



**WHO International Standard
Clostridium septicum (Gas-Gangrene) Antitoxin Equine, 3rd
International Standard
NIBSC code: VI
Instructions for use
(Version 7.0, Dated 24/01/2014)**

1. INTENDED USE

This material has been prepared and characterised by the Statens Serum Institut (SSI), Copenhagen, Denmark. With effect from 1st July 1997, the National Institute for Biological Standards and Control (NIBSC), Potters Bar, UK is the custodian and distributor of this material. For details of this International Standard, please refer to the enclosed package insert from the Statens Serum Institut.

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

The total contents of each ampoule contains 500 International Units of Gas-Gangrene Antitoxin (Clostridium septicum).

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze-dried residue of approximately 0.25ml equine antiserum.

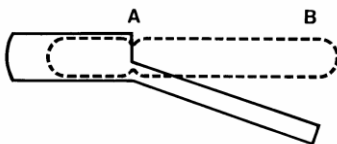
5. STORAGE

Unopened ampoules should be stored 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

Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure ampoule is scored all round at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement before attempting to open. Place the ampoule in the ampoule opener, positioning the score at position 'A'; shown in the diagram below. Surround the ampoule with cloth or layers of tissue paper. Grip the ampoule and holder in the hand and squeeze at point 'B'. The ampoule will snap open. Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.



Side view of ampoule opening device containing an ampoule positioned ready to open. 'A' is the score mark and 'B' the point of applied pressure.

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.

It is the policy of WHO not to assign an expiry date to their International Reference Materials.

Units assigned to this material were valid at the time of calibration and there is no data available on long term stability. However, freeze-dried serum standards are expected to undergo negligible loss of activity during long term storage at the indicated storage temperature [1].

Once reconstituted, users should determine the stability of the material according to their own method of preparation, storage and use. Users who have data supporting any changes in the characteristics of this material are encouraged to contact NIBSC.

9. REFERENCES

1. Jerne NK and Perry WLM. The Stability of Biological Standards, Bull. Wld. Hlth. Org. 1956, vol. 14 pp 167-182.
2. WHO Techn. Rep. Series No. 147, 1958, 15.
3. WHO Techn. Rep. Series No. 530, 1973, 11..

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: Freeze dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Contains horse serum	
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: Approx. 25mg
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. Attached: No

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_Inter_bio_lefstandardsrev2004.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. For details of this International Standard, please refer to the enclosed package insert from the Statens Serum Institut.



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**STATENS
SERUM
INSTITUT**

*prevention and control
of infectious diseases
and congenital disorders*

**THE INTERNATIONAL STANDARD
for
GAS-GANGRENE ANTITOXIN (CL. SEPTICUM)
(3rd international standard preparation)**

1. THE STANDARD PREPARATION

The standard preparation was established in 1957¹. It is prepared from a batch of hyperimmune horse serum prepared at the Statens Serum Institute, Copenhagen. Chinosal was added as preservative. The serum was diluted 1:3 in phosphate buffered saline pl. 7.38, filled into ampoules with one ml per ampoule and freeze-dried. The standard preparation was originally named International Standard for Gas-Gangrene Antitoxin (Vibriion Septique) but was renamed in 1973².

2. AMPOULE CONTENTS

By definition³ the total contents of each ampoule contains 500 International Units (IU) of Gas-Gangrene Antitoxin (Cl. Septicum).

3. USE OF THE STANDARD

A solution of the total contents of one ampoule contains in the total volume 500 IU. If the contents are dissolved in 10 ml of diluent (the diluent to be used in the test) the concentration of the solution will be 50 IU/ml. The standard was examined in a small collaborative study in three laboratories. One laboratory used challenge test in mice and two used intradermal titration on guinea pigs.

4. GENERAL REMARKS ABOUT INTERNATIONAL REFERENCE MATERIALS

International biological standards and international biological reference reagents provide a means of ensuring uniformity throughout the world in the designation of the potency or activity of preparations used in the prophylaxis, therapy, or diagnosis of disease, where this cannot be expressed in terms of physical or chemical quantities. The International Units are units of quantities of "effective constituent"³.

The standard is the material as it exists in the ampoules; the "material" thus includes the effective constituents together with all the other constituents that may be present (moisture, carrier, buffer, salt etc., according to the form in which the standard is available).

International biological reference materials are intended for use in the calibration of the contents of "effective constituent" in national or working standard preparations and for the expression of these contents in the respective International Units. For the routine use in the laboratory the national or working standards should be used in order to save as much as possible the international reference materials. These are only sent to individual laboratories in very limited amounts. International Reference Materials are distributed free of charge to National Control Laboratories of Member States of the World Health Organization. Other laboratories are due to pay a handling charge.

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August 1996

6. REFERENCES

1. WHO Techn. Rep. Series No. 147, 1958, 15
2. WHO Techn. Rep. Series No. 530, 1973, 11
3. The Validity and Meaning of the Results of Biological Assays, Jerne & Wood, Biometrics vol. 5, December 1949.