Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
IVIG Negative Control from AB plasma, for use with 07/306
NIBSC code: 17/240
Instructions for use
(Version 1.0, Dated 05/01/2021)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This material is a Negative control preparation for standardising haemagglutination tests performed to control the levels of anti-A and anti-B in normal intravenous immunoglobulin (IVIG) products, and ensuring that such tests are sufficiently sensitive and specific. This preparation should not show agglutination of cells of any phenotype when assayed from a 1 in 2 dilution using the direct 'spin' haemagglutination method using papain-treated red cells(1). This negative control preparation can be used with WHO Reference Reagent 07/306 which is a positive contol with defined titres of anti-A and anti-B.

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

Negative Control

4. CONTENTS

Country of origin of biological material: United Kingdom.

The Negative control IVIG preparation consists of ampoules containing the lyophilised residue of approximately 0.5 mL of a 5% IVIG preparation, diluted from 10% with a sterile buffer (250mM glycine and 0.4% NaCl). The 10% IVIG preparation was manufactured exclusively from plasma collected from blood group AB donors, by CSL Behring. Group AB plasma does not contain antibodies against the A and B blood group antigens. Anti-A and anti-B activities were not detected in direct haemagglutination assays carried out at NIBSC. The mean weight of the dispensed solution was 0.5151g, the imprecision of the filling (CV) was 0.45%, and the residual moisture was 0.16%.

5. STORAGE

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

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.

RECONSTITUTE THE CONTENTS OF THE AMPOULE WITH 0.5 ML DISTILLED OR DEIONISED WATER CONTAINING 0.02% SODIUM AZIDE

Allow several minutes, with occasional vortexing, for reconstitution. Transfer the reconstituted contents to a capped tube and store at 4°C. Once reconstituted, users should determine the stability of the reconstituted material according to their own storage facilities. The reconstituted contents are 5% (w/v) IgG.

This preparation is intended to be used as a negative control along with WHO positive reference reagent 07/306 in the direct 'spin' haemagglutination method using papain-treated red cells (1) for testing anti-A and anti-B titres in batches of IVIG products. IVIG products with anti-A and/or anti-B titres that are higher than those obtained with 07/306 should be compared with the 'Anti-A and anti-B in IVIG: Limit Reference Preparation', 07/310, if applicable.

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.
It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned activity and status until withdrawn or amended. NIBSC follows the policy of WHO with respect to its reference materials.

Accelerated degradation studies on 17/240 have been carried-out after storage of ampoules at -70°C, -20°C, 4°C, 20°C, 37°C, 45°C and 56°C for 19 months. Although the haemagglutination titres are not suitable for analysis using the usual Arrhenius model of accelerated degradation, there is no haemagglutination or HPLC data to suggest that 17/240 will not be adequately stable at -20°C and at ambient temperature for distribution.

9. REFERENCES

1. Anon. Human normal immunoglobulin for intravenous administration; 2.6.26. Test for anti-D antibodies in intravenous immunoglobulin. In European Pharmacopoeia, Directorate for the Quality of Medicines of the Council of Europe, Strasbourg.

10. ACKNOWLEDGEMENTS

We especially thank CSL Behring for donating the Negative control IVIG preparation manufactured specifically from type AB plasma.

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

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

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: Lyophilisate		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: 0.04g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.** **Attached:** No

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