



Working Standard
Biotinylated Brad-5 (Bio-Brad-5)
NIBSC code: 02/230
Instructions for use
(Version 1.0, Dated 30/06/2014)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The reagent is intended for use in the European Pharmacopoeia competitive EIA for anti-D quantitation in immunoglobulin preparations.

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

N/A

4. CONTENTS

Country of origin of biological material: United Kingdom.
The human IgG1 monoclonal anti-D antibody Brad-5 (kindly provided by the Bio Products Laboratory, Elstree, Herts, UK) was biotinylated and diluted in phosphate-buffered saline (PBS) containing 5% (w/v) human serum albumin before distribution into ampoules and lyophilisation. This preparation, coded 02/230, replaces Bio-Brad-5 preparation 99/774. Parallel testing at NIBSC has shown that there is no significant difference between anti-D potency estimates with the two reagents 02/230 and 99/774.

5. STORAGE

Store unopened ampoules 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 manufacturer's 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 ampoule contents with 1.0 ml of distilled/deionised water containing 0.02% sodium azide. Transfer solution to a stoppered tube and store at 4°C.

The concentration of biotinylated Brad-5 is approximately 10 µg/ml.

Dilute 1/40 to give working concentration i.e. 0.25 µg/ml for addition to equal volumes of dilutions of anti-D immunoglobulin standard and samples.

Tests at NIBSC have shown that when using 02/230, increasing the substrate incubation time from 10 min to 12 min gives comparable absorbances to those given by preparation 99/774.

8. STABILITY

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 its 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. For information specific to a particular biological standard, contact NIBSC (see Section 11).

In addition, once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use. However, tests at NIBSC have shown that reconstituted biotinylated Brad-5 is stable for at least 1 month at 4°C in a tightly-lidded tube in the presence of 0.02% (w/v) sodium azide.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

1. European Pharmacopoeia 'Assay of human anti-D immunoglobulin' 2.7.13.
2. SJ Thorpe, CE Turner, A Heath and D Sands. Competitive enzyme linked immunoassay using erythrocytes fixed to microtitre plates for anti-D quantitation in immunoglobulin products. Vox Sang 2000;79:100-107.
3. SJ Thorpe, D Sands, G Rautmann and G Schäffner. International collaborative study to evaluate methods for quantification of anti-D in immunoglobulin preparations. Vox Sang 2002;83:42-50.
4. SJ Thorpe, B Fox and D Sands. A stable lyophilized reagent for use in a potential reference assay for quantitation of anti-D in immunoglobulin products. Biologicals 2002;30:315-321.

10. ACKNOWLEDGEMENTS

Brad-5 was kindly donated by the Bio Products Laboratory, Elstree, U.K.

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: Lyophilisate	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	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 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: 0.06g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. Attached: No