Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Bordetella pertussis, filamentous heamaglglutinin (FHA)
NIBSC code: JNIH-4
Instructions for use
(Version 7.0, Dated 09/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This material is intended to be used for the characterisation of acellular pertussis vaccines from different origins. It was originlally held by the Statens Serum Institut (SSI) Copenhagen, Denmark. with effect from 1st July 1997, The National Institute for Biological Standards and Control (NIBSC) Potters Bar, UK became the custodian and distributor of this material.

Details from the original SSI package insert are incorporated into this Instruction for Use.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The material is not of human or bovine origin. 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

No initage is assigned to this material (see section 7).

4. CONTENTS

Country of origin of biological material: Japan.
Each ampoule contains about 107 mg of dry material as estimated by weighing after freeze drying, with a moisture content of about 2%. Each ampoule has been stated to contain:

Protein nitrogen	10.0 µg
Filamentous Haemagglutinin (FHA)	10.0 µg
Glucose	30.0 mg
Lactose	30.0 mg
Sucrose	30.0 mg
Arginine	30.0 mg

5. STORAGE

Unopened ampoules should be stored at -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

JNIH-4 is a freeze dried purified preparation of pertussis filamentous haemagglutinin (FHA) manufactured by the Biken Kanonji Institute in Japan on September 6th 1984. Ampoules have been marked JNIH-4 (Japanese National Institute of Health)
So far this preparation has not been finally established as an international reference material but it is stated by the manufacturer that when tested by ELISA it has an FHA activity (anti-FHA) of 2812 units per ampoule. This is not an internationally defined IU.

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.

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

9. REFERENCES

J.G. Kreeftenberg,
Collaborative study on the candidate refeence materials JNIH-3,JNIH-4, JNIH-5 for the assay of acellular pertussis vaccines.

10. ACKNOWLEDGEMENTS

N/A

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: Freeze dried powder.		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	Contains material of biological 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

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

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*: Japan * 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: 0.5 – 1.0 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable**.** **Attached:** No

Statens Seruminstitut

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infectious diseases and congenital disorders
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Leaflet of instructions for users of
CANDIDATE INTERNATIONAL REFERENCE MATERIAL OF PURIFIED PERTUSSIS FILAMENTOUS HEMAGGLUTININ (FHA) (JNIH-4)

1. THE PREPARATION

JNIH-4 is a freeze-dried purified preparation of pertussis filamentous hemagglutinin (FHA) manufactured by the Biken Kanonji Institute in Japan on September 6th, 1984. Ampoules have been marked: JNIH-4 (Japanese National Institute of Health).

2. AMPOULE CONTENTS

Each ampoule contains about 107 mg of dry material as estimated by weighing after freeze-drying with a moisture content of about 2%. Each ampoule has been stated to contain:

Protein nitrogen	10.)	ug PN
Filamentous Hemagglutinin (FHA)	10.)	ug PN
Glucose	30	mg
Lactose	30	mg
Sucrose	30	mg
Arginine	30	mg

3. UNITAGE

So far this preparation has not been established as international reference material and no international unit for pertussis FHA has yet been defined. JNIH-4 is stated by the manufacturer to have, when tested by ELISA method, an FHA activity (anti-FHA) of 2812 units per ampoule. This unit is not an internationally defined IU.

4. PROPOSED USAGE

The reference material is intended to be used for the characterization of acellular pertussis vaccines from different origin. Guidelines are described as part of a WHO collaborative study[1].

5. STORAGE

The ampoules have to be stored at 4-8°C or lower.

6. GENERAL REMARKS ABOUT INTERNATIONAL REFERENCE MATERIALS

International biological standards and international biological reference reagents provide a means of ensuring uniformity throughout the world in the designation of the potency of preparations used in the prophylaxis, therapy, or diagnosis of disease, where the potency cannot be expressed in terms of physical or chemical quantities. The International Units are units quantities of "effective constituent"[2].

The reference material is the material as it exists in the ampoules; the "material" thus includes the effective constituents together with all the other constituents that may be present (moisture, carrier, buffer, salt etc., according to the form in which the standard is available).

International biological reference materials are intended for use in the calibration of the contents of "effective constituent" in national or working standard preparations and for the expression of these contents in the respective International Units. For the routine use in the laboratory the national or working standards should be used in order to save as much as possible the international reference materials. These are only sent to individual laboratories in very limited amounts. International Reference Materials are distributed free of charge to National Control Laboratories of Member States of the World Health Organization. Other laboratories are due to pay a handling charge.

February 1996

7. REFERENCES

1. Proposed guidelines and protocols for the quality control of acellular pertussis vaccines.
J.G. Kreeftenberg, National Institute of Public Health and Environmental Protection, P.O.Box 1, NL-3720 BA BILTHOVEN, Netherlands.

2. N.K. Jerne & E.C. Wood, "The Validity and Meaning of the Results of Biological Assays", Biometrics 5, 273-299 (1949)