

PEI Reference Preparation HBV DNA (#3620/05)

Each vial contains 0.5 ml of lyophilized human Hepatitis B Virus positive plasma representing genotype D, HBsAg subtype ayw2/3.

The reference preparation is intended to be used by NAT assays for the detection of HBV DNA in human plasma samples.

RECONSTITUTION

Before reconstitution the vial should be allowed to equilibrate to ambient temperature.

Each vial should be reconstituted in **0.5 ml of sterile nuclease-free water** and left for a minimum of 10 minutes with occasional agitation before use.

The reconstituted preparation has been assigned a HBV DNA concentration of

80,000 IU/ml (International Units/ml)

STORAGE

The material is supplied lyophilized and should be stored at or below -20°C.

For the preparation of e.g. "Run Controls" dilute the reconstituted material in HBV-negative human plasma or pooled human plasma and store aliquots at or below -70°C.

DETAILED INFORMATION

The reference standard was prepared from human plasma of an HBsAg- and HBeAg-positive carrier.

The material was diluted in HBV-, HCV-, HIV-1-, Parvovirus B19- and HAV-negative pooled plasma and lyophilized in 0.5 ml aliquots.

The PEI Reference Preparation HBV DNA (#3620/05) was calibrated against the WHO International Standard for HBV DNA, NIBSC code 97/746 (Saldanha et al. 2001; Vox Sang 80: 63-71) using four different quantitative NAT assays.

These calibrations resulted in an assigned HBV DNA concentration of **80,000 IU / ml** for the PEI Reference Preparation.

The exact conversion factor IU to “copies” is NAT assay specific. On average 1 IU corresponds to 5 copies.

SAFETY INFORMATION

This preparation contains material of human origin, and contains potentially infectious HBV. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used only by trained personal and discarded according to the national laboratory's safety procedures.

ORDERING AND SHIPMENT INFORMATION

The PEI Reference Preparation HBV DNA (#3620/05) can be ordered by **fax** (+49 6103 77 1280) or **email** (Sigrid.Hanitsch@pei.de, Ines.Amberg@pei.de or Christine.Hanker-Dusel@pei.de), using the PEI Order Form available from our website:

www.pei.de/pei-reference-material

There is a fee of 20 € per vial, and 15 € for packaging (maximum of 20 vials per box).

If you have any questions, please do not hesitate to contact us:

Email: Sigrid.Hanitsch@pei.de

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