WHO International Standard
1st International Standard for Chagas (anti-Trypanosoma cruzi II) antibody in human plasma
NIBSC code: 09/186
Instructions for use
(Version 7.0, Dated 02/11/2015)

1. INTENDED USE
Freeze-dried preparation 09/186 contains anti-Trypanosoma cruzi antibodies and is representative for seropositive samples from autochthonous individuals living in Brasil, the region where T. cruzi II is endemic. However the parasite could not be isolated from blood of individual donors who are in the chronic stage of disease. Thus the T. cruzi genotype could not be confirmed. The preparation has been assessed in a collaborative study for its suitability for use in various enzyme linked immunosorbent assays, immunofluorescence assays, agglutination assays, lateral flow assays or rapid immunochromatographic assays, western blots and a radioimmunoprecipitation assay. The collaborative study report contains full details on the reactivity of 09/186 [1]. The preparation can be used to assess the analytical sensitivity of the tests for detection of antibodies to T. cruzi. 09/186 is one of two standards that make up the 1st WHO Anti Trypanosoma cruzi I and II Antibody Reference Panel and should be used concurrently with standard 09/188.

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

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, has been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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
This material is assigned a unitage of 0.5 IU per ampoule or 1 IU per mL.

4. CONTENTS
Country of origin of biological material: Brasil.

The vial contains the freeze-dried residue from 0.5 ml aliquot taken from pooled delibrinated human plasma, which contained 0.05% Bronidox L5 as a preservative. The pool consists of plasma donations by ten individual donors who are in the chronic stage of disease. Thus the T. cruzi genotype could not be confirmed. The preparation has been assessed in a collaborative study for its suitability for use in various enzyme linked immunosorbent assays, immunofluorescence assays, agglutination assays, lateral flow assays or rapid immunochromatographic assays, western blots and a radioimmunoprecipitation assay. The collaborative study report contains full details on the reactivity of 09/186 [1]. The preparation can be used to assess the analytical sensitivity of the tests for detection of antibodies to T. cruzi. 09/186 is one of two standards that make up the 1st WHO Anti Trypanosoma cruzi I and II Antibody Reference Panel and should be used concurrently with standard 09/188.

5. STORAGE
Vials should be stored at – 20 °C or below on receipt.
It is recommended that reconstituted material is held for no longer than 1 month at 4°C. Unused contents should be frozen.

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 manufactures 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.

The contents of vials should be reconstituted with 0.5 ml distilled water using safety precautions as described above. It is recommended that a sequential dilution range (e.g. 1/2 to 1/64) of the material is prepared and tested in duplicate (see [1]).

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. Accelerated degradation studies over 9 and 21 months have shown that the loss in potency puts the sample in a range observed for other plasma derived antibody standards. Therefore the plasma derived antibody sample stored in unopened ampoules at -20°C is considered to be stable [1].

9. REFERENCES

10. ACKNOWLEDGEMENTS
We thank members of the Chagas serology study group for their expertise and contributions to CS411.

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/mlm/
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
Physical and Chemical properties

<table>
<thead>
<tr>
<th>Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Off white cake</td>
</tr>
<tr>
<td>Corrosive: No</td>
</tr>
<tr>
<td>Stable: Yes</td>
</tr>
<tr>
<td>Oxidising: No</td>
</tr>
<tr>
<td>Hygroscopic: Yes</td>
</tr>
<tr>
<td>Irritant: No</td>
</tr>
<tr>
<td>Flammable: No</td>
</tr>
<tr>
<td>Handling: See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify): Contains material of human origin and preservative Bronidox L5 (0.05%)</td>
</tr>
</tbody>
</table>

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**: 0.0392 g
- **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 Biolstandardsrev2004.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.