SSI DIAGNOSTICA

SUMMARY
STABILITY STUDY
Salmonella Vi monoclonal

AUTHOR: Jesper Broberg Schou (JBS)

PRODUCT GROUP(S):

The SSI Diagnostica product range of Salmonella Vi monoclonal antibodies is made from cell lines that makes antibodies against the Vi antigene

DESCRIPTION F STUDY:

The stability study has been performed from 2012. The report 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.

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 2012. The study includes one lot antisera for each product. Each lot were bottled in tree lots.

2. **Lot no.:** 188H-a, 188H-b, and 188H-c

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

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

ssidiagnostica.com

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.
   Salmonella Vi 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 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 meet the acceptance criteria described above.

- **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
	Vi
Start of study	POS
End of study	POS

CONCLUSION:

Salmonella Vi monoclonal 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: 2020-09-08

SIGNATURE:

IVD TEAMLEAD

IVD MANAGER