

NATIONAL INSTITUTE OF BIOLOGICALS

Ministry of Health and Family Welfare

HBsAg PERFORMANCE PANEL (NIB- HBsAg -01/09)

INTENDED USE

This panel of naturally occurring plasma specimens is intended for use by kit manufacturers for evaluating HBsAg detection assays (Rapid/ ELISA) using well characterized specimens. The panel should not be used for any other purpose. Manufacturers, procuring the panels, are required to reflect the results of the in-house tests in the production protocols and certificate of analysis of each batch.

PRODUCT DESCRIPTION

NIB HBsAg Panel No. 01/09 consists of 50 panel positive members and 150 negative members. The plasma members were characterized by using commercially available rapid, ELISA and confirmatory kits. The tests were performed at NIB by individuals who routinely use these test procedures. Ratios > 1 are considered positive. The panel members were tested with EIA for HIV, HCV and syphilis.

No preservative is added.

The panel of 200 members has 0.50 ml per 1 vial for each member.

STORAGE

Panel members should be stored frozen at -20°C or below. Repeated freeze-thaw cycles should be avoided.

PRECAUTIONS

Biohazard caution: Potentially infectious material. Follow universal precautions. The panel should be handled as potentially infectious material. Negative results do not ensure the absence of these or other human pathogens. The material should be disposed off in a manner that will inactivate pathogenic agents.

INTENDED USERS AND CONDITIONS FOR SUPPLY

The panel will be provided to indigenous licensed manufacturers of the kits on production of the following documents: valid license for manufacture.

An undertaking will have to be given by the manufacturer that the panel will be used only for the purpose for which it has been provided. Kits submitted for batch lot release should contain full information of the tests.

Disclaimer: The Institute is not liable for the improper storage and use of the panel by the manufacturer. Batches of the kits will be tested in any designated National Reference Laboratory and the results of the NRL will be final.

NOTE: Kindly Centrifuge the sample at 10000g for 10 minutes before use.

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