Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Working Standard
Working reagent for anti-Zika virus antibody
NIBSC code: 16/320
Instructions for use
(Version 1.0, Dated 22/11/2018)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The working standard for anti-Zika virus antibody consists of the freeze-dried equivalent of 0.25 mL of pooled plasma obtained from two donations tested positive for Zika infection, kindly provided by Joseph Mauro from Boca Biolistics, Florida, USA. The preparation has been evaluated in parallel to the WHO 1st International Standard for anti-Asian lineage Zika virus antibody in an International collaborative study (1). The preparation contains antibodies reactive to Dengue virus, and possibly other arboviruses which have not been investigated; therefore 16/320 is not suitable for the validation of cross reactivity to other arboviruses by Zika antibody.
The material has been solvent detergent treated (2).

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

16/320 was calibrated as part of the collaborative study for the establishment of the WHO 1st International Standard for anti-Asian lineage Zika virus antibody (NIBSC cat no. 16/352) (1) and was found to have an unitage of 2756 IU/mL, with 95% confidence limits of 2003 to 3792 in neutralisation assay, when recostituted with 0.25 mL of water as indicated in paragraph 7.

4. CONTENTS

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

5. STORAGE

16/320 should be stored at -20ºC 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

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.
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.

16/320 is a working reagent for measuring antibody titre of serological sample by neutralisation assay and report the results as IU/mL. If other in-house working reagents are used, they should be calibrated against the WHO International Standard (NIBSC 16/352).

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
2) Wilkinson, D.E., et al., WHO collaborative study to assess the suitability of an interim standard for antibodies to Ebola virus. 2015. WHO Expert Committee for Biological Standardization. WHO/BS/2015.2280 post-ECBS

10. ACKNOWLEDGEMENTS

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We also thank Steven A. Rubin, Swati Verma, Hira Nakhasi and Uwe Scherf (FDA/CBER, USA) for facilitating the sample permits and shipments to laboratories in the USAt

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
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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: 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: 0.25 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

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