



WHO Reference Reagent

WHO International Reference Reagent for Diphtheria Antitoxin for use in Flocculation Test (Equine)

NIBSC code: 23/102

Instructions for use

(Version 3.0, Dated 21/03/2024)

This material is not for in vitro diagnostic use

1. INTENDED USE

This material is a freeze-dried preparation of hyperimmune horse diphtheria antitoxin [1]. It is intended for use as a reagent (not a calibrant) in the in vitro flocculation (Lf) test for diphtheria toxoid [1, 2, 3]. When used in the flocculation test, the Lf equivalent (Lf-eq) value must be determined in-house against the WHO IS diphtheria toxoid (13/212). The equine antitoxin was prepared by repeated immunisation of horses with diphtheria toxoid/toxin, followed by F(ab)₂ purification.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The material is not of human or bovine origin. 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

There are no units assigned to this reagent - it must be pre-calibrated for use in the flocculation test in Lf-eq against the WHO IS Diphtheria Toxoid for use in Flocculation Test (13/212) within each laboratory. However, to aid users with preparation of the dilutions of the antitoxin in the flocculation test, we provide a nominal value of 1032 International Units (IU) per ampoule of horse diphtheria antitoxin, which was determined in a single guinea pig toxin neutralisation assay.

4. CONTENTS

Country of origin of biological material: India.
Each ampoule contains the freeze-dried residue of 1.0 ml horse antitoxin. The source material was obtained from Premium Serums and Vaccines Pvt. Ltd., India.

5. STORAGE

Unopened ampoules should be stored in the dark at -20°C. 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 manufacturers 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

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

1. Tierney, R., Hockley, J., Stickings, P., Hassall, L. 2024. Collaborative study for a proposed WHO International Reference Reagent for Diphtheria Antitoxin Equine for use in Flocculation Test. WHO Expert Committee on Biological Standardization. WHO/BS/2024.2469.

2. Coombes, L., Rigsby, P., Sesardic, D., Stickings, P. 2016. Collaborative study: Calibration of Replacement International Standard for Diphtheria Toxoid for use in Flocculation Test. WHO Expert Committee on Biological Standardization. WHO/BS/2015.2254.

3. Coombes, L., Rigsby, P., Sesardic, D., Stickings, P. 2016. Collaborative Study for the calibration of a replacement International Standard for diphtheria toxoid for use in flocculation test. *Biologicals*. 2016 (44): 556-566.

10. ACKNOWLEDGEMENTS

Not applicable.

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: White freeze-dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: Unknown
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains material of biological origin and 0.15% phenol.
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: 0.107 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. Attached: Yes Premium Serums and Vaccines Pvt. Ltd. Certificate

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_1nter_biolestandardsrev2004.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.



Date-07/01/2022

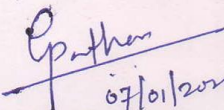
CERTIFICATE OF HEALTH

(To whom so ever it may concern)

This is to state that equines maintained by Premium Serums & Vaccines Pvt.Ltd. for manufacturing of various therapeutic products such as Snake Venom Antiserum, Scorpion Venom Antiserum, Diphtheria Antitoxin, Tetanus Antitoxin and Rabies Antiserum are regularly inspected for health condition and periodically subjected to haematological/biochemical and disease screening procedures as per surveillance program so as to ensure their fitness.

The equines are free of any signs of infectious/contagious diseases.




07/01/2022
Dr Akbar Pathan

(Manager Veterinary Department)

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Branch :- 2. 132/4/1, Engineers Enclave, Gangaram, Chanda Nagar, Hyderabad, (Telangana) 500 050
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