SSI DIAGNOSTICA

# SUMMARY
# STABILITY STUDY
# Pneumococcus antisera
# Transport study

**AUTHOR:** Jesper Broberg Schou (JBS)

**PRODUCT Group(s):**

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

- Pneumococcal type antiserum represented by **type 46**
- Pneumococcal factor antiserum antiserum represented by **factor 6b**
- Pneumococcal pool serum antiserum represented by **Pool I**
- 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 2013 and reports the stability of the above-mentioned antiserum. The report is conducted according to ISO 23640:2015.

The chosen antisera must undergo different storage temperature (simulating shipping conditions) and were tested after 1, 3, 6, 9, 12, and 18 months, then 2, 3, and 4 years or until reactions are no longer positive. Minimum 3-5 strains were tested at the different time point. All the antisera were in ready-to-use products and there was not a single vial for each time point meaning that the same vial have been opened serval 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 summery are reported here.

SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød
Denmark
T +45 4829 9100

ssidiagnostica.com

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 2013. The study includes one lot antisera for each product. Each lot were bottled in tree lots.

2. **Lot no.:** CL11(Pool I), b4615 (Type 46), N6b12 (Factor 6b), 110 (Omni).

3. **TEMPERATURE:** During this study the different storage conditions have been as follow:
   A. 37° C throughout the entire study
   B. 37° C for 2 weeks then at fridge (2-8° C) for the rest of study
   C. 37° C for 4 weeks then at fridge (2-8° C) for the rest of study
   D. 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. Exception for this are the Omni serum that only have been tested once every year from 2013 to 2019.
   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 date see report "Drop-test for ImmuView, antisera and Culture Media".

8. **IN-USE STABILITY:** Equal to 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 transport study for Pneumococ antisera over 4 years.

| antiSera | Start of study | | | | End of study | | | |
|---|---|---|---|---|---|---|---|---|
| | A | B | C | D | A | B | C | D |
| Pool I | Pos | Pos | Pos | Pos | Neg | Pos | Pos | Pos |
| Type 46 | Pos | Pos | Pos | Pos | Neg | Pos | Pos | Pos |
| Factor 6b | Pos | Pos | Pos | Pos | Neg | Pos | Pos | Pos |
| Omni | Pos | Pos | Pos | Pos | Neg | Pos | Pos | Pos |

*(POS=Positive)*

*(NEG=Negative)*

**CONCLUSION:**

*Pneumococ* antiserum stored at 2-8° C results in no difference in performance and stability after 4 years of storage. The shelf life is therefore set to 4 years from date of manufacturing at a temperature range of 2-8° C. If antiserum is left in temperatures for up to 37° C for two to four weeks and then back in cold store the shelf life is not affected.

We have tested that antisera can be stored at 37° C for 12 month and then the antisera are still fully functional but shelf life after this cannot be guaranteed.

**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 throughout the day 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 after from the date of manufacturing. Also, the shelf life and performance are not affected by working with the antiserum on the bench throughout the day if it is stored at 2-8° C, overnight and for no longer than 4 years form manufacturing date

**APPROVED:**

**DATE: 2020-09-09**

**SIGNATURE:**

IVD TEAMLEAD

IVD MANAGER