Non WHO Reference Material
Chorionic Gonadotrophin, Human, for Radiiodination
NIBSC code: 75/533
Instructions for use
(Version 5.0, Dated 28/03/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE
This consists of a batch of micro-ampoules (coded 75/533) containing highly purified human chorionic gonadotrophin (hCG) for radiiodination. The purification and characterization of this batch of hCG is described by Canfield and Ross (1976). It is part of the same batch of hCG which was used to prepare the third International Standard for Chorionic Gonadotrophin in ampoules coded 75/537 (Storring et al, 1980).

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. CONTENTS
Country of origin of biological material: United Kingdom.
Each siliconized micro-ampoule contains the residue, after freeze-drying, of 5μl of a solution which contained:-

- Human Chorionic Gonadotrophin
- Mannitol
- Acetic Acid
- Nitrogen gas at slightly less than atmospheric pressure

4. STORAGE
Unopened ampoules should be stored at -20°C

5. 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.

Use of the contents of micro-ampoules – method of using micro-ampoules with the aid of the vaccine bulb provided.
1. Open the micro-ampoule in the horizontal position by gently marking 2-3mm from each end with glass file (supplied) and breaking off both ends. If the lyophilized plug has fragmented, tap the fragments away from the ends of the micro-ampoule before opening.
2. Manipulate one of the open ends of the micro-ampoule into the small hole in the vaccine bulb provided, without creating pressure (i.e. without covering the large opening).
3. When the vaccine bulb is in place, and keeping the micro-ampoule as close as possible to the horizontal, place the free end into a measured or non-measured volume of solvent. If a small measured volume is to be used, it may be found convenient to expel it from a pipette as a discrete drop on a non-wettable surface (e.g. Parafilm).
4. Gently squeeze the teat, still without covering the large opening.
5. When teat has been partially compressed, cover the large opening with a finger and allow the bulb to expend very slowly. Liquid will be drawn into the micro-ampoule.
6. When the liquid has reached the distal end of the lyophilized plug, stop the rise of liquid by removing the finger from the large opening of the teat.
7. When the plug has dissolved (which takes only seconds), the solution may be discharged into a suitable collecting vessel by closing the large opening and squeezing the teat.
8. A large measured volume of solvent has been used, the micro-ampoule can be washed out into it by repeating the above procedure a number of times.

6. STABILITY
NIBSC follows the policy of WHO with respect to its reference materials. It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

7. REFERENCES

8. ACKNOWLEDGEMENTS
Grateful acknowledgements are due to the Center for Population Research, USA and Reproduction Research Branch of the National Institute of Child Health and Human Development, USA for providing the hormone preparation; Drs R.E.Canfield and G.T.Ross and their colleagues for its purification and characterization and Dr P.J.Campbell for ampouling.

9. FURTHER INFORMATION
Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biological/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en-committees/jc格林/ Derivation of International Units:
http://www.nibsc.org/standardsation/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
10. 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

11. 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.

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

13. 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.

14. 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: 0.1mg |
| Toxicity Statement: Non-toxic |
| Veterinary certificate or other statement if applicable. Attached: No |

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