

**BIOLOGICAL HEALTH RISKS
QUALITY OF LABORATORIES**

COMITEE OF EXPERTS

**EXTERNAL QUALITY ASSESSMENT
IN VETERINARY DIAGNOSIS**

**DEFINITIVE GLOBAL REPORT
VETERINARY MEDECINE
CLASSICAL SWINE FEVER (CSF)
SURVEY 2022/4**

Sciensano/PT VET CSF/2-E

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TABLE OF CONTENTS

1	INTRODUCTION	4
2	AIM	4
3	MATERIALS AND METHODS	4
3.1	Serology	4
3.1.1	The participants	4
3.1.2	the samples.....	4
3.1.3	Homogeneity.....	4
3.1.4	Target values	5
3.1.5	Stability	5
3.1.6	Randomisation and panel composition	6
4	SURVEY TIMELINE	6
5	RESULTS	7
5.1	Serology on serum	7
5.1.1	Results per sample	7
5.1.2	Used method.....	7
5.1.3	Conclusion	7
6	ANNEXES (NOT UNDER ACCREDITATION)	8
6.1	Annex 1: Quantitative results	8
6.1.1	serology on serum	8
6.2	Annex 2: Additional information	14

1 INTRODUCTION

Details relevant to the proficiency test (PT) are available in the procedure SOP 2.5/01 'Management of the proficiency tests organized by the scientific directorate infectious diseases in animals'. The PT was organized according to the ISO17043 'Conformity assessment - General requirements for proficiency testing' norm.

2 AIM

This PT was dedicated detecting the agent of Classical Swine Fever (CSF) (CSF virus) by ELISA (Ab) in serum.

3 MATERIALS AND METHODS

3.1 Serology

3.1.1 THE PARTICIPANTS

Five laboratories participated in the proficiency test of CSF serology on serum. The names of the participating laboratories are:

- Sciensano
- ARSIA
- DGZ
- Laboratoire de médecine vétérinaire de l'état (LMVE, Luxembourg)
- IDEXX Technologies GmbH (Bern, Switzerland)

3.1.2 THE SAMPLES

The samples were prepared by the National Reference Laboratory (NRL), Service of Viral reemerging enzootic and BEE diseases, Infectious diseases in animals Directorate, Sciensano.

Information about the **origin** and **preparation** of the samples:

- PT2022CSFSERPS1 is the first line weak positive CSF Ab control (WPOS CSF 16-01). This is a preparation done by dilution 1/10 of CSF positive serum (unknown production condition) in negative serum.
- PT2022CSFSERPS2, PS3, and PS4 are sera collected on three domestic pigs (gilts) surviving an experimental contact infection with CSFV strain (genotype 2.1, 93-94 Belgian epizootic) and euthanized between 45 to 65 days post infection.
- PT2022CSFSERPS5 and PS6 are sera collected on two domestic pigs surviving an experimental infection with CSFV strain (genotype 2.1, 97-98 Belgian epizootic) and euthanized 45 days post infection.
- PT2022CSFSERN1, NS2 and NS3 are sera collected on three naïve domestic pigs.

3.1.3 HOMOGENEITY

The homogeneity of the samples was tested by the NRL on 10 aliquots (250 µl) of each sample using ELISA method before the PT. The samples were considered as homogeneous.

3.1.4 TARGET VALUES

The target values were determined by the NRL based on the homogeneity tests. The panel consisted of 14 positive and 6 negative samples:

Sample ID	Status
PT2022CSFSERSERUMPS1	POS (weak)
PT2022CSFSERSERUMPS2	POS
PT2022CSFSERSERUMPS3	POS
PT2022CSFSERSERUMPS4	POS
PT2022CSFSERSERUMPS5	POS
PT2022CSFSERSERUMPS6	POS
PT2022CSFSERSERUMNS1	NEG
PT2022CSFSERSERUMNS2	NEG
PT2022CSFSERSERUMNS3	NEG

(POS = positive; NEG = negative)

3.1.5 STABILITY

The samples were tested before and after the PT. The results were compared, and the samples were considered as stable.

3.1.6 RANDOMISATION AND PANEL COMPOSITION

Since a specific number has been assigned to each laboratory, the randomization has been performed as follow:

Sample ID: CSFSER SERUM	97505	97507	97508	97516	97544
22-1	NS1	PS1	PS5	NS2	PS1
22-2	NS3	PS6	PS4	PS4	PS1
22-3	PS2	PS3	NS1	PS6	PS5
22-4	PS5	PS6	NS3	PS3	NS3
22-5	NS1	PS3	PS2	PS5	PS6
22-6	PS6	NS2	PS4	PS2	PS6
22-7	PS5	PS4	PS1	PS5	PS5
22-8	PS2	NS3	NS2	PS1	NS2
22-9	PS1	PS4	PS6	PS1	NS3
22-10	PS1	PS5	PS5	PS6	PS2
22-11	PS4	PS1	NS3	NS2	PS4
22-12	NS2	PS5	PS3	PS5	NS1
22-13	PS6	PS2	PS1	NS3	PS3
22-14	PS5	PS1	PS2	NS1	PS5
22-15	PS3	PS2	NS1	PS2	PS1
22-16	PS3	NS2	PS3	PS4	PS2
22-17	NS2	NS1	PS1	PS3	NS2
22-18	PS4	PS5	PS5	NS1	PS4
22-19	NS3	NS3	PS6	NS3	PS3
22-20	PS1	NS1	NS2	PS1	NS1

4 SURVEY TIMELINE

Transfer of the samples from NRL to QL: 24/03/2022

Randomization of the samples by QL: 24/03/2022

Sending samples (cooled at 4 °C) to participants: 29/03/2022

Deadline for submitting the results: 22/04/2022

Preliminary report: 09/05/2022

5 RESULTS

5.1 Serology on serum

The panel consisted of 9 different samples. Samples PS1 and PS5 were repeated three times, whereas the other samples were repeated twice. Therefore, in total, the panel consisted of 20 samples (14 positive and 6 negative samples).

5.1.1 RESULTS PER SAMPLE

Sample ID	Status	Number of repetitions (total results)	Observed result
PS1	POS (weak)	3	15 POS
PS2	POS	2	10 POS
PS3	POS	2	10 POS
PS4	POS	2	10 POS
PS5	POS	3	15 POS
PS6	POS	2	10 POS
NS1	NEG	2	10 NEG
NS2	NEG	2	10 NEG
NS3	NEG	2	10 NEG

(POS = positive; NEG = negative)

5.1.2 USED METHOD

Method	N	NR	NCR	%
Idexx - IDEXX CSFV Ab Test	5	100	100	100
TOTAL	5	100	100	100

(N= number of laboratories; NR = number of results; NCR = number of correct results)

5.1.3 CONCLUSION

Only one method was used by the laboratories. This method achieved 100% correctness, which means that 100 correct results were submitted.

6 ANNEXES (NOT UNDER ACCREDITATION)

The boxplots, shown down below, were created by using the following software programme: shiny.chemgrid.org/boxplotr/

6.1 Annex 1: Quantitative results

6.1.1 SEROLOGY ON SERUM

PT2022CSFSERSERUMPS1

Lab number	97505	97507	97508	97516	97544
Method	Idexx - IDEXX CSFV Ab Test				
REP1	77.6	69.5	70.5	70.0	74.0
REP2	79.6	73.1	72.0	73.0	74.0
REP3	77.5	69.5	70.9	77.2	74.0
Mean	78.2	70.7	71.1	73.4	74.0
SD	1.2	2.1	0.7	3.6	0.0
CV (%)	1.6	2.9	1.0	4.9	0.0

(REP = repetition; SD = standard deviation; CV = coefficient of variation)

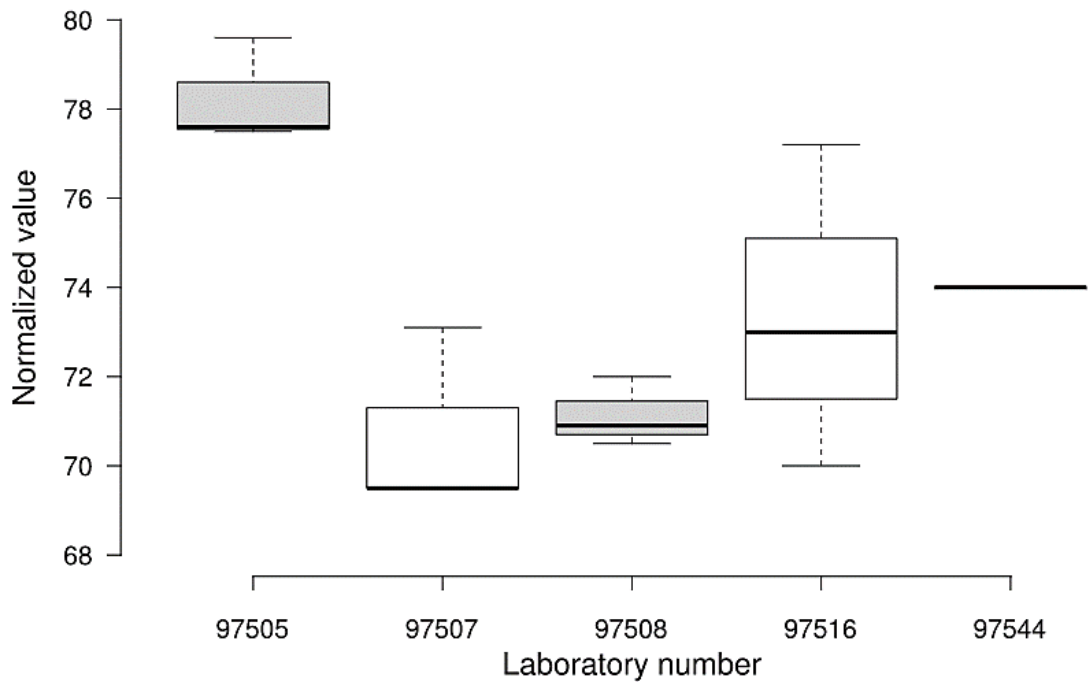


Figure 1. Distribution of the normalized values (box-plots) per laboratory.

PT2022CSFSERSERUMPS2

Lab number	97505	97507	97508	97516	97544
Method	Idexx - IDEXX CSFV Ab Test				
REP1	100.6	96.3	91.3	94.9	95.0
REP2	100.4	96.1	89.5	95.0	95.0
Mean	100.5	96.2	90.4	95.0	95.0
SD	0.1	0.1	1.3	0.0	0.0
CV (%)	0.1	0.1	1.4	0.1	0.0

(REP = repetition; SD = standard deviation; CV = coefficient of variation)

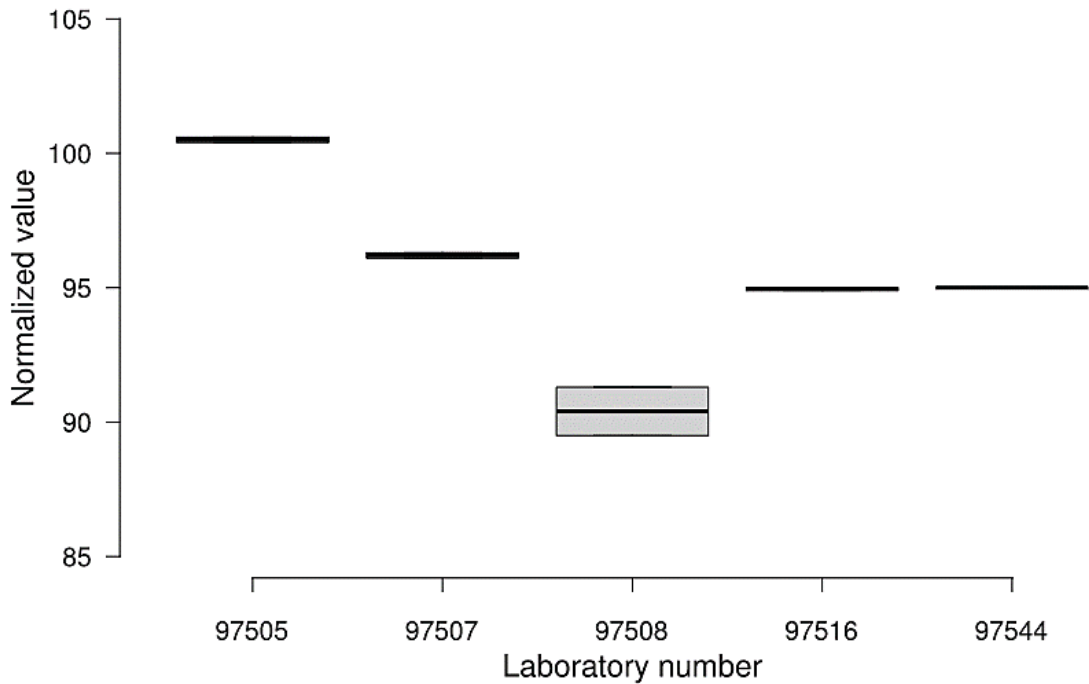


Figure 2. Distribution of the normalized values (box-plots) per laboratory.

PT2022CSFSERSERUMPS3

Lab number	97505	97507	97508	97516	97544
Method	Idexx - IDEXX CSFV Ab Test				
REP1	99.5	95.3	90.8	92.9	94.0
REP2	99.8	95.4	89.4	94.6	94.0
Mean	99.6	95.3	90.1	93.8	94.0
SD	0.2	0.1	1.0	1.2	0.0
CV (%)	0.2	0.1	1.1	1.3	0.0

(REP = repetition; SD = standard deviation; CV = coefficient of variation)

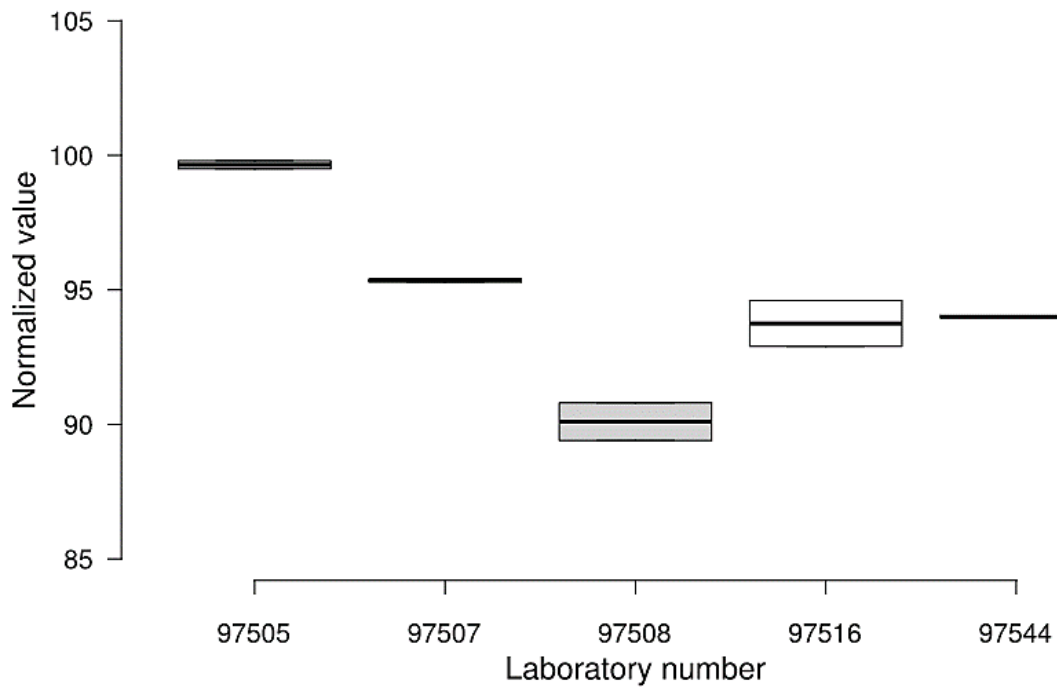


Figure 3. Distribution of the normalized values (box-plots) per laboratory.

PT2022CSFSERSERUMPS4

Lab number	97505	97507	97508	97516	97544
Method	Idexx - IDEXX CSFV Ab Test				
REP1	100.1	95.7	91.1	94.8	94.0
REP2	100.0	95.3	90.7	94.7	94.0
Mean	100.1	95.5	90.9	94.7	94.0
SD	0.1	0.3	0.3	0.0	0.0
CV (%)	0.1	0.3	0.3	0.1	0.0

(REP = repetition; SD = standard deviation; CV = coefficient of variation)

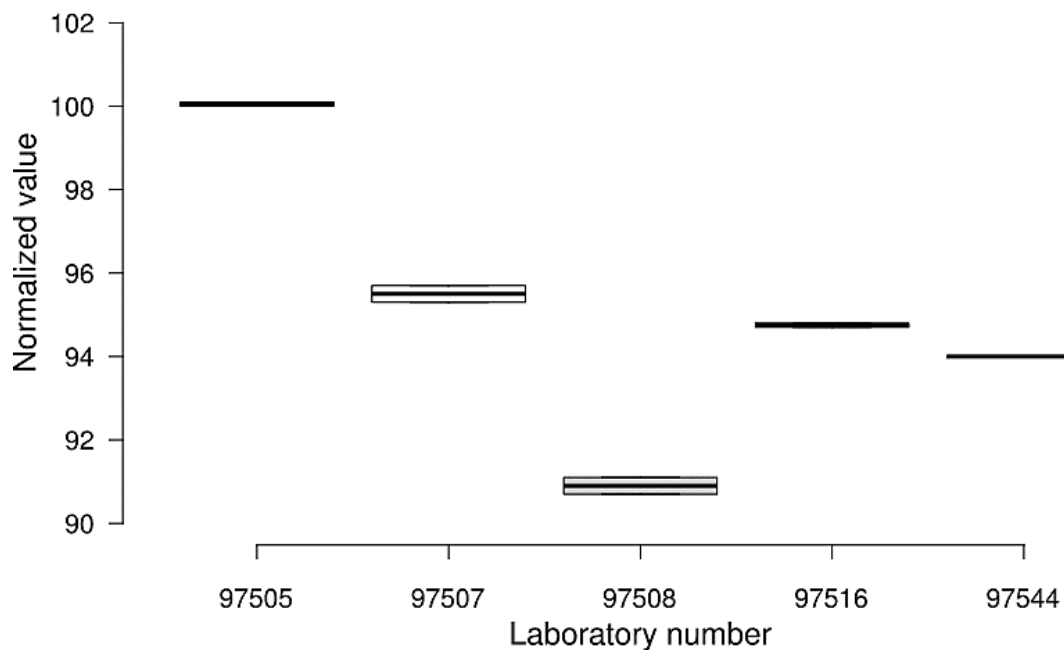


Figure 4. Distribution of the normalized values (box-plots) per laboratory.

PT2022CSFSERSERUMPS5

Lab number	97505	97507	97508	97516	97544
Method	Idexx - IDEXX CSFV Ab Test				
REP1	98.5	93.3	88.8	92.8	93.0
REP2	98.0	93.4	90.1	92.8	93.0
REP3	97.8	92.4	89.3	95.5	93.0
Mean	98.1	93.1	89.4	92.7	93.0
SD	0.4	0.6	0.7	0.2	0.0
CV (%)	0.4	0.6	0.7	0.2	0.0

(REP = repetition; SD = standard deviation; CV = coefficient of variation)

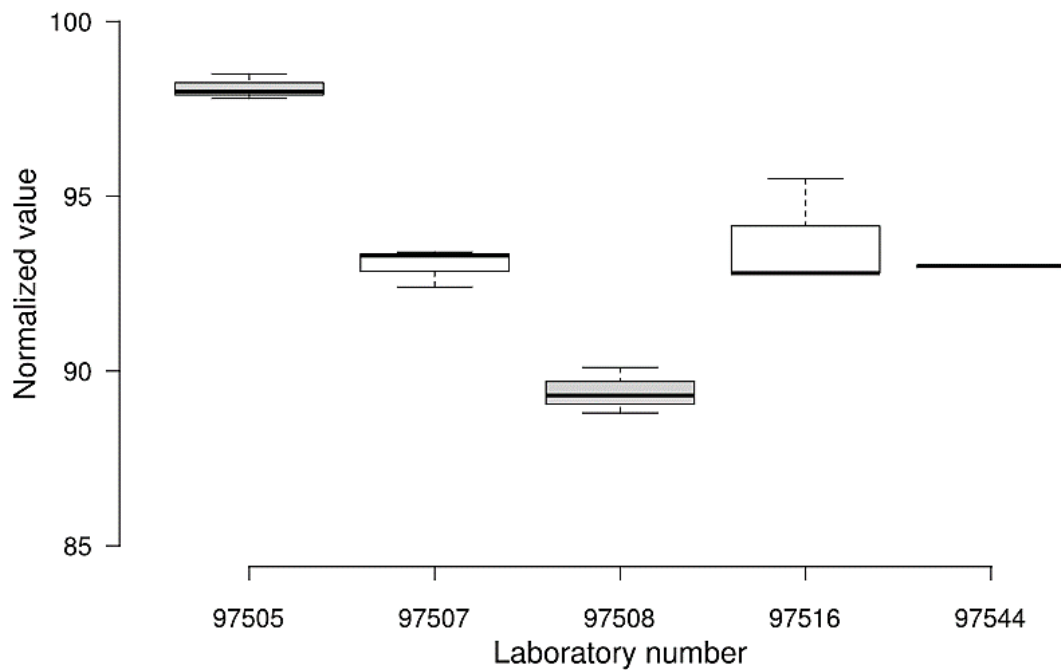


Figure 5. Distribution of the normalized values (box-plots) per laboratory.

PT2022CSFSERSERUMPS6

Lab number	97505	97507	97508	97516	97544
Method	Idexx - IDEXX CSFV Ab Test				
REP1	101.7	98.3	92.6	96.2	96.0
REP2	101.9	98.3	92.0	96.4	96.0
Mean	101.8	98.3	92.3	96.3	96.0
SD	0.2	0	0.4	0.1	0.0
CV (%)	0.1	0	0.5	0.2	0.0

(REP = repetition; SD = standard deviation; CV = coefficient of variation)

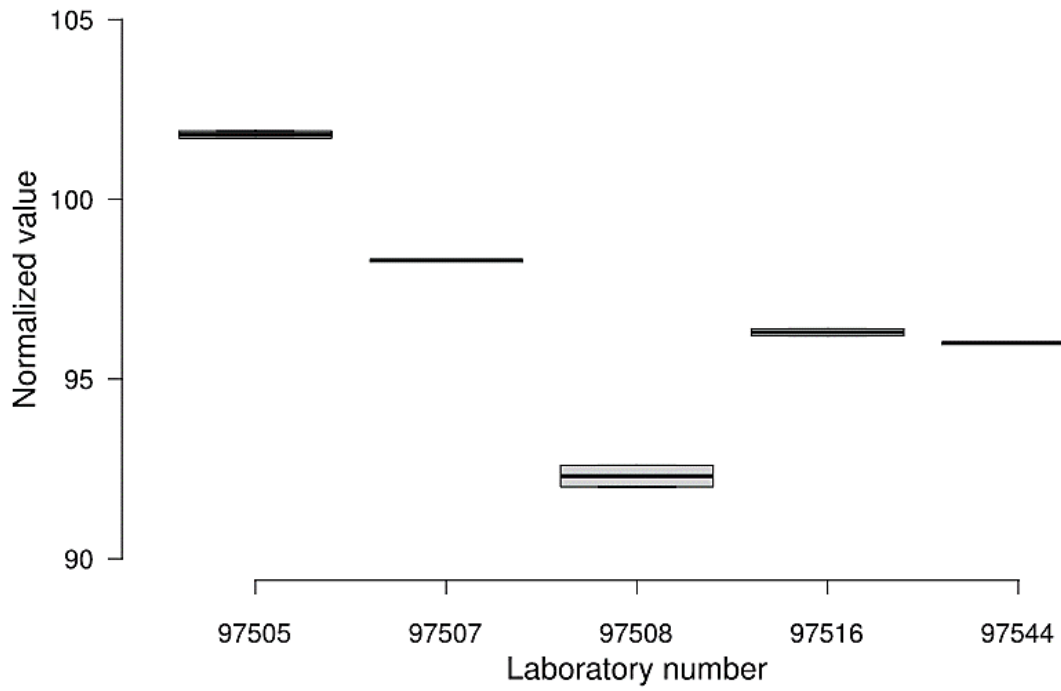


Figure 6. Distribution of the normalized values (box-plots) per laboratory.

PT2022CSFSERSERUMNS1

Lab number	97505	97507	97508	97516	97544
Method	Idexx - IDEXX CSFV Ab Test				
REP1	-7.6	-15.1	-2.1	7.4	-29.0
REP2	-6.3	-6.2	-13.5	11.6	-24.0
Mean	-6.9	-10.6	-7.8	9.5	-26.5
SD	0.9	6.3	8.0	3.0	3.5
CV (%)	-13.3	-59.2	-102.6	31.4	-13.3

(REP = repetition; SD = standard deviation; CV = coefficient of variation)

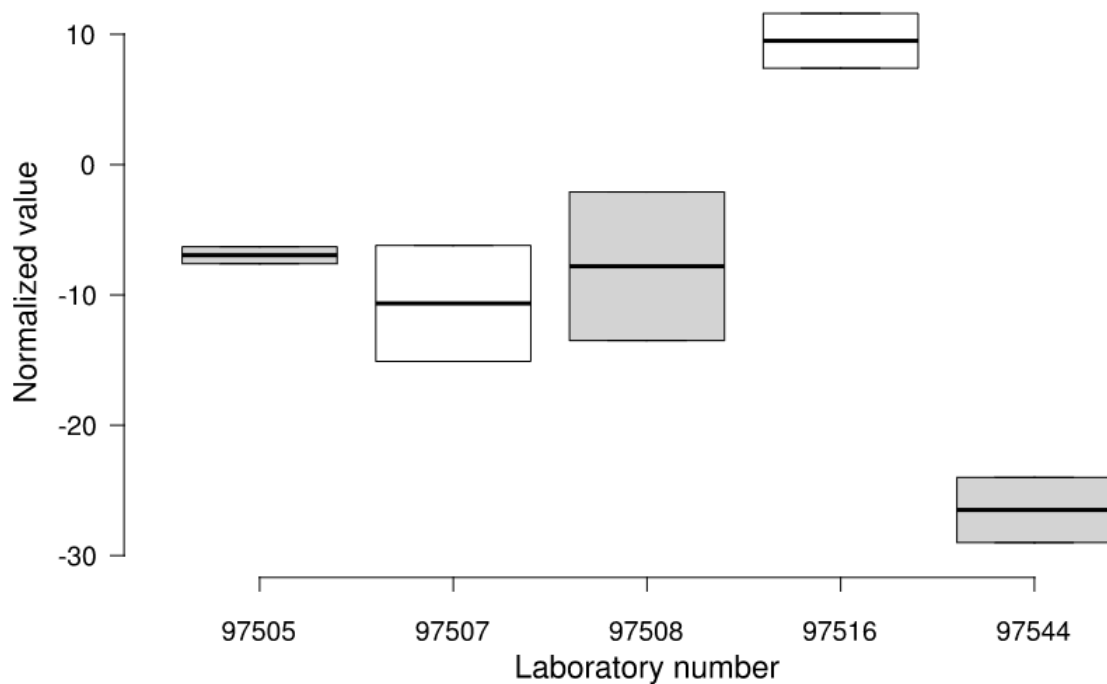


Figure 7. Distribution of the normalized values (box-plots) per laboratory.

PT2022CSFSERSERUMNS2

Lab number	97505	97507	97508	97516	97544
Method	Idexx - IDEXX CSFV Ab Test				
REP1	1.5	20.7	-5.0	3.5	-17.0
REP2	17.5	-12.5	7.6	-1.1	-22.0
Mean	9.5	4.1	1.3	1.2	-19.5
SD	11.3	23.4	8.9	3.2	3.5
CV (%)	118.9	573.2	681.4	262.6	-18.1

(REP = repetition; SD = standard deviation; CV = coefficient of variation)

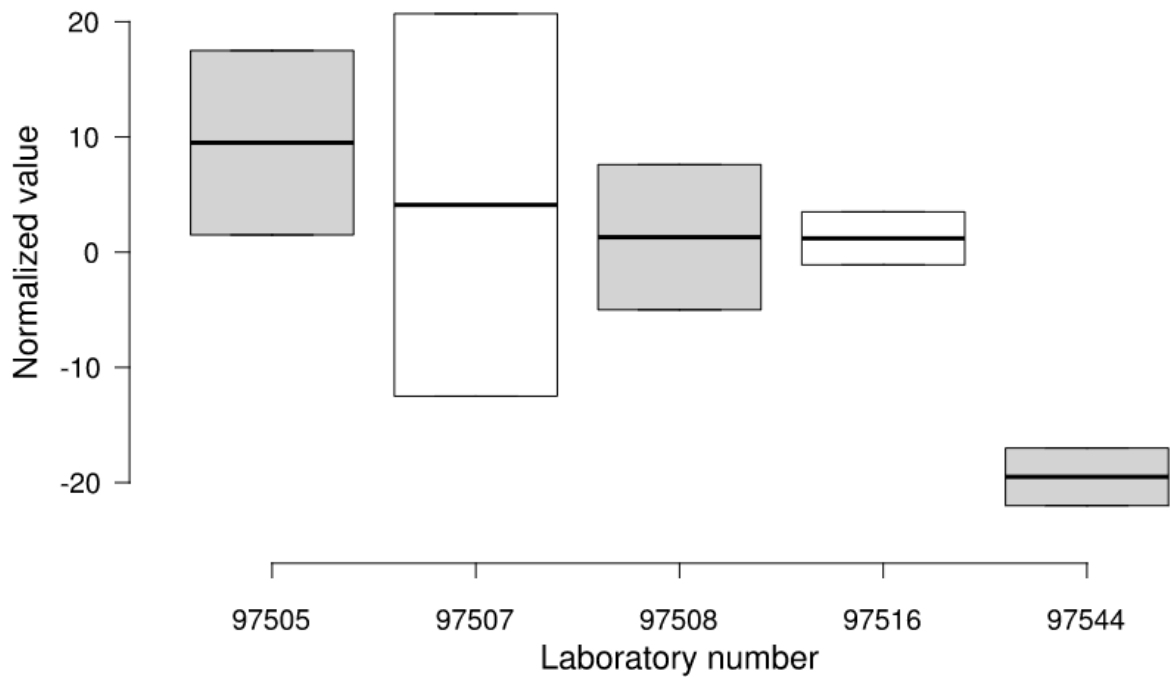


Figure 8. Distribution of the normalized values (box-plots) per laboratory.

PT2022CSFSERSERUMNS3

Lab number	97505	97507	97508	97516	97544
Method	Idexx - IDEXX CSFV Ab Test				
REP1	-7.0	-12.0	3.5	3.2	-20.0
REP2	-1.5	6.6	4.9	-0.7	-11.0
Mean	-4.1	-2.7	4.2	1.3	-15.5
SD	3.7	13.2	1.0	2.8	6.4
CV (%)	-91.4	-490.8	24.2	220.6	-41.1

(REP = repetition; SD = standard deviation; CV = coefficient of variation)

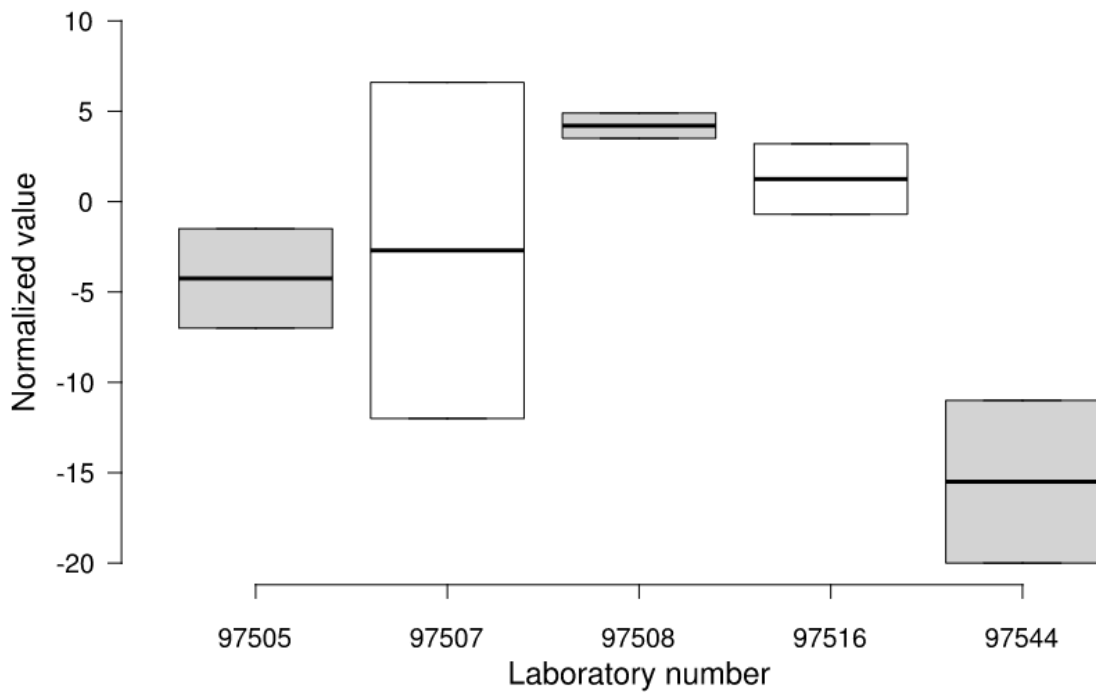


Figure 9. Distribution of the normalized values (box-plots) per laboratory.

6.2 Annex 2: Additional information

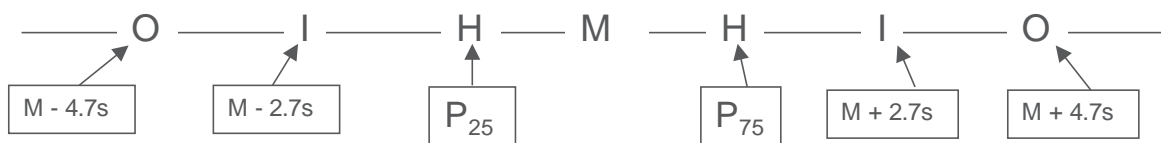
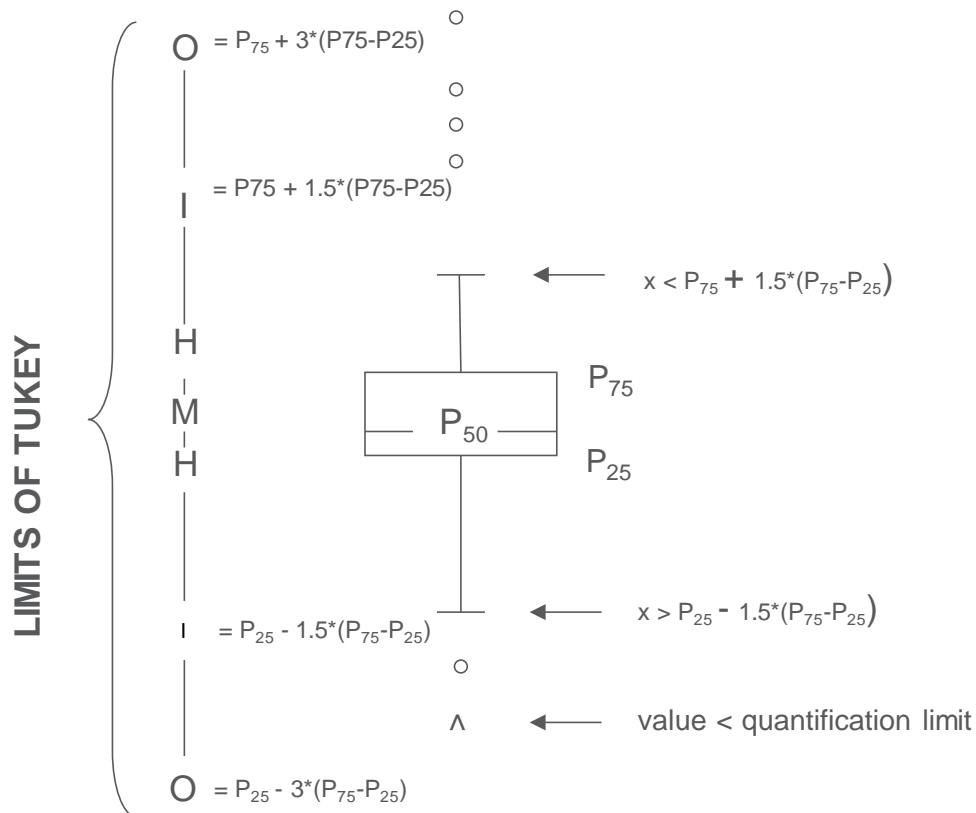
The preliminary report of this survey is available on our website via the following link:
https://www.wiv-isp.be/QML/activities/PT%20VET/fr/originaux/rapports_annee.htm

The calendar for Proficiency Testing in Veterinary diagnosis is available on our website:
https://www.wiv-isp.be/QML/activities/external_quality/calendar/kalender.htm

Graphical representation

Besides the tables with the results a "Box and whisker" plot is added. It contains the following elements for the methods with at least 3 participants:

- a rectangle ranging from percentile 25 (P_{25}) to percentile 75 (P_{75})
- a central line representing the median of the results (P_{50})
- a lower limit showing the smallest value $x > P_{25} - 1.5 * (P_{75} - P_{25})$
- an upper limit representing the largest value $x < P_{75} + 1.5 * (P_{75} - P_{25})$
- all points outside this interval are represented by a dot.



Corresponding limits in case of normal distribution

END

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