



Non WHO Reference Material
NIBSC HEV IgM Serology Reagent
NIBSC code: 25/B925
Instructions for use
(Version 2.0, Dated 24/01/2025)

This material is not for in vitro diagnostic use

1. INTENDED USE

This reagent is intended for performance monitoring of immunoassays detecting antibodies to HEV IgM.

The reagent is expected to be detected by assays for HEV IgM assays, different batches of the same assay kit, and/or different assay conditions, may give different values with this reagent.

The reagent is not intended to be used for assay calibration purposes, or for in vitro diagnostic use.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

25/B925 has been prepared from a pool of anti-HEV IgM reactive defibrinated plasma donations, repeatedly reactive in commercial EIA kits. The reactive donations used to prepare 25/B925 were non-reactive for HBsAg, anti-HIV1/2 and anti-HCV using commercial EIA kits. The reactive donations were pooled and then diluted in a pool of defibrinated human plasma donations. These samples were non-reactive for HBsAg, anti-HCV and anti-HIV1/2, Anti-HTLV and Anti-Syphilis using commercial EIA kits. Bronidox® was added to a concentration of 0.05%(w/v) as a preservative. As with all materials of biological origin, this preparation 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 should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE

There is no unitage assigned to this product

4. CONTENTS

Country of origin of biological material: United Kingdom.
Ready-to-use reagent
REF 25/B925 1x7mL Blood Tube
Defibrinated Plasma 4mL
Bronidox® 0.05% (w/v)

5. STORAGE

Reagents are to be kept at 2-8°C upon receipt
o Reagents may be stored at 2-8°C until use by date
o Reagents should be divided into measured sub-aliquots of one use and stored below -20°C to avoid freeze/thaw cycles
o Reagents may be stored at -20°C until use by date
o When thawed for use, store at 2-8°C. Once thawed, use within one month and do not refreeze.
Ensure all containers are properly sealed to avoid drying out of the reagent
o Avoid microbial contamination of this product as this may alter product performance
o Avoid excessively high temperatures or humidity

Material type: Liquid – will be shipped according to the storage and shipping conditions of the product

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

Use of this reagent is to be restricted to trained laboratory staff only
2. Use suitable (latex/nitrile) gloves and eye/skin protection
3. Include reagent as a normal sample in routine work list
4. Allow reagent to reach room temperature before use
5. Plot reagent result on a QC chart to monitor performance

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

Stability studies are carried out to ensure stated stability.

9. REFERENCES

10. ACKNOWLEDGEMENTS

11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
<http://www.who.int/biologicals/en/>
JCTLM Higher order reference materials:
<http://www.bipm.org/en/committees/jc/jctlm/>
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
<http://www.nibsc.org/products/ordering.aspx>
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. 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 enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified



Physical and Chemical properties	
Physical appearance: Liquid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	
Toxicological properties	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin
Suggested First Aid	
Inhalation:	Seek medical advice
Ingestion:	Seek medical advice
Contact with eyes:	Wash with copious amounts of water. Seek medical advice
Contact with skin:	Wash thoroughly with water.
Action on Spillage and Method of Disposal	
Spillage of ampoule 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.	

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.

Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: 7g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable.
Attached: No