Non WHO Reference Material NIBSC Mumps IgG Serology Reagent NIBSC code: 25/B961 Instructions for use (Version 2.0, Dated 10/11/2025)

This material is not for in vitro diagnostic use

1. INTENDED USE

NIBSC Mumps IgG Serology Reagent (25/B961) is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to the mumps virus. The NIBSC Mumps IgG Serology Reagent should be included in each run as part of a continuing quality control programme to monitor the performance of the assay. Data obtained with the 25/B961 can be used to construct quality control charts that can be visually monitored each time the assay is run, to check for consistency of performance of the assay. Examples of how these charts are constructed and used have been described elsewhere 1. 25/B961 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.

2. CAUTION

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

Human Source Material. 25/B961 has been prepared from a pool of anti-Mumps donations repeatedly reactive in commercial EIA kits. The reactive donation used to prepare 25/B961 was non-reactive for anti-HIV, HBsAg and anti-HCV using commercial EIA kits. The reactive donations were then diluted in a pool of defibrinated human plasma samples non-reactive for anti-Mumps. These samples were also non-reactive for HBsAg, anti-HCV and anti-HIV 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 NIBSC Mumps IgG Serology Reagent 1x4mL Nalgene bottles or 1x7mL Blood Tubes

Defibrinated Plasma 4mL

Bronidox® (Sigma-Aldrich) 0.05% (w/v)

5. STORAGE

- o 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 For single use only reagents should be divided into measured aliquots of one use and stored below -20°C to avoid freeze/thaw cycles. Once thawed use immediately.Do not refreeze
- o 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

- 1. 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 STARILITY

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

NIBSC follows the policy of WHO with respect to its reference materials.

Real Time stability studies are carried out to ensure stated stability of this product.

9. REFERENCES

1. Levey, S. and Jennings, E.R. (1950) The use of control charts in clinical laboratories. Am.J.Clin.Pathol. 20, 1059-1066

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.

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14. MATERIAL SAFETY SHEET

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

(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):			
Toxicological properties			
Effects of inhalation: Not		established, a	avoid inhalation
Effects of ingestion: No		established, avoid ingestion	
Effects of s absorption:	skin Not skin		avoid contact with
Suggested First Aid			
Inhalation: Seek medica		al advice	
Ingestion: Seek medica		al advice	
Contact with W	ash with	copious amoi	unts of water. Seek
eyes: m	medical advice		
Contact with W	/ash thoro	ughly with wa	ater.
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: 4g

Toxicity Statement: Toxicity not assessed

Veterinary certificate or other statement if applicable.

Attached: No