Non WHO Reference Material
Chorionic Gonadotrophin Alpha Subunit, Human For Radioiodination
NIBSC code: 76/508
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 76/508) containing
highly purified Alpha Subunit of human chorionic gonadotrophin (hCG-α) for
radioiodination. The purification and characterization of this hCG-α is
described by Canfield and Ross (1976). It is part of the same batch of
hCG-α which was used to prepare the International Reference
Preparation of Chorionic Gonadotrophin in Alpha Subunit, Human, for
Immunoassay ampoules coded 75/569 (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.
However, as with all preparations of human origin, this material cannot be
assumed to be free from infectious agents. Suitable precautions should
be taken in the use and disposal of the ampoule and its contents. Such
safety procedures probably will 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 ampoule contains the freeze-dried residue of 0.5 ml of a solution
which contained:
Each siliconic micro-ampoule contains the residue, after freezer-drying,
of 5µl of a solution which contained:
- α Subunit of human chorionic gonadotrophin approx 2µg
- Mannitol approx 100µg
- Acetic acid approx 3µg
Nitrogen gas at slightly less than atmospheric pressure.

4. 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.

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 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.

DIRECTIONS FOR OPENING

A  B

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.

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.
Unopened ampoules should be stored on receipt as indicated on the
label. In addition, once reconstituted, diluted or aliquoted, users should
determine the stability of the material according to their own method of
preparation, storage and use.

7. REFERENCES
Storring P L, Gaines Das R E & Bangham D R (1980). J.Endocrinol., 84,
295-310.

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 characterisation 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/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

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)

The entire drop (or an unmeasured aliquot from a larger measured
volume) can then be drawn up into the micro-ampoule by the following
procedure:
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. If 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.

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UK Official Medicines Control Laboratory
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>
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<tbody>
<tr>
<td><strong>Physical appearance:</strong></td>
<td><strong>Corrosive:</strong> No</td>
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<tr>
<td>Freeze-dried powder</td>
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<tr>
<td><strong>Stable:</strong></td>
<td><strong>Oxidising:</strong> No</td>
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<tr>
<td>Yes</td>
<td></td>
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<tr>
<td><strong>Hygroscopic:</strong></td>
<td><strong>Irritant:</strong> No</td>
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<tr>
<td>Yes</td>
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<tr>
<td><strong>Flammable:</strong></td>
<td><strong>Handling:</strong> See caution, Section 2</td>
</tr>
<tr>
<td>No</td>
<td></td>
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<tr>
<td><strong>Other (specify):</strong></td>
<td>Contains material of human origin</td>
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**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.

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<tbody>
<tr>
<td><strong>Net weight:</strong></td>
<td>0.1mg</td>
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<tr>
<td><strong>Toxicity Statement:</strong></td>
<td>Non-toxic</td>
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Veterinary certificate or other statement if applicable. Attached: No