Non WHO Reference Material
Clostridium oedematiens (Cl. novyi, Gas Gangrene) Antitoxin, 3rd
British Standard
NIBSC code: 64/024

Instructions for use
(Version 8.0, Dated 24/01/2014)

This material is not for in vitro diagnostic use.

1. INTENDED USE
This material is the freeze-dried residue of a hyperimmune horse
antiserum to Clostridium oedematiens (Cl. novyi) toxin. It is intended for
calibration of bioassays for the measurement of the antitoxic activity of
Clostridium oedematiens (Cl. novyi). The material was established in 1966
as the 3rd British Standard.

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
1100 International Units per ampoule

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze-dried residue of approximately 1ml of
horse serum. Each ampoule contains 1100 International Units of gas
gangrene antitoxin Clostridium oedematiens (Cl. novyi).

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
For practical purposes, each ampoule contains the same quantity of serum.
The entire contents of each ampoule should be completely dissolved in 1ml
of sterile distilled water, and the solution kept cool (e.g. +4°C) prior to use.
The reconstituted solution may be subsequently diluted to 55ml with saline to
give a solution containing 20 IU/ml. This should be used immediately for
bioassay or calibration of a laboratory standard.

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.

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

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/
Derivation of International Units: http://www.nibsc.org/standardisation/international_standards.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
referred, 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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
<th></th>
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<tbody>
<tr>
<td>Physical appearance: Freeze dried powder</td>
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<tr>
<td>Corrosive: No</td>
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<td>Stable: Yes</td>
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<td>Oxidising: No</td>
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<td>Hygroscopic: Yes</td>
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<td>Irritant: No</td>
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<td>Flammable: No</td>
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<tr>
<td>Handling: See caution, Section 2</td>
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<tr>
<td>Other (specify): Contains equine serum</td>
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<thead>
<tr>
<th>Toxicological properties</th>
<th></th>
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<tr>
<td>Effects of inhalation: Not established, avoid inhalation</td>
<td></td>
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<tr>
<td>Effects of ingestion: Not established, avoid ingestion</td>
<td></td>
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<tr>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
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</tbody>
</table>

**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. 100mg
- **Toxicity Statement:** Non-toxic
- **Veterinary certificate or other statement if applicable. Attached:** No