Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

**WHO Reference Reagent**
**Human Monoclonal Antibody for Poliovirus Type 2**
**NIBSC code: 20/252**
**Instructions for use**
**(Version 1.0, Dated 05/01/2023)**

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## 1. INTENDED USE

WHO Reference Reagent, Human Monoclonal Antibody for Poliovirus Type 2 was established by the WHO Expert Committee on Biological Standardisation (ECBS) in October 2022. It is intended for use in an ELISA as a coating antibody for the D-Antigen potency testing of Type 2 Poliovirus in Inactivated Poliovirus Vaccines.

## 2. CAUTION

**The material is not of human or bovine origin. This preparation is not for administration to humans or animals**

## 3. UNITAGE

0.25 mg/ampoule

## 4. CONTENTS

Country of origin of biological material: United Kingdom.
Lyophilised material, each vial should be reconstituted in 0.5ml of sterile distilled water.

## 5. STORAGE

This material should be stored at -20°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
This product is intended for use as a coating antibody in an ELISA to calculate the D-Antigen content of the Type 2 component in Inactivated Poliovirus Vaccines. This antibody should be used in accordance with the SOP - see report for details. End users should validate reagents for their own specific use.

## 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

Report on the WHO collaborative study to establish Universal Reagents for the D-Antigen potency testing of Inactivated Polio Vaccines. WHO/BS/2022.2432

## 10. ACKNOWLEDGEMENTS

The participants of the 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

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

| **Physical and Chemical properties** | |
|---|---|
| Physical appearance: Powder | Corrosive: No |
| Stable: Yes | Oxidising: No |
| Hygroscopic: Yes | Irritant: No |
| Flammable: No | Handling: See caution, Section 2 |
| Other (specify): N/A | |
| **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. |

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

World Health Organization

| 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**

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|---|
| **Country of origin for customs purposes*:** United Kingdom<br>* 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:** 0.5g |
| **Toxicity Statement:** Toxicity not assessed |
| **Veterinary certificate or other statement** if applicable.<br>**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.