Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Working Standard
Tetanus Toxoid Monoclonal Antibody TT010
NIBSC code: TT010
Instructions for use
(Version 3.0, Dated 13/11/2023)

This material is not for in vitro diagnostic use

1. INTENDED USE

Monoclonal antibody clone TT010 is intended to be used in immunoassays that measure the content and quality of tetanus toxoid antigen in vaccines for human or veterinary use.

Batch 2 (Batch ID 211216-TT010)

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-tetanus monoclonal antibody clone TT010 at a total protein concentration of 1 mg/mL. TT010 is a rat IgG1 antibody produced from hybridoma and Protein G purified. The antibody is in Phosphate Buffer pH 7.4 (155 mM NaCl, 50 mM Na_2HPO_4 and 1.8 mM KH_2PO_4). 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

TT010 has been used as a capture antibody in an ELISA developed by NIBSC (with 8E1-1H1.2.1 used as the detection antibody). A dilution of 1/250 for TT010 has been shown to be suitable for coating ELISA plates.

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, Shalini Rajagopal, Bazbek Davletov, Ciara Doran, Alexandre Dobly, Antoine Francotte, Paul Stickings,
Characterisation of tetanus monoclonal antibodies as a first step towards the development of an in vitro vaccine potency immunoassay. Biologicals, Volume 71, 2021, Pages 31-41,
https://doi.org/10.1016/j.biologicals.2021.04.002

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.

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

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.

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

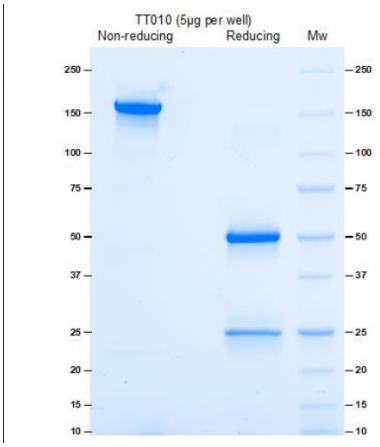
17. ADDITIONAL PRODUCT INFORMATION FOR THIS BATCH

SDS-PAGE profile for TT010

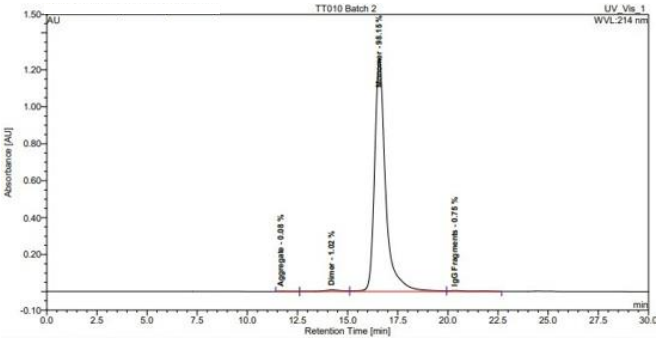
SDS-PAGE control

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 TT010



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