Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
1st International Standard for Human Anti-pneumococcal capsule Reference Serum
NIBSC code: 007sp
Instructions for use
(Version 6.0, Dated 06/06/2025)

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1. INTENDED USE

007sp is for use in the enzyme-linked immunosorbent assay (ELISA) protocol for quantification of human IgG antibodies specific for Streptococcus pneumoniae capsular polysaccharides (Pn PS ELISA). 007sp is a pooled serum from 278 healthy volunteers following vaccination with a 23 valent pneumococcal polysaccharide vaccine (Pneumovax II®). In order to estimate the concentration of antibodies, 007sp antibody concentrations were defined through bridging to the previously established standard 89SF [1].

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

Initially, 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) of the candidate standard were calibrated in an International Collaborative Study involving 5 laboratories [2]. These values were derived following double adsorption of 007sp with cell wall polysaccharide (CPS) and polysaccharide 22F and thus in future, when used as a standard, both standard and unknown sera should be double adsorbed (Lot 89SF values were derived following single adsorption and thus the standard and unknown sera are dealt with differently in the current ELISA protocol). Following bridging to the standard 89SF, antibody concentrations in µg/ml were established (see table page 3). Subsequently, 11 additional serotypes (8, 10A, 11A, 12F, 15B, 22F, 33F, 2, 9N, 17F and 20A) were bridged by 3 laboratories [3, 4]. In these studies absorption of 007sp was undertaken by using two absorbents prepared from unencapsulated S. pneumoniae mutant strains incorporating both mono- and di-substituted CPS.

4. CONTENTS

Country of origin of biological material: USA.
007sp consists of 6 ml of freeze-dried human serum. Using FDA licensed methods, and in accordance with the requirements of directive 98/79, the sera were demonstrated to be free from Hepatitis B and C viruses, syphilis and HIV.

5. STORAGE

Lyophilised serum should remain stable at room temperature, but, as a precautionary measure for prolonged storage, ampoules should be kept in a cold (-20°C) and dark environment.
Please note because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

7. USE OF MATERIAL

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

The lyophilized serum as received should be suspended in 6 ml of sterile water. Aliquots sufficient for one assay should be prepared and stored at -20°C or colder (not in a freezer with an automatic defrost cycle). Thawed aliquots can be stored for up to two week at 4°C.

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.

Dried serum standards are expected to undergo negligible loss of potency during long-term storage at the intended storage temperature [6].
Once reconstituted, users should determine the stability of the material according to their own method of preparation, storage and use. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

1. WHO Technical Report Series, No. 927, 2005.
2. Establishment of a New Human Pneumococcal Standard Reference Serum, 007sp : Clin. Vaccine Immunol. October 2011 ; 18:1728-1736.
3. Goldblatt D, et al. 2015. Assignment of Weight-Based Antibody Units for Seven Additional Serotypes to a Human Pneumococcal Standard Reference Serum, 007sp. CVI 22:1154-1159.
4. Goldblatt D, et al. 2017. Assignment of weight-based antibody units for four additional serotypes to a human anti-pneumococcal standard reference serum 007sp. CVI doi:10.1128/CVI.00194-17.
5. Jones S, et al. 2019. Assignment of Serotype-Specific IgG1, IgG2, and IgA Weight-Based Antibody Units to the Human Pneumococcal Standard Reference Serum, 007sp. mSphere 2019 Jun 19;4(3):e00400-19. doi: 10.1128/mSphere.00400-19.
6. Jerne NK and Perry WLM. The Stability of Biological Standards, Bull. Wld. Hlth. Org. 1956, Vol. 14 pp 167-182.

10. ACKNOWLEDGEMENTS

Dr Milan Blake who initiated the 007sp development in 2006. This study (Study Protocol number 06-0093) was sponsored by CBER, USFDA.

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

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

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:	Unknown
Flammable:	No	Handling:See caution, Section 2	
Other (specify):	N/A		

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*: USA * 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: Approximately 6.12g
Toxicity Statement: Non-toxic
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 https://www.who.int/publications/m/item/annex2-trs932(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.

Assigned antibody concentrations of pneumococcal ELISA WHO international standard 007sp

Pneumococcal capsular serotype	IgG ELISA concentration (µg/ml)	95% CI (µg/ml)	
		Lower	Upper
1	8.50	7.88	9.16
2	24.63	21.25	28.55
3	1.45	1.36	1.55
4	3.33	2.95	3.77
5	7.51	7.04	8.02
6A	3.93	3.74	4.14
6B	9.05	7.59	10.80
7F	8.30	8.14	8.46
8	14.24	13.26	15.30
9N	7.03	5.52	8.94
9V	6.44	6.06	6.84
10A	12.98	12.16	13.85
11A	5.08	4.36	5.91
12F	2.21	2.09	2.33
14	37.99	34.86	41.39
15B	16.94	16.04	17.88
17F	8.51	6.74	10.73
18C	7.30	6.80	7.84
19A	13.87	11.51	16.73
19F	14.61	12.68	16.82
20A	10.47	8.55	12.81
22F	9.50	9.04	9.99
23F	5.95	5.21	6.81
33F	10.66	10.18	11.16