WHO International Standard
2nd International Standard for Sex Hormone Binding Globulin
NIBSC code: 08/266
Instructions for use
(Version 2.0, Dated 28/03/2013)

1. INTENDED USE
The first International Standard (IS) for Sex Hormone Binding Globulin (SHBG) in ampoules coded 95/560 was established in 1998 and has been widely used for the calibration of immunocassays and binding assays for the measurement of human serum SHBG levels. The World Health Organization (WHO) Expert Committee on Biological Standardization (ECBS) has recognized (2008) the need for a replacement International Standard for sex hormone binding globulin (SHBG) for the calibration of assays for the measurement of human serum SHBG levels that are important for the diagnosis of conditions associated with abnormal sex steroid function. The 2nd IS, coded 08/266, was established at the 61st Meeting of the ECBS. This material replaces the 1st IS, which is discontinued.

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 180 INTERNATIONAL UNITS, equivalent to 180 pmol per ampoule.

4. CONTENTS
Country of origin of biological material: United Kingdom.

The 2nd IS for SHBG consists of a batch of ampoules, coded 08/266, containing freeze dried serum obtained from a pool of normal healthy female volunteers. Each ampoule contains the residue after freeze-drying of 1ml of human serum with 40mM HEPES.

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 SHBG. The entire content of each ampoule should be completely dissolved in an accurately measured amount of distilled water or appropriate assay diluent. The use of PBS to reconstitute ampoule contents is not recommended. If the contents are to be diluted extensively, the addition of 0.05%–0.1% protein (HSA or BSA) is recommended to minimise adsorption. The material has not been sterilized and the ampoules contain no bacteriostat.

8. STABILITY

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 aliquotted, 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. ACKNOWLEDGEMENTS
We gratefully acknowledge the important contributions of all the participants and Dr Jonathan Middle of the UK NEQAS scheme who kindly collected and tested serum samples used in this project.

11. FURTHER INFORMATION
Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
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></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance:</td>
<td>Corrosive: No</td>
</tr>
<tr>
<td>Yellow Powder</td>
<td></td>
</tr>
<tr>
<td>Stable:</td>
<td>Oxidising: No</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Hygroscopic:</td>
<td>Irritant: No</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Flammable:</td>
<td>Handling: See caution, Section 2</td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Other (specify):</td>
<td>Contains material of human origin</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 thorougly with water.

Action on Spillage and Method of Disposal
Spillage of ampoule contents should be taken up with absorbent material wetted with a virucidal agent. Rinse area with a virucidal agent 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
* 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: 12mg
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_biol_estandsrev2004.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.