Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
1st International Standard for Chagas (anti-Trypanosoma cruzi I) antibody in Human Plasma
NIBSC code: 09/188
Instructions for use
(Version 12.0, Dated 02/11/2015)

1. INTENDED USE

Freeze-dried preparation 09/188 contains anti-Trypanosoma cruzi antibodies and consists of seropositive samples from autochthonous individuals living in Mexcio, the region where T. cruzi I 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 genotyope 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/rapid immunographic assays, western blots and a radioimmunoprecipitation assay. The collaborative study report contains full details on the reactivity of 09/188 [1]. The preparation can be used to assess the analytical sensitivity of the tests for detection of antibodies to T. cruzi. 09/188 is one of two international standards that make up the 1st WHO Chagas (anti-Trypanosoma cruzi) Antibody Reference Panel and concurrent use with international standard 09/186 is recommended.

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

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: México.
The vial contains the freeze-dried residue of 0.5 ml aliquot taken from pooled defibrinated human plasma, which contained 0.05% Bronidox L5 as a preservative. The pool consists of plasma donations by four volunteers, who reside in an area endemic for T.cruzi I.

5. STORAGE

Vials should be stored at – 20 ^{0}C or below on receipt.
It is recommended that reconstituted material is held for no longer than 1 month at 4^{0}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.
Tap the ampoule gently to collect the material at the bottom (labeled) end. Ensure that the disposable ampoule safety breaker provided is pushed down on the stem of the ampoule and against the shoulder of the ampoule body. Hold the body of the ampoule in one hand and the disposable ampoule breaker covering the ampoule stem between the thumb and first finger of the other hand. Apply a bending force to open the ampoule at the coloured stress point, primarily using the hand holding the plastic collar.

Care should be taken to avoid cuts and projectile glass fragments that might enter the eyes, for example, by the use of suitable gloves and an eye shield. Take care that no material is lost from the ampoule and no glass falls into the ampoule. Within the ampoule is dry nitrogen gas at slightly less than atmospheric pressure. A new disposable ampoule breaker is provided with each DIN ampoule.

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 -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

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. BS 2011.2181. Accessible at: http://apps.who.int/iris/bitstream/10665/152895/1/WHO_BS_2011.2181_eng.pdf?ua=1

10. ACKNOWLEDGEMENTS

We thank members of the Chagas serology study group for their expertise and contribution 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/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.

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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_biolefstandardsrev2004.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			
Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: 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):	Contains 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 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: 0.0376 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

17. CERTIFICATE OF ANALYSIS

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