Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO Reference Reagent
1st International Reference Reagent (Low Virus Reference) for MAPREC analysis of poliovirus type 2
NIBSC code: 97/756
Instructions for use
(Version 6.0, Dated 07/12/2015)

1. INTENDED USE

This WHO International Reference Reagent was established by the WHO Expert Committee on Biological Standardisation at its 2003 meeting†.
It is intended to be used as a control to determine whether an individual determination is valid in the MAPREC assay. Each assay should additionally include a high virus control, coded 98/596, and the International Standard 97/758. An individual determination is not valid unless 98/596 gives a fail result and 97/756 gives a pass result compared to 97/758.

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

The assigned mutation value of 0.65% 481-G, is based on WHO collaborative study data for MAPREC Type 2.

4. CONTENTS

Country of origin of biological material: USA.
Each vial contains approximately 0.5ml of a mixture of poliovirus type 2 (Sabin) grown in serum free medium. A suspension of HEp2c grown virus was spiked with Vero grown virus to produce the bulk suspension that was filled as 97/756.

Thermal stabilisers were not added to this preparation

5. STORAGE

The material should arrive frozen. Unopened ampoules should be stored at –70°C or below. Repeated freeze-thawing should be avoided.
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

This material is supplied for use in its final form and should be used as specified in the current version of the Standard Operating Procedure for the MAPREC Assay which is available from Chief, BLG, WHO, Geneva.

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

1.WHO (2002) WHO Technical Report Series, 904, 31-91.
2.European Pharmacopoeia, 5th Edition (2006) Vaccines for human use, Poliomyelitis vaccine oral 01-2006:0215.

† 'Proposal to establish a new International Standard and three new International Reference Preparations for the MAPREC Test of Poliovirus Type 2. Report of a WHO Collaborative Study.' WHO Expert Committee on Biological Standardization (53rd : 2003, Geneva).

10. ACKNOWLEDGEMENTS

We acknowledge the help of the participants of the MAPREC type 2 Collaborative Study.

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

Physical and Chemical properties			
Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: **Not applicable or not classif** Physical appearance: Liquid		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling: Section 2	See caution,
Other (specify):	None		
Toxicological properties			
Effects of inhalation:	Not established, avoid inhalation		
Effects of ingestion:	Not established, avoid ingestion		

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

World Health Organization

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: 1.0g
Toxicity Statement: Toxicity not assessed
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.