WHO Reference Reagent
Anti-Thyroglobulin Serum, Human
NIBSC code: 65/093
Instructions for use
(Version 3.0, Dated 28/03/2013)

1. INTENDED USE
As a result of collaboration between NIBSC and the Immunology Unit, Geneva, a research standard was prepared for assaying autoimmune antibodies to human thyroglobulin (WHO 1966-1969). In 1970 the WHO Expert Committee on Biological Standardization established the preparation, coded 65/093, as the International Reference Preparation of Anti-thyroglobulin serum, human, and defined the potency as 1,000 International Units per ampoule (WHO 1979).

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 ampoule contains 1000 INTERNATIONAL UNITS of anti-thyroglobulin activity (by definition).

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each ampoule contains the residue, after freeze-drying, of 0.1ml of a solution containing:
0.3ml of a human plasma pool exhibiting anti-thyroglobulin autoantibodies;
isotonic diluent

5. STORAGE
Unopened ampoules should be stored at -20°C
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING
Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure ampoule is scored all round at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement before attempting to open. Place the ampoule in the ampoule opener, positioning the score at position 'A'; shown in the diagram below. Surround the ampoule with cloth or layers of tissue paper. Grip the ampoule and holder in the hand and squeeze at point ‘B’. The ampoule will snap open. Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.

7. USE OF MATERIAL
For all practical purposes each ampoule contains the same amount of the same materials. Reconstitute the total contents in 1ml distilled water. A suitable buffer should be used for further dilutions. No attempt should be made to weigh out portions of the freeze-dried material.

8. STABILITY
Ampoules kept at +37°C for six months showed no changed of potency when compared with materials stored at -20°C.

9. REFERENCES

10. 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/standatisation/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

11. PREPARATION OF AMPOULES
Side view of ampoule opening device containing an ampoule positioned ready to open. ‘A’ is the score mark and ‘B’ the point of applied pressure.

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

Page 1 of 2
A number of human plasma samples containing antibodies to thyroglobulin were pooled. The pool was clotted by the addition of calcium and the serum diluted 1:23 in isotonic diluent. The batch of ampoules coded 65/093 was prepared according to the procedures used for international biological standards (WHO, 1978). A sample of the plasma pool was diluted 1:23 in isotonic diluent. This solution was passed through a membrane filter (mean pore diameter 0.4 µ) and distributed in 1.0ml aliquots into ampoules. The ampouled solution was lyophilized, and after secondary desiccation, the ampoules containing pure dry nitrogen were sealed by heat fusion of the glass and have since been stored at –20 °C in the dark.

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
Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
<th>Corrosive: No</th>
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<tbody>
<tr>
<td>Physical appearance: Freeze dried powder</td>
<td>Stable: Yes Oxidising: No</td>
</tr>
<tr>
<td>Hygroscopic: Yes Irritant: No</td>
<td></td>
</tr>
<tr>
<td>Flammable: No Handling: See caution, Section 2</td>
<td></td>
</tr>
<tr>
<td>Other (specify): Contains material of human origin</td>
<td></td>
</tr>
</tbody>
</table>

Toxicological properties
- Effects of inhalation: No adverse effects were reported for this material
- Effects of ingestion: No adverse effects were reported for this material
- Effects of skin absorption: No adverse effects were reported for this material

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 |
| Net weight: 20mg |
| Toxicity Statement: Non-toxic |
| Veterinary certificate or other statement if applicable. Attached: No |

17. CERTIFICATE OF ANALYSIS
NIHC 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_eftstandardsrev2004.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.

* 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.