



# HBsAg (Hepatitis – B surface Antigen)

Cat. No. 101-0460  
Cat. No. 101-0461

Size 50 tests (complete kit)  
Size 100 tests (complete kit)

## PRINCIPLE:

The Hepatitis latex reagent is a suspension of polystyrene latex particles coated with monoclonal antibodies to HbsAg. When HbsAg is present in the sample, the latex suspension changes and a specific agglutination becomes evident. The sensitivity range of this reagent is approximately 20 ng/ml (Paul Ehrlich Institute).

## SAMPLE:

Serum.

Use only fresh serum or serum stored at + 2 °C to +8 °C for no longer than 48 hours. For longer storage freeze the serum.

## REAGENTS:

1. Anti-HbsAg latex reagent
2. Positive Control
3. Negative Control
4. Disposable slides
5. Disposable sticks

All reagents and controls are ready for use and stable up to the expiry date when stored at + 2 °C to +8 °C. Do not freeze any of the reagents.

Shake the latex reagent well before use.

The sensitivity of the test depends on the drop volume (50 µl), do not use others than those provided and place the dropper perpendicular to the slide surface.

## PROCEDURES:

1. Bring the reagents and samples to room temperature and mix the latex reagent well before use. Make sure that the latex reagent is completely suspended.
2. Prepare dilution of serum sample 1:40 by mixing 50 µl of serum with 2 ml of saline solution (40 µl of serum + 1.6 ml 0.9% NaCl).
3. Place 50 µl (one drop) of diluted serum (1:40) onto appropriate cell on slide.
4. Place 50 µl (one drop) of undiluted serum onto another cell on the slide.
5. Place 50 µl (one drop) of each positive and negative control to the appropriate cell on slide. Do not dilute controls.
6. Add a drop of Latex reagent next to the drops of the serum samples and controls.
7. Mix with separate sticks and spread the fluid over the entire area of the cells.
8. Tilt the slide back and forth slowly for 5 minutes
9. Read for the presence or absence of agglutination after the time has been completed.

## INTERPRETATION OF RESULTS

	Undiluted sample (-; -)	Diluted sample (1:40)
<b>Negative</b> -	No agglutination (-)	No agglutination (-)
<b>Positive</b> (low conc.) + (medium conc.) ++ (high conc.) +++	Agglutination (+) Agglutination (+) No agglutination (-)	No agglutination (-) Agglutination (+) Agglutination (+)
Low conc.:	HBsAg concentration < 1µg/mL	
Medium conc.:	HBsAg concentration 1-100 µg/mL	
High conc.:	HBsAg concentration 100µg/mL – to 3.2 mg/mL	

## NOTES:

1. Positive and negative controls should be run with each series and the results compared with the unknown specimens to distinguish possible granularity from agglutination. The positive control should show a distinct agglutination within 5 minutes. The negative control should show a smooth suspension with no visible agglutination after 5 minutes.
2. Though the probability is low (less than 1% of all samples) a false positive reaction (agglutination) might occur due to the presence of other antigens, e.g. Rf. For confirmation of such results a confirmatory test should be used.
3. As with all diagnostic methods, the final diagnosis should not be made on the results of a single test, but should be based on correlation of test results with other clinical findings.
4. The HBsAg positive control has been kept for 10 hours at 60°C and is therefore not expected to be infectious. It should be handled carefully as potentially infectious material.
5. The reagents contain sodium azide as preservative. Do not swallow. Avoid contact with skin and mucous membranes.

## REFERENCES:

1. Crivelli, O.M- Rizzato, J. Clin. Microbiolog.. 14:173-177, 1981.
2. Hollinger, F.B. et al. J. Infec. Dis, 128; 753-760, 1973.
3. Dressman, GR et al. Appli Microb. 24 ; 1001-1002, 1975
4. Wallis, C. Appli. Microb, 21 ; 867-869, 1971.