Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
4th IS for Antibodies, Human, to Toxoplasma gondii
NIBSC code: 13/132
Instructions for use
(Version 6.0, Dated 16/01/2020)

1. INTENDED USE

A collaborative study compared the potency of 13/132, the 4th International Standard (IS) for Antibodies, Human, to Toxoplasma gondii in the Sabin Feldman dye test relative to TOXM (3rd IS for anti-Toxoplasma Serum, Human; 1000 IU per ampoule) and 01/600 (1st IS for anti-Toxoplasma IgG, Human; 20 IU per ampoule) [1-3]. 13/132 is suitable for use in Enzyme Linked Fluorescence Assays and Enzyme Linked Immuno Sorbent Assays for Ig, IgA, IgM, IgG and IgG avidity, and for agglutination assays, Immuno Fluorescence Assays and Immunoblot assays to detect IgG and IgM. 13/132 reacted strongly positive for Ig, IgA, IgG and IgM in all these assays [1,2]. The avidity of IgG from 13/132 is low and similar to TOXM [1-3]. In terms of antibody potency, IS 13/132 falls between TOXM and 0/1600. More information on the antibody reactivity of 13/132 in various immunoassays can be found in the collaborative study report or in the peer reviewed publication [1,2].

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

A unitage of 160 IU per ampoule or 320 IU per mL (GCV of 41.0%, n=5) for anti-Toxplasma gondii antibodies by dye test was assigned to 13/132, the 4th IS for Antibodies, Human, to Toxoplasma gondii, relative to TOXM. 13/132 contains a high level of IgG and IgM; the avidity of IgG is similar to the avidity of IgG from TOXM and considerably lower than the avidity of IgG from 01/600 [1-3]. For TOXM, unitages for IgG and IgM were estimated at 1000 and 3000 U per ampoule respectively, but a unitage was not assigned [4,5]. Therefore 13/132 can only act as a reference reagent for IgG and IgM. Based on 12 data sets from IgG assays, 13/132 contains 263 U of IgG per ampoule relative to TOXM, and a high IgM content was noted [1,2].

4. CONTENTS

Country of origin of biological material: France.
13/132 is a freeze dried preparation of 0.5 mL pooled human plasma, taken from 6 donors, who experienced a recent Toxoplasma gondii infection. The material is free from antibodies to HIV1 and HIV2, Hepatitis C RNA and Hepatitis B surface antigen.

5. STORAGE

On receipt, store ampoules at -20^{0}C. It is recommended that reconstituted material is held for no longer than one week 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. 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
Samples should be reconstituted with 0.5 ml distilled water immediately before use.

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.

9. REFERENCES

1) Rijpkema S, Hockley J, Rigsby P, Guy EC. A WHO collaborative study to evaluate candidate International Standard 13/132 for anti-Toxoplasma Ig (Human) as a replacement for TOXM. WHO Tech Rep Series 2015;999:60-61. WHO/BS/2015.2266
2) Rijpkema S, Hockley J, Rigsby P, Guy EC and the Toxoplasma Study Group. Establishment of replacement International Standard 13/132 for human antibodies to Toxoplasma gondii. Biologicals 2016;44:448-455
3) Rigsby P, Rijpkema S, Guy EC, Francis J, Gaines Das R. Evaluation of a candidate international standard preparation for human anti-Toxoplasma IgG. J Clin Microbiol 2004;42:5133-5138.
4) Hansen GA, Lyng J, Petersen E. Calibration of a replacement preparation for the second international standard for anti-Toxoplasma serum, Human. 1994; WHO/BS/94.1761
5) WHO Expert Committee on Biological Standardization. Anti-toxoplasma serum. WHO Tech Rep Series 1995;858:9.

10. ACKNOWLEDGEMENTS

We are grateful to Dr G Carrard and Mr C Bena of Cerba Specimen Services of France for organising the transfer of the source material.

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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Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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: Dry powder		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Contains human plasma		

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: 0.04 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_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.