Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
1st International Reference DNA for MAPREC analysis of poliovirus type 2 (Sabin)
NIBSC code: 98/524
Instructions for use
(Version 4.0, Dated 25/03/2008)

1. INTENDED USE

This WHO International Reference DNA was established by the WHO Expert Committee on Biological Standardisation at its 2003 meeting†.
98/524 is control DNA for the MAPREC assay of polio virus type 2 (Sabin) and is intended to be used as a validation sample for the assay. It is used to control the performance of the restriction enzyme used in the assay. Bsp 1286I, for example, should digest this sample completely but assay conditions may reduce the efficiency of digestion. Conditions of restriction enzyme digestion should be optimized with this sample and monitored for consistency thereafter.

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 preparation 98/524 is 100% 481-G.

4. CONTENTS

Country of origin of biological material: USA.
Each DIN ampoule contains the freeze-dried residue of chemically synthesized DNA that spans nucleotides 431-521 of type 2 poliovirus (Sabin) RNA. The DNA was prepared at a nominal concentration of 0.01µg/ml in TE buffer pH7.5 (10mM Tris-HCl and 1mM EDTA) and 0.1% w/v lactose was added as a bulking agent prior to freeze-drying.

5. STORAGE

Unopened ampoules should be stored at -20°C or below.
Rehydrate preparation 97/758 in 0.1ml of distilled water. Aliquot the rehydrated material in 10µl volumes, to avoid repeated freeze-thawing, and store at -70ºC.
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
A Standard Operating Procedure for the MAPREC assay is available from; Chief. Biologicals, World Health Organisation. A Standard Operating Procedure for the MAPREC assay is available from; Chief, Biologicals, World Health Organization. This procedure requires that an aliquot of 98/524 is tested in each MAPREC assay and is used to validate the test.

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)Please complete this section manually by typing over this text

10. ACKNOWLEDGEMENTS

We thank the participants of the MAPREC type 2 WHO 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 classifie Physical appearance: white solid		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		
Effects of skin absorption:	Not established, avoid contact with skin		

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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: 0.1g
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.