

SUMMARY
STABILITY STUDY
Pneumococcal antisera

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PRODUCT GROUP(S):

The SSI Diagnostica product range of Pneumococcal antisera, are divided into the following categories:

- Pneumococcal type antiserum represented by **type 2, type 4, type 36 and type 46**
- Pneumococcal factor antiserum antiserum represented by **factor 16b, factor 35b and factor 43b**
- Pneumococcal group antiserum antiserum represented by **group 28, group 32, group 41 and group 47**
- Pneumococcal pool serum antiserum represented by **Pool A and Pool H**
- Pneumococcal omni serum.

The above-mentioned antisera represent the Pneumococcal antisera product range not coupled to latex particles. The results are therefore applicable for the entire range of polyclonal Pneumococcal antisera products not coupled to latex particles.

DESCRIPTION OF STUDY:

The stability study has been performed from 2000 and reports the stability of the above mentioned antiserum. This report is conducted according to ISO 23640:2015.

The chosen antisera were stored at 2-8°C and were tested after 0, 3, 6, 9, 12, and 18 months, then 2, 3, and 4 years or until reactions are no longer positive. Positive strain was tested at the different time points. All the antisera were ready-to-use products and there was not a single vial for each time point meaning that the same vial have been opened several

times. All tests are made on non-sealed vials and no sterility testing have been performed during the study. All results are stored locally and a summary is reported here.

1. **NUMBER OF LOTS:** The ready-to-use antisera used in this study were from bulk antisera produced at different timepoints, but all were bottled in 2000. The study includes one lot antisera for each product, since three lots were not available. Each lot were bottled in three lots.
2. **LOT NO.:** z213A1 (Type 2), m4115A1 (Type 4), p3613A1 (Type 36), b4615A1 (Type 46). F16b11A1 (Factor 16b), a35b16A1 (factor 35b), D43b11A1 (factor43b). z2811A1 (Group 28), l3211A1 (Group 32), c4117A1 (Group 41), c4715A1 (Group 47), Com1B1 (Omni), BA12A1 (pool A), UH15A1 (Pool H).
3. **TEMPERATURE:** The temperature was 2-8°C throughout the entire study.
4. **TEST:** Test has been performed every three months over the first year, every six months over the second year, and annually thereafter in 4 years. The test methods are performed according to the IFU.
Pneumococcus are tested by Neufeld. Dispense 1 droplet (2-4 µL) of an overnight broth culture (grown at 35-37° C) on a glass slide. Add an equal amount of antiserum and mix thoroughly. Examine the mixture under a phase contrast microscope within 5 min. If the capsule becomes visible (the bacterium appears swollen) the reaction is positive.
All tests are performed with the control strains for each specific antiserum. All strains used are documented in the raw data of the study.
5. **RETEST:** N/A
6. **HUMIDITY:** N/A
7. **TEST OF INTEGRITY DURING TRANSPORT:** The antisera product line might obtain bruises to their containers when handled roughly but it will not affect the performance of the products. For raw data see report "Drop-test for ImmuView,

antisera and Culture Media".

8. IN-USE STABILITY: Equal to the storage stability.

ACCEPTANCE CRITERIA:

The acceptance criteria are met if the capsule becomes visible (the bacterium appears swollen) then the reaction is positive

- **Titer:** The titer for Pneumococcal antisera are controlled during the stability study, but if the antisera meets the acceptance criteria in the ready-to-use solution we do not state the titer in this study.
- **Long-term stability:** At the termination of the stability study, the antisera must show a positive reaction in ready-to-use solution for the control strains.
- **Other:** Strains used as QC panel can be substituted with strains with similar antigen combination during the stability study if needed.

RESULTS:

All results are recorded throughout the period of 4 years.

In table 1 the results are visualized, stating performance at the beginning and the end of the study, all raw data are available on request.

Table 1: Summarizing of results from stability study for Pneumococcal antisera over 4 years

			Start of study	End of study
Antiserum	Type	2	POS	POS
		4	POS	POS
		36	POS	POS
		46	POS	POS
	Group	28	POS	POS
		32	POS	POS
		41	POS	POS
		47	POS	POS
	Factor	16b	POS	POS
		35b	POS	POS
		43b	POS	POS
	Pool	Pool A	POS	POS
		Pool H	POS	POS
	Omni	Omni	POS	POS

(POS = positive)

CONCLUSION:

Pneumococcal anti serum (ready-to-use) stored at 2-8° C have a duration of minimum 4 years. The shelf life determined as 4 years from date of manufacturing at a temperature range of 2-8° C.

Transport: The antisera product line might obtain bruises to their containers when handled roughly but it will not affect the performance of the products.


In-use: The in-use stability is not affected by working with the antiserum on the bench. During testing if it is stored at 2-8° C for no longer than 4 years form production date.

In conclusion the shelf life and performance of the antiserum are set to four (4) years from the date of manufacturing.

APPROVED:

DATE: 2020-09-09

SIGNATURE:



IVD TEAMLEAD



IVD MANAGER