BIOLOGICAL HEALTH RISKS
QUALITY OF LABORATORIES

EXTERNAL QUALITY ASSESSMENT
IN VETERINARY DIAGNOSIS

DEFINITIVE GLOBAL REPORT

VETARINARY MEDECINE
Paratuberculosis serology

SURVEY 2021/9
Corrected version

Sciensano/PT VET Paratuberculosis/1-E-CV

Biological health risks
Quality of laboratories
J. Wytsmanstreet, 14
1050 Bruxelles | Belgique

www.sciensano.be

ISSN: 2294-3498

NATIONAL REFERENCE LABORATORIES

Sciensano					
Secretariat		PHONE:	02/642.55.22	FAX:	02/642.56.45
Name scheme coordinator	Ynse Van de Maele	PHONE	02/642.55.24		
		email	Ynse.vandemaele@sciensano.be		
Name alternate scheme coordinator	Bernard China	PHONE:	02 642 53 85		
		e-mail:	Bernard.China@sciensano.be		
Experts	**Institute**				
Sylvie Marche	**Sciensano**				
David Fretin	**Sciensano**				

A preliminary version of this report was submitted to the National reference laboratory: 07/12/2021

The changes in the corrected report are indicated in blue. The pages which are adjusted are pages 7 and 11.

This report replaces the previous version of the global report of 17/01/2022.

Authorization of the report: by Ynse Van de Maele, scheme coordinator.

Date of publication: 02/05/2022

All the reports are also available on our webpage:
https://www.wiv-isp.be/QML/activities/PT%20VET/fr/originaux/rapports_annee.htm
https://www.wiv-isp.be/QML/activities/PT%20VET/nl/originaux/rapports_annee.htm

TABLE OF CONTENTS

I. Introduction

This survey was dedicated to the detection of specific antibodies against Mycobacterium avium ssp. Paratuberculosis in serum and milk.

1. The samples

The samples were prepared by the National Reference Laboratory, Bacteriology, Infectious diseases in animals Directorate, Sciensano.

1.1. Serum

Homogeneity

The homogeneity of the samples was tested on 10 repetitions of each sample using ID.VET - ID Screen Paratuberculosis Indirect Screening Test an dIDEXX Mycobacterium paratuberculosis Antibody Test kit ELISA methods by the NRL before the survey. The samples were considered as homogeneous.

Target Values

The target value was determined by the NRL based on the homogeneity tests.

Sample ID	repetition	Final status
PT2021PTUSERNS1	5	Negative
PT2021PTUSERNS2	3	Negative
PT2021PTUSERPS1	5	Positive
PT2021PTUSERPS2	2	Positive
PT2021PTUSERPS3	5	positive

A panel consisted of 20 serum samples: 8 negative and 12 positive samples.

Stability

The stability was determined by comparison of the pre-survey results with the results obtained by the NRL during and after the survey. The samples were considered as stable.

The participants

7 laboratories participated to this survey:

Sciensano, ARSIA, DGZ, Lavetan, LNCR/ACSEDATE (France), ANSES Niort (France), LMVE (GD Lux.)

Randomisation and panel composition

Since a specific number has been assigned to each laboratory, the randomisation has been performed as follows:

Laboratory	97504	97507	97508	97509	97510	97513	97516
Sample ID							
PTUSER21-1	SERPS1	SERPS1	SERPS3	SERPS1	SERPS1	SERNS1	SERPS2
PTUSER21-2	SERNS1	SERPS3	SERNS1	SERPS1	SERNS2	SERNS2	SERPS3
PTUSER21-3	SERPS1	SERNS1	SERPS2	SERNS2	SERPS1	SERPS1	SERNS1
PTUSER21-4	SERPS1	SERNS1	SERNS2	SERNS2	SERPS3	SERNS1	SERNS1
PTUSER21-5	SERPS3	SERNS2	SERPS3	SERNS2	SERNS1	SERPS2	SERPS1
PTUSER21-6	SERPS3	SERNS2	SERPS2	SERPS2	SERPS3	SERPS3	SERNS1
PTUSER21-7	SERNS2	SERPS1	SERNS1	SERPS1	SERNS1	SERPS3	SERNS2
PTUSER21-8	SERPS3	SERNS1	SERNS2	SERNS1	SERPS1	SERPS1	SERPS1
PTUSER21-9	SERNS1	SERNS2	SERPS1	SERNS1	SERNS2	SERPS3	SERPS3
PTUSER21-10	SERPS3	SERPS3	SERPS1	SERNS1	SERPS3	SERNS1	SERPS2
PTUSER21-11	SERPS3	SERPS1	SERPS3	SERPS1	SERNS1	SERPS1	SERNS2
PTUSER21-12	SERNS2	SERNS1	SERNS2	SERPS2	SERNS1	SERPS2	SERNS1
PTUSER21-13	SERPS1	SERPS3	SERNS1	SERNS1	SERPS3	SERNS2	SERNS1
PTUSER21-14	SERNS2	SERNS1	SERNS1	SERPS3	SERNS2	SERNS1	SERPS1
PTUSER21-15	SERPS2	SERPS3	SERPS3	SERPS1	SERPS1	SERPS1	SERPS3
PTUSER21-16	SERPS1	SERPS1	SERPS1	SERPS3	SERPS3	SERPS3	SERPS3
PTUSER21-17	SERNS1	SERPS2	SERPS3	SERPS3	SERPS2	SERPS1	SERPS3
PTUSER21-18	SERNS1	SERPS2	SERNS1	SERNS1	SERPS1	SERNS1	SERNS2
PTUSER21-19	SERPS2	SERPS1	SERPS1	SERPS3	SERNS1	SERPS3	SERPS1
PTUSER21-20	SERNS1	SERPS3	SERPS1	SERPS3	SERPS2	SERNS2	SERPS1

1.2. Milk

Homogeneity

The homogeneity of the samples was tested on 10 repetitions of each sample using ID.VET - ID Screen Paratuberculosis Indirect Screening Test an dIDEXX Mycobacterium paratuberculosis Antibody Test kit ELISA methods by the NRL before the survey. The samples were considered as homogeneous.

Target Values

The target value was determined by the NRL based on the homogeneity tests.

Sample ID	Status	Repetitions
PT2021PTUSERNM1	Negative	4
PT2021PTUSERNM2	Negative	3
PT2021PTUSERPM1	Positive	4
PT2021PTUSERPM2	Positive	5
PT2021PTUSERPM3	Positive	4

A panel consisted of 20 milk samples, 7 negative and 13 positive samples.

Stability

The stability was determined by comparison of the pre-survey results with the results obtained by the NRL during and after the survey. The samples were considered as stable.

The participants

6 laboratories participated to this survey:
Sciensano, Lavetan, MCC Vlaanderen, Comité du lait, ANSES Niort (France), LMVE (GD Lux.)

Randomisation and panel composition

Since a specific number has been assigned to each laboratory, the randomisation has been performed as follows:

Laboratory	97504	97509	97511	97512	97513	97516
Sample ID						
PTUSER21-1	SERPM1	SERNM1	SERPM2	SERPM2	SERPM1	SERPM2
PTUSER21-2	SERPM2	SERPM3	SERNM1	SERPM1	SERPM3	SERNM1
PTUSER21-3	SERNM1	SERPM2	SERPM2	SERPM1	SERNM2	SERNM2
PTUSER21-4	SERPM3	SERPM2	SERNM1	SERNM2	SERPM3	SERPM1
PTUSER21-5	SERPM3	SERNM1	SERNM2	SERNM2	SERPM1	SERPM2
PTUSER21-6	SERPM2	SERPM1	SERPM1	SERPM3	SERPM2	SERPM3
PTUSER21-7	SERPM3	SERPM1	SERPM3	SERPM1	SERPM2	SERPM3
PTUSER21-8	SERNM1	SERPM2	SERPM1	SERNM1	SERPM2	SERPM2
PTUSER21-9	SERPM1	SERPM3	SERNM1	SERNM1	SERPM2	SERPM3
PTUSER21-10	SERPM3	SERPM2	SERPM3	SERNM2	SERNM2	SERPM1
PTUSER21-11	SERPM2	SERNM2	SERNM1	SERPM3	SERNM1	SERNM1
PTUSER21-12	SERNM2	SERPM2	SERPM1	SERNM1	SERNM1	SERNM2
PTUSER21-13	SERPM2	SERNM2	SERPM2	SERPM3	SERPM3	SERNM1
PTUSER21-14	SERPM1	SERNM2	SERPM1	SERPM3	SERPM1	SERPM2
PTUSER21-15	SERPM1	SERPM1	SERNM2	SERPM2	SERNM1	SERNM1
PTUSER21-16	SERNM1	SERPM3	SERNM2	SERPM2	SERPM3	SERPM1
PTUSER21-17	SERPM2	SERPM1	SERPM3	SERPM1	SERNM1	SERNM2
PTUSER21-18	SERNM2	SERPM3	SERPM3	SERPM2	SERNM2	SERPM2
PTUSER21-19	SERNM2	SERNM1	SERPM2	SERNM1	SERPM1	SERPM1
PTUSER21-20	SERNM1	SERNM1	SERPM2	SERPM2	SERPM2	SERPM3

2. Survey Timeline

Transfer of the samples from NRL to QL: 14/09/2021 (serum) and 21/09/2021 (milk)
Randomization of the samples by QL: 16/09/2021 (serum) and 23/09/2021 (Milk)
sending samples to participants: 20/09/2021 (serum) and 27/09/2021 (milk)
Deadline for the results encoding: 22/10/2021
Preliminary report: 9/11/2021

II. Results

1. Serum

The panel consisted of 20 serum samples (8 positive and 12 negative).

Results per sample

5 laboratories encoded one dataset and 2 laboratories encoded 2 datasets giving 180 results.

Table R1. Results per sample

Sample ID	N	Rep	NR	Expected result	NCR	%
PT2021PTUSERNS1	9	5	45	Negative	45	100
PT2021PTUSERNS2	9	3	27	Negative	27	100
PT2021PTUSERPS1	9	5	45	Positive	44*	97.8
PT2021PTUSERPS2	9	2	18	Positive	18	100
PT2021PTUSERPS3	9	5	45	positive	45	100
	9		180		179	100

N: number of datasets, Rep: number of repetitions; NR: number of results; NCR: number of correct results

* = For one lab, a false negative result was submitted for the PS1 sample. However, the quantitative values of this lab showed a very clear negative result. Therefore, this sample was re-analyzed by the NRL and confirmed that the sample was negative instead of positive.

Results per method

Table R2. Results per method

Method	N	NR	NCR	%
ID.VET - ID Screen Paratuberculosis Indirect Screening Test	5	100	100	100
IDEXX Paratuberculosis Screening Mycobacterium paratuberculosis Antibody Test Kit	4	80	79	98.75

N: number of datasets, NR: number of encoded results; NCR: Number of correct results, %: percentage of correct results.

For the 2 laboratories encoding 2 datasets, they used both ID-vet and Idexx tests

Conclusion

All the participants submitted correct results (100% correctness).

2. Milk

Results par sample

A panel consisted of 20 samples (7 negative and 13 positive). 6 laboratories encoded one dataset giving 120 results

Table R3. Results per sample

Sample ID	N	REP	NR	Expected result	NCR	%
PT2021PTUSERNM1	6	4	24	Negative	24	100
PT2021PTUSERNM2	6	3	18	Negative	18	100
PT2021PTUSERPM1	6	4	24	Positive	24	100
PT2021PTUSERPM2	6	5	30	Positive	30	100
PT2021PTUSERPM3	6	4	24	Positive	24	100
	6		120		120	100

Results per method

Table R4. Results per method

Method	N	NR	NCR	%
ID.VET - ID Screen Paratuberculosis Indirect Screening Test	1	20	20	100
Idexx – Paratuberculosis Screening Mycobacterium paratuberculosis Antibody Test kit	5	100	100	100
Total	6	120	120	100

N: number of participants; NR: number of results; NCR: number of correct results

Conclusion

All the participants submitted 100% of correct results despite the used method.

Annex 1: Quantitative results (not under accreditation)

Serum

Sample PT2021PTUSERNS1

	97504	97507	97508-1	97508-2	97509	97510-1	97510-2	97513	97516
Method	M1	M1	M1	M2	M2	M2	M1	M1	M2
rep1	6.0	5.8	7.1	6.9	3.0	4.5	7.4	6.2	7.1
rep2	5.4	5.8	5.6	5.7	2.6	4.5	6.9	7.7	7.9
rep3	5.3	8.1	7.2	6.5	3.1	4.3	8.7	7.0	6.9
rep4	5.4	7.0	6.7	5.8	2.3	4.9	8.9	7.1	7.1
rep5	5.1	8.1	5.8	6.0	2.8	5.3	9.1	6.9	7.4
average	5.5	7.0	6.5	6.2	2.7	4.7	8.2	7.0	7.3
SD	0.3	1.2	0.7	0.5	0.3	0.4	1.0	0.5	0.4
CV	6.1%	16.7%	11.3%	8.4%	11.0%	8.3%	12.2%	7.5%	5.5%

M1: ID.VET - ID Screen Paratuberculosis Indirect Screening Test
M2: IDEXX Paratuberculosis Screening Mycobacterium paratuberculosis Antibody Test Kit
Repx: repetition x

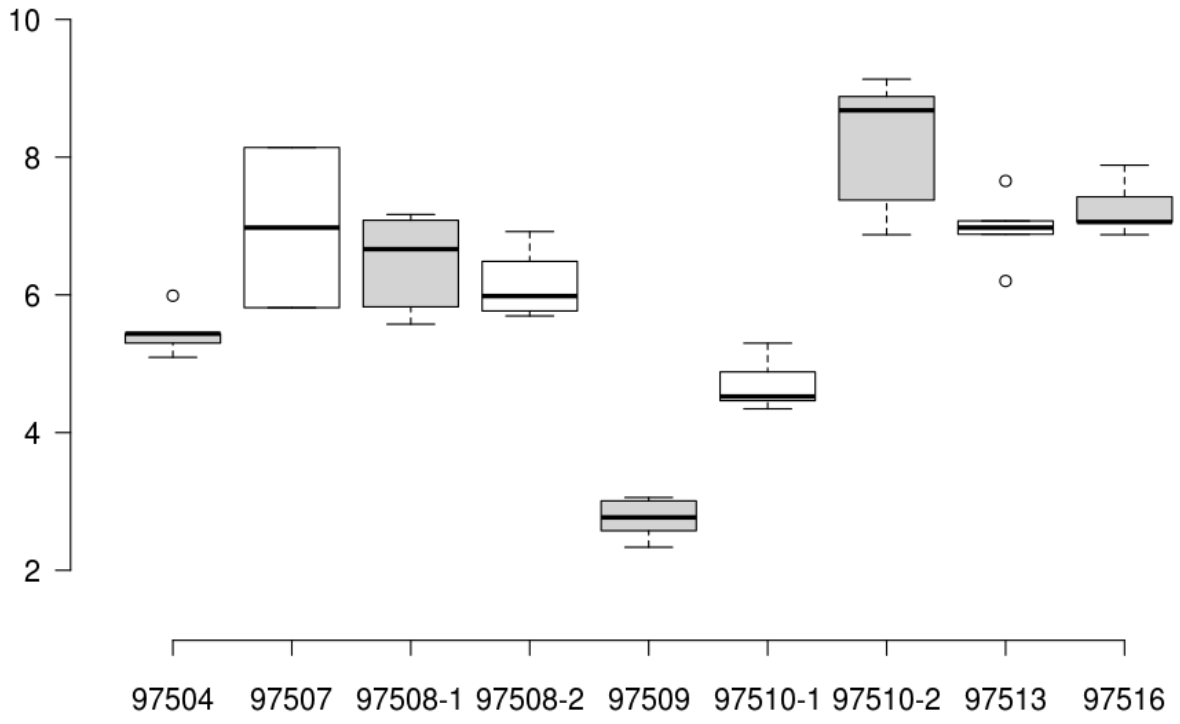

Figure S1. Distribution of the normalized values (box-plot) per dataset.

Sample PT2021PTUSERNS2

	97504	97507	97508-1	97508-2	97509	97510-1	97510-2	97513	97516
	M1	M1	M1	M2	M2	M2	M1	M1	M2
rep1	4.9	5.8	9.2	9.5	4.8	7.4	9.1	7.9	9.8
rep2	5.8	5.8	5.2	8.9	4.7	7.9	8.6	8.4	9.2
rep3	4.7	8.1	9.2	9.2	4.8	6.5	7.3	9.9	9.0
average	5.3	5.8	7.2	9.2	4.8	7.6	8.9	8.2	9.5
SD	0.5	1.1	1.9	0.2	0.04	0.5	0.8	0.8	0.3
CV	9.0%	18.9%	25.8%	2.6%	0.8%	7.1%	8.8%	10.1%	3.7%

M1: ID.VET - ID Screen Paratuberculosis Indirect Screening Test
M2: Idexx - Mycobacterium paratuberculosis Antibody Test kit
Repx: repetition x

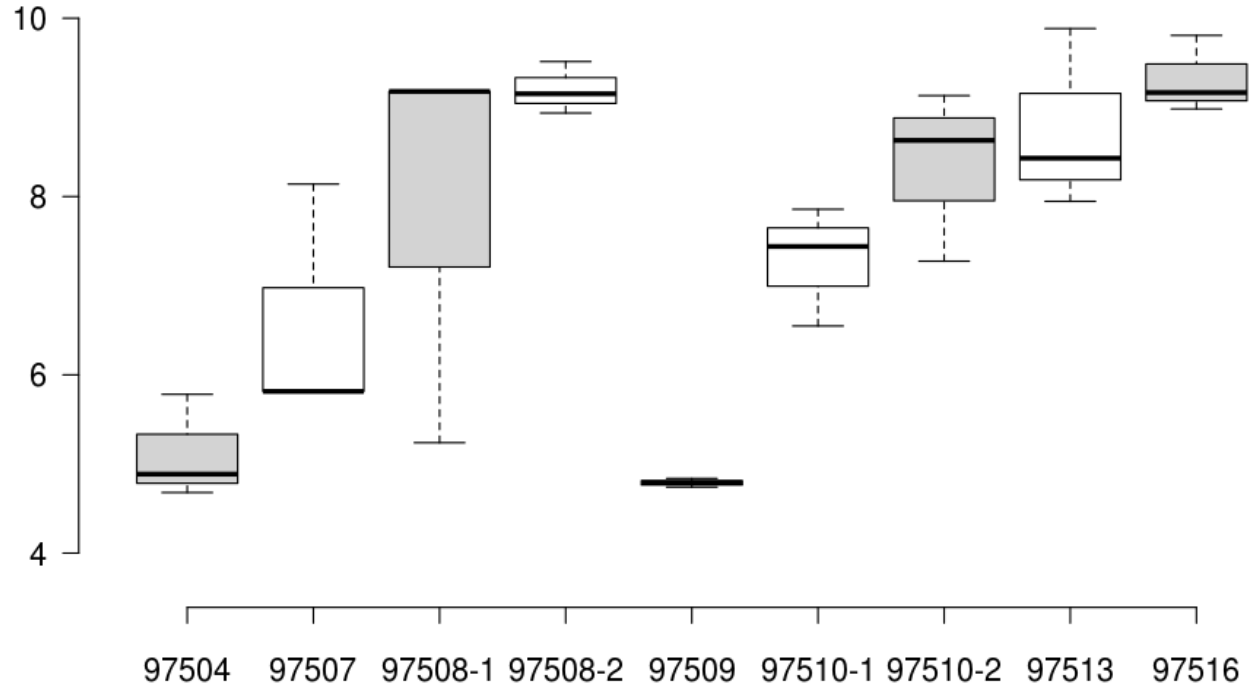

Figure S2. Distribution of the normalized values (box-plot) per dataset.

Sample PT2021PTUSERPS1

	97504	97507	97508-1	97508-2	97509	97510-1	97510-2	97513	97516
	M1	M1	M1	M2	M2	M2	M1	M1	M2
rep1	246.800	325.581	202.557	145.874	114.296	124.762	134.270	317.151	149.129
rep2	222.230	311.628	222.339	148.468	114.152	107.500	143.552	249.031	151.237
rep3	232.140	283.721	181.098	148.613	109.723	126.429	136.327	310.271	133.364
rep4	223.469	334.884	230.637	144.865	ND	125.476	127.647	276.938	134.830
rep5	232.966	282.558	244.971	151.712	106.017	125.476	149.272	287.403	136.572
average	231.521	307.674	216.320	147.906	111.047	121.929	138.214	288.159	141.026
SD	9.837	23.881	24.960	2.678	3.969	8.088	8.390	27.327	8.468
CV	4.2%	7.8%	11.5%	1.8%	3.6%	6.6%	6.1%	9.5%	6.0%

M1: ID.VET - ID Screen Paratuberculosis Indirect Screening Test
M2: Idexx - Mycobacterium paratuberculosis Antibody Test kit
Repx: repetition x
ND: not taken into account due to a wrong sample.

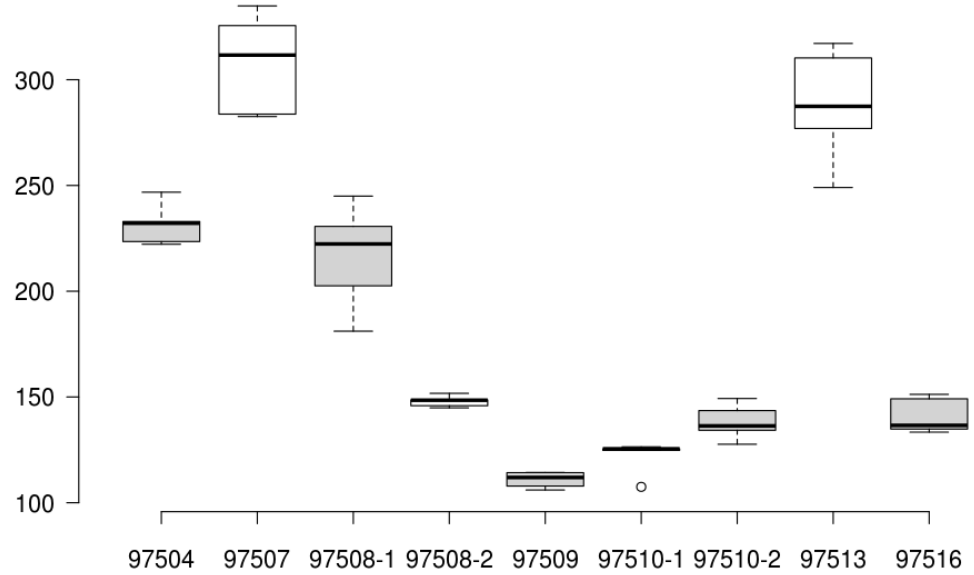

Figure S3. Distribution of the normalized values (box-plot) per dataset.

Sample PT2021PTUSERPS2

	97504	97507	97508-1	97508-2	97509	97510-1	97510-2	97513	97516
	M1	M1	M1	M2	M2	M2	M1	M1	M2
rep1	351.961	370.930	302.640	202.955	161.901	163.690	143.904	383.140	245.188
rep2	280.730	366.279	307.330	220.108	157.569	149.881	156.397	383.140	223.923
Average	316.346	368.605	304.985	211.532	159.735	156.786	150.151	383.140	234.556
SD	50.368	3.289	3.316	12.129	3.063	9.764	8.834	0.000	15.037
CV	15.9%	0.9%	1.1%	5.7%	1.9%	6.2%	5.9%	0.0%	6.4%

M1: ID.VET - ID Screen Paratuberculosis Indirect Screening Test
M2: Idexx - Mycobacterium paratuberculosis Antibody Test kit
Repx: repetition x

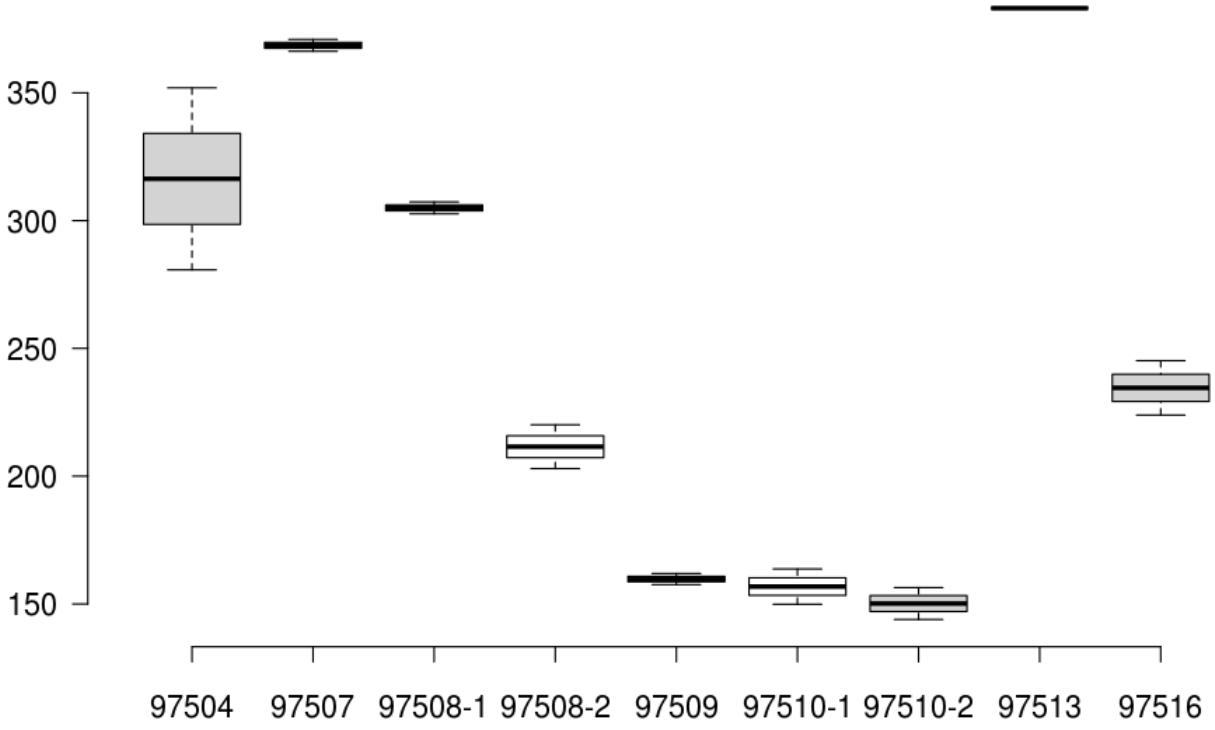

Figure S4. Distribution of the normalized values (box-plot) per dataset.

Sample PT2021PTUSERPS3

	97504	97507	97508-1	97508-2	97509	97510-1	97510-2	97513	97516
	M1	M1	M1	M2	M2	M2	M1	M1	M2
rep1	177.151	236.047	188.220	123.387	89.844	97.798	144.205	240.504	115.857
rep2	192.292	248.837	156.450	123.748	88.640	93.214	138.786	233.527	127.864
rep3	198.486	243.023	196.270	117.477	84.838	102.976	141.746	225.581	106.141
rep4	209.360	269.767	155.950	117.333	85.030	93.690	133.016	204.070	112.924
rep5	173.365	225.581	122.420	125.910	85.319	104.762	108.881	261.628	116.957
average	190.131	244.651	163.862	121.571	86.734	98.488	133.327	233.062	115.949
SD	14.948	16.498	29.490	3.924	2.335	5.263	14.289	21.024	7.879
CV	7.9%	6.7%	18.0%	3.2%	2.7%	5.3%	10.7%	9.0%	6.8%

M1: ID.VET - ID Screen Paratuberculosis Indirect Screening Test
M2: Idexx - Mycobacterium paratuberculosis Antibody Test kit
Repx: repetition x

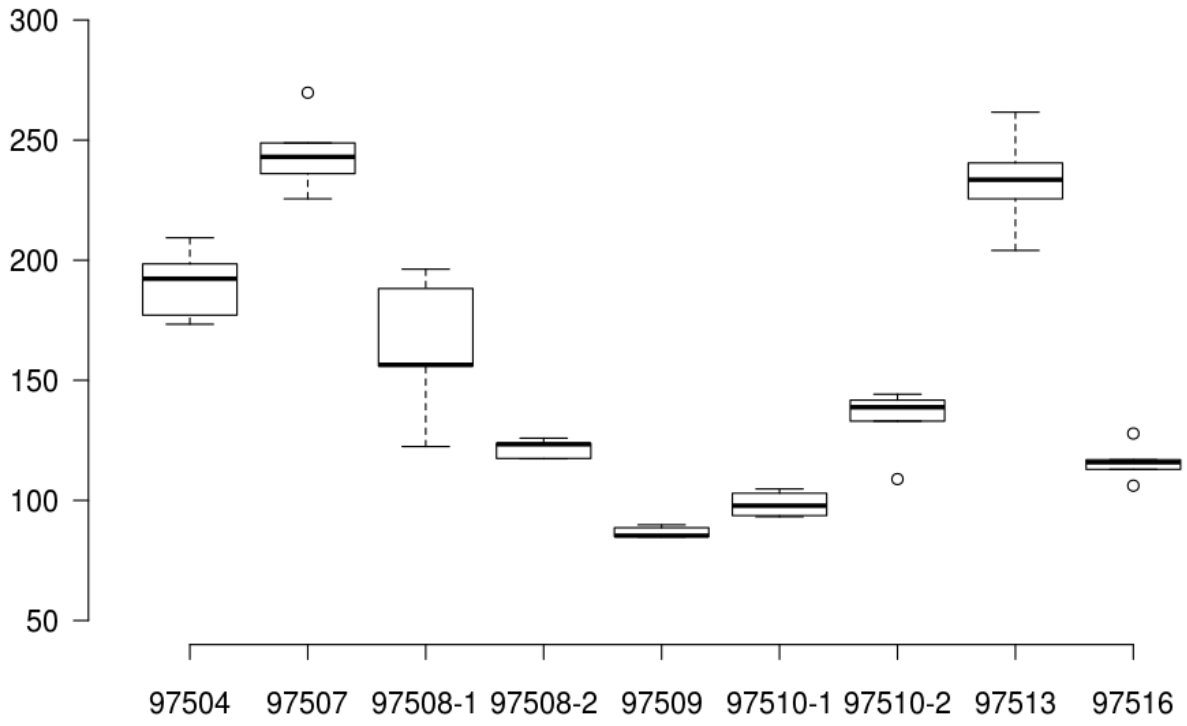

Figure S5. Distribution of the normalized values (box-plot) per dataset.

Milk

Sample PT2021PTUSERNM1

	97504	97509	97511	97512	97513	97516
Method	M2	M2	M2	M2	M1	M2
rep1	0	0.676	0	-0.316	-0.076	0.177
rep2	-0.153	0.225	-0.133	-0.19	1.366	-0.088
rep3	-0.23	0.451	-0.13	-0.253	0.379	0.265
rep4	0.077	0.113	0.013	-0.316	0.303	-0.265
average	-0.0765	0.3662	-0.0625	-0.269	0.493	0.0223
SD	0.140	0.2498	0.0799	0.0603	0.615	0.243
CV	-183%	68%	-128%	-22%	125%	1093%

M1: ID.VET - ID Screen Paratuberculosis Indirect Screening Test
M2: Idexx - paratuberculosis screening Mycobacterium paratuberculosis Antibody Test kit
repX: repetition number x

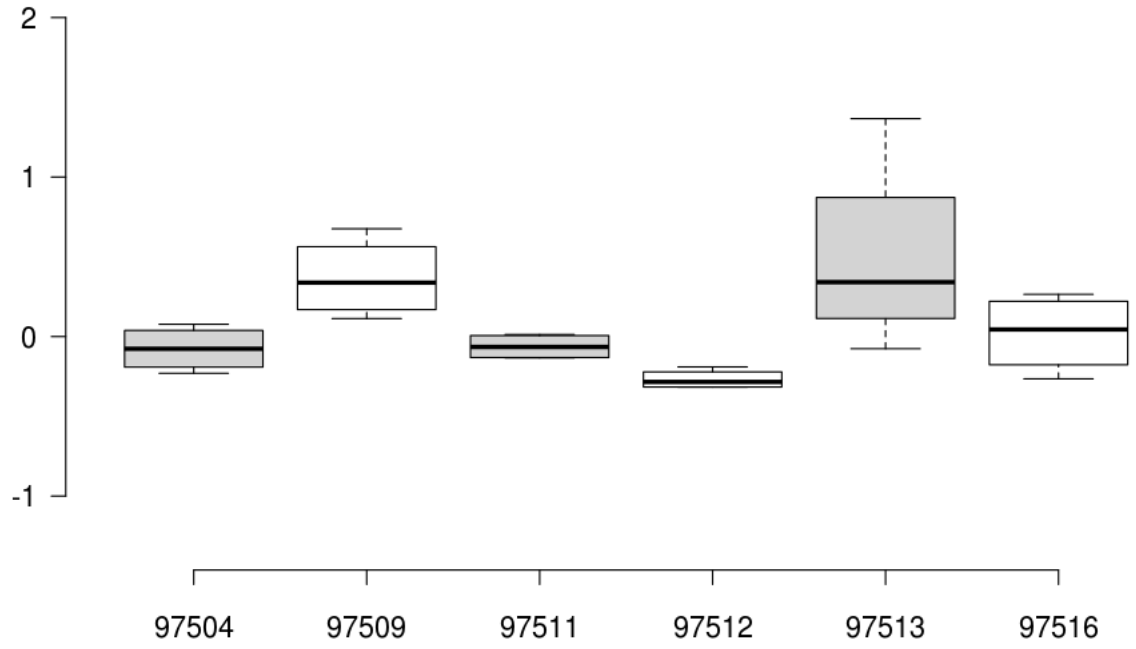

Figure M1. Distribution of the normalized values (box-plot) per laboratory.

Sample PT2021PTUBSERNM2

	97504	97509	97511	97512	97513	97516
Method	M2	M2	M2	M2	M1	M2
rep1	1.377	1.578	1.41	0.506	1.214	1.15
rep2	1.071	1.015	1.235	0.695	0.455	1.593
rep3	0.918	0.789	1.553	0.632	0.759	1.681
average	1.122	1.127	1.399	0.611	0.809	1.475
SD	0.234	0.406	0.159	0.0962	0.382	0.2846
CV	20.8%	36.0%	11.4%	15.8%	47.2%	19.3%

M1: ID.VET - ID Screen Paratuberculosis Indirect Screening Test
M2: Idexx - paratuberculosis screening Mycobacterium paratuberculosis Antibody Test kit
repX: repetition number x

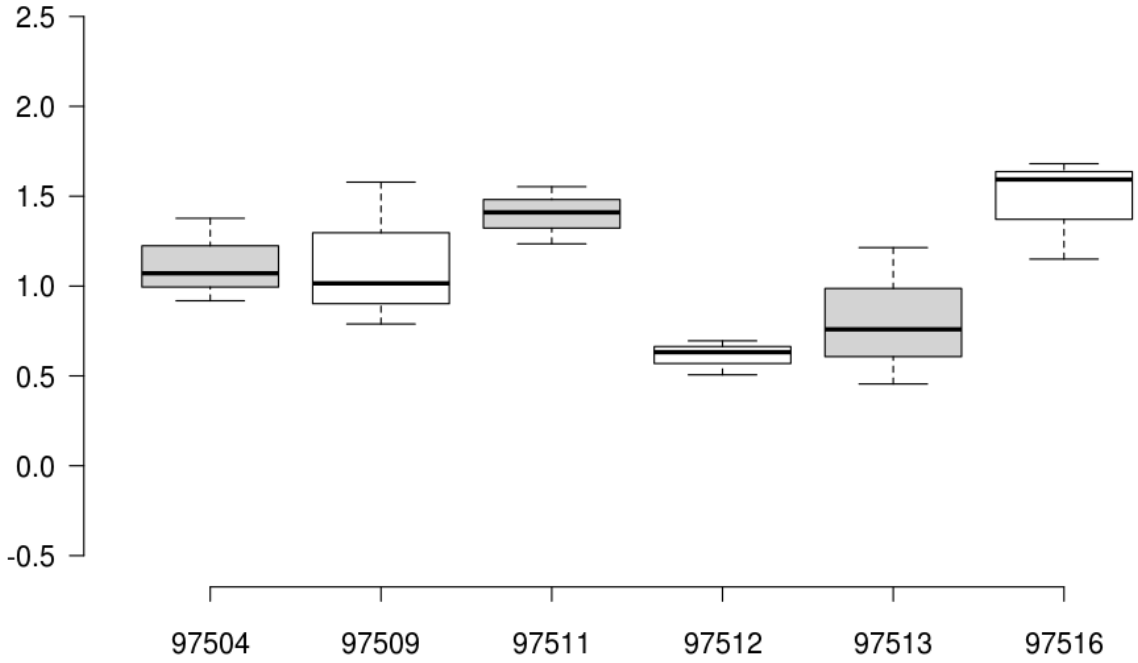

Figure M2. Distribution of the normalized values (box-plot) per laboratory

Sample PT2021PTUSERPM1

	97504	97509	97511	97512	97513	97516
Method	M2	M2	M2	M2	M1	M2
rep1	71.232	87.035	68.463	60.619	102.276	65.841
rep2	60.061	83.089	76.035	59.545	110.622	62.655
rep3	63.122	83.766	71.77	62.958	99.317	66.549
rep4	67.177	82.976	73.948	64.223	109.408	63.186
average	65.398	84.2165	72.554	61.836	105.406	64.558
SD	4.860	1.911	3.236	2.136	5.480	1.924
CV	7.4%	2.3%	4.5%	3.5%	5.2%	3.0%

M1: ID.VET - ID Screen Paratuberculosis Indirect Screening Test
M2: Idexx - paratuberculosis screening Mycobacterium paratuberculosis Antibody Test kit
repX: repetition number x

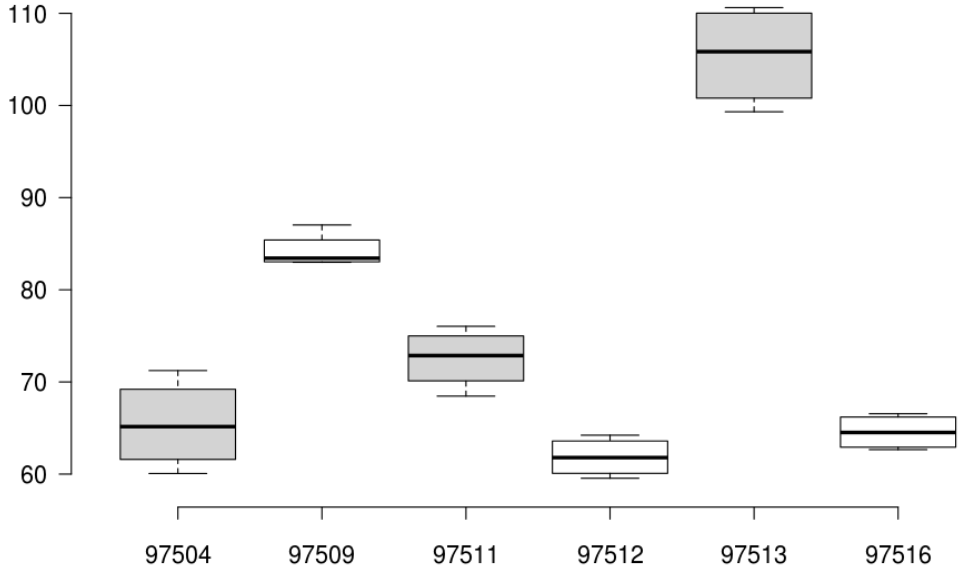

Figure M3. Distribution of the normalized values (box-plot) per laboratory

Sample PT2021PTUSERPM2

	97504	97509	97511	97512	97513	97516
Method	M2	M2	M2	M2	M1	M2
rep1	46.366	63.021	44.84	47.155	67.678	49.469
rep2	46.825	65.276	44.11	42.478	62.064	44.071
rep3	43.076	64.938	50.305	47.535	62.367	37.345
rep4	43.764	66.516	47.063	44.311	59.863	43.805
rep5	41.928	59.865	53.193	46.46	62.898	39.292
average	44.392	63.923	47.902	45.588	62.974	42.796
SD	2.122	2.591	3.815	2.139	2.873	4.721
CV	4.8%	4.1%	8.0%	4.7%	4.6%	11.0%

M1: ID.VET - ID Screen Paratuberculosis Indirect Screening Test
M2: Idexx - paratuberculosis screening Mycobacterium paratuberculosis Antibody Test kit
repX: repetition number x

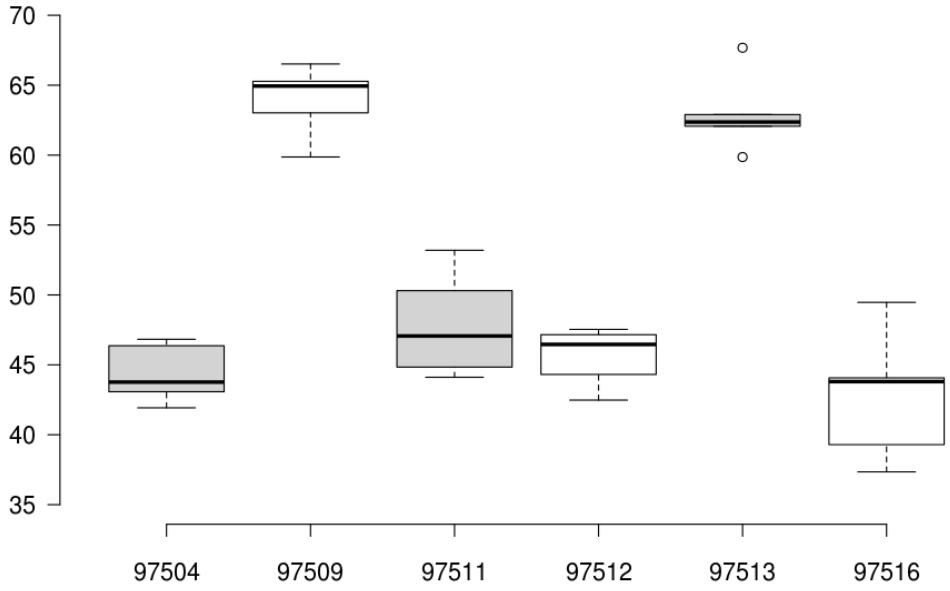

Figure M4. Distribution of the normalized values (box-plot) per laboratory

Sample PT2021PTUSERPM3

	97504	97509	97511	97512	97513	97516
Method	M2	M2	M2	M2	M1	M2
rep1	115.761	126.494	128.68	100.063	183.232	89.912
rep2	113.619	119.617	127.835	99.81	185.357	86.195
rep3	112.318	121.533	131.49	100.885	178.832	105.398
rep4	104.667	133.371	130.763	100.316	177.693	92.566
average	111.591	125.254	129.692	100.268	181.278	93.518
SD	4.829	6.139	1.718	0.460	3.619	8.340
CV	4.3%	4.9%	1.3%	0.5%	2.0%	8.9%

M1: ID.VET - ID Screen Paratuberculosis Indirect Screening Test
M2: Idexx - paratuberculosis screening Mycobacterium paratuberculosis Antibody Test kit
repX: repetition number x

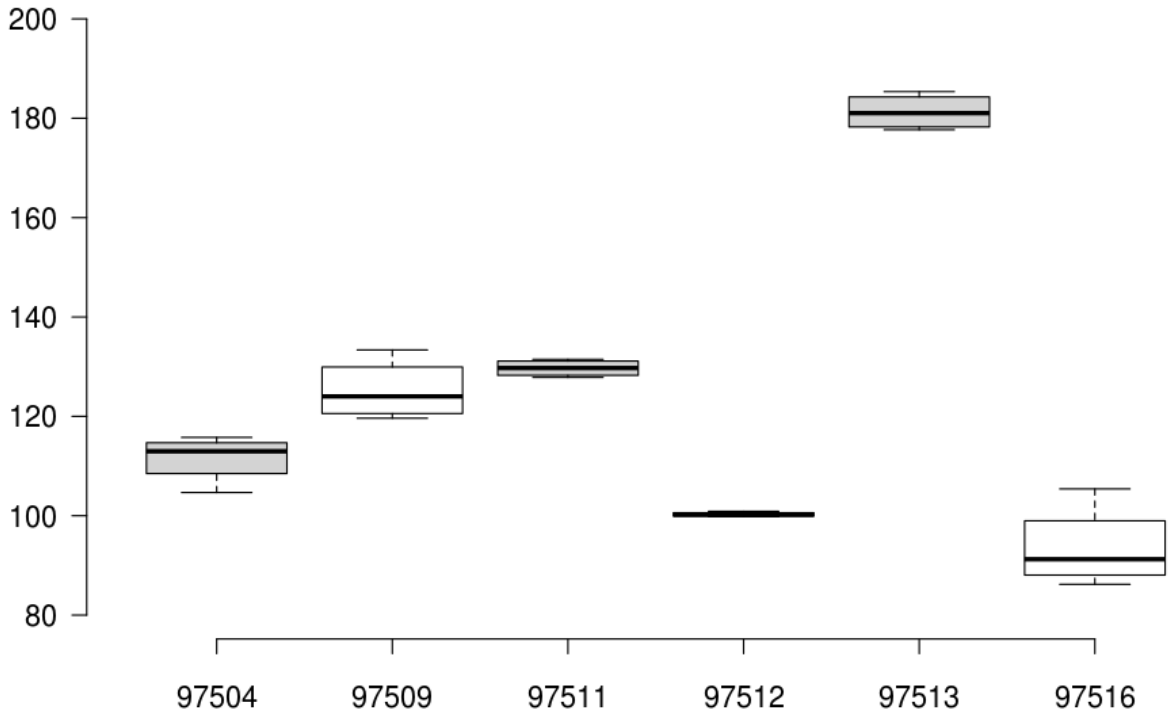

Figure M4. Distribution of the normalized values (box-plot) per laboratory

Annex 2 : additional information

PRELIMINARY REPORT

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:

The link is:

https://www.wiv-isp.be/QML/activities/external_quality/calendar/calender_PT%20VET/_fr/Calendrier_2021-PT%20VET.htm

END