



**Working Standard**  
**Working reagent for anti-monkeypox antibodies**  
**NIBSC code: 22/218**  
**Instructions for use**  
**(Version 1.0, Dated 17/11/2022)**

This material is not for in vitro diagnostic use

#### 1. INTENDED USE

The research reagent for anti-monkeypox virus antibodies is intended to be used for the development and evaluation of serological assays for the detection of antibodies against monkeypox virus, as a positive control. This material is for research use only.

#### 2. CAUTION

**The preparation contains material of human origin, and has been tested and found negative for anti-HIV and HCV RNA, but positive for HBsAg. As the preparation has been solvent-detergent treated is still deemed not infectious for shipping.**

**This preparation is not for administration to humans or animals**

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

No unitage has been currently assigned to the reagent 22/218. The material has been evaluated in house and the 50% neutralisation titer against monkeypox virus was 100. In our in-house ELISA a 5-step 2 fold dose response curve could be obtained with a starting dilution 1:50. A pilot study is currently ongoing to evaluate the potency of this reagent in different serological assay.

#### 4. CONTENTS

Country of origin of biological material: Democratic Republic of Congo.

Each vial contains 0.25 mL of a pool of human plasma from 100 individuals from DRC recovered from monkeypox. The material has been lyophilised. The material has been solvent detergent treated, to minimise the risk of envelope viruses present, using a validated method [1,2].

#### 5. STORAGE

The research reagent 22/218 should be stored at -20°C upon receipt or below.

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.

#### 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 ampoule 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.

No stability studies have been conducted on this material yet.

#### 9. REFERENCES

[1] Dichtelmuller, H.O., et al., Robustness of solvent/detergent treatment of plasma derivatives: a data collection from Plasma Protein Therapeutics Association member companies. *Transfusion*, 2009. 49(9): p. 1931-43.

[2] Wilkinson, D.H., et al., WHO collaborative study to assess the suitability of the 1<sup>st</sup> International Standard and the 1<sup>st</sup> International Reference Panel for antibodies to Ebola virus. 2017

#### 10. ACKNOWLEDGEMENTS

We would like to wholeheartedly thank the anonymous donors of the plasma samples for their consent which has allowed this reagent to be prepared. We would like to express our gratitude to Infiuss Health for the collection of the plasma samples. This work has been funded and facilitated by the Coalition for Epidemic Preparedness Innovations (CEPI).

#### 11. FURTHER INFORMATION

Further information can be obtained as follows;

This material: [enquiries@nibsc.org](mailto: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](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](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](mailto: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 material of human origin (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](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

<b>Country of origin for customs purposes*:</b> 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.
<b>Net weight:</b> 0.25 g
<b>Toxicity Statement:</b> Non-toxic
<b>Veterinary certificate or other statement</b> if applicable.
<b>Attached:</b> No