 10mIU/ml. The HBsAb detectability is equivalent to that of EIA test. A result of 99% concordance to EIA test was determined by a clinical study of 1300 specimens.

LIMITATIONS

False reactive results may be obtained with any diagnostic test and usually consist of two types.

1. NONSPECIFIC REACTIVES

Nonspecific reaction may result from cross-reactions in the immune "sandwich" complex. Nonspecific reactions may include reactions with certain glycoproteins, such as concanavalin A, which interact with HBsAg. Miliman and McMichael have shown that this hepatitis B binding substance is not antibody. Any highly sensitive immunoassay system has the potential for nonspecific reaction with a specimen.

2. NONREPEATABLE REACTIVES

Nonrepeatable reactive specimens, as the name implies, test nonreactive upon repeat. This phenomenon is highly dependent upon technique. The most common sources of such nonrepeatable reactive is cross-contamination of non-reactive specimens caused by transfer of residual droplets of high titer, antibody-containing sera on the pipetting device.

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