1st World Health Organization International Standard for Hepatitis B Virus e Antigen (HBeAg)

PEI code 129097/12

(Version 1.0, September 2013)

1. INTENDED USE

The 1st World Health Organization (WHO) International Standard for hepatitis B virus (HBV) e Antigen is intended to be used in the standardization and calibration of quantitative and/or qualitative diagnostic HBeAg assays and for therapeutic and quality control purposes. The establishment of an international standard is an urgent need in the standardization, harmonization and quality control of serological tests and patient management (1). The standard represents a lyophilized preparation of the PEI HBe-Referenzantigen 82, deriving from HBV positive human serum. The material has been lyophilized in 0.5 ml aliquots and stored at -20°C. The material has been evaluated in an international collaborative study involving 19 laboratories performing 14 different HBeAg assays. Further details of the collaborative study are available in the report WHO/BS/2013.2228.

2. UNITAGE

This reagent has been assigned a unitage of 100 International Units/ml.

3. CONTENTS

Each vial contains 0.5 ml of lyophilized serum containing infectious HBV.

4. CAUTION

THIS PREPARATION IS NOT FOR ADMINISTRATION TO HUMANS.

The preparation contains material of human origin, and contains infectious HBV. It was characterized as follows: high positive for HBV DNA, HBsAg, anti-HBc, anti-HCV, and anti-HAV. HCV RNA was tested positive (<30 IU/ml). The material tested negative for markers anti-HBs, anti-HBc IgM, anti-HBe IgG, HCV core antigen, anti-HIV-1/2 and anti-HDV. This preparation should be regarded as hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures probably will include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

5. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution.

The material is supplied lyophilized and should be stored at or below -20ºC. Each vial should be **reconstituted in 0.5 ml sterile ultrapure water**. The product should be reconstituted just prior to use, once reconstituted, multiple freeze thawing of the product is not recommended. If not all the material is used immediately, laboratories may aliquot the remaining material into suitable volumes which should be stored at or below -20ºC.

6. STABILITY

It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

The reference materials are held at the PEI within assured, temperature-controlled storage facilities. Reference materials should be stored on receipt as indicated on the label. Once, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact PEI.

7. REFERENCES

Reissinger A., Volkers P., Scheiblauer H., Nick S. and the Collaborative Study Group: Collaborative Study to Establish a World Health Organization International Standard for Hepatitis B e Antigen (HBeAg).
WHO Report, WHO/BS/2013.2228

8. ACKNOWLEDGEMENTS

We thank the participants and laboratories staff for their expertise and contribution.

9. FURTHER INFORMATION

Further information for this material can be obtained as follows: whoccivd@pei.de or pei-ivd@pei.de
WHO Biological Reference Preparations:
http://www.who.int/biologicals/en/

10. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to whoccivd@pei.de or pei-ivd@pei.de.

11. CITATION

In any circumstance where the recipient publishes a reference to PEI materials, it is important that the correct name of the preparation, the PEI code number, the name and the address of PEI are cited correctly.

12. MATERIAL SAFETY SHEET

Physical properties (at room temperature)		
Physical appearance:	Lyophilized powder	
Fire hazard:	None	
Chemical properties		
Stable:	Yes	Corrosive:No
Hygroscopic:	No	Oxidising:No
Flammable:	No	Irritant: No
Other (specify): CONTAINS HUMAN SERUM & INFECTIOUS HEPATITIS B VIRUS (HBV)		
Handling:	See caution, section 4	
Toxicological properties		
Effects of inhalation: Avoid – *contains infectious HBV*		
Effects of ingestion: Avoid – *contains infectious HBV*		
Effects of skin absorption: Avoid – *contains infectious HBV*		
Suggested First Aid		
Inhalation:Seek medical advice - *contains infectious HBV*		
Ingestion: Seek medical advice - *contains infectious HBV*		
Contact with eyes: Wash thoroughly with water. Seek medical advice – *contains infectious HBV*		
Contact with skin: Wash thoroughly with water. Seek medical advice – *contains infectious HBV*		
Action on Spillage and Method of Disposal		
Spillage of vial contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.		

13. LIABILITY AND LOSS

Information provided by the Institute is given after the exercise of all reasonable care and skill in its compilation, preparation and issue, but it is provided without liability to the Recipient in its application and use.

It is the responsibility of the Recipient to determine the appropriateness of the materials supplied by the Institute to the Recipient ("the Goods") for the proposed application and ensure that it has the necessary technical skills to determine that they are appropriate. Results obtained from the Goods are likely to be dependent on conditions of use by the Recipient and the variability of materials beyond the control of the Institute.

All warranties are excluded to the fullest extent permitted by law, including without limitation that the Goods are free from infectious agents or that the supply of Goods will not infringe any rights of any third party.

The Institute shall not be liable to the Recipient for any economic loss whether direct or indirect, which arise in connection with this agreement.

The total liability of the Institute in connection with this agreement, whether for negligence or breach of agreement or otherwise, shall in no event exceed 120% of any price paid or payable by the Recipient for the supply of the Goods.

The total liability of the Institute in connection with this agreement, whether for negligence or breach of agreement or otherwise, shall in no event exceed 120% of any price paid or payable by the Recipient for the supply of the Goods.

If any of the Goods supplied by the Institute should prove not to meet their specification when stored and used correctly (and provided that the Recipient has returned the Goods to the Institute together with written notification of such alleged defect within seven days of the time when the Recipient discovers or ought to have discovered the defect), the Institute shall either replace the Goods or, at its sole option, refund the handling charge provided that performance of either one of the above options shall constitute an entire discharge of the Institute's liability under this Condition.

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