WHO International Standard
4th IS for Antibodies, Human, to Toxoplasma gondii
NIBSC code: 13/132

Instructions for use
(Version 4.0, Dated 06/07/2016)

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 IgD 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 is given in the collaborative study report [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-Toxoplasma 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°C. It is recommended that reconstituted material is held for no longer than one week 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. 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

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) Rigkema 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/BS/2015.2266

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.

14. MATERIAL SAFETY SHEET

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
<th>Corrosive: No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008:</td>
<td>Not applicable or not classified</td>
</tr>
<tr>
<td>Physical appearance:</td>
<td>Dry powder</td>
</tr>
<tr>
<td>Stable: Yes</td>
<td>Oxidising: No</td>
</tr>
<tr>
<td>Hygroscopic: No</td>
<td>Irritant: No</td>
</tr>
<tr>
<td>Flammable: No</td>
<td>Handling: See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify):</td>
<td>Contains human plasma</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: 0.04 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_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.