Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Chlamydia trachomatis serology panel
NIBSC code: 25/218
Instructions for use
(Version 1.0, Dated 07/10/2025)

This material is not for in vitro diagnostic use

1. INTENDED USE

The panel contains one vial of each of the following *Chlamydia trachomatis* (Ct) plasma samples: 25/208 (positive A), 25/210 (postitive B), 25/212 (positive C), 25/214 (positive D) and 25/216 (negative E). Each plasma sample is a pool made from individual samples selected based on their Major Outer Membrane Protein (MOMP) and pgp3 reactivity [1]. The panel is intended to be used to monitor the performance of immunoassays used to measure anti-Ct antibodies in human serum or plasma to facilitate assay development and validation.

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

Antibody reactivity against MOMP and pgp3 has been determined in two laboratories. One laboratory also determined reactivity against other representative Ct antigens (translocated actin-recruiting phosphoprotein [Tarp], Heat Shock Protein 60 [HSP-60], CT142, CT223, CT798, CT858F2, CT823, CT067 and CT051). See Table 1, Appendix for a summary of the results.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each vial contains 0.1 mL of liquid plasma.

5. STORAGE

The material should be stored between -20°C and -80°C
Material type: Liquid – will be shipped according to the storage and shipping conditions of the product

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

The panel has been used in ELISA and a multiplex fluorescent bead-based assay [1]. The most suitable dilution(s) should be determined by the end user for their specific application.

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

[1] da Silva et al. (2024). Candidate antibody reference reagents for Chlamydia trachomatis serology. J. Immunol. Methods 534. https://doi.org/10.1016/j.jim.2024.113761.

10. ACKNOWLEDGEMENTS

We would like to acknowledge UKHSA for the donation of the plasma samples.

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.

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

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: Liquid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): None	
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: 0.5 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. **Attached:** No

Appendix

Table 1: Antibody reactivity of plasma samples against Ct antigens. Laboratory A determined reactivity against MOMP and pgp3 using a commercial assay and in-house ELISA respectively. Laboratory 2 determined serological reactivity using a multiplex fluorescent bead-based assay [1].

Laboratory	Antigen	*n*	Plasma pool				
			A	B	C	D	E
A	pGP3	*4*	356	359	415	240	<100
	MOMP	*3*	+	+	±	–	–
B	pGP3 D-CT	*2*	807	958	919	429	<200
	MOMP D-UW	*2*	539	1199	<200	<200	<200
	MOMP A-Har	*2*	294	606	<200	<200	<200
	MOMP L2	*2*	581	1040	<200	<200	<200
	TARP D-UW F2	*2*	374	600	<200	<200	<200
	TARP D-UW F1	*2*	415	801	<200	<200	<200
	HSP60–1	*2*	340	577	285	<200	<200
	CT142	*2*	405	338	409	495	<200
	CT223	*2*	339	536	290	<200	<200
	CT798	*2*	480	475	801	<200	<200
	CT858F2	*2*	391	332	731	887	<200
	HtrA CT823	*2*	<200	<200	574	<200	<200
	TroA CT067	*2*	<200	<200	602	<200	<200
	CT051	*2*	<200	417	<200	492	<200

Data represent Mean midpoint (50 %) titers from *n* independent tests, as indicated. Samples with estimated binding titers less than the lowest dilution evaluated are designated as <100 (Lab A) or < 200 (Lab B). Lab A MOMP reactivity was derived using a commercial IgG assay where serostatus was based upon the assay signal / cut-off (–, <1; ±, 1–1.4; + >1.4).

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