

SUMMARY
STABILITY STUDY
Streptococcus

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PRODUCT Group(s):

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

- *Streptococcus group B (GBS) represented by Type Ib, III, VIII.*
- *Streptococcus Suis (S. suis) represented by Type 10 and 23.*
- *ImmuLex Streptococcus group B represented by Type II, V, VII.*

By selecting the above-mentioned antisera, we represent the majority of the streptococcus product range. The results are therefore applicable for the complete product range within *Streptococcus* antisera.

Description of study:

The study is performed according to ISO 23640:2015.

All the antisera and ImmuLex were ready-to-use products.

All results are stored locally and a summary are reported here.

1. NUMBER OF LOTS:

The study includes one lot antisera/ImmuLex for each selected product, and two to three lots with in each product group.

2. Lot no.:

GBS: Htot.01.12-3068 (B-type Ib), SBIII-1-2 (B-type III), LBVIII-1-2 (B-type VIII)

S. suis: NSU10-1-3 (S. suis type 10), NSU23-2 (S. suis type 23)

Immulex: LSBII-4 (B-type II), LoLBV-10 (B-type V), LPBVII-5 (B-type VII)

3. TEMPERATURE:

The samples have been stored at 2-8 C throughout the time period.

4. TEST:

The chosen antisera were stored at 2-8°C and were tested after 0 and 6 or 7 years.

Streptococcus group B and *S. suis* are tested by Lancefield and Immulex *Streptococcus* group B are tested by slide agglutination. *Both methods* according to the respective IFU.

5. RETEST: N/A

6. HUMIDITY: N/A

7. TEST OF INTEGRITY DURING TRANSPORT: The 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 storage stability.

Acceptance criteria:

The acceptance criteria for a positive agglutination are as described in the IFU.

- **Titer:** The titer was not tested, as the products are ready to use.
- **Long-term stability:** At the termination of the stability study, the antisera must show a positive reaction in the 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 6 years. In table 1 the results are visualized, starting 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.

	Sera				
	GBS type Ib	GBS type III	GBS type VIII	S. suis type 10	S. suis type 23
Time = 0	POS	POS	POS	POS	POS
Time = 6 years	POS	POS	POS	POS	POS

	Immulex		
	GBS type II	GBS type V	GBS type VII
Time = 0	POS	POS	POS
Time = 6 years	POS	POS	POS

(POS = positive)

CONCLUSION:

Streptococcus antiserum stored at 2-8°C results in no difference in performance and stability after 6 years of storage. The shelf life is therefore set to 6 years from date of manufacturing at a temperature range of 2-8°C.

APPROVED:

DATE: 2022-06-15

SIGNATURE:



IVD Project Employee



IVD Manager

