SLIDE TEST FOR HEPATITIS B SURFACE ANTIGEN

SUMMARY
Blood containing Hepatitis B virus (HBV) is potentially infectious. In most cases detectable levels of Hepatitis B surface antigen (HBsAg) circulate in the bloodstream of an infected person, two to three weeks prior to the appearance of clinical symptoms. These levels are especially elevated in the symptomatic phase, thereafter the levels slowly decline. Detection of HBV using HBsAg as a marker to screen blood donors is essential to reduce the risk of transmission of Hepatitis B by blood transfusion.

REAGENTS
1. Virutex® HBsAg reagent: A uniform suspension of polystyrene latex particles coated with IgG class of monoclonal Anti-HBsAg antibodies.
2. Positive control, reactive with the Virutex® latex reagent.
3. Negative control, non-reactive with Virutex® latex reagent.

Virutex® HBsAg reagent conforms to the sensitivity requirements of a "Third generation" test. Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY
1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

PRINCIPLE
Latex particles coated with Anti-HBsAg antibodies will agglutinate when mixed with serum or plasma containing Hepatitis B surface antigen within the detectable levels. Agglutination is absent when the Hepatitis B surface antigen is absent or not within the detectable levels.

NOTE
1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and Anti-HIV antibody and are found to be non-reactive. However handle the material as if infectious.
3. Reagent contains 0.1% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or exposure to elevated temperatures. It is recommended that the performance of the reagents be verified by testing with the negative or positive controls provided with the kit.
5. Shake the latex antigen vial gently before use to disperse latex particles uniformly and improve the test readability.
6. Use only a thoroughly clean and dry glass slide. Clean the slide with distilled water and wipe dry before use.
7. Accessories provided with the kit only must be used for optimum results.

SAMPLE COLLECTION AND STORAGE
No special preparation of the patient is required prior to sample collection by approved techniques. Do not use haemolysed samples. Though plasma may be used, fresh serum is preferable. In case of delay in testing, store the samples at 2-8°C for up to 24 hours.

MATERIAL PROVIDED WITH THE KIT
Reagent Pack
Latex reagent coated with Anti-HBsAg antibody, Positive control reactive with the latex reagent, Negative control non-reactive with the latex reagent.

Accessories Pack
Glass slide with six reaction circles, Mixing sticks, Rubber teats, Sample dispensing pipettes.
ADDITIONAL MATERIAL REQUIRED
Test tubes (10 x 75 mm), Pipettes, Isotonic saline, Stop watch, Direct light source.

PROCEDURE
Bring reagent and samples to room temperature before testing.
1. Pipette one drop of sample to be tested onto one of the reaction circles of the glass slide using a sample dispensing pipette, provided with the kit.
2. Prepare a 1:40 dilution (0.05 ml serum + 1.95 ml isotonic saline) of samples to be tested in isotonic saline.
3. Pipette one drop of the diluted sample on the next reaction circle of the glass slide.
3a. In steps 1 and 3 above, carefully aspirate the sample into the dispensing pipette avoiding sample entering the rubber teat and subsequent cross contamination.
4. Place one drop of positive and negative control onto the remaining reaction circles of the slide. (Do not dilute controls).
5. Shake the latex reagent vial gently to uniformly disperse the reagent suspension. Add one drop of the latex reagent to each of the samples and controls on the slide.
6. Mix with separate mixing sticks, spreading the mixture uniformly over the entire reaction circle.
7. Immediately start a stopwatch. Rock the slide gently back and forth, observing for agglutination macroscopically at five minutes.

INTERPRETATION OF RESULTS
1. No agglutination with diluted and neat samples is a negative test result. : HBsAg Absent
2. Agglutination with neat sample but no agglutination with diluted sample is a positive test result. : HBsAg Present (Weak positive)
3. Agglutination with both neat and diluted samples is a positive test result. : HBsAg Present (Moderate positive)
4. Agglutination with diluted sample but no agglutination with neat sample is a positive test result. : HBsAg Present (Strong positive)

REMARKS
1. The positive control has been inactivated at 60°C for 10 hours and is not expected to be infectious.
2. Presence of autoantibodies such as RF and heterophile antibodies may interfere with the test giving a false positive result. Probability of such an occurrence is low (less than 1% of all samples).
3. Since Virutex is only a quick screening test, for confirmation of the results, a confirmatory test should be used.
4. Positive and negative controls should be run with each series of tests and the results compared with unknown specimens to distinguish possible granularity from agglutination.
5. It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.
6. The reusable glass slide should be first immersed in sodium hypochlorite 5% solution and then rinsed with tap water and then distilled water. Wipe thoroughly dry before use.
7. As the biggest risk to laboratory personnel is from uncharacterised random samples, it is strongly recommended that as a safety measure hand gloves should be worn during the entire test procedure.
8. Samples that are contaminated, haemolysed, lipemic or highly icteric may give non specific reactions.

WARRANTY
This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY
2. Data on File: Tulip Diagnostics (P) Ltd.