



**WHO International Standard
3rd International Standard Anti-Poliovirus serum Types 1, 2 and 3
NIBSC code: 82/585
Instructions for use
(Version 3.0, Dated 11/03/2008)**

PRODUCT SUMMARY FOR THE PROPOSED 3RD INTERNATIONAL STANDARD FOR ANTI-POLIOVIRUS SERUM TYPE 1, 2, and 3.	
Presentation	Ampoule
Excipients/additives	Cortisol
Coefficient of variation of liquid fill	0.53%

1. INTENDED USE

The dual International Standard for anti-measles and anti-polio sera (2nd International Standard Anti-Measles serum (Human)/ 2nd International Standard for anti-poliovirus serum types 1, 2, and 3: NIBSC Code 66/2020 was established by the Expert Committee on Biological Standardization of the World Health Organization in 1991 (Wood and Heath 1991)

Stocks of the above are now exhausted and a collaborative study was run in 2005/2006 to establish a replacement. The 3rd International Standard was established by ECBS in 2006 (WHO, 2007) and is available from NIBSC.

The 3rd International Standard serum is the primary material for the assay of human serum containing antibodies to the three poliovirus serotypes. The methodology used to assess the standard was a neutralizing antibody assay, with constant virus-varying serum (WHO/VSQ97.94) The report of this study is WHO/BS/06.2038, and is available from Access to Technologies (V&B ATT), World Health Organization, CH.1211, Geneva, Switzerland.

2. CAUTION

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

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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 reconstituted material will contain the following amounts of International units (IU):

- 11 IU of neutralizing antibody to poliovirus type 1
- 32 IU of neutralizing antibody to poliovirus type 2
- 3 IU of neutralizing antibody to poliovirus type 3

It is recommended the contents of each vial be reconstituted in volume 1.0ml of sterile distilled water

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains a freeze-dried residue comprising (under an atmosphere of nitrogen) human serum containing antibodies against poliovirus types 1, 2, and 3. Each ampoule should be reconstituted in 1ml of distilled water.

Preparation of the Standard

The 3rd IS (NIBSC number 82/585) was produced from pooled human sera received at NIBSC on 02/09/82. The material was filled, lyophilized and sealed into ampoules by the Division of Biological Standards at NIBSC on the 25/11/82. The serum was spiked with Cortisol as the material was destined for use as a BCR cortisol reference material but was never established

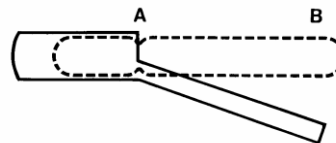
5. STORAGE

The material has been stored at -20°C since production. It is recommended that samples be used as soon after receipt as possible..

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

6. DIRECTIONS FOR OPENING

Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure ampoule is scored all round at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement before attempting to open. Place the ampoule in the ampoule opener, positioning the score at position 'A'; shown in the diagram below. Surround the ampoule with cloth or layers of tissue paper. Grip the ampoule and holder in the hand and squeeze at point 'B'. The ampoule will snap open. Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.



Side view of ampoule opening device containing an ampoule positioned ready to open. 'A' is the score mark and 'B' the point of applied pressure.

7. USE OF MATERIAL

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

After re-constitution samples may be aliquotted and stored frozen (ideally at -70°C) for further use. Studies have shown that reconstituted samples are stable for up to 28 days at this temperature. For longer periods of storage recipients should use their own in-house criteria to determine the length of time which reconstituted samples can be retained.

Please note that the 3rd IS is provided as a reference reagent for calibrating your own in-house reference material(s). With this in mind recipients should remember that the supply of this reagent will be limited to 3 vials per organization per year.

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

The report of this study is WHO/BS/06.2038, and is available from Access to Technologies (V&B ATT), World Health Organization, CH.1211, Geneva, Switzerland.

10. ACKNOWLEDGEMENTS

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: Freeze dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains material of human origin
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 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: 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_biol_standardsrev2004.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.