



**WHO International Standard  
1st WHO International Standard for Insulin-like Growth Factor-1,  
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-1, 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 87/518, 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 7.73-9.23 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 manufactures 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**

1. WHO Technical Report Series No.800, 1990; 181-214

**10. FURTHER INFORMATION**

Further information can be obtained as follows;

This material: [enquiries@nibsc.org](mailto: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](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](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](mailto: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

Physical and Chemical properties	
Physical appearance:	Freeze dried powder
Corrosive:	No
Stable:	Yes
Oxidising:	No
Hygroscopic:	No
Irritant:	No
Flammable:	No
Handling:	See caution, Section 2
Other (specify):	Can react with oxidising materials. Avoid contact with acids and alkalis
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



<b>Suggested First Aid</b>	
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.
<b>Action on Spillage and Method of Disposal</b>	
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](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

<b>Country of origin for customs purposes*:</b> 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.
<b>Net weight:</b> 10mg
<b>Toxicity Statement:</b> Non-toxic
<b>Veterinary certificate or other statement</b> if applicable.
<b>Attached:</b> 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\\_bi\\_olefstandardsrev2004.pdf](http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_bi_olefstandardsrev2004.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.