Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
Anti-β2 Glycoprotein I Immunoglobulin G in Serum
NIBSC code: 21/266
Instructions for use
(Version 2.0, Dated 14/02/2022)

This material is not for in vitro diagnostic use

1. INTENDED USE

The International Standard is intended for use as a calibrant for working standards only, where the latter is used to calibrate and harmonize methods used to measure antibody levels against ß2GP1 IgG in serum. These antibodies are recognized biomarkers for antiphospholipid syndrome (APS).

2. CAUTION

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.

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.

3. UNITAGE

The 1st IS for anti-β2GPI IgG has an assigned potency of 200 IU per vial.

4. CONTENTS

Country of origin of biological material: United States of America. Each vial contains the residue after freeze-drying of 1.0ml serum. The plasma was collected through plasmapheresis from two consenting donors diagnosed with antiphospholipid syndrome and converted to serum by the precipitation of clotting factors and removal of fibrin. The donations were pooled and diluted with an equal volume of normal human serum and sterile filtered. **The final combined pool contains 0.2% sodium azide.**

5. STORAGE

Vials are to be shipped on dry ice. Store unopened ampoules at -20°C or below.
Please note because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

Ensure vial reaches room temperature before use. Prior to reconstitution, tap the bottom of the vial on a firm surface to make sure contents are at the bottom of the vial and remove the screw cap. Lift the rubber stopper to expose the groove. Reconstitute with 1ml of ultra-pure water by adding to the groove, replace stopper and leave at room temperature for one hour. Gently mix by inversion at least 5 times during the next hour (do not shake). Leave the vial at room temperature for two days. On the 3rd day, gently mix by inversion five times in a one hour period prior to starting the analysis. The minimum sample intake after reconstitution is 5 microlitres. CAUTION: MATERIAL CONTAINS 0.2% SODIUM AZIDE FOLLOWING RECONSTITUTION

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.

Accelerated degradation studies have indicated that this material is suitably stable when stored at -20°C or below for assigned values to remain valid until the material is withdrawn or replaced. This material should be shipped at a temperature below -20°C. Post-reconstitution stability after day 3 should be determined by the end user in accordance with local conditions. Users who have data supporting any deterioration in the characteristics of any reference material are encouraged to contact NIBSC.

9. REFERENCES

10. ACKNOWLEDGEMENTS

The European Commission Joint Research Centre were responsible for producing the standard and organising and conducting the evaluation studies. We are grateful to the Antiphospholipid Standardisation Laboratory of the Medical Branch of the University of Texas for the donation of the human sera and to the participating laboratories in the study.

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 robust cakes		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	*Irritant:*	*No*
Flammable:	No	*Handling: See caution, Section 2*	
Other (specify):	MATERIAL CONTAINS 0.2% SODIUM AZIDE, HANDLE ACCORDING TO LOCAL LABORATORY PRACTICE		

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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: 0.8g
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_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.