



Working Standard
Diphtheria Toxoid Monoclonal Antibody DiM9
NIBSC code: DiM9
Instructions for use
(Version 2.0, Dated 23/08/2022)

This material is not for in vitro diagnostic use

1. INTENDED USE

Monoclonal antibody clone Dim9 is intended to be used in immunoassays that measure the content and quality of diphtheria toxoid antigen in vaccines for human use.

Batch 1 (Batch ID 220201-Dim9)

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-diphtheria monoclonal antibody clone Dim9 at a total protein concentration of 1 mg/mL. Dim9 is a mouse IgG1 antibody produced from hybridoma and Protein A purified. The antibody is in Phosphate Buffer pH 7.4 (155 mM NaCl, 50 mM Na₂HPO₄ and 1.8 mM KH₂PO₄). The antibody was filtered (0.2 µM) 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

Dim9 has been used as a detection antibody in an ELISA developed by NIBSC (with DT05 used as the capture antibody). A dilution of 1/3000 of Dim9 has been shown to be suitable for use as the 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

1. Rebecca Riches-Duit, Laura Hassall, Amy Kogelman, Janny Westdijk, Alexandre Dobby, Antoine Francotte, Paul Stickings, Characterisation of diphtheria monoclonal antibodies as a first step towards the development of an in vitro vaccine potency immunoassay. *Biologicals*, Volume 69, 2021, Pages 38-48, <https://doi.org/10.1016/j.biologicals.2020.12.002>

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.



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: Liquid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): None	
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.

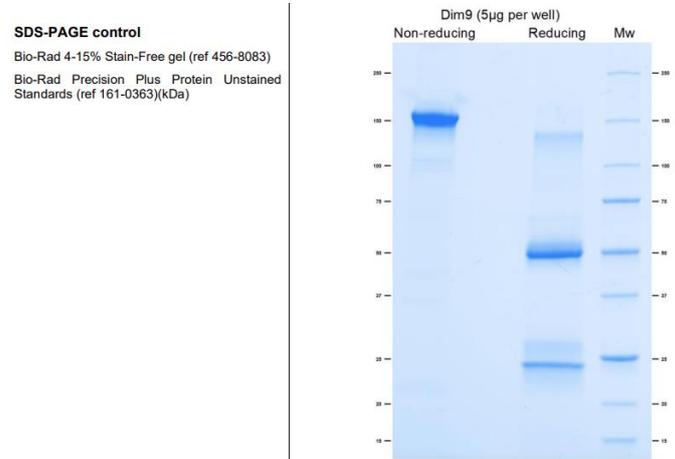
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16. INFORMATION FOR CUSTOMS USE ONLY

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 Dim9:



SE-HPLC chromatogram for Dim9:

