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Project title:	**ImmuView *S. pneumoniae* Stability and reproducibility study**		
Reference (Danish):	L:\R&D\ImmuView R&D projects\Type 1\PUT\Holdbarhed		
		Protocol number	1
Date:	24-03-2017	**Final version approved:**	ICS
Date:	24-03-2017 to 12-08-2019	**Experiment performed by:**	SBI / JNT /GSJ /CFI

Aim

To investigate the stability of ImmuView *S. pneumoniae* Antigen Test at three different degrees for up to 24 months. Furthermore, to investigate the reproducibility of the assay using three different productions (lots).

Method

This stability report includes test strips or kits from three different lots of ImmuView *S. pneumoniae* antigen test (see table 1).

The kits were stored at different conditions (see table 1). Testing was respectively performed at different times (see table 1).
The kits used were manufactured and stored at -20°C, 02-08°C, room temperature within 15-25° C and 37°C.

Table 1

Validation lot	Storage temperature	Timeslots (months after storage)
P20170601	-20°C, 2-8°C, 15-25°C, and 37°C	2, 6, 12, 18, and 24
P20170602	-20°C, 2-8°C, 15-25°C, and 37°C	2, 6, 12, 18, and 24
P20170629	-20°C, 2-8°C, 15-25°C, and 37°C	2, 6, 12, 18, and 24

One kit contained vials of positive and negative controls for three (3) test runs, which also was the number of opening and closing each of the vials. Thus, positive/negative control vials were opened 3 times in total.

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Table 2

Panel ID	Explanation
Positive control	Positive control vial included in the kit tested. Stored in accordance with the kit. Opened/closed three times
Borderline sample	Borderline artificial spiked urine with CWPS. Made each testing time and tested unfrozen.
Negative control	Negative control included in the kit
D7	Clinical S. pneumoniae positive human urine. Stored frozen in one large vial, so frozen/thawed repeatedly.
NC49	Clinical negative urine

The panel included in each testing included both clinical urine samples and artificial spiked urine samples (table 2).

Recording and acceptance criteria
A strong positive sample result was recorded as *pos*, a weak positive sample as (*pos*) and a negative as *neg*.

The stability was accepted if the panel results agreed with time zero.

The reproducibility was accepted if the results at time zero did not differentiate between the three different lots.

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Results

Validation at room temperature (15-25°C)						
LOT nr. P20170601						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	POS	POS
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	NEG	NEG
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG
LOT nr. P20170602						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	POS	POS
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	NEG	NEG
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG
LOT nr. P20170629						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	POS	POS
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	NEG	NEG
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG

The results of the panel after 24 months were equal to time zero for all three lots stored at room temperature (15-25°C). Thus, the kit is stable for 24 months when stored at 15-25°C. The results from the three different lots did not differentiate, thus the reproducibility was accepted.

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Validation refrigerator (2-8°C)						
LOT nr. P20170601						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	POS	POS
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	NEG	NEG
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG
LOT nr. P20170602						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	POS	POS
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	NEG	NEG
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG
LOT nr. P20170629						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	POS	POS
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	NEG	NEG
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG

The results of the panel after 24 months were equal to time zero for all three lots stored in the refrigerator (2-8°C). Thus, the kit is stable for 24 months when stored at 2-8°C.

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Validation warm temperature (37°C)						
LOT nr. P20170601						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	N/A	N/A
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	N/A	N/A
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG
LOT nr. P20170602						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	POS	N/A
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	NEG	N/A
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG
LOT nr. P20170629						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	N/A	N/A
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	N/A	N/A
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG

The results of the panel after 24 months were equal to time zero for all three lots stored at warm temperature (37°C), with the exception that it was not possible to test the positive and negative control included in the kit after 18 months for two of them and 24 months for the last lot due to a volume mistake, not enough was included in the study. The positive and negative controls are one-point use in order to verify that the strips function properly first time the lot is used.

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Validation at room temperature (-20°C)						
LOT nr. P20170601						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	POS	POS
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	NEG	NEG
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG
LOT nr. P20170602						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	POS	POS
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	NEG	NEG
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG
LOT nr. P20170629						
	T = 0 month	T = 2 months	T = 6 months	T = 12 months	T = 18 months	T = 24 months
Positive control	POS	POS	POS	POS	POS	POS
Borderline sample	(POS)	(POS)	(POS)	(POS)	(POS)	(POS)
Negative control	NEG	NEG	NEG	NEG	NEG	NEG
D7	POS	POS	POS	POS	POS	POS
NC49	NEG	NEG	NEG	NEG	NEG	NEG

The results of the panel after 24 months were equal to time zero for all three lots stored in the refrigerator (-20°C). Thus, the kit is stable for 24 months when stored at -20°C.

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Conclusion

The ImmuView *S. pneumoniae* antigen kit can be stored at -20 to 37°C for up to 24 months (two years from production date) without compromising the stability of the assay.

Overall, the reproducibility of the ImmuView *S. pneumoniae* Antigen Test was accepted.

Due to stability at freezing and warm temperature the transportation of the kit can happen under variating conditions (temperature) without compromising the quality of the assay.

15.09.2022	C. Fischer
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15.09.2022	
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