Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
2nd WHO International Standard for Human Immunodeficiency Virus type 2 RNA for Nucleic Acid Amplification Techniques
NIBSC code: 16/296
Instructions for use
(Version 1.0, Dated 04/12/2018)

1. INTENDED USE

HIV-2 was first isolated in 1986 by the Paris Pasteur Institute from an endemic region in West Africa. Sooty mangabeys carrying SIVsmm, were found to be the origin of HIV-2 in humans. Nine distinct lineages, A-I, have since been isolated, endemic groups are A, B and a circulating recombinant form CRF01_AB. Nucleic acid Amplification Techniques (NAT) are the most widely used and the most sensitive method for the detection of HIV-2 RNA in human serum and plasma. NAT is routinely used to manage HIV infections and there remains a risk of transfusion-transmitted infection due to window-period donations. A range of NAT-based methods are available for the detection and quantification of HIV-2 RNA, including both commercial and laboratory-developed assays.

Following the establishment of the 1st WHO IS for HIV-2 RNA, many users contacted NIBSC stating that this titre is too low for calibration purposes. It was therefore proposed to formulate a higher titre replacement material. The intended use of this standard will be to calibrate secondary HIV-2 NAT standards for onward calibration of HIV-2 NAT assays, by a range of laboratories including kit manufacturers, blood fractionators, reference laboratories, diagnostics labs, EQA providers and OMCL's.

This preparation has been heat inactived.

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 reagent has been assigned a unit of 144200 IU/Vial (~5.16 Log10 IU/Vial).

4. CONTENTS

Country of origin of biological material: UK
The plasma used to dilute this product was sourced from the UK Blood Transfusion Service, the viral isolate (HIV-2 CAM2) was heat inactivated at 60C for 1hr and then spiked into human plasma at the required concentration .

5. STORAGE

This prodcut may be shipped at ambient temperature but should be stored at -20C on reciept.
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 material should be reconstituted using 0.5 ml of molecular grade water, it would be left for at least 20minutes with occasional gentle agitation. The product should be reconsitued just prior to use, freeze thawing of the product once reconstituted is not recommended.

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

Accelerated thermal degradation tests have been carried out at NIBSC are are avaible in the ECBS report referenced below.

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

9. REFERENCES

WHO/BS/2018.2343 2nd HIV-2 WHO International Standard.

10. ACKNOWLEDGEMENTS

We thank all the participants that took part in the collaborative study to eastblish this material as a WHO International Standard.

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: Lyophilised		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):			

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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: 0.5g
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.