

## STREPTOCOCCUS PNEUMONIAE ANTISERA

FOR RESEARCH USE ONLY  
NOT FOR USE IN DIAGNOSTIC PROCEDURES

**RUO**

*Streptococcus pneumoniae* (*S. pneumoniae*) is the most common cause of community-acquired bacterial pneumonia (CAP), and otitis media, and the second most common cause of meningitis in infants and children which may lead to learning disabilities and hearing impairment. Mortality occurs in approximately 10-15% of hospitalised adults with invasive disease. While vaccines are available, widespread overuse of antibiotics has contributed to the emergence of drug resistant strains.

*S. pneumoniae* is serotyped based on the antigenicity of the capsular polysaccharide. This product contains antibodies specific to the capsular antigens of *S. pneumoniae*. The sera are prepared by hyperimmunising healthy rabbits with reference strains (ATCC) of *S. pneumoniae*, heating at 56°C for 30 minutes, and removing cross agglutinins by absorption and aseptic filtration.

### PRODUCTS

*Streptococcus pneumoniae* typing antisera: 2mL of serum in a bottle with dropper, each containing 0.08% w/v sodium azide as a preservative. The product is ready to use.

Set: 47 vials

Polyvalent antisera: 8 vials

Monovalent antisera: 39 vials

Each serotype is listed as follows.

Polyvalent	Monovalent
1	1, 2, 3, 4, 5
2	6, 8, 9, 10
3	11, 12, 14, 15, 16
4	17, 18, 21, 22
5	20, 29, 31, 33, 34, 35, 47
6	23, 25, 28, 41, 46
7	27, 32, 36, 38, 39
8	7, 19, 24, 40

Each serum is individually available.

### INTENDED USE

The *Streptococcus pneumoniae* antisera are intended for serotyping research into prepared *Streptococcus pneumoniae* bacterial cultures, using slide agglutination to qualitatively detect the presence of bacterial antigens. *Streptococcus pneumoniae* antisera are intended for use by trained laboratory personnel.

**This product is for research use only and must not be used in diagnostic procedures.**

### PRINCIPLE OF MEASUREMENT

When *Streptococcus pneumoniae* cells are mixed with the reagent that has corresponding antigens, an antigen-antibody reaction occurs to produce agglutination. The reaction is macroscopically observed to determine each serotype.

### PRECAUTIONS

#### 1. General precautions

- 1) Only bacteriological trained laboratory staff should handle the reagents.
- 2) Reagents should only be used for the intended use.
- 3) Reagents should be used according to the described procedures.
- 4) Antigenic factors of *Streptococcus pneumoniae* are shared widely with other bacteria. It is important to identify the specimen as *Streptococcus pneumoniae* by biochemical properties.

#### 2. Handling precautions

- 1) All specimens, samples and containers coming into contact with samples should be treated as infectious.
- 2) If reagent comes into contact with skin, mucous membranes or eyes, wash immediately with copious amounts of water and seek medical attention if necessary.
- 3) Do not freeze the reagents or use past the expiration date as this may result in poor reagent performance.
- 4) Reagents should be allowed to stand at 15 – 25°C for at least 30 minutes before use.
- 5) Used containers should not be used for other purposes.

- 6) Sera with different lot numbers should not be mixed.
- 7) Special precautions should be taken to ensure that the reagent caps are not exchanged.
- 8) Avoid microbial contamination of opened reagent bottles. Do not use reagents if they are contaminated or cloudy.

#### 3. Precautions for disposal

- 1) The reagent contains 0.08% w/v sodium azide. Sodium azide may react with lead or copper pipes to form explosive heavy metal azides so the reagent should be disposed of with a large amount of water.
- 2) All specimens, spills, inoculated products and equipment used in this test should be disposed of after treating by one of the following methods:
  - [1] Soaking in 0.1% w/v hypochlorite for 1 hour or more.
  - [2] Autoclave at 121°C for 20 minutes or more.

### PROCEDURES

#### 1. Material required but not provided

Physiological saline, pipettes, micropipettes and tips, fluorescent light, bacteriological loops, glass slides, glass pencil, blood agar plate, 37°C incubator.

#### 2. Preparation of reagents

Ready to use.

#### 3. Specimens

Pure cultures of *Streptococcus pneumoniae* identified by biochemical properties should be tested. If the specimen consists of multiple strains or is contaminated, it may not show correct results.

#### 4. Method

##### A) Cultivation of specimen

Inoculate test strains on a blood agar plate and incubate at 37°C for 18 to 24 hours under aerobic conditions. Because *S. pneumoniae* cells easily cause autolysis, serotyping must be done in a same day after cultivation.

##### B) Agglutination test

- 1) Place a drop of polyvalent serum and physiological saline (30µL) on different sections of the partitioned slide.
- 2) Place a small but visible amount of bacterial cells on the area above each drop of serum or physiological saline and mix well using the loop.
- 3) Tilt the glass slide back and forth for one minute and observe for agglutination.
- 4) Check whether spontaneous agglutination occurs with the physiological saline.
- 5) When polyvalent antiserum gives a positive result, place a drop of each monovalent antiserum on a glass slide, and repeat the procedures above to determine the result.

### INTERPRETATION OF THE RESULTS

Agglutination can be grossly observed using an indirect light source over a darkened background. It should be confirmed that no agglutination is found in the control (reaction with test antigen and physiological saline). Only strong agglutination observed within 1 minute of the reaction with each serum should be regarded as positive. Delayed or weak agglutination is regarded as negative (refer to the table below interpretation)

Results of polyvalent sera	Determination and additional tests
Some polyvalent sera test positive.	Serotyping is performed using monovalent sera contained within the polyvalent sera which tested positive.
Multiple polyvalent sera test positive.	Serotyping is performed using monovalent sera contained within the polyvalent sera which tested positive.

Results of monovalent sera	Determination
One monovalent sera tests positive.	The name of the monovalent serum, which tested positive is interpreted as the serotype of the specimen.
Multiple monovalent sera test positive or all monovalent sera test negative.	Determination is suspended.

#### Precautions for interpretation

- When the tested strain shows a multi-positive reaction, confirm the purity of the test specimen. If the tested strain is pure and shows multi-positive result, the strain may possess complex antigens.
- Regarding types 29, 35, and 47. These serotypes share common antigenic factors and show positive reactions with these antisera. The interpretation of these serotypes is done according to the table below.

		Antiserum		
		Type 29	Type 35	Type 47
Type of bacterium	Type 29	+	-	-
	Type 35	(+)	+	-
	Type 47	-	+	+

#### PERFORMANCE CHARACTERISTICS

- Sensitivity test**  
When a drop of the product reacts on a glass slide with a reference strain of a known serotype, granular agglutination is observed.
- Specificity test**  
When the product is tested according to a similar manner to the sensitivity test, agglutination is observed in the reaction with a reference strain of the corresponding serotype, but not observed in the reaction with a reference strain of a different serotype (Types 29, 35, and 47 show cross-reactivity).









#### STORAGE AND SHELF LIFE

Storage: 2-10°C

Shelf life: Up to the expiry date on the label.

#### REFERENCES

- Oguri, T.: *Streptococcus pneumoniae*, Clinical and Microbe 23, 685 (1996).
- Fukumi, H. et al.: The Clinical Study of *Streptococcus pneumoniae*, The Journal of Infectious Disease Study 58, 39 (1984).

	Manufacturer
	Consult instruction for use
	Catalogue number
	Batch code
	For research use only – not for use in diagnostic procedures
	Storage temperature limitation
	Use by
	Contains or presence of natural rubber latex



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