BIOLOGICAL HEALTH RISKS
QUALITY OF LABORATORIES

COMMITEE OF EXPERTS

EXTERNAL QUALITY ASSESSMENT
IN VETERINARY DIAGNOSIS

DEFINITIVE GLOBAL REPORT

VETERINARY MEDECINE

VISNA MAEDI (VM)

PROFICIENCY TEST 2022/13

Sciensano/PT VET VM/2-E

Biological health risks
Quality of laboratories
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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 the PT was to evaluate the ability of the participating laboratories to detect the absence or presence of antibodies against the Visna Meadi virus in serum of sheep.

3 MATERIALS AND METHODS

3.1 Serology (serum)

3.1.1 THE PARTICIPANTS

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

- Sciensano, department of Veterinary Virology (viral reemerging enzootic and bee diseases')
- ARSIA
- Dierengezondheidszorg Vlaanderen (DGZ)
- LAVETAN

3.1.2 THE SAMPLES

The samples (refrigerated serum) were prepared by the National Reference Laboratory (NRL), department of Veterinary virology, Sciensano.

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

- Sample PS1: 6612/16 Positive field samples (sheep)
- Sample PS2: 6622 Positive field samples (sheep)
- Sample PS3: 9562 Positive field samples (sheep)
- Sample PS4: Biowest b:S00 Fe positive goat serum (commercial)
- Sample NS1: Commercial FCS
- Sample NS2: M73: negative experimental serum
- Sample NS3: M102: negative experimental serum
- Sample NS4: M103: negative experimental serum
- Sample NS5: M81: negative experimental serum
- Sample NS6: M63: negative experimental serum

All samples are serum samples and are stored in -20°C before aliquotation and refrozen for transport.

3.1.3 HOMOGENEITY

The homogeneity of the samples was tested by the NRL on 3 aliquots (250 µl) of each sample using ELISA method before the PT. The samples were considered as homogeneous.

For the laboratory, the criteria to consider that the homogeneity is correct is when the coefficient of variation (CV) between the 3 values is < 15%.

3.1.4 TARGET VALUES

The target values were determined by the NRL based on the homogeneity tests. The panel consisted of 10 different of samples: 4 positive and 6 negative samples.

Sample ID	Repetition	Status
PT2022VMSERPS1	1	POS
PT2022VMSERPS2	1	POS
PT2022VMSERPS3	1	POS
PT2022VMSERPS4	1	POS
PT2022VMSERNS1	1	NEG
PT2022VMSERNS2	1	NEG
PT2022VMSERNS3	1	NEG
PT2022VMSERNS4	1	NEG
PT2022VMSERNS5	1	NEG
PT2022VMSERNS6	1	NEG

(POS = positive; NEG = negative)

3.1.5 STABILITY

The criteria for stability is that the status of the sample in Post-PT remains the status assigned in pre-PT test. The stability check was conform.

3.1.6 RANDOMISATION AND PANEL COMPOSITION

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

Sample ID: VMSER	97505	97507	97508	97509
22-1	PS1	NS6	NS3	NS2
22-2	NS6	NS4	NS1	NS5
22-3	NS5	PS2	NS6	PS2
22-4	PS2	NS2	NS2	NS6
22-5	NS3	NS1	NS4	NS4
22-6	NS1	NS5	PS1	PS4
22-7	NS2	PS3	PS4	NS1
22-8	PS4	NS3	NS5	NS3
22-9	NS4	PS1	PS3	PS1
22-10	PS3	PS4	PS2	PS3

4 TIMELINE

Transfer of the samples from NRL to QL: 21/11/2022
Randomization of the samples by QL: 21/11/2022
Sending samples to participants: 28/11/2022

- Samples serology: cooled at 4 °C

Deadline for submitting the results: 16/12/2022
Preliminary report: 09/01/2023

5 RESULTS

5.1 Serology (serum)

5.1.1 RESULTS PER SAMPLE

The panel consisted of 10 different samples. No repetitions were included. Therefore, in total, the panel consisted of 10 samples (4 positive and 6 negative samples).

Sample ID	Status	Number of repetitions (total results)	Observed result
PS1	POS	1 (4)	4 POS
PS2	POS	1 (4)	4 POS
PS3	POS	1 (4)	4 POS
PS4	POS	1 (4)	4 POS
NS1	NEG	1 (4)	4 NEG
NS2	NEG	1 (4)	4 NEG
NS3	NEG	1 (4)	4 NEG
NS4	NEG	1 (4)	4 NEG
NS5	NEG	1 (4)	4 NEG
NS6	NEG	1 (4)	4 NEG

(POS = positive; NEG = negative)

5.1.2 USED METHOD

Method		Short or long incubation protocol	N	NR	NCR	%
ELISA Indirect	ID.VET - ID Screen MVV/CAEV Indirect	Not applicable	**2**	**20**	**20**	**100**
ELISA Indirect	Hyphen Biomed - ELITEST MVV/CAEV	Short	**2**	**20**	**20**	**100**
TOTAL			**4**	**40**	**40**	**100**

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

5.1.3 CONCLUSION

In 2022, four laboratories participated in proficiency test of Visna Maedi serology (serum) organized by Sciensano. The method ID Screen MVV/CAEV Indirect from ID.VET and ELITEST MVV/CAEV from Hyphen Biomed were selected by the participants for the detection of antibodies against the Visna Maedi virus in serum. These methods fall 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. All laboratories succeeded in achieving the maximum score (100%) for this test. As a results, it can be concluded that the methods from ID.VET and Hyphen Biomed are suitable options for antibody detection against the Visna Maedi virus in serum of sheep.

6 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/fr/biblio/eke-kalender-2023
- FR: https://www.sciensano.be/en/biblio/calendrier-eeq-2023
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END