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.
Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure that the disposable ampoule safety breaker provided is correctly engaged, holding the plastic collar.
End stress point, primarily using the hand holding the plastic collar.
Care should be taken to avoid cuts and projectile glass fragments that might enter the eyes, for example, by the use of suitable gloves and an eye shield. Take care that no material is lost from the ampoule and no glass falls into the ampoule. Within the ampoule is dry nitrogen gas at slightly less than atmospheric pressure. A new disposable ampoule breaker is provided with each DIN ampoule.

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

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/
JCITLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jciltm/
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

<table>
<thead>
<tr>
<th>physical and Chemical properties</th>
<th>Corrosive</th>
<th>Oxidising</th>
<th>Irreptant</th>
<th>Handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: White solid</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>See caution, Section 2</td>
</tr>
<tr>
<td>Stable:</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Hygroscopic:</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Flammable:</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Other (specify):</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Inhalation:</th>
<th>Seek medical advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion:</td>
<td>Seek medical advice</td>
</tr>
<tr>
<td>Contact with eyes:</td>
<td>Wash with copious amounts of water. Seek medical advice</td>
</tr>
<tr>
<td>Contact with skin:</td>
<td>Wash thoroughly with water.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Country of origin for customs purposes*: United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 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.</td>
</tr>
<tr>
<td>Net weight:</td>
</tr>
<tr>
<td>Toxicity Statement:</td>
</tr>
<tr>
<td>Veterinary certificate or other statement if applicable:</td>
</tr>
</tbody>
</table>

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_biolrefstandardsrev2004.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.