In addition to 001_ImmuView Stability study report (2)

In addition to the stability report (2) lot five and six were stored at -20°C. Testing was respectively performed at different timeslots (see table 1).

Table 1

Validation lot	Storage temperature	Timeslots (months after storage)
5	-20°C	1, 3 & 6
6	-20°C	1, 3 & 6

Fully equipped kit contained a volume of positive/negative control, and RB for three (3) testing times, which also was the number of opening and closing the vials (table 2), were stored at the represented temperature. Thus, buffer and positive/negative control vials were opened 3 times in total.

Panel ID	Explanation
Positive kontrol	Positive control vial included in the kit tested. Stored in accordance to the kit. Opened/closed three times
+/- kontrol	Bordeline artifical spiked urine with CWPS & LPS. Made each testing time and tested unfrozen.
NEG	Negative control included in the kit
3192/08 (Binax EIA 28 aU/mL)	Clinical Lpn positive urine. Stored frozen in one large vial, so frozen/thawed repeatedly.
3317/08 (Binax EIA 72 aU/mL)	Clinical Lpn positive urine. Stored frozen in one large vial, so frozen/thawed repeatedly.
D7	Clinical Spn positive human urine. Stored frozen in one large vial, so frozen/thawed repeatedly.

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

The color intensities of the *S. pneumoniae* (Spn) and *L. pneumophila* (Lpn) lines were validated, using a scoreboard ranking from 0-10.

A positive sample should be recorded when the score is above zero (F and VF are also perceived as positive).

Results

Figure 1: Validation lot 5 at freezing temperature (-20°C)

Validation 5 LOT nr. PL20150220-Val5 **-20°C**	**T = 1 month**			**T = 3 month**			**T = 6 months**		
	Date/Ini.	13.04.15/JNT		Date/Ini.	08.06.15/JNT		date/Ini.	20.08.15/JNT	
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive kontrol	4	6	+	4	F	+	3	VF	+
+/- kontrol	3	3	+	3	3	+	VF	2	+
NC1	0	0	+	0	0	+	0	0	+
3192/08 (Binax EIA 28 aU/mL)	3	0	+	3	0	+	3	0	+
3317/08 (Binax EIA 72 aU/mL)	10	0	+	10	0	+	10	0	+
D7	0	10	+	0	10	+	0	10	+
Comments	Fine stability, no changes from earlier observations.			The Spn line is lost after the kit has been frozen.			Positive control unstabil when frozen. Borderline urine (+/-) ajusted, so the intensity is a bit decreased		

Figure 2:Validation lot 6 at freezing temperature (-20°C)

Validation 6 LOT nr. PL20150224-Val6 **-20°C**	**T = 1 month**			**T = 3 month**			**T = 6 months**		
	Date/Ini.	13.04.15/JNT		Date/Ini.	08.06.15/JNT		date/Ini.	20.08.15/JNT	
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive kontrol	3	5	+	4	F	+	3	0-VF	+
+/- kontrol	2	3	+	3	6	+	0-VF	2	+
NC1	0	0	+	0	0	+	0	0	+
3192/08 (Binax EIA 28 aU/mL)	2	0	+	3	0	+	3	0	+
3317/08 (Binax EIA 72 aU/mL)	10	0	+	6	0	+	10	0	+
D7	0	10	+	0	10	+	0	10	+
Comments	Fine stability, no changes from earlier observations.			The Spn line is lost after the kit has been frozen.			Positive control unstabil when frozen. Borderline urine (+/-) ajusted, so the intensity is a bit decreased		

The kits were not stable at all when stored at freezing temperature (-20°C). The Spn line was false negative after three (3) months of storage.

There was no change in stability after one (1) month.

Conclusion

The kit cannot be stored under freezing conditions as this will decrease the function of the *S. pneumoniae* line.

However, after one month there are no change in stability. Thus, the transportation of the kit can happen under variating conditions (temperature) without compromising the quality of the assay.

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