WHO 1st International Standard Anti-hepatitis B virus e antigen (anti-HBe) code 129095/12

Instructions for Use (Version 1, October 2013)

1. INTENDED USE

The International Standard was established for determination of the analytical sensitivity of anti-HBe assays. It may also serve for calibration of anti-HBe test kits and for quality control.

A WHO Collaborative Study organised by the Paul-Ehrlich-Institut (PEI) was undertaken to assess the suitability of a candidate international standard (code 129095/12) for antibodies to hepatitis B virus e antigen (anti-HBe) in diagnostic assays. Twenty-one laboratories from 12 countries tested the above described material using 16 different assays.

2. UNITAGE

This material has been assigned a unitage of 120 IU/mL.

3. CONTENTS

Each vial contains 0.5 mL of freeze-dried anti-HBe positive human plasma.

4. CAUTION

This preparation is not for administration to humans. The preparation contains material of human origin, and is infectious for hepatitis B virus (HBV).

Testing for anti-HIV 1/2, anti-HCV, HIV RNA and HCV RNA was negative. The standard is also negative for HBeAg, anti-HBc IgM and anti-HBs. The material should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures 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.

Each ampoule should be **reconstituted with 0.5 mL distilled water**.

6. STABILITY

The standard is supplied lyophilized and should be stored at or below -20°C. 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 They remain valid with the assigned potency and status until withdrawn or amended. Stability of the standard nevertheless is monitored by PEI at regular intervals. The results obtained so far indicate long-term stability at or below -20°C. Also remains of the reconstituted material may be stored at -20°C or below, provided the user determines stability under its own conditions for preparation of the material, storage and use. Multiple freeze/thaw cycles should be avoided.

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

7. REFERENCES

Knauer O., Volkers P., Nick S., Scheiblauer H.: Collaborative Study to establish a World Health Organization International Standard for detection of antibodies to hepatitis B virus e antigen (anti-HBe). WHO Report, WHO/BS/2013.2229.

8. ACKNOWLEDGEMENTS

We thank the participants of the collaborative study for their expertise and contribution.

9. FURTHER INFORMATION

Further information for this material can be obtained as follows: pei-ivd@pei.de or 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 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: CONTAINS INFECTIOUS HEPATITIS B VIRUS (HBV) & HUMAN PLASMA	
Handling: See caution, section 4	
Toxicological properties	
Avoid inhalation , ingestion or skin absorption – *contains infectious HBV*	
Suggested First Aid	
Inhalation and ingestion: Seek medical advice – *contains infectious HBV*	
Contact with eyes or 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. 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.

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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.