Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO Reference Reagent
1st WHO International Reference Panel for Parvovirus B19 Genotypes for NAT based assays
NIBSC code: 09/110
Instructions for use
(Version 1.0, Dated 10/03/2010)

1. INTENDED USE

Based upon DNA sequence analysis, parvovirus B19 (B19V) can be divided into three main genotypes (1-3) and sub-genotypes which vary by up to 15% nucleotide identity (Servant et al.,2002; Toan et al., 2006; Parsyan et al., 2007). The International Committee on Taxonomy of Viruses has classified prototype viruses representing each the genotypes as species of B19V according to both their biological properties and sequence analysis. Many NAT assays have only been able to detect genotype 1 B19V, and whilst methodologies have improved, some assays still fail to detect variant viruses or under quantify viral loads. Because of these issues the WHO agreed that there was a need to develop a reference panel of well characterized samples for B19V. The panel has been evaluated in an international collaborative study and the panel members with concurrent testing of the 2nd WHO International Standard for parvovirus B19 DNA (99/802).

The 1st WHO International Reference Panel for parvovirus B19 (B19V) genotypes for nucleic acid amplification technique (NAT)-based assays, 09/110, consists of a four different panel members (Members 1-4). Members 1, 2, and 3 consists of a genotype 1, genotype 2, genotype 3a B19V positive plasma samples. Member 4 is a negative plasma sample. Each of the high titre B19V positive stocks have been diluted in a pool of defibrinated human source plasma where each individual unit has been tested and found negative for the following markers: HIV-1 RNA, HAV RNA, HBV DNA, HCV RNA, B19V DNA, WNV RNA, anti-HIV-1/2, anti_HCV, HBsAg, anti-HBc (IgG and IgM, Abbott Corzyme) and anti-B19V (IgG and IgM,Biotrin). Materials for the formulation of the panel were kindly provided by CSL Behring, Baxter BioScience, Talecris Biotherapeutics and the National Genetics Institute.

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

In the international collaborative study (based upon data returned by 27 laboratories from quantitative assays), the geometric means of the panel Members 1-3 were determined and are given below. The minimum and maximum ranges for the reported values for each panel member are indicated in brackets.

Member 1 5.98 log10 IU/ml (5.61-6.32 log10 IU/ml)
Member 2 5.94 log10 IU/ml* (5.43-6.52 log10 IU/ml)
Member 3 5.97 log10 IU/ml** (5.21-6.54 log10 IU/ml)

*Two laboratories obtained estimates below this value for Member 2.
**Three laboratories found Member 3 negative.
The values were obtained by comparison to the genotype 1 International Standard using current assays represented in the collaborative study.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each vial contains 1.1 ml of plasma. Members 1, 2 and 3 contain infectious B19V.

5. STORAGE

The material is supplied as liquid/frozen material and should be stored at or below-70ºC.
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
The material is supplied as liquid/frozen material and should be stored at or below-70ºC. If all the material is not used immediately, laboratories may aliquot the remaining material into suitable volumes which should be stored at or below -70ºC. The panel members may be used to validate assays for the detection of different genotypes of B19V.

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

10. ACKNOWLEDGEMENTS

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.

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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

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

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: 5 g
Toxicity Statement: Toxicity not assessed
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.