**i-CHROMA™ Anti-HBs**

**ImmunoAssay for Quantitative Measurement of Hepatitis B virus surface Antibody (HBsAb) in serum or plasma with the i-CHROMA™ Reader system**

**INTENDED USE**

i-CHROMA™ Anti-HBs along with i-CHROMA™ Reader is a fluorescence immunoassay that measures HBsAb in serum or plasma.

**INTRODUCTION**

Viral hepatitis is a serious global health problem affecting over two billion people worldwide, with 350 million suffering from chronic hepatitis infection. The majority of hepatitis viral infections are caused by three distinct virus types: hepatitis A (HAV), hepatitis B (HBV) and hepatitis C (HCV) virus. Approximately one million people die each year worldwide due to cirrhosis of the liver and hepatocellular carcinoma (HCC), which are commonly associated with chronic hepatitis. Hepatitis B is caused by infection with the hepatitis B virus (HBV). Most adults recover completely from HBV infection. However, the risk of developing chronic infection varies inversely with age and is highest for infants infected at birth compared to older children and adults. Up to 90% of infants infected with HBV will develop chronic infection leading to cirrhosis of the liver or HCC compared to 6-10% of adults who acquire HBV infection. Determination of antibodies directed against hepatitis B virus surface antigen (anti-HBs or HBs Ab) is used to evaluate a person’s immune status to HBV infection or to aid in the laboratory diagnosis of hepatitis B infection when used in conjunction with other laboratory methods. The test is performed to assess the need for vaccination (if HBs Ab is absent or below levels considered protective), following completion of vaccination against hepatitis B virus surface antigen (anti-HBs or HBs Ab) is used to evaluate a person’s immune status to HBV infection or to aid in the laboratory diagnosis of hepatitis B infection when used in conjunction with other laboratory methods.

**PRINCIPLE**

i-CHROMA™ Anti-HBs uses a sandwich immuno-detection method, such that the detector antigen in buffer binds to anti-HBsAg in serum or plasma specimen and antigen-antibody complexes are captured to another antigen that has been immobilized on test strip a matrix. The signal intensity of fluorescence of the sample mixture through the nitrocellulose matrix. The signal intensity of fluorescence of the sample mixture through the nitrocellulose matrix. The signal intensity of fluorescence of the sample mixture through the nitrocellulose matrix.

**COMPOSITION OF REAGENTS**

i-CHROMA™ Anti-HBs consists of a test device and a detection buffer in separate containers. The Test Device is individually sealed with a desiccant in the aluminum pouch, and the detection buffer is packed and delivered separately from the Test Device in a styrofoam box filled with ice packs.

- The Test Device contains a test strip in which human HBsAg has been immobilized on the test line, and streptavidin on the control line.
- The detection buffer contains fluorescence-labeled HBsAg, fluorescence-labeled Biotin, BSA as a stabilizer, and Sodium Azide as a preservative in PBS.

**WARNINGS AND PRECAUTIONS**

- IVD For In Vitro Diagnostic Use.
- Carefully follow the instructions and procedures described in this insert. REF Catalog No. HBSB13025
- Do not use the Test Device if its lot # does not match with that on the ID chip to be inserted into the instrument.
- i-CHROMA™ Anti-HBs is only operational in the i-CHROMA™ Reader. And tests should be performed by professionally trained personnel working in certified laboratories. The sample should be taken by qualified medical personnel.
- LOT Do not inter-change materials from different product lots or use beyond the expiration date. The use of medical device beyond the expiration date may affect the result.
- i-CHROMA™ Anti-HBs should remain in its original sealed pouch until ready to use. Do not use the Test Device if the pouch is damaged or the seal is broken. Discard after single use.
- i-CHROMA™ Anti-HBs and Reader should be used away from the mechanical vibration and the excessive magnetic field. During normal usage, i-CHROMA™ Anti-HBs may introduce minute vibration, which should be regarded normal.
- Use separate clean pipette tips and sample vials for different specimens. The pipette tips and sample vials should be used for one specimen only. Discard after single use.
- Blood specimens, used Test Devices, pipette tips and sample vials are potentially infectious. Proper laboratory techniques, handling and disposal methods should be provided in accordance with standard procedures and regulations observed by microbiological hazard materials.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.

**STORAGE AND STABILITY**

- Store the detection buffer in a refrigerator at 2° - 8°C. The detection buffer is stable up to 20 months if stored in a refrigerator under the designated temperature.
- Once removed from refrigerator, allow the detection buffer for 30 minutes to warm it up to the room temperature before testing.
- Store i-CHROMA™ Anti-HBs at 4°-30°C in its sealed pouch. The i-CHROMA™ Anti-HBs is stable for 20 months (while in the sealed pouch) if stored at 4°-30°C.
**Boditech Med Inc.**

**i-CHROMA™ Anti-HBs**

- If stored, if stored in a refrigerator, allow a minimum of 30 minutes for the test device to warm up to the room temperature with the device still in the pouch.
- Do not remove the device from the pouch until ready to use. The test device should be used immediately once opened.
- The storage and shipping of *i-CHROMA™ Anti-HBs* should be complied as indicated in manual. However, it is remotely possible that only part of *i-CHROMA™ Anti-HBs* is affected by stability problems.

**SAMPLE COLLECTION AND PREPARATION**

The test can be performed with either the serum or the plasma specimen.

- For the serum sample, collect the blood in a tube without anticoagulant and allow it to be clotted. Remove the serum from the clot as soon as possible to avoid hemolysis. For the plasma sample, collect the blood in a tube treated with EDTA. Anticoagulants other than EDTA for the plasma specimen have not been evaluated. If testing cannot be conducted within an hour after preparation of the specimen, the serum/plasma should be stored at -20°C until tested. Apply the sample as soon as possible after specimen has been taken.
- The specimen must be at room temperature and be homogeneous before testing. Frozen specimens must be completely thawed, thoroughly mixed, and brought to the room temperature prior to testing. If specimens are to be shipped, they should be packed in compliance with regulations.
- It is recommended not to use excessively hemolyzed specimens whenever possible. If a specimen appears to be excessively hemolyzed, another specimen should be obtained and tested.

**MATERIALS PROVIDED**

Boditech Med Incorporated *i-CHROMA™ Anti-HBs* Test

REF Catalog No. HBSB13025

**Kit contains:**

- test devices: 25T/box
- sample mixing tubes: 25ea/box
- detection buffer: 1vial (2ml/vial)
- ID Chip: 1ea/box
- Insert: 1ea/box

**MATERIALS REQUIRED BUT NOT PROVIDED**

*i-CHROMA™ Reader* REF Catalog No. FR-203

Thermal Printer

Transfer pipette (75µL size)

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**PROCEDURE**

- Image of the test kit

1. Set a test device and an empty sample mixing tube on a dust-free clean surface.
2. Check/insert ID Chip into the instrument. Make sure that the test device lot # matches with that of the ID Chip.
3. Take out the vial of the detection buffer from the refrigerator and leave it at room temperature for 30 minutes or longer.
4. Draw 75µL of serum, plasma or control with a transfer pipette to an empty tube and then add 75µL detection buffer.
5. Mix the specimen and detection buffer thoroughly with the pipette.
6. Take 75µL of sample mixture and load it onto the sample well of the Test Device.
7. Leave the Test Device at the room temperature for 12 min before inserting the device into the holder of the reader.
8. To start the test, insert test device onto the holder of *i-CHROMA™ Reader* and press the “SELECT” button. The instrument will automatically start to scan the test device immediately.
9. Read the results on the display screen of *i-CHROMA™ Reader*.

- Refer to *i-CHROMA™ Reader* Operation Manual for the complete instructions on the use of the reader.

**RESULT**

*i-CHROMA™ Reader* calculates *Anti-HBs* test results automatically and displays *Anti-HBs* concentration on the screen in units mIU/mL. For further information, refer to the Operation Manual for the *i-CHROMA™ Reader*.

**Quality Control**

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- A quality control test using commercially available controls should be performed as a part of good testing practice, to confirm the expected QC results, to confirm the validity of the assay, and to assure the accuracy of patient results.
- A quality control test should be performed at regular intervals. Before using a new kit with patient specimens, controls should be tested to confirm the test procedure, and to verify that tests are producing the expected QC results. QC specimens should also be run whenever there is any question concerning the validity of results obtained. Upon confirmation of the expected results, the Test Device is ready to use with patient specimens.
Control standards are not provided with this test kit. For information about obtaining the controls, contact the technical assistance section at Boditech Med Inc.

Procedure Control

- Each *i*-CHROMA™ Anti-HBs contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the Test Device was inserted and read properly by *i*-CHROMA™ Reader. An invalid result from the internal control causes an error message on *i*-CHROMA™ Reader indicating that the test should be repeated.

LIMITATIONS OF THE PROCEDURE

- The results of *i*-CHROMA™ Anti-HBs should be evaluated with all clinical and laboratory data available. If Anti-HBs Test results do not agree with the clinical evaluation, additional tests should be performed.

- The false positive results include cross-reactions with some components of serum from individual to antibodies; and non-specific adhesion of some components in serum or plasma that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of HBs antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degradation of other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.

- Plasma using anticoagulants (e.g. heparin or citrate) other than EDTA has not been evaluated in *i*-CHROMA™ Anti-HBs and thus should not be used.

- Other factors may interfere with *i*-CHROMA™ Anti-HBs and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

Boditech Med’s expressed and implied warranties (including implied warranties of merchantability and fitness) are conditional upon observance of Boditech Med’s published directions with respect to the use of Boditech Med’s products.

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