Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Lyophilized HBO-HA Antigen for ELISA, Lot 17, working reagent
NIBSC code: HBOHA
Instructions for use
(Version 2.0, Dated 18/10/2007)

This material is not for in vitro diagnostic use.

1. INTENDED USE

Lot 17 of lyophilized antigen from Haemophilus inluenzae type b contains the polysaccharide conjugated to human serum albumin (HbO-HA). It was prepared by Wyeth Lederle Vaccines, 211 Bailey Road, West Henrietta, New York, 14586-9728, USA and is distributed by NIBSC to third parties. This reagent has been prepared for use in ELISA as a coating antigen.

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

Each vial contains approximatley 1 mg of HbO-HA

4. CONTENTS

Country of origin of biological material: United Kingdom.

This material is supplied as a lyophilized powder which should be stored refrigerated until reconstituted with 1ml of sterile water per vial. When reconstituted as described above, the vial contains approximately 1mg/ml HbO-HA antigen.

5. STORAGE

This material is supplied as a lyophilized powder which should be stored refrigerated until reconstituted with 1ml of sterile water per vial. the reconstituted antigen should be stored at -20°C or below. Aliquots of a convenient volume are recommended for long term storage

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 'flip-up' circular cap. Either on the cap or the collar of the vial, there is an indication of the point at which to lever off the cap. This exposes an area of the stopper through which reconstitution and withdrawal of the preparation can be made using a hypodermic needle and syringe. If use of a pipette is preferred, then fully remove the metal collar using, for example, forceps, taking care to avoid cuts by wearing appropriate gloves. Remove the stopper for access. Care should be taken to prevent loss of the contents.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

The recommended coating concentration for use in ELISA is 1µg/ml. See Appendix I for graph showing determination of a coating concentration comparable to a previous lot of HbO-HA antigen.

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.

9. REFERENCES

Madore, DV et al. Interlaboratory study evaluating quantitation of antibodies to Haemophilus influenzae type b polysaccharide by enzyme-linked immunosorbent assay. Clinical & Diagnostic Laboratory Immunology. 1996:84-88.

Phipps, DC et al. An ELISA employing a Haemophilus influenzae type b oligosaccharide-human serum albumin conjugaste correlates witht eh radioantigen binding assay. Journal of Immunological Methods. 1990 (35): 121-128.

10. ACKNOWLEDGEMENTS

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

Physical and Chemical properties	
Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not Physical appearance: White powder	Corrosive: No
Stable: Yes	Oxidising: No

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

Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	
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

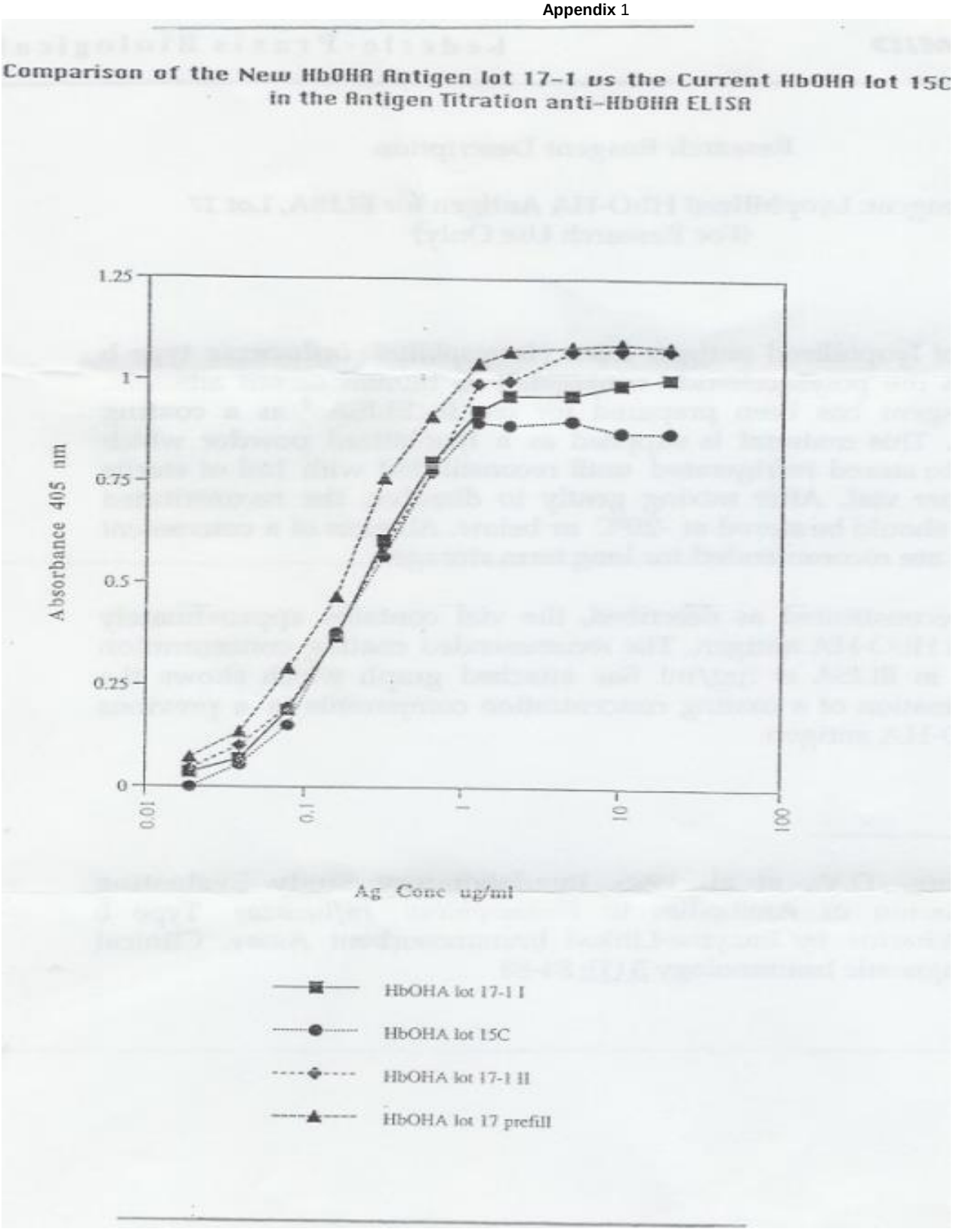
In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.

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

Appendix 1


Comparison of the New HbOHA Antigen lot 17-1 vs the Current HbOHA lot 15C
in the Antigen Titration anti-HbOHA ELISA
Absorbance 405 nm
1.25
1
0.75
0.5
0.25
0
0.01
0.1
1
10
100
Ag Conc ug/ml
HbOHA lot 17-1 I
HbOHA lot 15C
HbOHA lot 17-1 II
HbOHA lot 17 prefill