



WHO International Standard
WHO 1st International Standard for TAFI, Plasma
NIBSC code: 17/200
Instructions for use
(Version 1.0, Dated 15/02/2024)

This material is not for in vitro diagnostic use

1. INTENDED USE

The intended use for this standard is to calibrate the measurement of thrombin activatable fibrinolysis inhibitor (TAFI, also known as procarboxypeptidase U or CPB2 gene product) functional activity and antigen in human 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

Potency values in International Units (IU) for the 1st International Standard for TAFI, plasma (17/200) were determined by functional activity and antigen assays relative to local normal plasma pools, in a collaborative study that involved 10 laboratories from 7 different countries:

TAFI antigen: 0.92 IU per ampoule
TAFI activity: 0.87 IU per ampoule

A potency value for TAFI antigen in SI units was also determined by isotope dilution mass spectrometry (IDMS) in one laboratory:

TAFI antigen: 7.43 (7.05-7.82) µg per ampoule.
(expanded uncertainty limits = 7.05-7.82 with k=2 taken to correspond to a 95% level of confidence)

4. CONTENTS

Country of origin of biological material: United Kingdom.
Normal human plasma was sourced from the UK Blood Authority (North London Blood Transfusion Centre, Colindale, UK) Nineteen units of plasma (double-spun and rapidly frozen) were supplied to the MHRA and stored at -70 °C. Each plasma unit had been tested and found negative for HBsAg, HIV antibody, HCV antibody and HCV RNA. After thawing the units were pooled and supplemented with 1.0 M HEPES solution, pH 7.4 (4-(2-Hydroxyethyl) piperazine-1-ethanesulfonic acid) to a final concentration of 40 mmol/L HEPES. DIN ampoules were filled with 1.1 ml aliquots and lyophilised following WHO procedures at the MHRA South Mimms laboratories

5. STORAGE

Upon receipt unopened ampoules should be stored in the dark at or below -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

Allow the ampoules to warm to room temperature. Reconstitute the total contents with 1.0 ml of distilled water and allow to stand for 10 minutes at room temperature and aid reconstitution by regular gentle shaking/swirling. Transfer the reconstituted contents to a plastic tube and keep on melting ice.

Storage of the reconstituted standard under different conditions must be validated locally by users.

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.

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.

Based on the results of a stability test, it is advised that samples are stored on wet ice following reconstitution, and potency assays should be completed within 4 hours of reconstitution

9. REFERENCES

A report of the collaborative study to calibrate the standard is available from WHO, reference number WHO/BS/2023.2457

10. ACKNOWLEDGEMENTS

We are grateful to all the participants that took part in the collaborative study, and to the Fibrinolysis Subcommittee of the Standardization and Scientific Committee (SSC) of the International Society on Thrombosis and Haemostasis (ISTH).

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

Physical and Chemical properties	
Physical appearance: Off white solid	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: 93 mg
Toxicity Statement: Toxicity not assessed
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_1nter_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.