Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
4th Pneumococcal Validation Serum Panel
NIBSC code: 25/274
Instructions for use
(Version 1.0, Dated 17/11/2025)

This material is not for in vitro diagnostic use

1. INTENDED USE

This panel contains one ampoule of each of the following pneumococcal validation sera: 96/730, 96/732, 96/738, 96/754, 96/760, 96/762, 96/768, 96/770, 96/772 and 96/774. The material in each ampoule is the residue from freeze-drying defibrinated plasma from volunteers after immunisation with 23-valent pneumococcal polysaccharide vaccine. The panel sera are only to be used for assay validation to demonstrate the comparability of an ELISA procedure to the WHO protocol [1,2], and for this reason (along with only limited stock availability) the sale of this product is restricted to one panel per customer. For routine assay monitoring, laboratories should prepare their own supply of sera to use as an internal control.

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

Assignments of IgG antibody concentrations to pneumococcal types have been made by comparison to the 1st Anti-Pneumococcal Serum International Standard (007sp) when the test sera are absorbed with both C and 22F polysaccharides. For six of the panel members, the IgG concentrations assigned are consensus values from 3 different laboratories [2, 3 and 4]. For the other four panel members, preliminary assignments of IgG antibody concentrations have been made in 1 laboratory only. Please refer to the table in Appendix 1.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze-dried powder from 2 ml of defibrinated plasma.

5. STORAGE

Freeze-dried serum standards are expected to undergo negligible loss of activity during long-term storage at the indicated storage temperature [5]. Long-term storage after reconstitution (at +4°C or frozen) is yet to be established. 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 changes in the characteristics of this material are encouraged to contact MHRA/NIBSC.

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

Resuspend the contents of the ampoule in 2 ml of sterile distilled water. The reconstituted material should be stored frozen at -20ºC or below, preferably in aliquots in order to avoid excessive cycles of temperature change during prolonged use.

8. STABILITY

Reference materials are held at MHRA/NIBSC within assured, temperature-controlled storage facilities. Reference materials should be stored on receipt as indicated on the label.

9. REFERENCES

1.https://www.vaccine.uab.edu/uploads/mdocs/ELISAProtocol(007sp).pdf

2. Goldblatt D, et al. 2011. Establishment of a new human pneumococcal standard reference serum, 007sp. CVI 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. Jerne NK and Perry WLM. The Stability of Biological Standards, Bull. Wld. Hlth. Org. 1956, vol. 14 pp 167-182.

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

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. Similarly the collaborative study organised by Prof D. Goldblatt at the Institute of Child Health, London (ICH) to determine the antibody titre of this reference material should be appropriately cited.

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): 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*: 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: 1 g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** 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

APPENDIX 1

Table of assigned concentrations for 10 pneumococcal validation serum samples (determined with 007sp).
Shaded cells show preliminary assignments of IgG concentration obtained in 1 laboratory.

Capsular serotype	calibration serum (µg/ml)									
	96/730	96/732	96/738	96/754	96/760	96/762	96/768	96/770	96/772	96/774
1	4.67	0.23	4.16	2.65	3.81	3.14	6.51	1.92	1.46	6.93
2	24.14	1.21	4.06	18.43	112.91	5.29	2.45	78.11	33.05	0.60
3	0.27	0.19	1.24	1.08	1.65	1.30	0.24	0.84	0.58	0.09
4	3.79	0.19	2.20	9.59	2.98	0.47	1.15	2.79	1.26	0.16
5	28.23	0.40	2.07	3.17	5.21	0.54	2.33	2.86	3.30	0.49
6A	0.56	0.39	1.72	1.54	1.83	0.77	1.01	3.17	2.01	0.51
6B	4.17	0.21	13.86	2.39	1.37	0.47	2.17	9.75	1.95	0.52
7F	23.60	1.74	1.03	21.06	30.79	4.08	1.34	7.35	4.09	0.69
8	6.52	1.49	5.01	30.68	17.15	1.83	13.04	14.08	6.22	4.68
9N	5.43	2.00	12.52	16.02	10.01	0.88	8.68	13.44	3.06	1.82
9V	1.82	0.27	8.46	15.92	1.49	0.48	4.98	3.51	2.05	3.14
10A	10.30	0.47	1.24	1.23	13.00	0.19	16.91	0.57	5.85	2.02
11A	NR	0.61	NR	NR	5.48	2.01	NR	2.01	3.49	0.78
12F	3.15	0.58	0.33	0.60	4.03	0.24	1.27	1.22	0.68	0.22
14	91.08	1.49	26.50	135.69	13.64	5.03	16.28	105.27	1.86	3.38
15B	16.86	1.57	19.60	67.18	10.43	5.66	2.12	170.62	2.67	3.66
17F	6.72	1.36	NR	3.62	22.37	0.38	1.04	1.49	21.36	2.55
18C	4.33	0.52	7.36	4.47	3.02	0.40	1.32	3.76	2.03	0.23
19A	3.40	1.89	2.53	5.37	10.27	4.55	2.01	7.99	18.45	0.36
19F	4.26	0.67	1.80	10.44	6.29	2.86	3.36	7.04	6.56	0.44
20A	11.55	6.17	NR	3.44	12.79	29.56	17.48	167.72	34.56	1.48
22F	4.45	0.20	1.92	20.61	6.33	0.98	4.23	2.26	2.17	5.12
23F	0.93	0.15	0.71	6.33	1.91	0.72	1.45	12.06	3.13	1.96
33F	2.42	2.90	1.44	6.34	16.43	1.07	8.15	21.20	3.51	1.87

NR = No result

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