SSI DIAGNOSTICA

Instructions for use

PNEUMOCOCCUS ANTISERA

EN

PNEUMOCOCCUS ANTISERA

For *in vitro* diagnostic use

Intended use

The SSI Diagnostica pneumococcus antisera are intended for visual qualitative confirmation and serotyping of *Streptococcus pneumoniae* (pneumococcus) by use of the Neufeld test (also named the capsular reaction test or the Quellung reaction)[1].

This product is for testing of identified and confirmed pure cultured isolates and strains of pneumococcus.

Description

Pneumococcus antisera from SSI Diagnostica are supplied in vials of 1 mL (approximately 300 tests). Pneumococcus antisera are for visual qualitative confirmation of pneumococcus and serotyping of pure cultures of pneumococci using the Neufeld test. The pneumococcus antisera are polyclonal, raised in rabbits and absorbed to eliminate cross-reacting antibodies when necessary. The pneumococcus antisera are available as individual products in the following product groups: Pool, Group, Type, Factor, Omni and Anti-CWPS antiserum.

Note for factor antisera cross-reactions have been removed within the group only. The antisera may be used separately or in combination depending on the aim of the test.

The antisera may have a light yellow to brown colour. This will not affect the result of the Neufeld test.

SSI Diagnostica antisera are for use by laboratory professionals and/or healthcare professionals only.

Principle

The Neufeld test is performed by mixing antiserum and a pneumococcal isolate/strain. The antiserum-isolate mix is inspected in a phase contrast microscope. The pneumococcal capsule becomes visible and the pneumococci agglutinate if the reaction is positive. The pneumococcal capsule becomes visible and appears swollen as a result of a capsular reaction which is an *in situ* immunoprecipitation (an antigen-antibody reaction) between the pneumococcal capsular polysaccharide (the antigen) and its homologous

antibodies in the antiserum. The size and visibility of the capsule depend on the serotype as well as the growth conditions of the pneumococcal isolate/strain. SSI Diagnostica offers antisera to determine 92 serotypes specifically (see the section "Limitations").
Omni serum and anti-CWPS serum react with all pneumococcal serotypes.

Note: For anti-CWPS serum a positive reaction with the Neufeld test can be difficult to see with some isolates/strains. If that is the case, a slide agglutination test can be used with such strains when using the anti-CWPS serum. Please note that this is only applicable for anti-CWPS serum.

Precautions

- Before using SSI Diagnostica pneumococcus antisera, confirm that the isolate/strain is a pure culture of *Streptococcus pneumoniae*.

- Some isolates/strains, and in particular non-capsulated (rough) isolates/strains, may self-agglutinate and cause false positive reactions.

- If an isolate is difficult to serotype this may be because the isolate did not grow well and therefore also the polysaccharide capsule was not expressed well. A well-expressed polysaccharide capsule is crucial for serotyping.
  In such cases try to regrow the isolate several times, grow the isolate on 10% blood agar instead of 5% blood agar, in Serum broth instead of Todd Hewitt broth or grow the isolate in air with 5% CO_2 instead of in air without additional CO_2.

- Turbidity in the antisera may occur due to lipoprotein precipitation after prolonged storage. If you experience precipitation, it can be removed by centrifugation (10,000 x g) followed by sterile filtration (0.22 µm).

- For Factor antisera cross-reactions have been removed within the group only.

- For the antisera Group 25, Group 35, Type 29 and Type 42, all cross-reactions cannot be removed without also absorbing too much of the homologous antibody. Consequently, the four antisera are sometimes not group or type specific (see table 1). For antiserum Factor 7b and Factor 33f positive reactions may show for some isolates/strains (see table 2).

- For anti-CWPS serum for slide agglutination, please make sure the result is read within 10 seconds. Slide agglutination is only applicable for anti-CWPS serum.

- The antisera have only been validated for confirmation and serotyping with the serotypes indicated in the section “Limitations” and by the below described methods.

- Excessive amount of culture compared to antisera might cause false positive reactions.

- Antisera that have accidentally been frozen should not be used.

- Do not use the antisera after the expiry date.

- Inspect the vial before use to ensure it is intact. Any damaged vials should be discarded.

Materials provided

SSI Diagnostica pneumococcus antisera are supplied in vials containing 1 mL ready-to-use or high titer antisera.

Materials required but not provided

- Serum broth, Todd Hewitt broth or 5-10% blood agar plate
- Physiological saline (0.9% NaCl)
- Pipette
- 1 µL inoculation loop
- Glass slide and cover slip
- Immersion oil
- Phase contrast microscope (100 x magnification, oil immersion lens)
- Incubator (35-37 °C)
- Timer (to measure 10 seconds)

Storage and stability

Pneumococcus antisera must be stored at 2-8 °C in a dark place. Do not freeze. Stored under these conditions the antisera may be used up to the date of expiry shown on the product label.

The in-use stability is not affected by working with the antiserum on the bench throughout the day if it is stored at 2-8 °C when not in use.

Pneumococcus antisera have been tested after being stored at 37 °C for up to four weeks. The antisera were still fully functional.

Preservative

The pneumococcus antisera contain less than 0.1% sodium azide (NaN_3) as preservative.

Sample collection and storage

For sample collection and storage, please follow your local standard procedure.

Quality control

Before use, check the vial to ensure that there is no damage and/or leak. In case of damage or leak, discard the vial.

As positive controls, pneumococcal strains with known serotypes should be used.

As negative controls, physiological saline or growth media (without any strains) and pneumococcal strains with known serotypes should be used. These negative controls should show no agglutination.

Note for factor antisera cross-reactions have been removed within the group only. Therefore, negative control strains for Factor antisera must be of serotypes within the group, which the antiserum to test belongs to (see tables 2 and 3).

To confirm that an observed agglutination is not a false positive reaction, make a control on the isolate/strain for self-agglutination. The self-agglutination test is done by using physiological saline instead of antiserum in the Neufeld test. If a strain/isolate agglutinates when only saline is added, it is self-agglutinating and may cause false positive reactions. To consider self-agglutinating isolates/strains as true positive the capsule should become visible in the Neufeld test (see figure 1).

Before using a new lot, or a new shipment of the same lot or the product is used by a new operator, please perform quality control testing with positive and negative controls of pneumococcal strains with known serotypes before testing of isolates/strains.

Procedure

To perform the Neufeld test, do the following (after growing a pure isolate in broth or on a plate, see recommended media in the section "Materials required but not provided").

1. Dispense 1 drop (2-4 µL) of a freshly grown broth culture on a glass slide. Alternatively, freshly grown colonies from a blood agar plate can be suspended in physiological saline. The concentration of bacteria should be at a level where you can clearly see single cells distributed with distance in the microscope field.

2. Add an equal amount, one drop (2-4 µL) of antiserum and mix.

3. Immediately place a cover slip on top of the mixture (must not dry out).

4. Examine the mixture under a phase contrast microscope within 5 minutes.

5. If the capsule becomes visible (the bacterium appears swollen) the reaction is positive (see figure 1). The bacteria may also agglutinate. Note if you only see an agglutination and no swelling of the capsule, this agglutination may be a false positive reaction (see the section "Quality control").

6. Use the interpretation chessboard schemes (see tables 1, 2 and 3) to interpret the result and determine the serogroup or serotype of the isolate/strain.

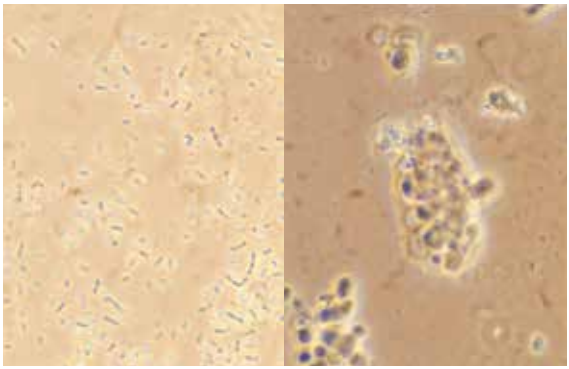

Figure 1. The Neufeld test on a pneumococcal strain serotype 3. A negative reaction is shown on the left panel. A positive reaction on the right panel.

Note for anti-CWPS serum.
A slide agglutination test can be used if the Neufeld test is difficult to interpret as positive or negative. Perform the agglutination test in the following way:

1. Dispense a drop (4-6 µL) of a dense pneumococcal suspension made of a freshly grown colony from a blood agar plate suspended in physiological saline, on a glass slide.

2. Add an equal amount, one drop (4-6 µL) of anti CWPS serum and mix.

3. Mix and gently move the glass slide back and forth vertically. Interpret the result within 10 seconds. If a visual agglutination on the glass slide shows within 10 seconds, the reaction is positive.

4. As a negative control, add physiological saline instead of anti CWPS serum to the drop of the dense pneumococcal suspension and perform the test.

Interpretation of results

For serotype determination of a pneumococcal isolate/strain using the Neufeld test:

Overview, see details below

A. First, test the isolate in pneumococcus Pool antisera.
B. Confirm the result with Group or Type antisera. When necessary, continue with C.
C. Test the isolate with Type and/or Factor antisera.

A. Test the isolate with pneumococcus Pool antisera.
   1. First, test the isolate in pneumococcus Pool A, B, C, D, E, F, G, H and I antisera.
   2. Proceed by testing the isolate in pneumococcus Pool P, Q, R, S and T antisera.
   3. Interpret the result on the chessboard scheme (table 1)[2]. If the isolate is positive in Pool A and Pool P and negative in all other Pool antisera, the isolate is a serotype 1. Is the isolate positive in Pool F and Pool S, and negative in all other Pool antisera, the isolate is a serogroup 17 (see table 1).

B. Confirm the result in the corresponding Type or Group antiserum.
   1. For an isolate positive in Pool A and Pool P, confirm the result with Type 1 antiserum (see table 1). Compare to a negative control with saline instead of antiserum.
   2. For an isolate positive in Pool F and Pool S, confirm the result with the Group 17 antiserum (see table 1).
   3. Thereafter proceed with Type and Factor antisera.

C. Test the isolate with pneumococcus Type or Factor antisera.
   Note before using Factor antisera, the Pool or serogroup of the isolate must be known. Use only Type and Factor antisera within that Pool or serogroup for further testing of the isolate (see table 1). This is important because cross-reactions of Factor antisera have been removed within the group only.
   1. When the Pool or Group antisera provide a non-unique serotype result, test the isolate in the relevant Type or Factor antisera of the Pool or Group (see tables 1 and 2).
      A non-unique result is e.g. an isolate only positive in Pool E that contains both serotype 21 and 39 or an isolate positive in serogroup 17 (positive reaction in Pool F and S), that contains both serotype 17F and 17A (see table 1).
   2. For an isolate positive only in Pool E, test the isolate with Type 21 and Type 39 antisera (see table 1). Is the isolate positive in the Neufeld test with Type 21 and negative with Type 39 antiserum, the isolate is serotype 21. Use a negative control with saline instead of antiserum to compare with.
   3. For an isolate positive in group 17, test the isolate with Factor serum 17b and 17c (see table 2). Read the serotyping result from the reactions (see table 2). Is the Neufeld test positive with Factor serum 17b and negative with Factor serum 17c, the isolate is serotype 17F. Use a negative control with saline instead of antiserum to compare with.

Table 3 shows an overview of 92 pneumococcal serotypes, and which antisera products are recommended to use for determination of each of the serotypes.

Omni serum and anti-CWPS serum react with all pneumococcal serotypes.

Chessboard scheme for identification of pneumococcus serogroups/serotypes

POOL	P	Q	R	S	T	Non-vaccine groups/ types
A	**1**	**18** (18F, 18A, 18B, **18C**)	**4**	**5**	**2**	
B	**19** (**19F**, **19A**, 19B, 19C)	**6** (6A, **6B**, 6C, 6D)	**3**	**8**		
C	**7** (**7F**, 7A, 7B, 7C)				**20**	24 (24F, 24A, 24B) 31, 40
D			**9** (9A, 9L, **9N**, **9V**)		**11** (11F, **11A,** 11B, 11C, 11D)	16 (16F, 16A) 36, 37
E			**12** (**12F**, 12A, 12B)	**10** (10F, **10A**, 10B, 10C)	**33** (**33F**, 33A, 33B, 33C, 33D)	21, 39
F				**17** (**17F**, 17A)	**22** (**22F**, 22A)	27 32 (32F, 32A) 41 (41F ,41A)
G						29, 34 35 (35F, 35A, 35B, 35C) 42 47 (47F, 47A)
H	**14**	**23** (**23F**, 23A, 23B)		**15** (15F, 15A, **15B**, 15C)		13 28 (28F, 28A)
I						25 (25F, 25A) 38, 43, 44, 45, 46, 48

Table 1. Chessboard scheme for identification of pneumococcus serogroups/serotypes[2]. 23-valent vaccine types are indicated by **boldface**. ( ) states types within the group.

Note:

For Group serum 25, cross-reactions may be observed to serotype 38.

For Group serum 35, cross-reactions may be observed to serotype 42 and 47F.

For Type serum 29, cross-reactions may be observed to serotype 35B.

For Type serum 42, cross-reactions may be observed to serotype 20, 31, 33A, 35A, 35B and 35C.

Key to pneumococcus factor antisera

Sero type	Reactions in factor antisera				Antigenic form
	6b	6c	6d		
6A	+	-	-		6a, 6b
6B	-	+	-		6a, 6c
6C	-	-	+		6a, 6d
6D	-	+	+		6a, 6c, 6d
	7b	7c	7e	7f	
7F	+	-	-	-	7a, 7b
7A	(+)	+	-	-	7a, 7b, 7c
7B	-	-	+	-	7a, 7d, 7e, 7h
7C	-	-	-	+	7a, 7d, 7f, 7g, 7h
	9b	9d	9e	9g	
9A	-	+	-	-	9a, 9c, 9d
9L	+	-	-	-	9a, 9b, 9c, 9f
9N	+	-	+	-	9a, 9b, 9e
9V	-	+	-	+	9a, 9c, 9d, 9g
	10b	10d	10f		
10F	+	-	-		10a, 10b
10A	-	+	-		10a, 10c, 10d
10B	+	+	-		10a, 10b, 10c, 10d, 10e
10C	+	-	+		10a, 10b, 10c, 10f
	11b	11c	11f	11g	
11F	+	-	-	+	11a , 11b, 11e, 11g
11A	-	+	-	-	11a, 11c, 11d, 11e
11B	+	-	+	+	11a, 11b, 11f, 11g
11C	+	+	+	-	11a, 11b, 11c, 11d, 11f
11D	+	+	-	-	11a, 11b, 11c, 11e
	12b	12c	12e		
12F	+	-	-		12a, 12b, 12d
12A	-	+	-		12a, 12c, 12d
12B	+	+	+		12a, 12b, 12c, 12e

Sero type	Reactions in factor antisera				Antigenic form
	15b	15c	15e	15h	
15F	+	+	-	-	15a, 15b, 15c, 15f
15A	-	+	-	-	15a, 15c, 15d, 15g
15B	+	-	+	+	15a, 15b, 15d, 15e, 15h
15C	-	-	+	-	15a, 15d, 15e
	16b	16c			
16F	+	-			16a, 16b, 11d
16A	-	+			16a, 16c
	17b	17c			
17F	+	-			17a, 17b
17A	-	+			17a, 17c
	18c	18d	18e	18f	
18F	+	-	+	+	18a, 18b, 18c, 18e, 18f
18A	-	+	-	-	18a, 18b, 18d
18B	-	-	+	-	18a, 18b, 18e, 18g
18C	+	-	+	-	18a, 18b, 18c, 18e
	19b	19c	19f	7h	
19F	+	-	-	-	19a, 19b, 19d
19A	-	+	-	-	19a, 19c, 19d
19B	-	-	-	+	19a, 19c, 19e, 7h
19C	-	-	+	+	19a, 19c, 19f, 7h
	22b	22c			
22F	+	-			22a, 22b
22A	-	+			22a, 22c
	23b	23c	23d		
23F	+	-	-		23a, 23b, 18b
23A	-	+	-		23a, 23c, 15a
23B	-	-	+		23a, 23b, 23d

Sero type	Reactions in factor antisera			Antigenic form
	24c	24d	24e	
24F	-	+	-	24a, 24b, 24d, 7h
24A	+	+	-	24a, 24c, 24d
24B	-	-	+	24a, 24b, 24e, 7h
	25b	25c		
25F	+	-		25a, 25b
25A	-	+		25a, 25c, 38a
	28b	28c		
28F	+	-		28a, 28b, 16b, 23d
28A	-	+		28a, 28c, 23d
	32a	32b		
32F	+	-		32a, 27b
32A	+	+		32a, 32b, 27b

Sero type	Reactions in factor antisera					Antigenic form
	33b	33e	33f	6a	20b	
33F	+	-	-	-	-	33a, 33b, 33d
33A	+	-	-	-	+	33a, 33b, 33d, 20b
33B	-	-	+	-	-	33a, 33c, 33d, 33f
33C	-	+	(+)	-	-	33a, 33c, 33e
33D	-	-	+	+	-	33a, 33c, 33d, 33f, 6a
	35a	35b	35c	29b	42a	
35F	+	+	-	-	-	35a, 35b, 34b
35A	+	-	+	-	-	35a, 35c, 20b
35B	+	-	+	+	-	35a, 35c, 29b
35C	+	-	+	-	+	35a, 35c, 20b, 42a
	41a	41b				
41F	+	+				41a, 41b
41A	+	-				41a
	47a	43b				
47F	+	-				47a, 35a, 35b
47A	+	+				47a, 43b

Table 2. Key to pneumococcus Factor antisera.
+ positive Neufeld reaction, – negative Neufeld reaction, (+) positive Neufeld reaction with some but not all isolates/strains.
23-valent vaccine types are indicated by **boldface**.

Note:

a In accordance with the international and Danish nomenclature of pneumococcal serotypes, all serotypes are written with capital letters e.g. serotypes 18F, 18A, 18B and 18C, whereas Factor antisera to determine the serotypes within serogroup 18, are written with non-capital letters e.g. Factor 18c, 18d, 18e and 18f antisera.

b Factor antisera are only specific within the serogroup.

c All serotypes within group 35 must react positive with Factor 35a serum because of cross-reactions to the serotypes 29 and 42 in the Group serum 35. Group serum 35 and Factor serum 35a cross-react with serotype 47F. Use the Group serum 47 to exclude types within group 35.

Key to pneumococcus antisera

Streptococcus pneumoniae	*Streptococcus pneumoniae* serotype	Positive capsular reaction (Neufeld) in:				Antiserum/antisera recommended for identification of type
		Pool serum	Type serum	Group serum	Factor serum	
Type 1	**1**	A, P	1			Type serum 1
Type 2	**2**	A, T	2			Type serum 2
Type 3	**3**	B, R	3			Type serum 3
Type 4	**4**	A, R	4			Type serum 4
Type 5	**5**	A, S	5			Type serum 5
Group 6	6A	B, Q		6	6b	Factor serum 6b
	6B	B, Q		6	6c	Factor serum 6c + 6d
	6C	B, Q		6	6d	Factor serum 6d + 6c
	6D	B, Q		6	6c, 6d	Factor serum 6c + 6d
Group 7	**7F**	C, P		7	7b	Factor sera 7b + 7c
	7A	C, P		7	7b, 7c	Factor serum 7c
	7B	C, P		7	7e	Factor serum 7e
	7C	C, P		7	7f	Factor serum 7f
Type 8	**8**	B, S	8			Type serum 8
Group 9	9A	D, R		9	9d	Factor sera 9d + 9g
	9L	D, R		9	9b	Factor sera 9b + 9e
	9N	D, R		9	9b, 9e	Factor serum 9e
	9V	D, R		9	9d, 9g	Factor serum 9g
Group 10	10F	E, S		10	10b	Factor sera 10b + 10d + 10f
	10A	E, S		10	10d	Factor sera 10d + 10b
	10B	E, S		10	10b, 10d	Factor sera 10b + 10d
	10C	E, S		10	10b, 10f	Factor serum 10f
Group 11	11F	D, T		11	11b, 11g	Factor sera 11g + 11f
	11A	D, T		11	11c	Factor sera 11c + 11b
	11B	D, T		11	11b, 11f, 11g	Factor sera 11f + 11g
	11C	D, T		11	11b, 11c, 11f	Factor sera 11c + 11f
	11D	D, T		11	11b, 11c	Factor sera 11b + 11c + 11f
Group 12	**12F**	E, R		12	12b	Factor sera 12b + 12c
	12A	E, R		12	12c	Factor sera 12c + 12b
	12B	E, R		12	12b, 12c, 12e	Factor serum 12e
Type 13	13	H	13			Type serum 13
Type 14	**14**	H, P	14			Type serum 14
Group 15	15F	H, S		15	15b, 15c	Factor sera 15b + 15c
	15A	H, S		15	15c	Factor sera 15c + 15b
	15B	H, S		15	15b, 15e, 15h	Factor serum 15h
	15C	H, S		15	15e	Factor sera 15e + 15h

Streptococcus pneumoniae	*Streptococcus pneumoniae* serotype	Positive capsular reaction (Neufeld) in:				Antiserum/antisera recommended for identification of type
		Pool serum	Type serum	Group serum	Factor serum	
Group 16	16F	D		16	16b	Factor serum 16b
	16A	D		16	16c	Factor serum 16c
Group 17	**17F**	F, S		17	17b	Factor serum 17b
	17A	F, S		17	17c	Factor serum 17c
Group 18	18F	A, Q		18	18c, 18e, 18f	Factor serum 18f
	18A	A, Q		18	18d	Factor serum 18d
	18B	A, Q		18	18e	Factor sera 18e + 18c
	18C	A, Q		18	18c, 18e	Factor sera 18c + 18f
Group 19	**19F**	B, P		19	19b	Factor serum 19b
	19A	B, P		19	19c	Factor serum 19c
	19B	B, P		19	7h	Factor sera 7h + 19f
	19C	B, P		19	19f, 7h	Factor serum 19f
Type 20	**20**	C, T	20			Type serum 20
Type 21	21	E	21			Type serum 21
Group 22	**22F**	F, T		22	22b	Factor serum 22b
	22A	F, T		22	22c	Factor serum 22c
Group 23	**23F**	H, Q		23	23b	Factor serum 23b
	23A	H, Q		23	23c	Factor serum 23c
	23B	H, Q		23	23d	Factor serum 23d
Group 24	24F	C		24	24d	Factor serum 24d + 24c
	24A	C		24	24c, 24d	Factor serum 24c
	24B	C		24	24e	Factor serum 24e
Group 25	25F	I		25	25b	Factor serum 25b
	25A	I		25	25c	Factor serum 25c
Type 27	27	F	27			Type serum 27
Group 28	28F	H		28	28b	Factor serum 28b
	28A	H		28	28c	Factor serum 28c
Type 29	29	G	29			Type serum 29
Type 31	31	C	31			Type serum 31
Group 32	32F	F		32	32a	Factor sera 32a + 32b
	32A	F		32	32a, 32b	Factor sera 32b
Group 33	**33F**	E, T		33	33b	Factor sera 33b + 20b
	33A	E, T		33	33b, 20b	Factor serum 20b
	33B	E, T		33	33f	Factor sera 33f + 33e + 6a
	33C	E, T		33	33e (33f)	Factor serum 33e
	33D	E, T		33	33f, 6a	Factor serum 6a

Streptococcus pneumoniae	*Streptococcus pneumoniae* serotype	Positive capsular reaction (Neufeld) in:				Antiserum/antisera recommended for identification of type
		Pool serum	Type serum	Group serum	Factor serum	
Type 34	34	G	34			Type serum 34
Group 35	35F	G		35	35a, 35b	Factor sera 35a + 35b
	35A	G		35	35a, 35c	Factor sera 35a + 35c + 29b + 42a
	35B	G		35	35a, 35c, 29b	Factor sera 35a + 29b
	35C	G		35	35a, 35c, 42a	Factor sera 35a + 42a
Type 36	36	D	36			Type serum 36
Type 37	37	D	37			Type serum 37
Type 38	38	I	38			Type serum 38
Type 39	39	E	39			Type serum 39
Type 40	40	C	40			Type serum 40
Group 41	41F	F		41	41a, 41b	Factor serum 41b
	41A	F		41	41a	Factor sera 41a + 41b
Type 42	42	G	42			Type serum 42
Type 43	43	I	43			Type serum 43
Type 44	44	I	44			Type serum 44
Type 45	45	I	45			Type serum 45
Type 46	46	I	46			Type serum 46
Group 47	47F	G		47	47a	Factor sera 47a + 43b
	47A	G		47	47a, 43b	Factor serum 43b
Type 48	48	I	48			Type serum 48

Table 3: Key to SSI Diagnostica pneumococcus antisera
23-valent vaccine types are indicated by **boldface**.

Note:

a In accordance with the international and Danish nomenclature of pneumococcal serotypes all serotypes are written with capital letters e.g. serotype 18F, 18A, 18B and 18C, whereas Factor antisera to determine the serotypes within serogroup 18, are written with non-capital letters e.g. Factor 18c, 18d, 18e and 18f antisera.

b Factor antisera are only specific within the serogroup.

c All serotypes within group 35 must react positive with Factor 35a serum because of cross-reactions to the serotypes 29 and 42 in the Group serum 35. Group serum 35 and Factor serum 35a cross-react with serotype 47F. Use the Group serum 47 to exclude types within group 35.

Disposal

Follow your local procedures and/or national guidelines for disposal of biological materials.

Limitations

- The culture must be confirmed *Streptococcus pneumoniae* before serotyping using antisera from SSI Diagnostica.

- In four antisera, Group 25, Type 29, Group 35 and Type 42, all cross-reactions cannot be removed without simultaneously absorbing too much of the homologous antibody. Consequently, the four antisera are sometimes not group or type specific (see notes under tables 1, 2 and 3).

- The pneumococcus antisera products have been validated with the following 92 serotypes: 1, 2, 3, 4, 5, 6A, 6B, 6C, 6D, 7F, 7A, 7B, 7C, 8, 9A, 9L, 9N, 9V, 10F, 10A, 10B, 10C, 11F, 11A, 11B, 11C, 11D, 12F, 12A, 12B, 13, 14, 15F, 15A, 15B, 15C, 16F, 16A, 17F, 17A, 18F, 18A, 18B, 18C, 19F, 19A, 19B, 19C, 20, 21, 22F, 22A, 23F, 23A, 23B, 24F, 24A, 24B, 25F, 25A, 27, 28F, 28A, 29, 31, 32F, 32A, 33F, 33A, 33B, 33C, 33D, 34, 35F, 35A, 35B, 35C, 36, 37, 38, 39, 40, 41F, 41A, 42, 43, 44, 45, 46, 47F, 47A, 48.

Performance

Sensitivity, specificity and repeatability

Pneumococcus antisera overall results		
	Percent (number positive/ actual positive)	95% confidence interval
Sensitivity	100% (204/204)	98%-100%
Specificity	100% (272/272)	99%-100%
Repeatability	100% (714/714)	99%-100%

Table 4: Sensitivity, specificity and repeatability for pneumococcus antisera

Reproducibility

The reproducibility within the different groups of antisera and all antisera combined is 100% (confidence interval 99.5%-100%). Therefore, all produced antisera have a high level of reproducibility throughout time and lots.

Incident reporting

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Quality certificate

SSI Diagnostica's development, production and sales of *in vitro* diagnostics are quality assured and certified in accordance with ISO 13485. Certificate of analysis can be downloaded from our website: ssidiagnostica.com

IVD CE

REF

For the list of products and composition, see our website:
https://www.ssidiagnostica.com/pneumococcus-neufeld-antisera/

References

1. Austrian R. The Quellung Reaction, A neglected Microbiologic Technique. The Mount Sinai Journal of Medicine, 43:669-09, 1976

2. Sørensen U.B.S., Typing of Pneumococci by Using 12 Pooled Antisera, J. Clin. Microbiol., 31: 2097-100, 1993

Information and ordering

SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød
Denmark
T +45 4829 9100
info@ssidiagnostica.com
ssidiagnostica.com
shop.ssidiagnostica.com

Revision history

Indication of 23 valent vaccine types in the tables 1, 2 and 3.
Change of logo of notified body

7th edition · August 2023 · 18056

SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød
Denmark

ssidiagnostica.com

Improving
Microbiology