



**WHO International Standard  
1st WHO anti-Trypanosoma cruzi I and II Antibody Reference  
Panel**

**NIBSC code: 11/216  
Instructions for use  
(Version 6.0, Dated 05/05/2015)**

### 1. INTENDED USE

The 1st WHO Chagas Antibody Reference Panel consists of two International standards (IS): IS 09/186 and IS 09/188.

In brief, 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.

09/188 contains anti-Trypanosoma cruzi antibodies and is representative of seropositive samples from autochthonous individuals living in México, a region where T. cruzi I is endemic TcI.

Concurrent use of both ISs is recommended. For full information on the ISs please access their respective Instructions for Use (IFU). For a draft version of the collaborative study report [1].

### 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, have 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

Each IS contains 1 IU per mL. Vials contain freeze dried residue of 0.5 mL plasma (representing 0.5 IU).

### 4. CONTENTS

Country of origin of biological material: Brasil and México.  
Please see IFU for detailed information.

### 5. STORAGE

Vials should be stored at  $-20^{\circ}\text{C}$  or below on receipt.  
Please see IFU for detailed information.

**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**

Please see IFUs for detailed information.

### 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 both 09/186 and 09/188 in a range observed for other plasma derived antibody standards. Therefore both plasma derived antibody samples stored in unopened ampoules at  $-20^{\circ}\text{C}$  are considered to be stable [1].

### 9. REFERENCES

1) Otani M, Hockley J, Rigsby P, Rijpkema S, Guzmán Bracho C, Luquetti AO, Padilla A, and the Chagas serology study group. Evaluation of two International Reference Standards for antibodies to Trypanosoma cruzi in a WHO collaborative study. BS2011.2181. Accessible at: <http://www.who.int/bloodproducts/catalogue/Alph2015.pdf?ua=1>

### 10. ACKNOWLEDGEMENTS

We thank members of the Chagas serology study group for their expertise and contribution to the collaborative study

### 11. FURTHER INFORMATION

Further information can be obtained as follows:

This material: [enquiries@nibsc.org](mailto: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](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](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](mailto: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.

[http://www.who.int/bloodproducts/publications/TRS932Annex2\\_Inter\\_biol\\_efstandardsrev2004.pdf](http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biol_efstandardsrev2004.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.

#### 14. MATERIAL SAFETY SHEET

Physical and Chemical properties	
<b>Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008:</b> Not applicable or not classified Physical appearance: Off white cake	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Both ISs contain material of human origin and Bronidox L5 (0.05%).
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](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

<b>Country of origin for customs purposes*:</b> 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.
<b>Net weight:</b> Please see IFU for detailed information.
<b>Toxicity Statement:</b> Non-toxic
<b>Veterinary certificate or other statement</b> if applicable. <b>Attached:</b> 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