



**WHO International Standard  
1st International Standard for MAPREC analysis of poliovirus type  
3 (Sabin) DNA 0.9% 472-C  
NIBSC code: 95/542  
Instructions for use  
(Version 3.0, Dated 17/03/2008)**

**1. INTENDED USE**

This International Standard is the primary biological standard for the MAPREC assay of poliovirus type 3 (Sabin). Preparation 95/542 is intended to be used as a concurrently tested reference to determine whether the monovalent poliovirus type 3 (Sabin) bulk passes or fails the MAPREC assay. It may also be used to calibrate consistency assays of poliovirus vaccine production that are assessed by the MAPREC test.

**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 a WHO collaborative Study, preparation 95/542 is assigned a value of 0.9% 472-C

**4. CONTENTS**

Country of origin of biological material: USA.  
Each DIN 58-377 ampoule contains the freeze-dried residue of chemically synthesised DNA that spans nucleotides 421-513 of type 3 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 95/542 in 0.1ml of distilled water. Aliquot the rehydrated material in 10µl volumes and store at -70°C.

**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 Organization. This procedure requires that two aliquots of 95/542 are tested in each MAPREC assay and used to calibrate 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.

**10. ACKNOWLEDGEMENTS**

We thank the participants of the WHO collaborative study for their help.

**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](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](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: White solid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
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
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](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**

<b>Country of origin for customs purposes*:</b> 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.
<b>Net weight:</b> 0.1g
<b>Toxicity Statement:</b> Toxicity not assessed
<b>Veterinary certificate or other statement</b> if applicable. <b>Attached:</b> 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\\_biologicalstandardsrev2004.pdf](http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biologicalstandardsrev2004.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.