



**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 seroprevalence 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 freeze-dried 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](http://nibsc.org)  
WHO International Laboratory for Biological Standards,  
UK Official Medicines Control Laboratory

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](mailto: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](mailto: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): 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](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\\_1nter\\_biolefststandardsrev2004.pdf](http://www.who.int/bloodproducts/publications/TRS932Annex2_1nter_biolefststandardsrev2004.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.