WHO International Standard
1st WHO International Standard for Insulin-like Growth Factor-I, recombinant, human, for immunoassay
NIBSC code: 02/254
Instructions for use
(Version 6.0, Dated 06/04/2013)

1. INTENDED USE
A preparation of recombinant IGF-1, coded 02/254, was ampouled and evaluated for its suitability to serve as a WHO International Standard by international collaborative study. It was established as the 1st International Standard for Insulin-like Growth Factor-I, Recombinant, Human, for immunoassay by the Expert Committee on Biological Standardization of the World Health Organization in October 2008. This replaces the International Reference Reagent, coded 07/518, as the primary reference material for the calibration of immunoassays.

2. CAUTION
This preparation is not for administration to humans or animals in the human food chain.

The material is not of human or bovine origin. 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 of 02/254 contains 8.5µg of IGF-I per ampoule (by definition). Uncertainty: When necessary the expanded uncertainty associated with the unitage is 7.73±2.93 µg of IGF-I per ampoule.

4. CONTENTS
Country of origin of biological material: USA.
Each ampoule contains the residue after freeze-drying of 1ml of a solution that contained:
10 mg/ml trehalose
20 mM sodium phosphate pH 7.0
Recombinant IGF-I

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
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 manufacturers 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.

For practical purposes each ampoule contains the same quantity of IGF-I. Depending upon intended use, dissolve the total contents of the ampoule in a known volume of a suitable diluent (e.g saline or assay buffer) with carrier protein (0.05 – 0.1% BSA or HSA). The inclusion of carrier protein is also recommended where extensive dilution is required. The ampoules do not contain bacteriostat and a solution of the reagent should not be assumed to be sterile.

8. STABILITY
Stability based on HPLC analysis of thermally accelerated degradation samples showed a predicted yearly loss of activity at -20°C of 0.08% and a predicted yearly loss of IGF-1 content at 37°C of 5.9%. These results indicate that 02/254 is likely to be highly stable under long term storage conditions at -20°C and that the material will also be stable during normal shipping at ambient temperatures.
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. 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. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

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/jctml/
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

11. 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

12. 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.

13. 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>
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</thead>
<tbody>
<tr>
<td><strong>physical</strong></td>
</tr>
<tr>
<td>Stable: Yes</td>
</tr>
<tr>
<td>Hygroscopic: No</td>
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<tr>
<td>Flammable: No</td>
</tr>
<tr>
<td>Other (specify):</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicological properties</th>
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<tbody>
<tr>
<td>Effects of inhalation:</td>
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<tr>
<td>Effects of ingestion:</td>
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<td>Effects of skin absorption:</td>
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WHO INTERNATIONAL LABORATORY FOR BIOLOGICAL STANDARDS, UK OFFICIAL MEDICINES CONTROL LABORATORY

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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 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.

14. 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.

15. 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: 10mg

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.