BIOLOGICAL HEALTH RISKS
QUALITY OF LABORATORIES

PROFICIENCY TEST
IN VETERINARY DIAGNOSIS

DEFINITIVE GLOBAL REPORT

PT-PROGRAM 2025-7

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

Sciensano/PT-program BSE/2025-7/E

Biological health risks
Quality of laboratories
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A draft version of this report was submitted to the expert on 15/10/2025.

The expert was invited to send the comments via e-mail.

Responsibilities:
The National Reference Laboratory (NRL) of Sciensano was consulted for advice about the content of the global report, the interpretation of the results and the evaluation criteria. The responsibility for the choice of the samples used was carried out by the NRL.

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

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All the global 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 are available in the procedure SOP 2.5/01 ‘Management of the proficiency tests organized by the scientific directorate infectious diseases in animals’. The proficiency test was organised according to the ISO17043 norm ‘Conformity assessment - General requirements for proficiency testing’.

2 AIM

The aim of this proficiency test was to assess the capability of the participating laboratories to detect BSE prions in nervous tissue (obex).

3 MATERIALS AND METHODS

3.1 Prions (brain tissue)

3.1.1 THE PARTICIPANTS

Two laboratories participated in the proficiency test “detection of Bovine Spongiform Encephalopathy prions in brain tissue samples”. The laboratory numbers of the participating laboratories are:

- 97505
- 97524

3.1.2 THE SAMPLES

The National Reference Laboratory (NRL) of Sciensano, within the scientific service of 'Viral Re-emerging Enzootic and Bee diseases' in the Scientific Directorate of 'Infectious diseases in animals', prepared the samples.

To obtain the samples for the proficiency test, homogenates of the obex of multiple TSE-positive and TSE-negative bovines were pooled. These homogenates were obtained from proficiency tests organized by the European reference laboratory. The homogenates and pools of homogenates are conserved in an ultra-low freezer (< -72 °C).

3.1.3 HOMOGENEITY

Because of the limited availability of positive samples, the homogeneity of the samples was tested once with the accredited method (ISO17025) by the NRL before the proficiency test (pre-PT testing). For mix D 1/5, two different dilutions were tested. All samples were considered as homogeneous.

3.1.4 TARGET VALUES

The target values were determined by the NRL based on the homogeneity tests.

Sample content	Expected result
Mix S	POS
Mix D 1/5	POS
Mix P	NEG

(POS = positive; NEG = negative)

3.1.5 STABILITY

Because of the limited availability of positive samples, only one vial of each sample was re-evaluated after the PT (post-PT testing) to assess the stability of the panel. The NRL used a commercial ELISA kit for this analysis, which is the accredited method at the NRL (ISO17025). All samples had the same qualitative results as in the pre-PT testing and were thus 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 follows:

Sample content:	97505	97524
Mix S	BSE25-4	BSE25-2
Mix D 1/5	BSE25-2	BSE25-5
Mix P (1)	BSE25-1	BSE25-1
Mix P (2)	BSE25-3	BSE25-3
Mix P (3)	BSE25-5	BSE25-4

3.1.7 THRESHOLD FOR QUALIFICATION

Following the procedure, a participating laboratory is only qualified if the level of agreement for the five reference samples is 100%.

4 TIMELINE

The randomisation of the samples by Quality of Laboratories took place on September 15, 2025. The samples were then sent to the participants on the same day. The deadline for submitting the results was set for October 10, 2025. All participants submitted their results on time. Finally, the individual reports were provided to the participants on October 15, 2025.

5 RESULTS

5.1 Prions (brain tissue)

5.1.1 RESULTS PER SAMPLE

The panel consisted of three different samples. However, negative sample “Mix P” was repeated three times. Therefore, the panel included five samples in total.

Sample content	Expected results	Total results	Observed results
Mix S	POS	2	2x POS
Mix D 1/5	POS	2	2x POS
Mix P	NEG	6	6x NEG

5.1.2 RESULTS PER METHOD

Below, the table displays the results for each method.

ELISA	Purification kit	N	NR	NCR	%
Bio-Rad - TeSeE ELISA	TeSeE Purification and Detection Kit	**1**	**10**	**10**	**100**
IDEXX - Herdcheck BSE-Scrapie Ag test (enzyme immunoassay)	*Not applicable*	**1**	**10**	**10**	**100**
TOTAL		**2**	**20**	**20**	**100**

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

5.1.3 CONCLUSION

In 2025, two laboratories participated in the proficiency test “detection of Bovine Spongiform Encephalopathy prions (brain tissue)” organised by Sciensano. According to the procedure currently in force, the performance of a participating laboratory is satisfactory if 100% of the results provided by the laboratory are in agreement with the status of the reference samples assigned by the NRL of the Scientific Directorate Infectious Diseases in Animals of Sciensano. All laboratories succeeded in achieving the maximum score (100%) for this test.

6 ANNEXES (NOT UNDER ACCREDITATION)

This quantitative data is not covered by BELAC accreditation and is provided solely for the information of the laboratories.

6.1 Annex : Quantitative results

Boxplots could not be generated for this proficiency test, as the data are purely qualitative rather than quantitative. Furthermore, no positive samples were duplicated within the panel.

6.2 Annex: Additional information

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

- NL: https://www.sciensano.be/nl/biblio/eke-kalender-2025
- FR: https://www.sciensano.be/fr/biblio/calendrier-eeq-2025
- EN: https://www.sciensano.be/en/biblio/eqa-calendar-2025

END