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and status until withdrawn or amended.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).

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

<table>
<thead>
<tr>
<th>Physical properties (at room temperature)</th>
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</thead>
<tbody>
<tr>
<td>Physical appearance: Lyophilized powder</td>
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<tr>
<td>Fire hazard: None</td>
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<table>
<thead>
<tr>
<th>Chemical properties</th>
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<tbody>
<tr>
<td>Stable: Yes</td>
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<tr>
<td>Corrosive: No</td>
</tr>
<tr>
<td>Hygroscopic: No</td>
</tr>
<tr>
<td>Oxidising: No</td>
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<tr>
<td>Flammable: No</td>
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<td>Irritant: No</td>
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<table>
<thead>
<tr>
<th>Other:</th>
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<tbody>
<tr>
<td>CONTAINS INFECTIOUS HEPATITIS B VIRUS (HBV) &amp; HUMAN PLASMA</td>
</tr>
<tr>
<td>Handling: See caution, section 4</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Toxicological properties</th>
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<tbody>
<tr>
<td>Avoid inhalation, ingestion or skin absorption</td>
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<td>- contains infectious HBV</td>
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<table>
<thead>
<tr>
<th>Suggested First Aid</th>
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<tbody>
<tr>
<td>Inhalation and ingestion: Seek medical advice – contains infectious HBV</td>
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<tr>
<td>Contact with eyes or skin: Seek medical advice – contains infectious HBV</td>
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<tr>
<td>Wash thoroughly with water. Seek medical advice – contains infectious HBV</td>
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<tr>
<th>Action on Spillage and Method of Disposal</th>
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<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>
13. LIABILITY AND LOSS
Information provided by the Institute is given after the
eexercise 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.

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.