

This material is not for in vitro diagnostic use

1. INTENDED USE

Monoclonal antibody clone FHADETOX/6 is intended to be used in immunoassays that measure the content and quality of Filamentous Haemagglutinin Antigen (FHA) in vaccines for human use.

Batch 1 (Batch ID 220125-SN6)

2. CAUTION

The material is not of human or bovine origin. 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

N/A

4. CONTENTS

Country of origin of biological material: France.

Each vial contains 0.5 ml of liquid anti-FHA monoclonal antibody clone FHADETOX/6 at a total protein concentration of 1 mg/mL. FHADETOX/6 is a mouse IgG2b antibody produced from hybridoma and Protein A purified. The antibody is in Phosphate Buffer pH 7.4 (155 mM NaCl, 50 mM Na $_2$ HPO $_4$ and 1.8 mM KH $_2$ PO $_4$). The antibody was filtered (0.2 μ M) and does not contain preservative.

5. STORAGE

The material should be stored in the dark at -80°C Material type: Liquid – will be shipped according to the storage and shipping conditions of the product

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

FHADETOX/6 can be paired with monoclonal antibody 32-1 in immunoassays requiring both a capture and detection antibody.

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.



9. REFERENCES

None

10. ACKNOWLEDGEMENTS

N/A

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.



NIBSC Confidence in Biological Medicines

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

(EC) No 1272/2008: Not applicable or not classified					
Physical and Chemical properties					
Physical appea	arance:		Corrosive:	No	
Stable:	Yes		Oxidising:	No	
Hygroscopi c:	No		Irritant:	No	
Flammable:	No		Handling: S	ee caution, Section 2	
Other (specify):	None				
Toxicological properties					
Effects of inhalation: N		Not	Not established, avoid inhalation		
Effects of ingestion:		Not established, avoid ingestion			
Effects of absorption:	skin	Not skin		avoid contact with	
Suggested First Aid					
Inhalation: Seek medic			al advice		
Ingestion: Seek n		nedical advice			
Contact with eyes:					
Contact with skin:	Wash	thoro	ughly with wa	ater.	
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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*: France
* 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

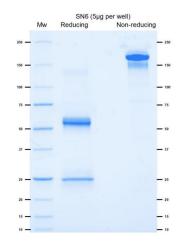
Veterinary certificate or other statement if applicable.

Attached: No

17. ADDITIONAL PRODUCT INFORMATION FOR THIS BATCH

SDS-PAGE profile for FHADETOX/6:

SDS-PAGE control
Bio-Rad 4-15% Stain-Free gel (ref 456-8083)
Bio-Rad Precision Plus Protein Unstained
Standards (ref 161-0363)(kDa)



SE-HPLC chromatogram for FHADETOX/6:

