

WHO International Standard 1st International Standard for anti-EV-D68 serum NIBSC code: 20/172 Instructions for use (Version 1.0, Dated 30/08/2022)

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1. INTENDED USE

WHO International Standard (IS) for anti-Enterovirus D68 (EV-D68) serum was established by the WHO Expert Committee on Biological Standardisation (ECBS) in April 2022. It is intended to aid in the evaluation of the immunogenicity of EV-D68 vaccines and for the assessment of the seroprevalance of human populations against EV-D68.

2. CAUTION

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. This preparation is not for administration to humans or animals

3. UNITAGE

1000 EV-D68 International units (IU) per ampoule.

4. CONTENTS

Country of origin of biological material: United Kingdom. Lyophilised material, each vial should be reconstituted in 0.4ml 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 freezedried material prior to reconstitution

This product is intended for use in immunogenicity assays. It is supplied lyophilised and should be resuspended in 0.4ml of sterile distilled water.

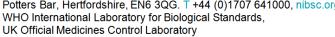
8. STABILITY

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

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





Report on the WHO collaborative study to establish the 1st International Standard for anti-EV-D68 serum (Human). WHO/BS/2022.2418

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 | | |
| Hygroscopi | Yes | | Irritant: | No | | |
| C: | | | | | | |
| Flammable: | No | | Handling: Se | e caution, Section 2 | | |
| Other | Contain | tains material of human origin | | | | |
| (specify): | | | | - | | |
| Toxicological properties | | | | | | |
| Effects of inhalation: Not | | established, a | void inhalation | | | |

| Effects of inhalation: | | tion: | Not established, avoid inhalation | | |
|------------------------|----|-------|-------------------------------------|--|--|
| Effects of ingestion: | | | Not established, avoid ingestion | | |
| Effects | of | skin | Not established, avoid contact with | | |
| absorption: | | | skin | | |

Suggested First Aid

| Inhalation: | Seek medical advice | | | |
|--------------|------------------------------------------|--|--|--|
| Ingestion: | Seek medical advice | | | |
| Contact with | Wash with copious amounts of water. Seek | | | |
| eyes: | medical advice | | | |
| Contact with | Wash thoroughly with water. | | | |
| skin: | | | | |







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: 0.4g | | | |
| 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_l nter_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.

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