HEPATITIS B LATEX TEST KIT
LATEX TEST KIT FOR RAPID DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBsAg)

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<td>HB/010</td>
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The PLASMATEC rapid, qualitative, HBsAg test kit is used to determine the presence of low levels of Hepatitis B Surface Antigen (HBsAg) in blood serum or plasma. The test principle utilises the ability of latex particles, coated with HBsAg specific antibodies, to agglutinate in the presence of the Hepatitis B Surface Antigen.

**ASSAY PRINCIPLE:**
Latex particles are coated with rabbit gammaglobulins containing highly purified antibodies to HBsAg. When serum or plasma from an individual infected with HBsAg is mixed with the sensitised particles, a distinct agglutination will occur as a result of antigen-antibody interaction. In the absence of detectable HBsAg in serum or plasma samples, no agglutination will occur. The test is therefore a direct test. The test is a third generation test according to the specifications of the FDA.

**MATERIALS PROVIDED**
1. HBsAg Latex Reagent: (Yellow label) a suspension of latex particles coated with antibodies against HBsAg in a buffer containing 0.1% Sodium Azide.
2. Negative HBsAg control with preservative. (Blue label)
3. Positive HBsAg control with preservative. (Red label)
4. Pipette-stirrers: single use specimen dropper/stirrers
5. Disposable agglutination slide.

**STORAGE AND STABILITY**
The components of this kit are stable until the expiration date of the kit when stored at 2-8°C.

**PRECAUTIONS**
This test is for in vitro diagnostic use only. The reagents must be stored at 2-8°C when not in use. Do not freeze. (See also notes.)

**TEST SPECIMEN**
Preferably use fresh serum, plasma may be used. (See also notes.)

**ASSAY PROCEDURE**
1. Bring the reagents and specimen(s) to room temperature before use.
2. Prepare dilution of serum sample 1:40 by mixing one drop (0.04 ml) of serum with 1.6 ml of saline (0.9% NaCl solution).
3. Place one drop of diluted serum onto a circle of the agglutination slide.
4. Place one drop of undiluted serum onto a circle of the agglutination slide.
5. Place one drop of positive HBsAg control onto an unallocated circle of the slide.
6. Place one drop of negative HBsAg control onto another unallocated circle of the slide.
7. Shake and resuspend the HBsAg latex reagent. Add one drop to each of the test circles of the agglutination slide.
8. Stir with individual Pipette-stirrers, spreading the mixture over the entire area of the test circle.
9. Gently rock the agglutination test slide for five minutes and observe the test circles for agglutination. Interpret the results at five minutes. Extended incubation may result in evaporation and erroneous results.

**INTERPRETATION OF RESULTS**
1. **Strong positive**: Agglutination with both diluted and undiluted serum samples.
2. **Weak Positive**: Agglutination with undiluted serum sample only.
3. **Negative**: No agglutination with either diluted or non-diluted serum samples.

**NOTES**
1. The serum sample should be fresh but it may be stored at 2-8°C for up to 48 hours or at -20°C for longer periods.
2. Though the probability is low, a false positive reaction may occur due to the presence of other antigens i.e. Rheumatoid Factor.
3. The HBsAg Positive control has been heat treated (kept at 60°C for 10 hours) and is therefore not expected to be infectious. However, like all biological material, it should be treated as being potentially hazardous and handled and disposed of accordingly.
4. The reagents contain Sodium azide as a preservative. Do not swallow. Avoid contact with the skin and mucous membrane.
5. As with all diagnostic methods, the results of the test should be considered in conjunction with other clinical data before a final diagnosis is reached.