Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO Reference Reagent
2nd International Reference Reagent for Measles Vaccine (Live)
NIBSC code: 92/648
Instructions for use
(Version 4.0, Dated 26/02/2008)

1. INTENDED USE

This International standard is the 2nd International Reference Reagent for Measles vaccine (Live), established by the Expert Committee on Standardisation (ECBS) in 1994

2. CAUTION

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

The material is not of human or bovine origin. 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

On the basis of the results of a collaborative study the Committee assigned a titre of 4.3 $\log_{10}$ as titrated on Vero cells, to the contents of each vial. For practical purposes the titre may be taken as the equivalent of 20,000 infectious units per vial.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each vial contains a freeze dried-residue comprising:

- measles virus (Schwartz vaccine strain), prepared on chick embryo fibroblasts
- stabilizer (including dextran and sorbitol)
- neomycin

5. STORAGE

Unopened vials should be stored at -20°C or below

Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Vials have a 'flip-up' circular cap. Either on the cap or the collar of the vial, there is an indication of the point at which to lever off the cap. This exposes an area of the stopper through which reconstitution and withdrawal of the preparation can be made using a hypodermic needle and syringe. If use of a pipette is preferred, then fully remove the metal collar using, for example, forceps, taking care to avoid cuts by wearing appropriate gloves. Remove the stopper for access. Care should be taken to prevent loss of the contents.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

Dissolve the total contents of the vial with 0.5ml of sterile distilled water. Rinse the vial with about 0.4ml of sterile distilled water and make up the total volume to 1.0ml with water. this solution will contain measles virus at a concentration of 20,000 infectious units/ml.

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.

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

9. REFERENCES

World Health Organisation, Expert Committee on Biological Standardisation, (1995) WHO Technical Report Series.

Unpublished document (1994), a copy of which may be obtained by making application to this Institution

10. ACKNOWLEDGEMENTS

Not applicable

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: Lyophilised powder	Corrosive:	No
Stable: Yes	Oxidising:	No
Hygroscopic: Yes	Irritant:	No
Flammable: No	Handling:	See caution, Section 2
Other (specify):	Not applicable	
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.	

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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: 0.1g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biolefstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.