BIOLOGICAL HEALTH RISKS
QUALITY OF LABORATORIES

PROFICIENCY TEST IN VETERINARY DIAGNOSIS

DEFINITIVE GLOBAL REPORT

PT-PROGRAM 2025-6

SCRAPIE

Sciensano/PT-program SCRAPIE/2025-6/E

Biological health risks
Quality of laboratories
Rue Juliette Wytsmanstraat, 14
1050 Brussels | Belgium

www.sciensano.be

ISSN: 2294-3498

NATIONAL REFERENCE LABORATORY

Sciensano					
Secretariat		Phone:	02/642.55.22	Fax:	02/642.56.45
		E-mail	ql_secretariat@sciensano.be		
Ynse Van de Maele	Coordinator	Phone:	02/642 55 24		
		E-mail:	Ynse.vandemaele@sciensano.be		
Bernard China	Alternate coordinator	Phone:	02/642 53 85		
		E-mail:	Bernard.china@sciensano.be		
Expert	**Institute**				
Severine Matthijs	Sciensano – NRL TSE diagnosis and PRNP genotyping				

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

Date of publication: 04/11/2025

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

TABLE OF CONTENTS

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 obtain the PRNP genotype (codons 136, 141, 154 and 171 of the PRNP gene) of EDTA-blood samples from sheep. In the table below, an overview is given of the genotypes.

Group	Genotype (codons 136, 154, 171)	Degree of resistance / susceptibility
Type 1	ARR/ARR	Sheep that are genetically most resistant to classical scrapie.
Type 2	ARR/AHQ	Sheep that are genetically resistant to classical scrapie, but will need careful selection when used for further breeding.
	ARR/ARH	
	ARR/ARQ	
Type 3	AHQ/AHQ	Sheep that genetically have little resistance to classical scrapie and will need careful selection when used for further breeding.
	AHQ/ARH	
	AHQ/ARQ	
	ARH/ARH	
	ARH/ARQ	
	ARQ/ARQ	
Type 4	ARR/VRQ	Sheep that are genetically susceptible to classical scrapie and should not be used for breeding unless in the context of controlled breeding programme.
Type 5	AHQ/VRQ	Sheep that are highly susceptible to classical scrapie and should not be used for breeding.
	ARH/VRQ	
	ARQ/VRQ	
	VRQ/VRQ	

3 MATERIALS AND METHODS

3.1 Genotyping (EDTA-blood)

3.1.1 THE PARTICIPANTS

Two laboratories participated in the proficiency test of PRNP genotyping on EDTA-blood samples. The laboratory numbers of the participating laboratories are:

- 97505
- 97507

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 'Infectious diseases in animals', prepared the samples.

The samples, collected from healthy sheep by veterinarians/clients/FASFC, are sourced from Belgian farms in 2022, 2023 and 2024.

3.1.3 HOMOGENEITY

All samples included in the panel were evaluated by testing an aliquot of each blood sample using both real-time PCR and sequencing (both methods performed under ISO17025 accreditation). This was performed before sending the samples for the PT.

3.1.4 TARGET VALUES

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

Sample content	Expected result (4 codons: 136, 141, 154, 171)
PT2025SCRAPIE_G1	ALRR/ALRR
PT2025SCRAPIE_G2	ALRR/ALRR
PT2025SCRAPIE_G3	ALRQ/ALRQ
PT2025SCRAPIE_G4	ALRQ/ALRQ
PT2025SCRAPIE_G5	ALRR/AFRQ
PT2025SCRAPIE_G6	ALRR/ALRQ
PT2025SCRAPIE_G7	ALRR/ALHQ
PT2025SCRAPIE_G8	ALRR/ALHQ
PT2025SCRAPIE_G9	ALRR/ALRH
PT2025SCRAPIE_G10	ALRR/VLRQ

3.1.5 STABILITY

To assess the stability of the panel, all samples included in the panel were evaluated by testing an aliquot of each blood sample using both real-time PCR and sequencing (both methods performed under ISO17025 accreditation).

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: PT2025SCRAPIE_	97505	97507
G1	SCRAPIE25-9	SCRAPIE25-7
G2	SCRAPIE25-10	SCRAPIE25-4
G3	SCRAPIE25-1	SCRAPIE25-6
G4	SCRAPIE25-6	SCRAPIE25-1
G5	SCRAPIE25-8	SCRAPIE25-5
G6	SCRAPIE25-5	SCRAPIE25-2
G7	SCRAPIE25-3	SCRAPIE25-10
G8	SCRAPIE25-4	SCRAPIE25-3
G9	SCRAPIE25-2	SCRAPIE25-8
G10	SCRAPIE25-7	SCRAPIE25-9

3.1.7 THRESHOLD FOR QUALIFICATION

Following the procedure, a participating laboratory is only qualified if the level of agreement for the ten reference samples is at least 90%.

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. The deadline for submitting the results was set for October 10, 2025. However, since the shipment date of the samples to the participants was changed, Lab 97507 requested an extension of the deadline. This request was granted. Nevertheless, the lab still submitted its results before October 10, 2025. Consequently, all participants submitted their results on time. Finally, the individual reports were provided to the participants on October 14, 2025.

5 RESULTS

5.1 Genotyping (EDTA-blood)

5.1.1 RESULTS PER SAMPLE

The panel consisted of ten different samples (see table below). No repetitions were included.

Sample content	Expected results	Total results	Observed results
G1	ALRR/VLRQ	2	2x ALRR/VLRQ
G2	ALRR/ALRR	2	2x ALRR/ALRR
G3	ALRQ/ALRQ	2	2x ALRQ/ALRQ
G4	ALRR/ALRH	2	2x ALRR/ALRH
G5	ALRR/ALHQ	2	2x ALRR/ALHQ
G6	ALRR/AFRQ	2	2x ALRR/AFRQ
G7	ALRQ/ALRQ	2	2x ALRQ/ALRQ
G8	ALRR/ALHQ	2	2x ALRR/ALHQ
G9	ALRR/ALRQ	2	2x ALRR/ALRQ
G10	ALRR/ALRR	2	2x ALRR/ALRR

5.1.2 RESULTS PER METHOD

Below, the table displays the results for each method.

Genotyping method		N	NR	NCR	%
Real-time PCR and sequencing	• Real-time PCR (SOP TSE/ANA/03) • Sequencing (SOP TSE/ANA/04)	**1**	**10**	**10**	**100**
ARMS PCR coupled with capillary electrophoresis	• ARMS PCR (codons 136, 154, 171): Master Mix Scrapie ARMS (SOP/DSP/ANA/03) and Scrapie Codon 141 • Revelation on capillary electrophoresis SeqStudio	**1**	**10**	**10**	**100**
TOTAL		**2**	**20**	**20**	**100**

(ARMS = amplification refractory mutation system; 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 of PRNP genotyping on EDTA-blood samples organised by Sciensano. According to the procedure currently in force, the performance of a participating laboratory is satisfactory if at least 90% 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 since the results are purely qualitative (genotype result - codons) rather than quantitative.

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