

Stability study ImmuView *S. pneumoniae* and *L. pneumophila* antigen test

This stability report includes test strips or kits from the first six production lots of ImmuView *S. pneumoniae* and *L. pneumophila* antigen test. Lot five and six are still undergoing stability testing at 2-8 degrees Celsius (2-8°C).

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 room temperature within 20-25° C. The kits stored at 02-05°C and 37°C were stored under controlled temperatures.

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

Table 1

Validation lot	Storage temperature	Timeslots (months after storage)
4	2-8°C	0, 1, 3, 5, 6, 7, 9, 12, 24 & 36
	20-25°C	0, 1, 3, 5, 6, 7, 9, 12, 24 & 36
	37°C	0, 1, 3, 5, 6, 7, 9, 12, 24 & 36
5	20-25°C	1, 3, 6 & 18
	37°C	1, 3, 6, 9, 12, 18 & 36
6	20-25°C	1, 3, 6 & 18
	37°C	1, 3, 6, 9, 12, 18 & 36

The panel included in each test run included both clinical urine samples and artificial spiked urine samples (table 2). The results were visual interpreted going on an intensity scale from F (faint color intensity) until 10 (high color intensity), zero (0) being a negative result.

Table 2

Panel ID	Explanation
Positive control	Positive control vial included in the kit tested. Stored in accordance to the kit. Opened/closed three times
NEG	Negative control included in the kit
Lpn 3192/08	Clinical Lpn positive urine. Stored frozen in one large vial, so frozen/thawed repeatedly.
Lpn 3317/08	Clinical Lpn positive urine. Stored frozen in one large vial, so frozen/thawed repeatedly.
Spn D7	Clinical Spn positive human urine. Stored frozen in one large vial, so frozen/thawed repeatedly.

Results

Table 3: Validation lot 4 at room temperature (20-25°C) stability

Validation 4 LOT: PL20140910-Val4 20-25°C	T = 1 month			T = 3 months			T = 5 months			T = 6 months			T = 7 months		
	Date/Ini. 2014.10.16/JNT			date/ini. 2014.12.11/JNT			date/ini. 2015.02.15/JNT			Date/ini. 2015.03.09/JNT			Date/ini. 2015.04.13/JNT		
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive Control	2	3	+	4	4	+	5	5	+	4	4	+	5	5	+
NEG	0	0	+	0	0	+	0	0	+	0	0	+	0	0	+
Lpn 3192/08	3	0	+	5	0	+	4	0	+	4	0	+	3	0	+
Lpn 3317/08	10	0	+	10	F	+	10	0	+	10	0	+	10	0	+
Spn D7	0	10	+	0	10	+	0	10	+	0	10	+	0	10	+
Comments	Passed stability			Passed stability			Passed stability			Passed stability			Passed stability		

T = 9 months			T = 12 months			T = 24 months			T = 36 months		
Date/ini. 2015.06.08/JNT			Date/ini. 2015.09.10/JNT			Date/ini. 2016.11.02/JNT			Date/ini. 2017.11.07/JNT&CFI		
Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
4	4	+	4	5	+	5	5	+	4	4	+
0	0	+	0	0	+	0	0	+	0	0	+
2	0	+	4	0	+	4	0	+	4	0	+
10	0	+	10	0	+	10	0	+	8	0	+
0	10	+	0	10	+	0	9	+	0	9	+
Passed stability			Passed stability			Passed stability			Passed stability		

Table 4: Validation lot 4 at refrigerator temperature (2-8°C)

Validation 4 LOT: PL20140910-Val4 2-8°C	T = 1 month			T = 3 months			T = 5 months			T = 6 months		
	Date/Ini. 2014.10.16/JNT			date/ini. 2014.12.11/JNT			date/ini. 2015.02.05/JNT			Date/ini. 2015.03.09/JNT		
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive Control	5	4	10	4	4	10	4	5	10	2	4	+
NEG	0	0	10	0	0	10	0	0	10	0	0	+
Lpn 3192	4	0	10	3	0	10	4	0	10	3	0	+
Lpn 3317/08	10	0	10	10	0	10	10	0	10	10	0	+
Spn Spn D7	0	10	10	0	10	10	0	10	10	0	10	+
Comments	Passed stability			Passed stability			Passed stability			Passed stability		

T = 7 months			T = 9 months			T = 12 months			T = 24 months			T = 36 months		
Date/ini. 2015.04.13/JNT			Date/ini. 2015.06.08/JNT			Date/ini. 2015.09.10/JNT			Date/ini. 2016.11.02/JNT			Date/ini. 2017.11.07/JNT&CFI		
Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
3	5	+	3	5	+	3	5	+	1	5	+	4	4	+
0	0	+	0	0	+	0	0	+	0	0	+	0	0	+
4	0	+	3	0	+	3	0	+	4	0	+	4	0	+
10	0	+	10	0	+	10	0	+	9	0	+	10	0	+
0	10	+	0	10	+	0	10	+	0	9	+	0	10	+
Passed stability			Passed stability			Passed stability			Passed stability			Passed stability		

Table 5: Validation lot 4 at elevated temperature (37°C)

Validation 4 LOT: PL20140910-Va4 37°C	T = 1 month			T = 3 months			T = 5 months			T = 6 months		
	Date/Ini. 2014.10.16/JNT			date/ini. 2014.12.11/JNT			date/ini. 2015.02.05/JNT			Date/Ini. 2015.03.09/JNT		
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive Control	5	5	10	4	4	10	4	4	10	4	4	+
NEG	0	0	10	0	0	10	0	0	10	0	0	+
Lpn 3192/08	4	0	10	4	0	10	4	0	10	3	0	+
Lpn 3317/08	10	0	10	10	0	10	10	0	10	10	0	+
Spn D7	0	10	10	0	10	10	0	10	10	0	10	+
Comments	Passed stability			Passed stability			Passed stability			Passed stability		

T = 7 months			T = 9 months			T = 12 months			T = 24 months			T = 36 months		
Date/Ini. 2015.04.13/JNT			Date/Ini. 2015.06.08/JNT			Date/Ini. 2015.09.10/JNT			Date/Ini. 2016.11.02/JNT			Date/Ini. 2017.11.07/JNT&CFI		
Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
4	5	+	4	5	+	4	4	+	1	4	+	QNS	QNS	QNS
0	0	+	0	0	+	0	0	+	0	0	+	0	0	+
4	0	+	3	0	+	3	0	+	2	0	+	2	0	+
10	0	+	10	0	+	10	0	+	7	0	+	8	0	+
0	10	+	0	10	+	0	10	+	0	8	+	0	9	+
Passed stability			Passed stability			Passed stability			Passed stability			Failed stability due to evaporation of positive control		

Lot 4 was stable when the kit was stored at room temperature 20-25° C, at 2-8°C, and at 37°C.

Table 6: Validation lot 5 at room temperature (20-25°C)

Validation 5 LOT: PL20150220-Va5 20-25°C	T = 1 month			T = 3 months			T = 6 months			T = 18 months		
	Date/Ini. 2015.04.13/JNT			Date/Ini. 2015.06.08/JNT			date/ini. 2015.08.20/JNT			date/ini. 2016.11.02/JNT		
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive Control	4	6	+	6	9	+	3	4	+	1	3	+
NEG	0	0	+	0	0	+	0	0	+	0	0	+
Lpn 3192/08	3	0	+	5	0	+	3	0	+	2	0	+
Lpn 3317/08	10	0	+	10	0	+	10	0	+	5	0	+
Spn D7	0	10	+	0	10	+	0	7	+	0	8	+
Comments	Passed stability			Passed stability			Passed stability			Passed stability		

Table 7: Validation lot 5 at elevated temperature (37°C)

Validation 5 LOT: PL20150220-Val5 37°C	<u>T = 1 months</u>			<u>T = 3 months</u>			<u>T = 6 months</u>			<u>T = 9 months</u>		
	Date/Ini. 2015.04.13/JNT			Date/Ini. 2015.06.08/JNT			date/Ini. 2015.08.20/JNT			date/Ini. 2015.12.14/JNT		
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive Control	4	6	+	4	6	+	3	6	+	3	5	+
NEG	0	0	+	0	0	+	0	0	+	0	0	+
Lpn 3192/08	3	0	+	3	0	+	3	0	+	3	0	+
Lpn 3317/08	10	0	+	10	0	+	10	0	+	10	0	+
Spn D7	0	10	+	0	10	+	0	10	+	0	10	+
Comments	Passed stability			Passed stability			Passed stability			Passed stability		

<u>T = 12 months</u>			<u>T = 18 months</u>			<u>T = 36 months</u>		
Date/Ini. 2016.03.17/JNT			Date/Ini. 2016.11.02/JNT			Date/Ini. 2017.11.07/JNT		
Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
4	4	+	1	3	+	1/F	4	+
0	0	+	0	0	+	0	0	+
2	0	+	2	0	+	F	0	+
10	0	+	5	0	+	5	0	+
0	10	+	0	7	+	0	6	+
Passed stability			Passed stability			Passed stability		

Lot 5 was stable when the kit was stored at room temperature 20-25° C and at 37°C.

Table 8: Validation lot 6 at room temperature (20-25°C)

Validation 6 LOT: PL20150224-Val6 20-25°C	<u>T = 1 month</u>			<u>T = 3 months</u>			<u>T = 6 months</u>			<u>T = 18 months</u>		
	Date/Ini. 2015.04.13/JNT			Date/Ini. 2015.06.08/JNT			Date/Ini. 2015.08.20/JNT			Date/Ini. 2016.11.02/JNT		
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive Control	3	5	+	4	5	+	4	5	+	2	3	+
NEG	0	0	+	0	0	+	0	0	+	0	0	+
Lpn 3192/08	2	0	+	3	0	+	3	0	+	2	0	+
Lpn 3317/08	10	0	+	7	0	+	10	0	+	4	0	+
Spn D7	0	10	+	0	9	+	0	10	+	0	7	+
Comments	Passed stability			Passed stability			Passed stability			Passed stability		

Table 9: Validation lot 6 at warm temperature (37°C)

Validation 6 LOT: PL20150224-Val6 37°C	T = 1 month			T = 3 months			T = 6 months			T = 9 months		
	Date/Ini.	13.04.15/JNT		Date/Ini.	26.05.15/JNT		Date/Ini.	20.08.15/JNT		Date/Ini.	14.12.15/JNT	
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive Control	3	4	+	3	5	+	2	4	+	3	4	+
NEG	0	0	+	0	0	+	0	0	+	0	0	+
Lpn 3192/08	3	0	+	3	0	+	3	0	+	3	0	+
Lpn 3317/08	10	0	+	10	0	+	10	0	+	10	0	+
Spn D7	0	10	+	0	10	+	0	10	+	0	10	+
Comments	Passed stability			Passed stability			Passed stability			Passed stability		

T = 12 months			T = 18 months			T = 36 months		
Date/Ini.	17.03.16/JNT		Date/Ini.	02.11.16/JNT		Date/Ini.	07.11.17/JNT	
Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
2	2	+	1	3	+	2	3	+
0	0	+	0	0	+	0	0	+
3	0	+	2	0	+	1	0	+
10	0	+	4	0	+	3	0	+
0	10	+	0	7	+	0	5	+
Passed stability			Passed stability			Passed stability		

Lot 6 was stable when the kit was stored at room temperature 20-25° C and at 37°C.

Table 10: two additional lots stored at 2-8°C. Testing ongoing

LOT: ES20180702 2-8°C	T = 2.5 months			T = 3.8 months			T = 6 months		
	Date/Ini.: 2018.11.29/LHI/JVP			Date/Ini.: 2019.01.02/LHI/CFI			Date/Ini.: 2019.03.14/CFI/JVP		
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive Control	4	3	+	4	3	+	4	3	0
NEG	0	0	+	0	0	+	0	0	0
Lpn 3192	0	3	+	0	3	+	0	2	0
Lpn 3317/08	0	6	+	0	6	+	0	6	0
Spn Spn D7	8	0	+	8	0	+	8	0	0
Comments	Passed stability			Passed stability			Passed stability		

LOT: ES20180704 2-8°C	T = 2.5 months			T = 3.8 months			T = 6 months		
	Date/Ini.: 2018.11.29/LHI/JVP			Date/Ini.: 2019.01.02/LHI/CFI			Date/Ini.: 2019.03.14/CFI/JVP		
	Lpn	Spn	Control	Lpn	Spn	Control	Lpn	Spn	Control
Positive Control	6	5	+	6	5	+	4	4	+
NEG	0	0	+	0	0	+	0	0	+
Lpn 3192	0	6	+	0	5	+	0	3	+
Lpn 3317/08	0	9	+	0	9	+	0	9	+
Spn Spn D7	9	0	+	9	0	+	9	0	+
Comments	Passed stability			Passed stability			Passed stability		

Two additional lots (ES20180702 and ES20180704) were stored at 2-8°C for 6 months and passed stability. Testing is ongoing for both lots.

Conclusion

Three (3) lots of ImmuView *S. pneumoniae* and *L. pneumophila* antigen kits were stored at 20-25° C and 37° C with passing results for up to 36 months.

One (1) kit lot was stored at 2-8° C for 36 months and tested with passing results. Two additional kit lots stored at 2-8 degrees C will be tested for up to 36 months to validate a storage claim of 2-37° C for the ImmuView *S. pneumoniae* and *L. pneumophila* urinary antigen test for 24 months. They have both passed stability after six months until now.

Signatures:

Lab technician: *Joanette Markes*

Date: 2019-07-26

Head of R&D: *[Signature]*

Date: 2019-09-30