



**WHO International Standard
1st International Standard for anti-Asian lineage Zika virus
antibody (human)
NIBSC code: 16/352
Instructions for use
(Version 1.0, Dated 16/11/2018)**

1. INTENDED USE

The WHO 1st International Standard for anti-Asian lineage Zika virus antibody is the freeze-dried equivalent of 0.25 mL of pooled serum obtained from six individuals tested positive for Zika infection, kindly donated by the National Health Service Blood and Transplant (NHSBT), United Kingdom. The preparation has been evaluated in a WHO International collaborative study (1). The intended use of the International Standard is for the standardization and calibration of neutralisation assay against Asian lineage Zika virus. The preparation contains antibodies reactive to Dengue virus, and possibly other arboviruses which have not been investigated; therefore, 16/352 cannot be used for the validation of cross reactivity to other arboviruses by Zika antibody. The material has not been heat inactivated.

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 WHO Expert Committee for Biological Standardization (ECBS) adopted the NHSBT preparation (NIBSC code 16/352) as the WHO 1st International Standard for anti-Asian lineage Zika virus antibodies with an assigned potency of 250 IU/ampoule. When reconstituted in 0.25 mL of distilled water, the final concentration of the preparation for calibration purposes is 1000 IU/mL.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze-dried equivalent of 0.25 mL pooled human serum.

5. STORAGE

16/352 should be stored at -20C or below upon receipt.
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Care should be taken to prevent loss of the contents.
The ampoules have an "easy-open" coloured stress point, where the narrow ampoule stem joins the wider ampoule body.
Tap the ampoule gently to collect the material at the bottom (labeled) end. Ensure that the disposable ampoule safety breaker provided is pushed down on the stem of the ampoule and against the shoulder of the ampoule body. Hold the body of the ampoule in one hand and the disposable ampoule breaker covering the ampoule stem between the thumb and first finger of the other hand. Apply a bending force to open the ampoule at the coloured stress point, primarily using the hand holding the plastic collar.
Care should be taken to avoid cuts and projectile glass fragments that might enter the eyes, for example, by the use of suitable gloves and an

eye shield. Take care that no material is lost from the ampoule and no glass falls into the ampoule. Within the ampoule is dry nitrogen gas at slightly less than atmospheric pressure. A new disposable ampoule breaker is provided with each DIN ampoule.

7. USE OF MATERIAL

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

This material should be reconstituted in 0.25 mL sterile distilled water. Following addition of water, the ampoules may be left at ambient temperature for approximately 30 minutes until dissolved and then mixed thoroughly, avoiding the generation of excessive foam.

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

1) M. Page et al. WHO collaborative study to assess the suitability of the 1st International Standard for antibody to Zika virus. 2018, WHO Expert Committee for biological Standardization . WHO/BS/2018.2345

10. ACKNOWLEDGEMENTS

We gratefully acknowledge the important contributions of the collaborative study participants. We would also like to thank NIBSC Standards Production and Development for distribution of the candidate materials. We also thank David Wood, Micha Nuebling and Ivana Knezevic of the WHO and participants of teleconferences for their support, guidance and advice.

Reference panel materials were kindly donated by Hua Wu, Eddie Sullivan (SAB Biotherapeutics, Sioux Falls, South Dakota, USA); Joseph Mauro, (Boca Biolistics, Florida, USA); Barney Graham Julie Ledgerwood (Vaccine Research Center, Bethesda, USA); Richard Brindle (Caribbean Public Health Agency, Trinidad and Tobago);; Ines Ushiro-Lumb (National Health Service Blood and Transplant, Colindale, UK).

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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

based on the report of the international collaborative study which established their suitability for the intended use.

Physical and Chemical properties	
Physical appearance: Freeze-dried	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	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.
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: 0.25g
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_biologicalstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS)