BIOLOGICAL HEALTH RISKS
QUALITY OF LABORATORIES

COMMITEE OF EXPERTS

EXTERNAL QUALITY ASSESSMENT
IN VETERINARY DIAGNOSIS

DEFINITIVE GLOBAL REPORT

VETERINARY MEDECINE

INFECTIOUS BOVINE RHINOTRACHEITIS (IBR)

PROFICIENCY TEST 2022/6

CORRECTED VERSION

Sciensano/PT VET IBR/3-E-CV

Biological health risks
Quality of laboratories
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A draft version of this report was submitted to the experts on: 28/10/2022.

Corrections, indicated in blue, are made on page 12 and 13.

This report replaces the previous version of the global report of 07/11/2022.

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

Signature of the scheme coordinator.

YnVa2851 Digitally signed by YnVa2851 Date: 2022.11.16 13:13:47 +01'00'

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All the reports are also available on our webpage:
https://www.wiv-isp.be/QML/activities/external_quality/rapports/_nl/rapports_annee.htm
https://www.wiv-isp.be/QML/activities/external_quality/rapports/_fr/rapports_annee.htm

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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

The aim of this PT was to evaluate the ability of the participating laboratories to identify the absence or presence of antibodies to infectious bovine disease (IBR) viruses in serum (gB/gE) of ruminants.

3 MATERIALS AND METHODS

3.1 Serology gB

3.1.1 THE PARTICIPANTS

Nine laboratories participated in the proficiency test of IBR serology on serum gB. The names of the participating laboratories are:

- Sciensano, department of Enzootic, vector-borne and bee diseases
- ARSIA
- DGZ
- LAVETAN
- LNCR / ACSEDIATE
- ANSES Unité Pathologie et Bien-être des ruminants (PBER)-Site de Niort
- Laboratoire de médecine vétérinaire de l'état (LMVE)
- IDEXX Diavet
- Poulpharm

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** of the samples:

- Samples originate from the field or from experimentation

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

- Serum was harvested from collected blood before aliquotation and freezing.

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 different of samples: 5 positive, 3 negative and 2 samples for which positive, negative or not interpretable results are accepted.

Sample ID	Repetition	Status
PT2022IBRgBSERPS1	2	POS
PT2022IBRgBSERPS2	1	POS
PT2022IBRgBSERPS3	2	POS – NEG – NI
PT2022IBRgBSERPS4	2	POS
PT2022IBRgBSERNS1	1	NEG
PT2022IBRgBSERNS2	1	NEG
PT2022IBRgBSERNS3	1	NEG

(POS = positive; NEG = negative, NI = Not Interpretable)

3.1.5 STABILITY

The samples were tested before and after the proficiency test. After performing the POST-PT for the positive sample PS3, the status was changed to POS/NEG/NI as the status did not correspond the status pre and during the PT. For the other samples, 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 randomisation has been performed as follow:

Sample ID: IBRSERgB	97505	97507	97508	97509	97510	97513	97516	97521	97540
22-1	NS2	PS2	NS3	PS3	PS3	PS3	PS3	PS1	NS1
22-2	PS3	PS3	NS1	PS1	NS1	PS4	PS2	PS3	NS2
22-3	PS1	PS4	NS2	NS3	PS1	PS3	NS2	PS3	PS4
22-4	PS1	PS1	PS1	NS1	PS4	NS3	PS4	NS2	PS1
22-5	NS3	PS1	PS1	PS4	PS1	NS1	NS3	PS4	PS2
22-6	PS2	NS2	PS4	PS1	PS4	PS1	PS3	PS2	PS1
22-7	PS4	PS3	PS4	PS4	PS3	PS2	NS1	NS3	PS4
22-8	PS3	NS3	PS3	PS3	PS2	PS4	PS4	PS1	PS3
22-9	PS4	PS4	PS2	NS2	NS2	PS1	PS1	PS4	PS3
22-10	NS1	NS1	PS3	PS2	NS3	NS2	PS1	NS1	NS3

3.2 Serology gE

3.2.1 THE PARTICIPANTS

Ten laboratories participated in the proficiency test of IBR serology on serum gE. The names of the participating laboratories are:

- Sciensano, department of Enzootic, vector-borne and bee diseases
- ARSIA
- DGZ
- LAVETAN
- LNCR / ACSEDIATE
- ANSES Unité Pathologie et Bien-être des ruminants (PBER)-Site de Niort
- Laboratoire de médecine vétérinaire de l'état (LMVE)
- IDEXX Diavet
- IDVET
- Poulpharm

3.2.2 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** of the samples:

- Samples originate from the field or from experimentation

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

- Serum was harvested from collected blood before aliquotation and freezing.

3.2.3 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.

3.2.4 TARGET VALUES

The target values were determined by the NRL based on the homogeneity tests. The panel consisted of different of samples: 5 positive and 5 negative samples.

Sample ID	Repetition	Status
PT2022IBRgESERPS1	2	POS
PT2022IBRgESERPS2	2	POS
PT2022IBRgESERPS3	1	POS
PT2022IBRgESERNS1	2	NEG
PT2022IBRgESERNS2	1	NEG
PT2022IBRgESERNS3	2	NEG

(POS = positive; NEG = negative)

3.2.5 STABILITY

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

3.2.6 RANDOMISATION AND PANEL COMPOSITION

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

Sample ID: IBRSERgE	97505	97507	97508	97509	97510	97513	97516	97521	97522	97540
22-1	NS3	NS3	NS2	PS1	NS3	PS1	NS3	NS1	PS1	NS1
22-2	NS1	PS2	PS1	PS2	PS3	PS2	PS1	PS3	PS2	PS1
22-3	PS1	NS1	PS2	NS3	NS1	NS1	PS1	NS2	NS1	PS3
22-4	PS1	PS1	NS3	NS2	NS2	PS3	PS3	NS1	NS3	NS1
22-5	NS2	PS1	NS1	NS1	PS1	NS3	NS1	NS3	NS2	PS2
22-6	NS3	PS3	NS3	NS3	PS1	PS1	NS3	NS3	PS3	PS2
22-7	PS3	NS1	PS2	PS3	PS2	NS3	NS2	PS2	NS1	NS2
22-8	NS1	PS2	PS3	PS2	NS1	NS2	PS2	PS1	PS2	NS3
22-9	PS2	NS2	NS1	PS1	PS2	NS1	PS2	PS2	PS1	NS3
22-10	PS2	NS3	PS1	NS1	NS3	PS2	NS1	PS1	NS3	PS1

4. SURVEY TIMELINE

Transfer of the samples from NRL to QL: 12/05/2022
Randomization of the samples by QL: 16/05/2022
Sending samples (cooled at 4 °C) to participants: 17/05/2022
Deadline for submitting the results: 03/06/2022
Preliminary report: 30/06/2022

5. RESULTS

5.1 Serology on serum gB

5.1.1 RESULTS PER SAMPLE

The panel consisted of 7 different samples. Samples PS1, PS3 and PS4 were repeated twice. Therefore, in total, the panel consisted of 10 samples (7 positive and 3 negative samples).

Sample ID	Status	Number of repetitions (total results)	Observed result
PS1	POS	2 (18)	18 POS
PS2	POS	1 (9)	9 POS
PS3	POS – NEG – NI	2 (18)	13 NEG 5 NI
PS4	POS	2 (18)	18 POS
NS1	NEG	1 (9)	9 NEG
NS2	NEG	1 (9)	9 NEG
NS3	NEG	1 (9)	9 NEG

(POS = positive; NEG = negative, NI = Not Interpretable)

5.1.2 USED METHOD

Method	N	NR	NCR	%
Idexx - IBR gB X3 Ab	9	90	90	100
TOTAL	**9**	**90**	**90**	**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 90 correct results were submitted.

5.2 Serology on serum gE

5.2.1 RESULTS PER SAMPLE

The panel consisted of 6 different samples. Samples PS1, PS2, NS1 and NS3 were repeated twice. Therefore, in total, the panel consisted of 10 samples (5 positive and 5 negative samples).

One lab had chosen to test two different methods on the same samples, implying that there were two datasets submitted. These additional results are included in the tables below.

Sample ID	Status	Number of repetitions (total results)	Observed result
PS1	POS	2 (22)	21 POS 1 NEG
PS2	POS	2 (22)	22 POS
PS3	POS	1 (11)	11 POS
NS1	NEG	2 (22)	22 NEG
NS2	NEG	1 (11)	11 NEG
NS3	NEG	2 (22)	22 NEG

(POS = positive; NEG = negative)

5.2.2 USED METHOD

Method	N	NR	NCR	%
Idexx - Bovine Rhinotracheitis Virus (BHV-1) gE Antibody Test Kit	8	80	80	100
ID.VET - ID SCREEN® IBR GE COMPETITION	3	30	29	97
TOTAL	**11**	**110**	**109**	**99**

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

5.2.3 CONCLUSION

In total, the laboratories used two different methods. The first method 'Idexx - Bovine Rhinotracheitis Virus (BHV-1) gE Antibody Test Kit' achieved 100% correctness, which means that 80 correct results were submitted. For the second method 'ID.VET - ID SCREEN® IBR GE COMPETITION', a misinterpretation was entered for one sample. The overall score for this method was 97% (29 correct results), which is still higher than the score of 90% that should at least be achieved.

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 GB

PT2022IBRgBSERPS1

Lab number	97505	97507	97508	97509	97510	97513	97516	97521	97540
Method	Idexx - IBR gB X3 Ab								
REP1	96,7	98,5	98,8	94,7	97,8	89,0	98,7	94,5	96,5
REP2	96,4	98,6	98,9	95,4	97,8	89,0	98,7	95,2	96,4
Mean	96,5	98,5	98,8	95,0	97,8	89,0	98,7	94,9	96,5
SD	0,2	0,1	0,1	0,5	0,0	0,0	0,0	0,5	0,1
CV (%)	0,3	0,1	0,1	0,5	0,1	0,0	0,0	0,5	0,1

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

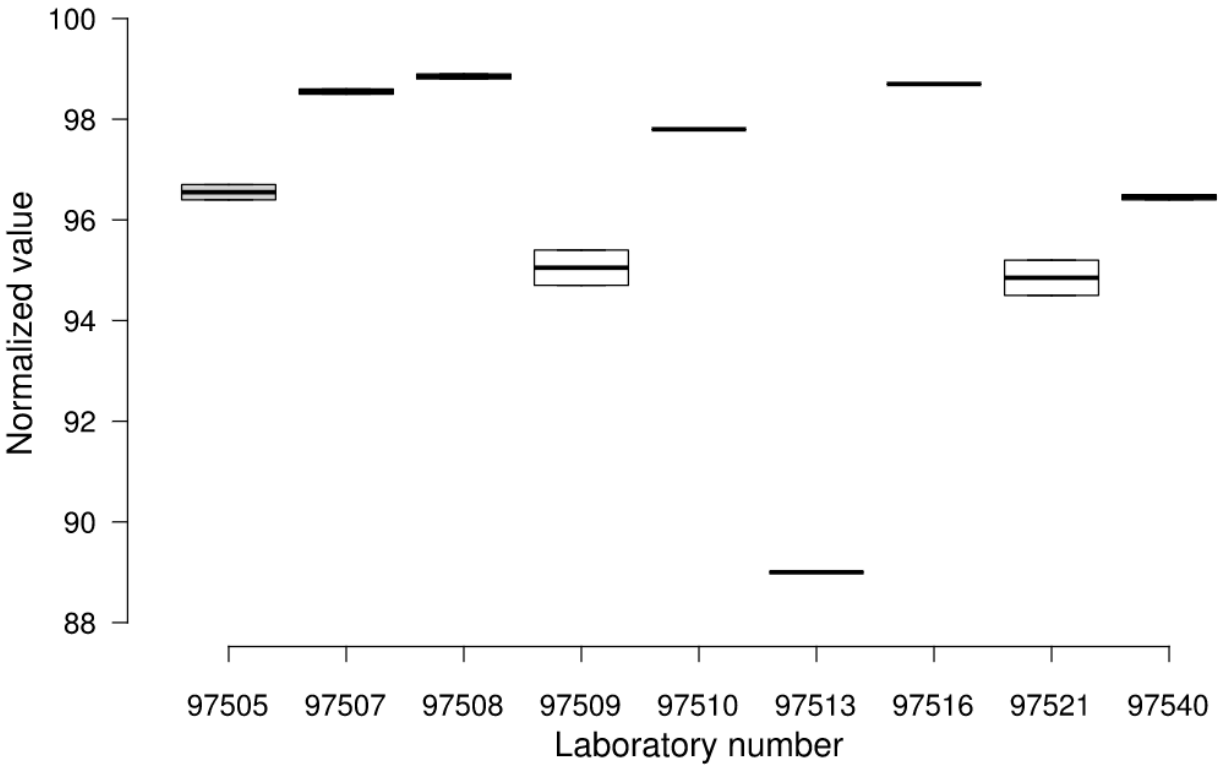


Figure 1. Distribution of the normalized values (box-plots) per laboratory.

PT2022IBRgBSERPS3

Lab number	97505	97507	97508	97509	97510	97513	97516	97521	97540
Method	Idexx - IBR gB X3 Ab								
REP1	43,0	26,4	45,6	48,6	41,6	41,0	50,0	43,2	33,3
REP2	42,9	28,3	47,0	47,0	43,6	38,0	39,9	41,0	40,4
Mean	43,0	27,4	46,3	47,8	42,6	39,5	45,0	42,1	36,8
SD	0,1	1,3	1,0	1,1	1,4	2,1	7,1	1,5	5,0
CV (%)	0,1	4,9	2,1	2,4	3,4	5,4	15,9	3,6	13,6

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

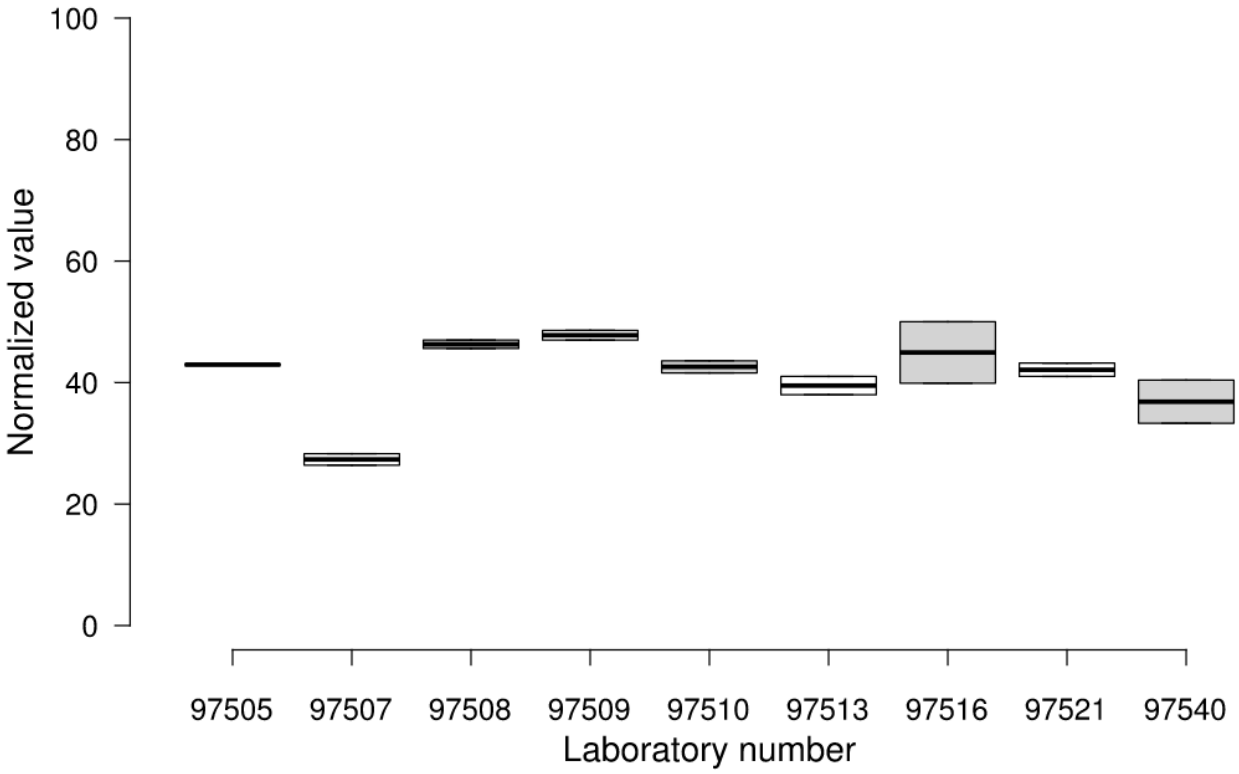


Figure 2. Distribution of the normalized values (box-plots) per laboratory.

PT2022IBRgBSERPS4

Lab number	97505	97507	97508	97509	97510	97513	97516	97521	97540
Method	Idexx - IBR gB X3 Ab								
REP1	77,1	62,5	77,9	79,1	75,6	64,0	79,2	70,1	60,9
REP2	79,4	65,4	82,1	79,2	78,8	65,0	78,3	70,1	68,6
Mean	78,2	63,9	80,0	79,2	77,2	64,5	78,8	70,1	64,8
SD	1,7	2,0	3,0	0,1	2,2	0,7	0,6	0,1	5,5
CV (%)	2,1	3,1	3,7	0,2	2,9	1,1	0,8	0,1	8,4

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

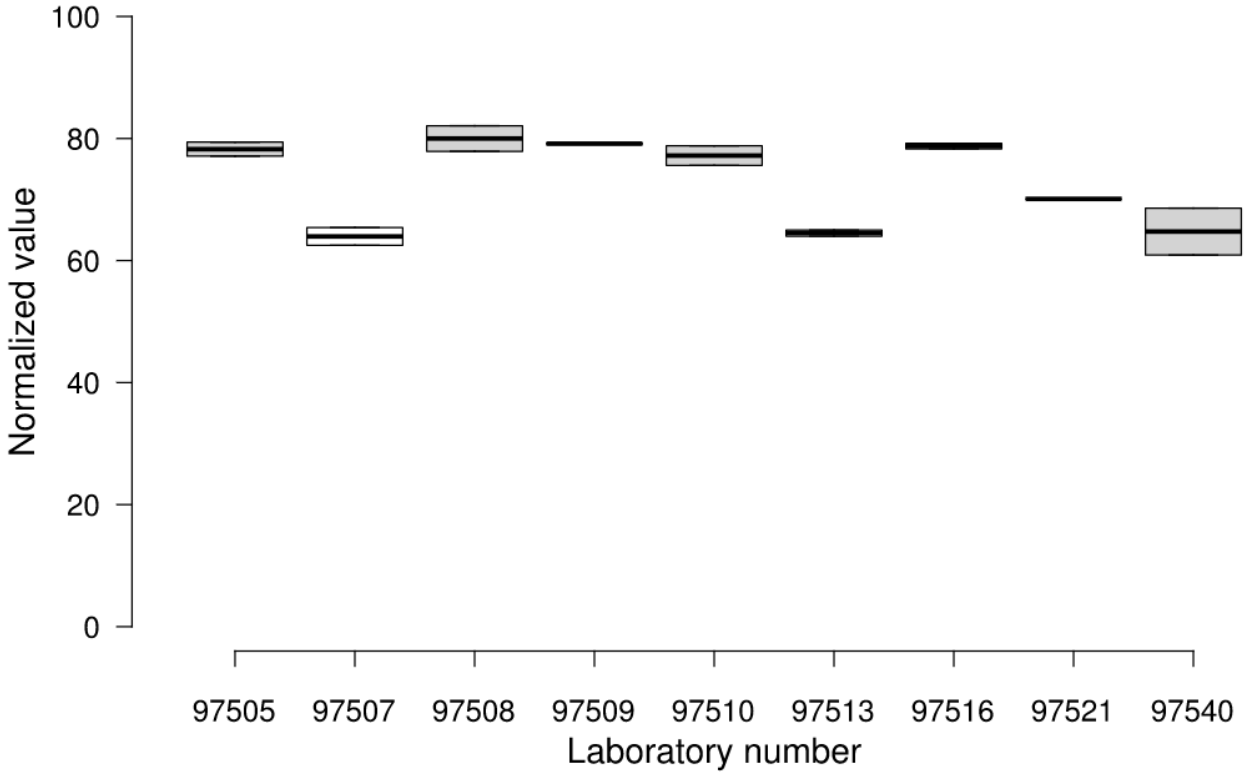


Figure 3. Distribution of the normalized values (box-plots) per laboratory.

6.1.2 SEROLOGY ON SERUM GE

PT2022IBRgESERPS1

Lab number	97505	97507	97508 (1)	97508 (2)	97509	97510	97513	97516	97521	97522	97540
Method	M_1	M_1	~~M_1~~ M_2 *	M_2	M_1	~~M_1~~ M_2 *	~~M_1~~ M_3 *	M_1	M_1	M_2	M_2
REP1	72,5	76,2	79,3	48,4	76,7	0,3	0,3	74,5	0,3	53,0	0,5
REP2	76,9	76,2	78,3	46,0	76,5	0,3	0,3	74,6	0,2	87,0	0,5
Mean	74,7	76,2	78,8	47,2	76,6	0,3	0,3	74,5	0,3	70,0	0,5
SD	3,1	0,0	0,7	1,7	0,1	0,0	0,0	0,1	0,1	24,0	0,0
CV (%)	4,2	0,0	0,9	3,7	0,2	2,7	0,0	0,1	28,3	34,3	4,2

(REP = repetition; SD = standard deviation; CV = coefficient of variation; M_1 = Idexx - Bovine Rhinotracheitis Virus (BHV-1) gE Antibody Test Kit; M_2 = ID.VET - ID SCREEN® IBR GE COMPETITION; M_3 = Idexx gE blocking ELISA)

* = The results visible on the boxplot for laboratories 97508 (for the first method), 97510 and 97513 are not in agreement with the other laboratories. This inconsistency is, on the one hand, due to the fact that laboratory 97508 (for the first method) used their own normalisation formula which can give high figures for low ODs and on the other hand, laboratories 97510 and 97513 have indicated an indirect method while the ODs are rather from a competition kit.

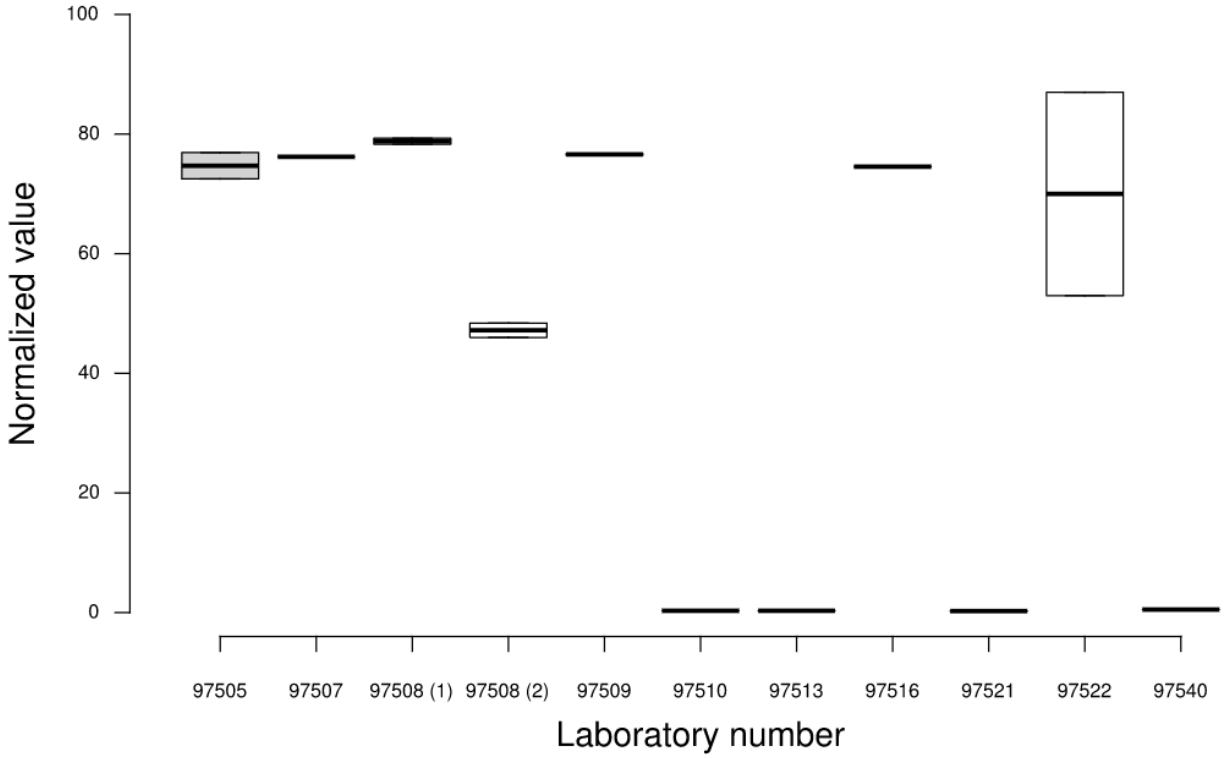


Figure 4. Distribution of the normalized values (box-plots) per laboratory.

PT2022IBRgESERPS2

Lab number	97505	97507	97508 (1)	97508 (2)	97509	97510	97513	97516	97521	97522	97540
Method	M_1	M_1	~~M_1~~ M_2 *	M_2	M_1	~~M_1~~ M_2 *	~~M_1~~ M_3 *	M_1	M_1	M_2	M_2
REP1	93,0	90,1	93,7	93,4	93,8	0,2	0,2	95,0	0,1	9,0	0,1
REP2	92,9	89,8	93,4	92,9	94,2	0,2	0,2	95,0	0,1	8,0	0,1
Mean	92,9	90,0	93,6	93,2	94,0	0,2	0,2	95,0	0,1	8,5	0,1
SD	0,1	0,2	0,2	0,4	0,3	0,0	0,0	0,0	0,0	0,7	0,0
CV (%)	0,1	0,3	0,2	0,4	0,3	0,0	7,0	0,0	2,2	8,3	1,1

(REP = repetition; SD = standard deviation; CV = coefficient of variation; M_1 = Idexx - Bovine Rhinotracheitis Virus (BHV-1) gE Antibody Test Kit; M_2 = ID.VET - ID SCREEN® IBR GE COMPETITION; M_3 = Idexx gE blocking ELISA)

* = The results visible on the boxplot for laboratories 97508 (for the first method), 97510 and 97513 are not in agreement with the other laboratories. This inconsistency is, on the one hand, due to the fact that laboratory 97508 (for the first method) used their own normalisation formula which can give high figures for low ODs and on the other hand, laboratories 97510 and 97513 have indicated an indirect method while the ODs are rather from a competition kit.

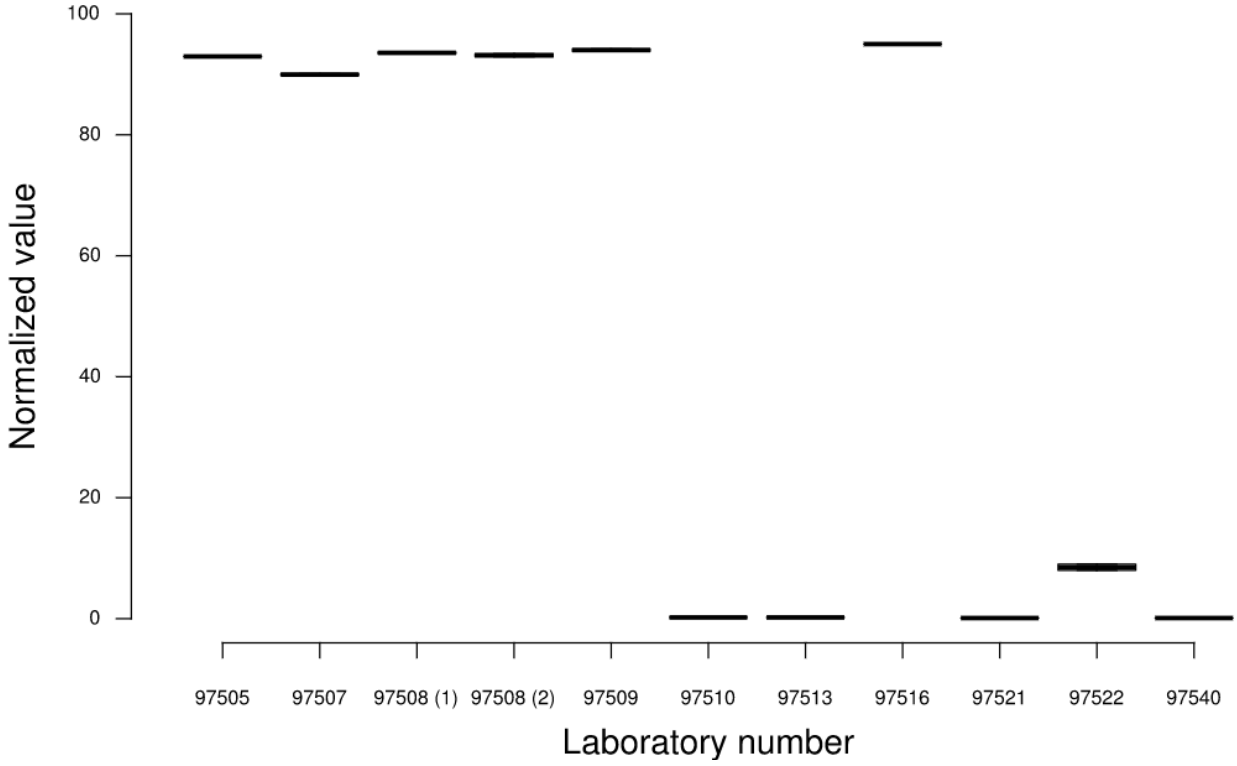


Figure 5. Distribution of the normalized values (box-plots) per laboratory.

6.2 Annex 2: Additional information

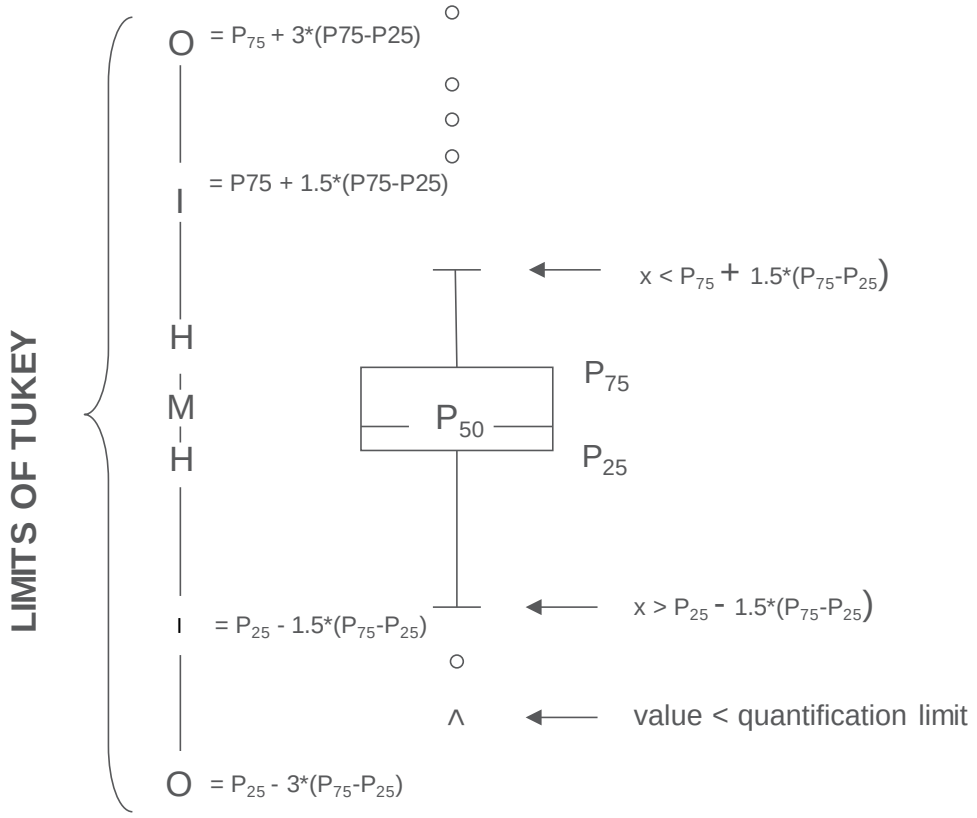
The preliminary report of this proficiency test is available on our website via the following link:
https://www.wiv-isp.be/QML/activities/PT%20VET/fr/originaux/rapports_annee.htm

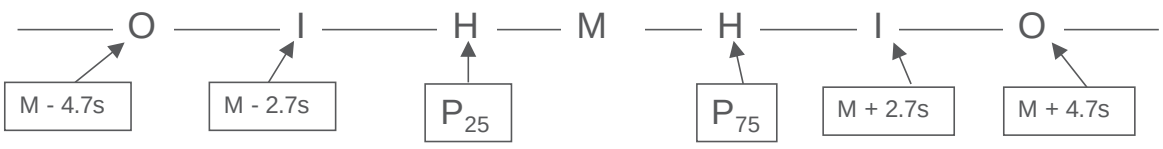
The calendar for Proficiency Testing in Veterinary diagnosis is available on our website:
https://www.wiv-isp.be/QML/activities/external_quality/calendar/kalender.htm

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