Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Zika Virus Working Reagent for Nucleic Acid Amplification Testing (NAT).
NIBSC code: 16/110-XXX
Instructions for use
(Version 2.0, Dated 07/10/2020)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The Non-WHO Reference Material for Zika Virus NAT assays 16/110-XXX consists of a dilution of Zika Virus in human plasma negative for HBsAg, anti-HCV, anti-HIV, anti HTLV1&2 and syphilis. The standard has been lyophilised in 1.0ml aliquots.

THIS MATERIAL IS NOT AN INTERNATIONAL STANDARD.

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

This material was calibrated as part of the collaborative study for the First International Standard for Zika Virus and was found to have a unitage of 5.49E+06 Units/ml with a 95% confidence range of 1.46E+06 to 2.06E+07

4. CONTENTS

Country of origin of biological material: United Kingdom.
The Zika virus working reagent consists of tissue culture supernatant from Vero (WHO) cells (ECACC: 88020401) infected with Zika virus obtained from the National Collection of Pathogenic Viruses (NCPV) (cat number 1308258v). The supernatant is diluted in normal human plasma. The virus has been heat inactivated and should be reconstituted in 1.0mls of sterile distilled water.

5. STORAGE

The control should be delivered at ambient temperature and then stored at -20°C until use. The material should be reconstituted once and not refrozen. Once reconstituted each vial should be stored between +2°C and +8°C and used within five days. After this point the material should be discarded. Users are encouraged to inform NIBSC of the performance of this preparation from reviews of their data monitoring. Any user who has data supporting the deterioration in the characteristics of any reference preparation is encouraged to contact NIBSC.
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

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

This Reference Material should NOT be used to calibrate in-house standards or working reagents. For this purpose the International Standard should be used, for example, by determining the titres of the reagent to be calibrated and the International Standard in parallel. All criteria of assay validity set by individual kit manufacturers should be satisfied.

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 and Section 5.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

None

10. ACKNOWLEDGEMENTS

None

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: Freeze dried powder		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Not applicable		

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

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

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

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UK Official Medicines Control Laboratory