BIOLOGICAL HEALTH RISKS
QUALITY OF LABORATORIES

COMMITEE OF EXPERTS

EXTERNAL QUALITY ASSESSMENT
IN VETERINARY DIAGNOSIS

DEFINITIVE GLOBAL REPORT

VETERINARY MEDECINE

ENZOOTIC BOVINE LEUKOSIS (EBL)

PROFICIENCY TEST 2022/8

Sciensano/PT VET EBL/2-E

Biological health risks
Quality of laboratories
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Signature of the scheme coordinator.

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All the reports are also available on our webpage:

- NL: https://www.sciensano.be/nl/externe-kwaliteitsevaluatie/diergezondheid-pt-vet
- FR: https://www.sciensano.be/fr/evaluation-externe-de-la-qualite/sante-animale-pt-vet
- EN: https://www.sciensano.be/en/external-quality-assessment/animal-health-pt-vet

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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 detect the absence or presence of enzootic bovine leukosis (EBL)-specific antibodies in serum of ruminants.

3. MATERIALS AND METHODS

3.1 Serology on serum

3.1.1 THE PARTICIPANTS

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

- Sciensano, department of Enzootic, vector-borne and bee diseases
- ARSIA
- DGZ
- ANSES Unité Pathologie et Bien-être des ruminants (PBER)- Site de Niort
- Laboratoire de médecine vétérinaire de l'état (LMVE)
- Kosovo Food And Veterinary Laboratory

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 historically infected animals from the field and from animals experimentally infected with BLV.

3.1.3 HOMOGENEITY

The homogeneity of the samples was tested by the NRL on 10 aliquots (200 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: 6 positive and 4 negative samples.

Sample ID	Repetition	Status
PT2022EBLSERPS1	1	POS
PT2022EBLSERPS2	1	POS
PT2022EBLSERPS3	2	POS
PT2022EBLSERPS4	1	POS
PT2022EBLSERPS5	1	POS
PT2022EBLSERNS1	2	NEG
PT2022EBLSERNS2	2	NEG

POS = positive; NEG = negative

3.1.5 STABILITY

The samples were tested before and after the proficiency test. 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 follows:

Sample ID: EBLSER	97505	97507	97508	97513	97516	97630
22-1	PS1	PS3	NS2	PS2	NS1	PS2
22-2	PS4	PS5	NS1	PS3	PS2	NS2
22-3	NS1	PS3	PS5	PS3	PS4	NS2
22-4	PS2	NS2	PS4	NS1	PS1	PS4
22-5	NS2	NS1	NS2	PS5	NS2	PS3
22-6	PS3	NS1	PS3	PS4	NS2	NS1
22-7	PS5	PS1	PS3	NS1	PS5	PS3
22-8	PS3	NS2	PS1	NS2	PS3	PS1
22-9	NS1	PS4	PS2	NS2	NS1	PS5
22-10	NS2	PS2	NS1	PS1	PS3	NS1

4. TIMELINE

Transfer of the samples from NRL to QL: 16/06/2022
Randomization of the samples by QL: 16/06/2022
Sending samples (cooled at 4 °C) to participants: 20/06/2022
Deadline for submitting the results: 15/07/2022
Preliminary report: 06/09/2022

5. RESULTS

5.1 Serology on serum

5.1.1 RESULTS PER SAMPLE

The panel consisted of 7 different samples. Samples PS3, NS1 and NS2 were repeated twice. Therefore, in total, the panel consisted of 10 samples (6 positive and 4 negative samples).

Sample ID	Status	Number of repetitions (total results)	Observed result
PS1	POS	1 (6)	6 POS
PS2	POS	1 (6)	6 POS
PS3	POS	2 (12)	12 NEG
PS4	POS	1 (6)	6 POS
PS5	POS	1 (6)	6 NEG
NS1	NEG	2 (12)	12 NEG
NS2	NEG	2 (12)	12 NEG

(POS = positive; NEG = negative)

5.1.2 USED METHOD

Method		Short or long incubation protocol	N	NR	NCR	%
ELISA Competition	Idexx - Leukosis Blocking Ab test	Short	2	20	20	100
ELISA Competition	ID.VET - ID Screen® BLV Competition	Short	2	20	20	100
ELISA Indirect	Idexx – Indirect ELISA test	Short	2	20	20	100
TOTAL			**6**	**60**	**60**	**100**

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

5.1.3 CONCLUSION

In 2022, six laboratories participated in proficiency test of enzootic bovine leukosis (EBL) (serology serum) organized by Sciensano. Three methods, Leukosis Blocking Ab test from Idexx, ID Screen® BLV Competition from ID.VET and Indirect ELISA test from Idexx, were selected by the laboratories for the detection of EBL-specific antibodies in serum of ruminants. Two methods fall under the ELISA blocking (competitive) format and one under the indirect format.

According to the procedure currently in force, the performance of a participating laboratory is satisfactory if at least 90% of the results provided by this laboratory is in agreement with the status of the reference serum samples assigned by the reference laboratory of the Scientific Directorate Infectious Diseases in Animals of Sciensano. Nevertheless, all the laboratories achieved a satisfactory performance (> 90%).

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

PT2022EBLSERPS3

Lab number	97505	97507	97508	97513	97516	97630
Method	M_1	M_2	M_2	M_3	M_1	M_3
OD (REP1)	0.24	0.27	0.35	2.01	0.41	1.36
OD (REP2)	0.24	0.34	0.35	2.03	0.38	1.27
Mean	0.24	0.31	0.35	2.25	0.39	1.32
SD	0.00	0.05	0.00	0.34	0.02	0.06
CV (%)	1.19	16.23	1.21	15.09	4.12	4.72

Numbers were rounded to 2 decimal places. (OD = optical density; REP = repetition; SD = standard deviation; CV = coefficient of variation, M_1 = Idexx - Leukosis Blocking Ab test; M_2 = ID.VET - ID Screen® BLV Competition; M_3 = Idexx - Indirect ELISA test)

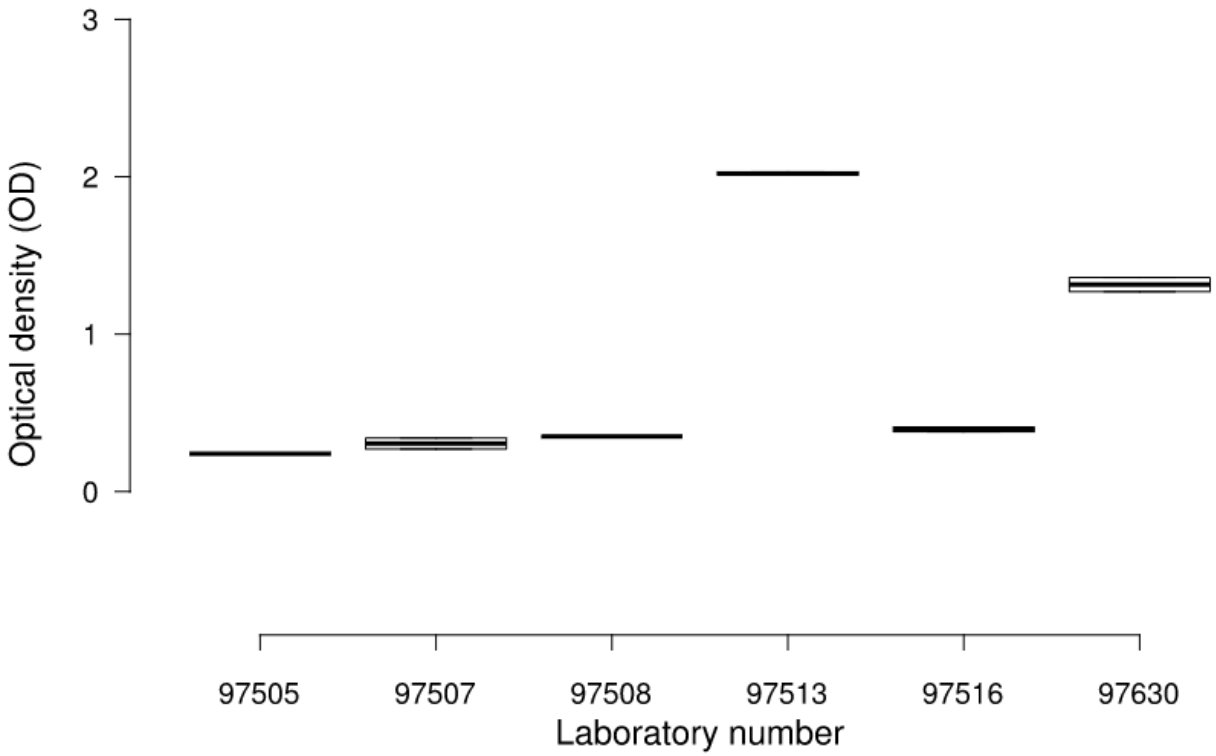


Figure 1. Distribution of the optical densities (box-plots) per laboratory.

6.2 Annex 2: Additional information

The **preliminary report** of this proficiency test is available on our website via the following link:

- NL: https://www.sciensano.be/nl/externe-kwaliteitsevaluatie/diergezondheid-pt-vet
- FR: https://www.sciensano.be/fr/evaluation-externe-de-la-qualite/sante-animale-pt-vet
- EN: https://www.sciensano.be/en/external-quality-assessment/animal-health-pt-vet

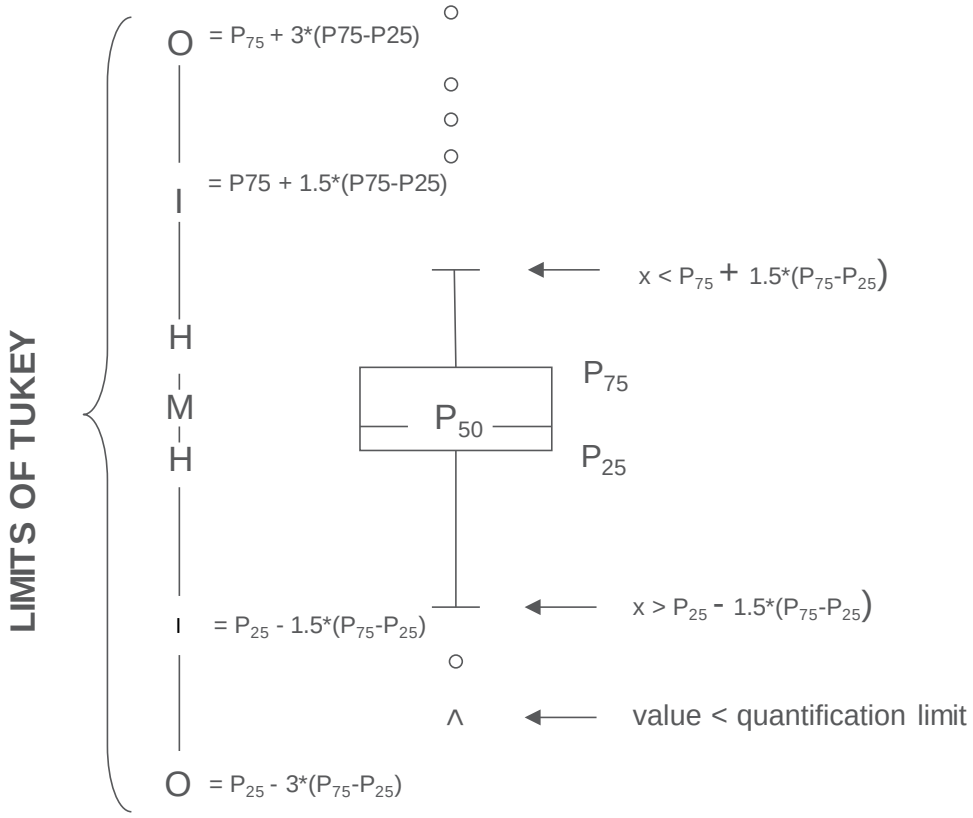
The **calendar** for Proficiency Testing in Veterinary diagnosis is available on our website:

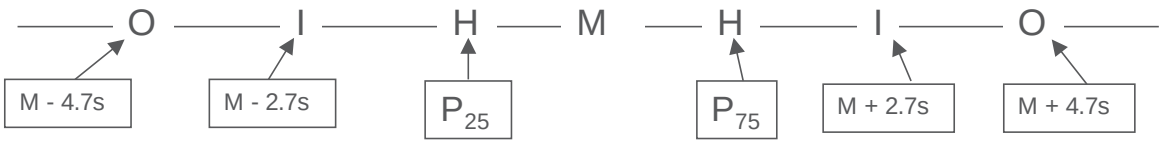
- NL: https://www.sciensano.be/nl/biblio/eke-kalender-2023
- FR: https://www.sciensano.be/en/biblio/calendrier-eeq-2023
- EN: https://www.sciensano.be/nl/biblio/eqa-calendar-2023

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