Report title:	ImmuView L. pneumophila & L. longbeachae Stability study					
Purpose code:	N/A	Report ID	ImmuView L. pneumophila and L. longbeachae stability study-V02			
DHF D4 no:	5898/version 8	Protocol ID	N/A			

Approval							
Position	Name	Signature	Date				
Laboratory							
technician	N/A						
Production manager	Sanne Otte						
Trial manager	N/A						
SVP NPD	Pernille Landsbo Elverdal (PEL)						

Roles and responsibilities:

Laboratory technician: responsible for that the study has been conducted in accordance with the protocol.

Project/product manager: responsible for the implementation of the results in technical documentation.

Trial manager: responsible for ensuring the correct and accurate transfer of data from the underlying studies into the current report, and that the conclusion is scientifically sound and correct.

SVP NPD: responsible for approval of the content of the file and takes responsibly for and secures independent review of the document.

Revision History							
Version No.	Revision Description	Author	Date				
2	Updated stability report to include 36 and 48 months. Previous report name: 10.1mmuView L. pneumophila and L. longbeachae stability study	GJS	16-08- 2023				

References:

1.	Excel file: Resultater holdbarhed LLVal 2 (L:\IVD
	Production\ImmuView\Holdbarhed\L&L\Holdbarhed LLVal2,LLVal3,LLVal4)
2.	Excel file: Resultater holdbarhed LLVal 3 (L:\IVD
	Production\ImmuView\Holdbarhed\L&L\Holdbarhed LLVal2,LLVal3,LLVal4)
3.	Excel file: Resultater holdbarhed LLVal 4 (L:\IVD
	Production\ImmuView\Holdbarhed\L&L\Holdbarhed LLVal2,LLVal3,LLVal4)

4.	
5.	

Purpose:

The purpose with the stability study is to find the stability of the ImmuView *L. pneumophila* and *L. longbeachae* Urinary Antigen Test.

Materials:

ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test:

- LLVal2
- LLVal3
- LLVal4

Table 1:

Panel ID	Explanation
Pos control (1:2)	Positive control vial included in the kit tested.
	Stored in accordance too the kit.
	Opened/closed three times.
+/- control +10%	Negative clinical urine spiked with LPS to be
	borderline positive.
	Made each testing time and tested unfrozen.
Neg control	Negative control vial included in the kit tested.
	Stored in accordance too the kit.
	Opened/closed three times.
NCP2	Negative clinical urine
	Stored frozen
DS9	Negative clinical urine (positive for S. pneumoniae)
	Stored frozen
KS4-19	Clinical urine positive for Legionella pneumophila
	Stored frozen
KS5-27	Clinical urine positive for Legionella longbeachae
	Stored frozen

Method:

This stability report includes test strips or kits from three different lots of ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test (see table 2).

The kits were stored at different conditions (see table 2). Testing was performed respectively at different times (see table 2).

The kits used were manufactured and stored at room temperature within 20-25° C (with and without humidity control, being closed or open strip container). The kits stored at 2-5°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 2:

Validation lot	Storage temperature	Timeslots (Months after storage)	
LLVal2	-20°C, 2-8°C, 15-25°C, and 37°C	2, 6, 12, 16, 36 and 48	
LLVal3	-20°C, 2-8°C, 15-25°C, and 37°C	6, 12, 18, 24, 36 and 48	
LLVal4	-20°C, 2-8°C, 15-25°C, and 37°C	6, 12, 18, 28*, 36 and 48	

*Due to an oversight timeslot 24 was tested at 28 months. This did not affect the result of the study.

The panel included in each testing included both clinical positive urine samples and artificial spiked clinical negative urine samples (table 1).

The colour intensities of the L. longbeachae (longbeachae) line and L. pneumophila (pneumophila) were validated visually, using an In-House 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).

Variation in score for each sample should be seen as a result of individual visual interpretation and can vary depending on the timeslot as well as of the operator.

In commercial use the results are recorded as either Negative or Positive with no regard to the colour intensity of the positive lines.

Gray lines, shadows and/or Dots must be read as Invalid, and a retest of the sample is required.

In this study retests were not conducted in the few cases where shadows or Dots were seen, due to lack of materials. This did not affect the result of the study.

Analytical and Statical Methods:

No statistical methods have been used for this stability study.

Results:

Figure 1: Validation at room temperature (15-25°C) Lot LLVal2

Lot no. LLVal2	T=0 r	nonths	T=2 n	nonths	T=6 months		T=12 months	
15-25°C	Date/Ini:	2016.12.22/MAJ	Date/Ini:	2017.02.21/MAJ	Date/Ini:	2017.06.22/MAJ	Date/Ini:	2017.12.21/JNT
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4-5	4	4-5	4	4	4	3	3
+/- control +10%	1	VF	1	VF	1	VF	F-1	F-1
Neg control	0	0	0	0	0	0	0	0
NCP2	0	0	0	0	0	0	0	0
DS9	0	0	0	0	0	0	0	0
KS4-19	0	3	0	3	0	3	0	2
KS5-27	7	0	7	0	7-8	0	7	0

Lot no. LLVal2	T=16 r	nonths	T=36 r	months	T=48 months		
15-25°C	Date/Ini:	2018.04.19/JNT	.19/JNT Date/Ini: 2020.01.02/CFI		Date/Ini:	2021.01.06/CFI	
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	
Pos control (1:2)	3	3	5	4	7	2	
+/- control +10%	1	1	2	1	1	F	
Neg control	0	0	0	0	0	0	
NCP2	0	0	0	0	0	0	
DS9	0	0	0	0	0	0	
KS4-19	0	2	0	1-2	0	1	
KS5-27	6	0	6	0	3	0	

Lot no. LLVal3	T=0 r	nonths	T=6 months		T=12 months	
15-25°C	Date/Ini:	2016.12.22/MAJ	Date/Ini:	2017.08.30/MAJ	Date/Ini:	2018.03.05/JNT
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4	4	4	4	4	4
+/- control +10%	1	VF	1-2	1	1	1-2
Neg control	0	0	0	0	0	0
NCP2	0	0	0	0	0	0
DS9	0	0	0	0	0	0
KS4-19	0	3	0	3-4	0	2-3
KS5-27	7	0	7	0	6-7	0

Figure 2: Validation at room temperature (15-25°C) Lot LLVal3

Lot no. LLVal3	T=18 r	nonths	T=24 r	months	T=36 months		T=48 months	
15-25°C	Date/Ini:	2018.08.28/CFI	Date/Ini:	2019.02.19/JVP	Date/Ini:	2020.02.21/CFI	Date/Ini:	2021.02.21/JVP
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4	4	4	3	8	5	8	4
+/- control +10%	1-2	1-2	2	2	2	2	1	1
Neg control	0	0	0	0	0	0	0	0
NCP2	0	0	0	0	0	0	0	0
DS9	0	0	0	0	0	0	0	0
KS4-19	0	3	0	2	0	2	0	2
KS5-27	5-6	0	4	0	5	0	5	0

Lot no. LLVal4	T=0 months		T=6 n	nonths	T=12 months		
15-25°C	Date/Ini:	2017.06.08/MAJ	Date/Ini:	2017.11.29/MAJ	Date/Ini:	20178.06.05/JNT	
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	
Pos control (1:2)	5	5	4	4	3	4	
+/- control +10%	1	1	1-2	1	1	1	
Neg control	0	0	0	0	0	0	
NCP2	0	0	0	0	0	0	
DS9	0	0	0	0	0	0	
KS4-19	0	3-4	0	3-4	0	3	
KS5-27	6-7	0	5	0	3-4	0	

Figure 3: Validation at room temperature (15-25°C) Lot LLVal4

Lot no. LLVal4	T=18 r	months	T=28 r	nonths	T=36 r	months	T=48 r	months
15-25°C	Date/Ini:	2018.11.26/CFI	Date/Ini:	2019.07.11/CFI	Date/Ini:	2020.05.27/CFI	Date/Ini:	2021.05.21/JVP
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4	4	4	4	3	3	3	3
+/- control +10%	2	2	2	1	1	1	1	1
Neg control	0	0	0	0	0	0	0	0
NCP2	0	0	0	0	0	0	0	0
DS9	0	0	0	0	0	0	0	0
KS4-19	0	2	0	3	0	2	0	2
KS5-27	3	0	3	0	3	0	2	0

The results of the panel (figure 1-3) after 48 months were equal to time zero for all three lots stored at room temperature with humidity control. This was however not the same without humidity control, the stability decreased (false positive lines after 6 months for Val3 (data not shown).

Lot no. LLVal2	T=0 r	nonths	T=6 n	nonths	T=12 m	months	
2-8°C	Date/Ini:	2016.12.22/MAJ	Date/Ini:	2017.06.22/MAJ	Date/Ini:	2017.12.21/JNT	
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	
Pos control (1:2)	4-5	4	4	4	4	4	
+/- control +10%	1	VF	1	VF	1	1	
Neg control	0	0	0	0	0	0	
NCP2	0	0	0	0	0	0	
DS9	0	0	0	0	0	0	
KS4-19	0	3	0	3	0	2-3	
KS5-27	7	0	7	0	7	0	

Figure 4: Validation at cool temperature (2-8°C) Lot LLVal2

Lot no. LLVal2	T=16 r	months	T=36 r	months	T=48 r	months
2-8°C	Date/Ini:	2018.04.19/JNT	Date/Ini:	2020.01.02/CFI	Date/Ini:	2021.01.06/CFI
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	3-4	3	5	4	7	5
+/- control +10%	1	F-1	2	F	3	1
Neg control	0	0	0	0	0	0
NCP2	0	0	0	0	0	0
DS9	0	0	0	0	0	0
KS4-19	0	2	0	2	0	2
KS5-27	6	0	6	0	7	0

Lot no. LLVal3	T=0 I	months	T=6 r	months	T=12 n	nonths
2-8°C	Date/Ini:	2017.02.28/MAJ	Date/Ini:	2017.08.30/MAJ	Date/Ini:	2018.03.05/JNT
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4	4	4	4	3-4	4
+/- control +10%	1	VF	1-2	1	1	1
Neg control	0	0	0	0	0	0
NCP2	0	0	0	0	0	0
DS9	0	0	0	0	0	0
KS4-19	0	3	0	3	0	2-3
KS5-27	7	0	5-6	0	5	0

Figure 5: Validation at cool temperature (2-8°C) Lot LLVal3

Lot no. LLVal3	T=18 r	months	T=24 r	months	T=36 I	months	T=48 r	months
2-8°C	Date/Ini:	2018.08.28/CFI	Date/Ini:	2019.02.19/JVP	Date/Ini:	2020.02.21/JVP	Date/Ini:	2021.02.22/CFI
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4	4	3	3	4	3	7	3
+/- control +10%	2	1	1	1	2	2	2	1
Neg control	0	0	DOT	0	0	0	0	0
NCP2	0	0	0	0	0	0	0	0
DS9	0	0	0	0	0	0	0	0
KS4-19	0	2	0	2	0	2	0	2
KS5-27	5-6	0	4	0	3	0	4	0

	Figure 6: Validation at	cool temperature (2-8°C) Lot LLVal4
--	-------------------------	-------------------------------------

Lot no. LLVal4	T=0 months		T=6 n	nonths	T=12 months		
2-8°C	Date/Ini: 2017.0		Date/Ini:	2017.11.29/MAJ	Date/Ini:	20178.06.05/JNT	
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	
Pos control (1:2)	5	5	4	4	3	4	
+/- control +10%	1	1	1-2	1	1	1	
Neg control	0	0	0	0	0	0	
NCP2	0	0	0	0	0	0	
DS9	0	0	0	0	0	0	
KS4-19	0	3-4	0	3	0	2	
KS5-27	6-7	0	5-6	0	4	0	

Lot no. LLVal4	T=18 r	nonths	T=28 r	nonths	T=36 r	months	T=48 months	
2-8°C	Date/Ini:	2018.11.26/CFI	Date/Ini:	2019.07.11/CFI	Date/Ini:	2020.05.27/CFI	Date/Ini:	2021.05.21/JVP
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	3	3	4	4	4	3	5	4
+/- control +10%	1	1	1	1	1	1	1	1
Neg control	0	0	0	0	0	0	0	0
NCP2	0	0	0	0	0	0	0	0
DS9	0	0	0	0	0	0	0	0
KS4-19	VF	2	0	3	DOT	2	0	2
KS5-27	3	0	3	0	4	0	4	0

The results of the panel (figure 4-6) after 48 months were equal to time zero for all three lots stored at cool temperature (2-8°C).

For LLVal3 (Figure 5) a dot was observed for T=24 months when tested with Negative control. This must be read as invalid (like stated in the IFU) and retest is required, but retest could not be conducted due to lack of materials. But since LLVal2 and LLVal4 did not give invalid results for T=24 moths, the dot for LLVal3 is considered to be a minor outlier.

For LLVal4 (Figure 6) a dot was observed for T=36 months when tested with KS4-19. This must be read as invalid (like stated in the IFU) and retest is required, but retest could not be conducted due to lack of materials. But since LLVal2 and LLVal3 did not give invalid results for T=36 moths, the dot for LLVal4 is considered to be a minor outlier.

Lot no. LLVal2	T=0 r	nonths	T=6 n	nonths	T=12 m	onths
37°C	Date/Ini:	2016.12.22/MAJ	Date/Ini:	2017.06.22/MAJ	Date/Ini:	2017.12.21/JNT
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4-5	4	4	4	3-4	4
+/- control +10%	1	VF	1	VF	1	1
Neg control	0	0	0	0	0	0
NCP2	0	0	0	0	0	0
DS9	0	0	0	0	0	0
KS4-19	0	3	0	3	0	2
KS5-27	7	0	7	0	6	0

Figure 7: Validation at warm temperature (37°C) Lot LLVal2

Lot no. LLVal2	T=16 r	nonths	T=36 r	months	T=48 r	nonths
37°C	Date/Ini:	2018.04.19/JNT	Date/Ini:	2020.01.02/CFI	Date/Ini:	2021.01.06/CFI
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	3-4	3	5	4	5	1
+/- control +10%	1	1	2	1-F	1	F
Neg control	0	0	0	0	0	0
NCP2	0	0	0	0	0	0
DS9	0	0	0	0	0	0
KS4-19	0	2	0	1	0	1
KS5-27	6	0	5	0	3-4	0

Lot no. LLVal3	T=0 months		T=6 n	nonths	T=12 months		
37°C	Date/Ini:	2017.02.28/MAJ	Date/Ini:	2017.08.30/MAJ	Date/Ini:	2018.03.05/JNT	
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	
Pos control (1:2)	4	4	4	4	4	4	
+/- control +10%	1	VF	1-2	1	1	1	
Neg control	0	0	0	0	F	0	
NCP2	0	0	0	0	0	0	
DS9	0	0	0	0	F	0	
KS4-19	0	3	0	3	0	2	
KS5-27	7	0	7	0	6	0	

Figure 8: Validation at warm temperature (37°C) Lot LLVal3

Lot no. LLVal3	T=18	months	T=24 r	months	T=36 I	months	T=48 m	nonths
37°C	Date/Ini:	2018.08.28/CFI	Date/Ini:	2019.02.19/JVP	Date/Ini:	2020.02.21/CFI	Date/Ini:	2021.02.22/CFI
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4	4	3	3	7	3	6	3
+/- control +10%	1	1	2	2	2	2	1	F
Neg control	F	0	F	0	0	0	DOT	0
NCP2	0	0	VF	0	0	0	0	0
DS9	0	0	0	0	0	0	0	0
KS4-19	0	3	0	3	0	2	0	2
KS5-27	5-6	0	4-5	0	4	0	3	0

Lot no. LLVal4	T=0 I	months	T=6 r	months	T=12 r	months	
37°C	Date/Ini:	2017.06.08/MAJ	Date/Ini:	2017.11.29/MAJ	Date/Ini:	20178.06.05/JNT	
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	
Pos control (1:2)	5	5	4	4	3	3	
+/- control +10%	1	1	1-2	1	1	1	
Neg control	0	0	shadow	0	shadow	0	
NCP2	0	0	shadow	0	0	0	
DS9	0	0	shadow	0	0	0	
KS4-19	0	3-4	0	2-3	0	3	
KS5-27	6-7	0	5	0	4	0	

Figure 9: Validation at warm temperature (37°C) Lot LLVal4

Lot no. LLVal4	T=18 r	months	T=28 r	28 months T=36 months		T=48 months		
37°C	Date/Ini:	2018.11.26/CFI	Date/Ini:	2019.07.11/CFI	Date/Ini:	2020.05.27/CFI	Date/Ini:	2021.05.21/JVP
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4	4	4	3	3	3	3	1
+/- control +10%	1	1	1-2	1	1	F	F	F
Neg control	0	0	shadow	0	0	0	0	0
NCP2	0	0	0	0	0	0	0	0
DS9	0	0	0	0	0	0	0	0
KS4-19	0	2	0	2	0	1	0	1
KS5-27	3	0	2-3	0	3	0	2	0

The results of the panel (figure 7-9) after 48 months were equal to time zero for all three lots stored at warm temperature (37°C).

For LLVal3 (Figure 8) a dot was observed for T=48 months when tested with Neg. control. This must be read as invalid (like stated in the IFU) and retest is required, but retest could not be conducted due to lack of materials. But since LLVal2 and LLVal4 did not give invalid results for T=48 moths, the dot for LLVal3 is considered to be a minor outlier.

For LLVal4 (Figure 9) shadows were observed at T=6, T=12 and T=28 months. This must be read as invalid and retest is required, but retest could not be conducted due to lack of materials. Since T=18, T=36 or T=48 did not give invalid results, the shadows are considered minor outliers.

Lot no. LLVal2	T=0 r	nonths	T=6 n	nonths	T=12 m	nonths
-20°C	Date/Ini:	2016.12.22/MAJ	Date/Ini:	2017.06.22/MAJ	Date/Ini:	2017.12.21/JNT
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4-5	4	3-4	3-4	3	3
+/- control +10%	1	VF	1	VF	1	1
Neg control	0	0	0	0	0	0
NCP2	0	0	0	0	0	0
DS9	0	0	0	0	0	0
KS4-19	0	3	0	2	0	2
KS5-27	7	0	6	0	7	0

Figure 10: Validation at freezing temperature (-20°C) Lot LLVal2

Lot no. LLVal2	T=16 r	nonths	T=36 r	months	T=48 r	months
-20°C	Date/Ini:	2018.04.19/JNT	Date/Ini:	2020.01.02/CFI	Date/Ini:	2021.01.06/CFI
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	3	3	5	4	6	2
+/- control +10%	1	1	2	1-F	1	F
Neg control	0	0	0	0	0	0
NCP2	0	0	0	0	0	0
DS9	0	0	0	0	0	0
KS4-19	0	2	0	3	0	1
KS5-27	6	0	6	0	6	0

Lot no. LLVal3	T=0 r	nonths	T=6 n	nonths	T=12 n	nonths
-20°C	Date/Ini:	2017.02.28/MAJ	Date/Ini:	2017.08.30/MAJ	2017.08.30/MAJ Date/Ini:	
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4	4	4	4	3-4	4
+/- control +10%	1	VF	1-2	1-2	1	1
Neg control	0	0	0	0	0	0
NCP2	0	0	0	0	0	0
DS9	0	0	0	0	0	0
KS4-19	0	3	0	3	0	2
KS5-27	7	0	5-6	0	5	0

Figure 11: Validation at freezing temperature (-20°C) Lot LLVal3

Lot no. LLVal3	T=18	months	T=24 r	months	T=36 months		T=48 months	
-20°C	Date/Ini:	2018.08.28/CFI	Date/Ini:	2019.02.19/JVP	Date/Ini:	2020.02.21/JVP	Date/Ini:	2021.02.22/JVP
	longbeachae	Philadelphila	longbeachae	Philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4	4	4	4	4	4	4	3
+/- control +10%	1	1	1	1	2	2	2	1
Neg control	0	0	0	0	0	0	0	0
NCP2	0	0	0	0	0	0	0	0
DS9	0	0	0	0	0	0	0	0
KS4-19	0	3	0	3	0	3	0	2
KS5-27	5-6	0	2	0	4	0	4	0

Lot no. LLVal4	T=0 I	months	T=6 r	months	T=12 r	months
-20°C	Date/Ini:	2017.06.08/MAJ	Date/Ini:	2017.11.29/MAJ	Date/Ini:	20178.06.05/JNT
	longbeachae	philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	5	5	3-4	3-4	3	4
+/- control +10%	1	1	1	1	1	1-2
Neg control	0	0	0	0	0	0
NCP2	0	0	0	0	0	0
DS9	0	0	0	0	0	0
KS4-19	0	3-4	0	2-3	0	3
KS5-27	6-7	0	3-4	0	3	0

Figure 12: Validation at freezing temperature (-20°C) Lot LLVal4

Lot no. LLVal4	T=18 r	months	T=24 r	nonths	T=36 months		T=48 months	
-20°C	Date/Ini:	2018.11.26/CFI	Date/Ini:	2019.07.11/CFI	Date/Ini:	2020.05.27/CFI	Date/Ini:	2021.05.21/JVP
	longbeachae	philadelphila	longbeachae	Philadelphila	longbeachae	philadelphila	longbeachae	philadelphila
Pos control (1:2)	4	4	3	4	4	3-4	3	3
+/- control +10%	1	1	1	1	1	1	1	1
Neg control	0	0	0	0	0	0	0	0
NCP2	0	0	0	0	0	0	0	0
DS9	0	0	0	0	0	0	0	0
KS4-19	0	3	0	2	0	3	0	2
KS5-27	4	0	3	0	4	0	3	0

The results of the panel (figure 10-12) after 48 months were equal to time zero for all three lots stored at freezing temperature (-

20°C).

Conclusion:

The ImmuView L pneumophila and L. longbeachae antigen test can be stored at -20 to 37°C for up to 48 months (4 years from production date) without compromising the stability of the assay.

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.