



WHO International Standard
3rd INTERNATIONAL STANDARD FIBRINOGEN PLASMA
NIBSC code: 09/264
Instructions for use
(Version 1.0, Dated 25/11/2011)

1. INTENDED USE

The WHO 3rd International Standard for Fibrinogen Plasma, consists of glass ampoules, coded 09/264, containing 1ml aliquots of a freeze-dried solvent-detergent treated pooled normal human plasma. This preparation was established by the Expert Committee on Biological Standardization of the World Health Organization in October 2011 and details of the preparation and value assignment are available in document WHO/BS/2011.2168. This standard is intended to be used in the measurement of fibrinogen in plasma and is primarily intended for calibration of secondary and/or in-house working standards of fibrinogen plasma.

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

The WHO 3rd International Standard was calibrated in an international collaborative study involving 21 laboratories in 11 countries. A potency of

2.7 mg per ampoule

has been assigned. This figure is based on comparison with the 2nd International Standard for Fibrinogen Plasma, using primarily Claus assays.

4. CONTENTS

Country of origin of biological material: United Kingdom

The WHO 3rd International Standard for Fibrinogen Plasma, consists of aliquots of a freeze-dried solvent-detergent treated pooled normal human plasma and was prepared at the National Institute for Biological Standards and Control (NIBSC) in January 2010.

After thawing of 50 units (10,000 ml) of the product, this material was pooled and kept on ice prior to being filled and freeze-dried in sealed glass ampoules at NIBSC, under conditions required for International Standards¹. One ml of this material was dispensed into each of approximately 10,000 ampoules. The mean filling weight was 1.0080 g (range 1.0020 g to 1.0150 g) and the coefficient of variation (CV) was 0.18% based on 396 check-weight samples. Mean residual moisture after freeze-drying was 0.34% (CV 24.8%, n=12) and mean oxygen headspace was 0.29% (CV 32.2%, n=12).

5. STORAGE

Unopened ampoules should be stored in the dark at -20°C. After reconstitution, any unused material must be discarded, not frozen for later use.

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

The total contents of the ampoule should be reconstituted at room temperature with 1 ml distilled water, dissolved by gentle swirling to avoid froth and transferred immediately to a suitable plastic tube. No attempt should be made to weigh out any portion of the freeze-dried material.

8. STABILITY

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 common with previous WHO Plasma Standards for blood coagulation factors, it is recommended that the standard is transferred, after reconstitution, to a plastic tube and if stored on melting ice, the standard should be used within 3 hours of reconstitution.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

1. Campbell P J. Procedures used for the production of biological standards and reference preparations. J Biol Standardization 1974; 2: 259-67.

10. ACKNOWLEDGEMENTS

The contributions of all the participants in the study are gratefully acknowledged. We are grateful to our colleagues in the Standards Processing Division and Process Development Section, NIBSC, for ampouling and processing the candidate and trial preparations and for the dispatch of collaborative study samples to participants. We are grateful to Kedrion S.p.A. (Italy) and Octapharma (Austria) for their kind donation of materials for the study. We further like to thank the ISTD/SSC Fibrinogen and Factor XIII Subcommittee for their support.

11. 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

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

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.

Physical and Chemical properties	
Physical appearance: Freeze dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See Caution (Section 2)
Other (specify):	Contains material of human origin
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.	

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: 0.08g
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_bi