



WHO International Standard
1st IS for Anti-Typhoid capsular Vi polysaccharide IgG (Human)
NIBSC code: 16/138
Instructions for use
(Version 5.0, Dated 23/01/2024)

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1. INTENDED USE

The International standard (IS) 16/138 contains human Ig directed against Vi capsular polysaccharide (Vi) of *Salmonella enterica* subspecies *enterica* serovar Typhi [1]. Seven laboratories assessed the suitability of IS 16/138 as a reference alongside U.S. reference reagent Vi-IgGR1, 2011 and NIBSC 10/126 in three ELISA formats: the VaccZyme ELISA (Binding Site), a biotinylated Vi ELISA developed at NIBSC and 7 in-house ELISAs based on locally prepared Vi [1,2]. The outcomes of the collaborative study (assay validity, variability in potency estimates, agreement between methods and laboratories) were similar for IS 16/138, 10/126 and Vi-IgGR1, 2011. Indirect, in-house ELISAs (which use a protein in a pre-coating or co-coating step) of native Vi are commutable with the VaccZyme ELISA. The intended use of IS 16/138 is for standardisation of Vi serology and Vi immuno assays used in clinical trial studies of Vi vaccines.

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

Arbitrary unitage of 100 IU anti-Vi IgG per ampoule was assigned to IS 16/138 [1].

4. CONTENTS

Country of origin of biological material: United Kingdom.
Ampoules of 16/138 contain 1 mL of freeze dried pooled serum and are stored at -20°C. The pool consists of post-vaccination sera from 9 volunteers immunized with Vi Tetanus Toxoid conjugate and 7 volunteers immunised with plain Vi. The material is free from antibodies to HIV1 and HIV2, Hepatitis C RNA and Hepatitis B surface antigen.

5. STORAGE

On receipt, store ampoules at -20°C. It is recommended that reconstituted material is held for no longer than one week at 4°C. Unused contents should be aliquotted and frozen at or below -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

The material should be reconstituted with 1.0 ml distilled water immediately before 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

- Rijpkema S, Hockley J, Logan A, Rigsby P, Atkinson E, Jin C, Goldblatt D, Liang H, Bachtiar NS, Yang JS, Goel A, Ramasamy V, Pasetti MF, Pollard AJ and the anti-Vi IgG working group. Establishment of the first International Standard for human anti-typhoid capsular Vi polysaccharide IgG. *Biologicals* 2018;56:29-38
- Szu SC, Hunt S, Xie G, Robbins JB, Schneerson R, Gupta RK, Zhao Z, Tan X. A human IgG anti-Vi reference for *Salmonella typhi* with weight-based antibody units assigned. *Vaccine* 2013;31:1970-1974.

10. ACKNOWLEDGEMENTS

We are grateful to volunteers of the VAST B study organised by the Oxford Vaccine Group for their donation of sera. We thank J Cipollo (CBER/FDA, Dep Health & Human Services, USA) for making U.S. reference Vi-IgGR1, 2011 available. Drs D Goldblatt, L-F Ma and D Steele of the Bill and Melinda Gates Foundation are thanked for their guidance and support.

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: off white dry powder	Corrosive:	No		
Stable:	Yes	Oxidising:		
Hygroscopic:	Yes	Irritant:		
Flammable:	No	Handling: See caution, Section 2		
Other (specify):	Contains human sera			
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: 0.0829 g
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_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.