



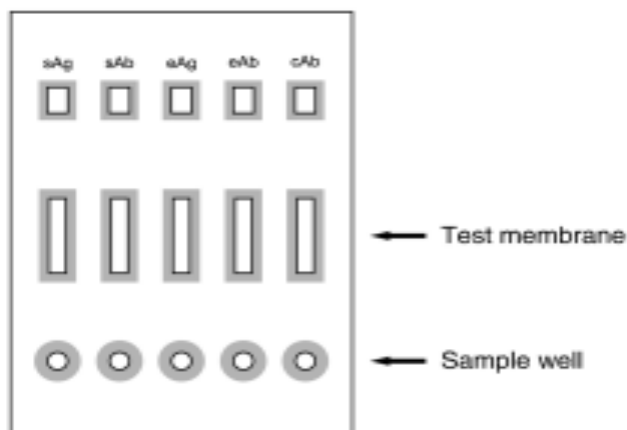
ADVANCED QUALITY™ One Step Multi-HBV TEST Device
(Whole Blood/Serum/ Plasma)

FOR IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

Both the testing and results are intended to be used by medical and forensic professionals only. The test should not be used without appropriate supervision.

One Step Multi-HBV Test Device is a rapid, qualitative, immunoassay for the determination of HBV Markers (HBsAg, HBeAg, anti-HBs, anti-HBe, and anti-HBc) in human whole blood, serum or plasma in a convenient one step test format.



one test five results

SUMMARY

Hepatitis B virus (HBV) is one of the most common and serious infectious diseases of the world. HBV is the leading cause of liver disease worldwide. More than 350 million people are chronic carriers of HBV.

Three distinct antigen-antibody systems are associated with HBV infection:

- Hepatitis B surface antigen (HBsAg) and its antibody anti-HBs;
- Hepatitis B core antigen (HBcAg) and its antibody anti-HBc;
- Hepatitis B e antigen (HBeAg) and its antibody anti-HBe.

Active HBV infection usually is confirmed by the presence of HBsAg. HBsAg is the first serologic marker to appear, preceding elevation of transaminase levels and persisting throughout the icteric and symptomatic phase of acute infection.

The temporal association between the appearance of anti-HBs and the resolution of symptoms, and the observation that the majority of persons with anti-HBs are protected from reinfection, led to the proposal that anti-HBs is the protective antibody against HBV infection.

Because hepatitis B core antigen (HBcAg) is sequestered within HBsAg, HBcAg is not routinely detectable in patients with HBV infection, but its derivative, the hepatitis B e antigen (HBeAg), can be measured. Antibody to the HBcAg (anti-HBc), on the other hand, is readily demonstrable, beginning 1 to 2 weeks after the appearance of HBsAg and preceding detectable levels of anti-HBs by weeks to months. In some patients, years after infection, anti-HBc remains detectable longer than anti-HBs, so that remote infection is manifest by the presence of anti-HBc in the absence of anti-HBs and HBsAg.

The other readily detectable HBV serologic marker is HBeAg, which appears concomitantly or shortly after HBsAg. Its appearance coincides with the phase of maximal viral replication and reflects the presence of circulating intact virions, DNA polymerase, and HBV DNA. Thus, the principal relevance of HBeAg is as a marker of maximal infectivity. In addition, HBeAg is a marker of active infection. In acute self-limited infections, HBeAg disappears shortly after peak transaminase elevations and before the disappearance of HBsAg. At this point, anti-HBe becomes detectable. In protracted infections, HBeAg may persist, indicating continuing replicative infection. Because HBeAg is present invariably in active infections, testing for its presence is indicated primarily during follow-up of chronic infection. Conversely, the presence of anti-HBe and the absence of HBeAg in chronic HBV infection indicates that the infection probably is nonreplicative.

PRINCIPLE OF THE PROCEDURE

One Step Multi-HBV Test Device consists of 5 chromatographic strips, each strip detects certain HBV marker.

1) Method of HBsAg strip

The method employs unique monoclonal (mouse) antibodies to selectively identify HBsAg in test samples. As the test sample flows through the absorbent device by chromatography, the labeled HBsAg antibody-dye conjugate binds to HBsAg in the specimen forming an antibody:antigen complex. This complex binds to the immobilized antibody in the positive reaction zone and will produce a magenta color band when the concentration of HBsAg is above the detection level of 1ng/ml which is suggested for the immunoassay method. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly. A **NEGATIVE** specimen produces only one distinct color bands in both the test line and control area. A **POSITIVE** specimen produces two color band in the control area. There is no meaning attributed to shades of color or its intensity of either the test line or the control line.

2) Method of anti-HBs strip

The method employs unique antigens to selectively identify HBsAb in test samples. As the test sample flows through the absorbent device by chromatography, the labeled HBsAg -dye conjugate binds to HBsAb in the specimen forming an antibody:antigen complex. This complex binds to the immobilized antibody in the positive reaction zone and will produce a magenta color band when the concentration of HBsAb is above the detection level of 30mIU/ml which is suggested for the immunoassay method. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly. A **NEGATIVE** specimen produces only one distinct color bands in both the test line and control area. A **POSITIVE** specimen produces two color band in the control area. There is no meaning attributed to shades of color or its intensity of either the test line or the control line.

3) Method of HBeAg strip

The method employs unique monoclonal (mouse) antibodies to selectively identify HBeAg in test samples. As the test sample flows through the absorbent device by chromatography, the labeled HBeAg antibody-dye conjugate binds to HBeAg in the specimen forming an antibody: antigen complex. This complex binds to the immobilized antibody in the positive reaction zone and will produce a magenta color band when the concentration of HBeAg is above the detection level of 2NCU/ml which is suggested for the immunoassay method. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly. A **NEGATIVE** specimen produces only one distinct color bands in both the test line and control area. A **POSITIVE** specimen produces two color band in the control area. There is no meaning attributed to shades of color or its intensity of either the test line or the control line.

4) Method of anti-HBe strip

The method employs unique monoclonal (mouse) antibody to selectively identify anti-HBe in test samples. As the test sample flows through the absorbent device by chromatography, the labeled anti-HBe monoclonal antibody-dye conjugate competes with anti-HBe in test sample in the positive reaction zone and will not produce a magenta color band when the concentration of anti-HBe in test sample is above the detection level of 2NCU/ml which is suggested for the immunoassay method. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly. A **NEGATIVE** specimen produces two distinct color bands in both the test line and control area. A **POSITIVE** specimen produces only one color band in the control area. There is no meaning attributed to shades of color or its intensity of either the test line or the control line.

5) Method of anti-HBc strip

The method employs unique monoclonal (mouse) antibody to selectively identify anti-HBc in test samples. As the test sample flows through the absorbent device by chromatography, the labeled anti-HBc monoclonal antibody-dye conjugate competes with anti-HBc in test sample in the positive reaction zone and will not produce a magenta color band when the concentration of anti-HBc in test sample is above the detection level of 2NCU/ml which is suggested for the immunoassay method. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly. A

NEGATIVE specimen produces two distinct color bands in both the test line and control area. A **POSITIVE** specimen produces only one color band in the control area. There is no meaning attributed to shades of color or its intensity of either the test line or the control line.

MATERIALS PROVIDED

- Test Device contained in foil pouch (**Do Not** open before use and if foil package is damaged do not use the device).
- Instructions for use.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection containers.
- Clock or Timer.
- dropper

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional use only.
3. Do not use the test strip beyond the expiration date imprinted on the outside of the foil pouch or if the foil pouch is damaged.
4. Use a new specimen container and dropper for each test to avoid cross contamination of urine samples.
5. Specimens may be infectious. Upon completion of ALL Testing dispose of residual sample in a medically approved manner. Properly handle and dispose of all used reaction devices in an approved biohazard container.
6. Visually inspect the foil package to insure it is intact. If the package is not intact discard the device.

STORAGE AND STABILITY

The reagents supplied can be stored under refrigeration (2° - 8 °)(36°-46°F) **[DO NOT FREEZE]** or at room temperature (18° - 30 °)(65°-85°F) and will be stable until the expiration date.

SAMPLE COLLECTION AND PREPARATION

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.**

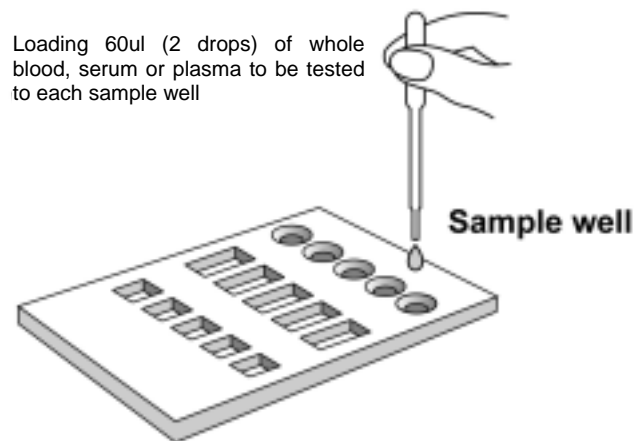
Serum or Plasma

1. Collect serum or plasma specimens following regular clinical laboratory procedures.

- Only those specimens that are clean, clear and with good fluidity can be used for the assay.
- Those specimens that are apparently hemolyzed, extremely thickened or with very high fat level are NOT suitable for the assay.
- 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 collection. 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 PROCEDURE

- Remove the test device from its protective foil wrapper by tearing at the notch. Holding the strip in a vertical position
- Add 60ul (2 drops) of whole blood, serum or plasma to each sample well and simultaneously start timing.
- Read the results after 15 minutes. Test results should not be interpreted after 20minutes.



READING THE TEST RESULTS

1. Positive:

1)HBsAg strip : One magenta band appears on the control region, a magenta band also appears on the test region (lower portion of the read area), This is an indication that the HBsAg level is above the cutoff level of 1 ng/ml.

2)HBeAg strip : One magenta band appears on the control region, a magenta band also appears on the test region (lower portion of the read area), This is an indication that the HBsAg level is above the cutoff level of 2NCU/ml.

3)anti-HBs strip: One magenta band appears on the control region, a magenta band also appears on the test region (lower portion of the read area), This is an indication that the HBsAb level is above the cut off level of 30mIU/ml.

4)anti-HBe strip: One magenta band appears on the control region, No visible band on the test region (lower portion of the read area). This is an indication that the anti-HBe level is above the cutoff level of 2NCU/ml.

5)anti-HBc : One magenta band appears on the control region, No visible band on the test region (lower portion of the read area). This is an indication that the anti-HBc level is above the cutoff level of 2NCU/ml.

2. Negative:

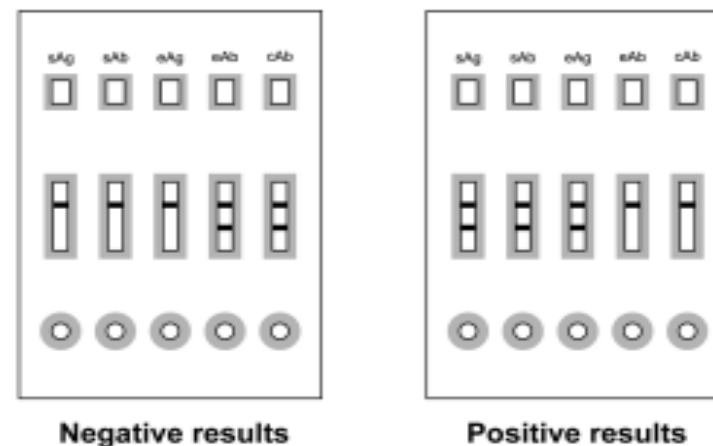
1)HBsAg strip : One magenta band appears on the control region, No visible band on the test region (lower portion of the read area).

2)HBeAg strip : One magenta band appears on the control region, No visible band on the test region (lower portion of the read area)

3)anti-HBs strip: One magenta band appears on the control region, No visible band on the test region (lower portion of the read area).

4)anti-HBe strip: One magenta band appears on the control region, a magenta band also appears on the test region (lower portion of the read area).

5)anti-HBc : One magenta band appears on the control region, a magenta band also appears on the test region (lower portion of the read area).



3. Invalid:

If there are no distinct color bands in both the upper and lower portions of the read area, (lower portion of the strip), or no band in the control region (upper portion of the read area), then the test results are invalid. It is recommended that the specimen be retested.