SSI DIAGNOSTICA

SUMMARY
STABILITY STUDY
Salmonella antisera

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PRODUCT GROUP(S):

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

- The Poly antisera (O and H) represented by **OMA, HMA** and **Poly A-S**
- O group pool, O group and O factor antiserum, represented by **O:4** and **O:9**
- H phase pool, H phase, H factor and H phase inversion antiserum. Represented by **H:i, H:2** and **H:m**

By selecting the above-mentioned antisera, we represent the majority of the *Salmonella* product range. The results are therefore applicable for the entire range of *Salmonella* products.

DESCRIPTION OF STUDY:

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

The chosen antisera were stored at 2-8°C 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. Two positive strains were tested at the different time points. 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 were made with non-sealed vials and no sterility testing were performed during the duration of the study. All results are stored locally and a summery are reported here.

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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. Each lot were bottled in tree lots.

2. **LOT NO.:** 579E and 579G[1] (OMA), 862C-H (Poly A-S), 633D (O:4), 636C (O:9), 386A and 386B[2] (HMA), 700F (H:2), 726B (H:i), and 692E (H:m).

3. **TEMPERATURE:** The temperature was 2-8°C throughout the entire study.

4. **TEST:** Tests have 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 have been performed according to the IFU.
   Salmonella O Group and O Factor and H Phase and H Factor antisera are intended for slide agglutination. 20µL antiserum and 3 representative colonies of the strain to be tested are mixed on a slide. The slide is tilted for 5-10 sec. A positive reaction is seen as a visible agglutination. A negative reaction is persistence of the homogeneous milky turbidity.
   Physiological saline pH 7.4 is used as a negative control and must be negative.
   All slide agglutination tests are performed with 3-5 representative positive strains for each specific antiserum. All strains used are documented in the raw data of the study.

5. **RETEST:** If strains during the study do not react with homologue antisera or auto agglutinates, the strain is substituted with another strain with similar antigen definitions.

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

[1] The two LOT numbers were a result of an empty vials after 2,5 years and a new Lot was started and tested at t=0 and t=3 years and the yearly for 6 years.
[2] The two LOT numbers were a result of an empty vials after 2,5 years and a new Lot was started and tested at t=0 and t=2 years and the yearly for 6 years

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 for antisera used for slide agglutination are met if a slide agglutination reaction is positive (visible agglutination) within 10 seconds of sliding.

- **Titer:** The titer for *Salmonella* antisera are not controlled during the stability study, as the antisera is tested in ready-to-use solution.
- **Long-term stability:** At the termination of the stability study, the antisera must show a positive reaction in ready-to-use solution for the reference strains.
- **Other:** Strains used as QC panel can be substituted with strains with similar antigen combination during the stability study.

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 the stability study over 4 years.

	Antisera							
	OMA	O:4	O:9	HMA	H:2	H:i	H:m	Poly A-S
Start of study	POS	POS	POS	POS	POS	POS	POS	POS
End of study	POS	POS	POS	POS	POS	POS	POS	POS

(POS=positive)

CONCLUSION:

Salmonella antiserum stored at 2-8° C have a duration of minimum 4 years of storage. The shelf life is 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: 2020-09-10

SIGNATURE:

IVD TEAMLEAD

IVD MANAGER