

Non WHO Reference Material NIBSC HCV IgG Serology Reagent NIBSC code: 25/B923 Instructions for use (Version 1.0, Dated 17/01/2025)

This material is not for in vitro diagnostic use

1. INTENDED USE

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

The reagent is expected to be detected by assays for HCV 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.

Please complete this section manually by typing over this text. 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

Ther is no unitage assigned to this product

4. CONTENTS

Country of origin of biological material: United Kingdom. Ready-to-use reagent REF 25/B923 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

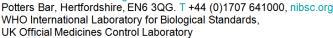
o Avoid excessively high temperatures or humidity

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

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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/jctIm/ 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
Hygroscopi No c:	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other	
(specify):	

Medicines & Healthcare products Regulatory Agency



Toxicological properties		
Effects of inhalation:	Not established, avoid inhalation	
Effects of ingestion:	Not established, avoid ingestion	
Effects of skin	Not established, avoid contact with	
absorption:	skin	
Suggested First Aid		
Inhalation: Seek	medical advice	
Ingestion: Seek	medical advice	
Contact with Wash	with copious amounts of water. Seek	
eyes: medi	cal advice	
Contact with Wash thoroughly with water. skin:		

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

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