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172-TEST

PROFICIENCY TESTING 2010

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)
Detection of BSE-specific prion antigens in brain tissue by
Enzyme-Linked Immunosorbent Assay (ELISA)

OPERATIONAL UNIT
COORDINATION OF VETERINARY DIAGNOSIS
EPIDEMIOLOGY AND RISK ASSESSMENT
(CVD-ERA)

DATE BEGIN PT: 26 OCTOBER 2010

DATE REPORT: 29 NOVEMBER 2010

I. Introduction

Details relevant to the proficiency test are available in the Procedure PRO/2.5/01 'Beheer van de proficiency testen/Gestion des essais d'aptitude'.

II. Aim

This proficiency test, focusing on the detection of BSE-specific prion antigens in brain tissue by an ELISA, aims to assess the analytical accuracy of tests conducted by participants.

III. Materials and methods

III.1. Conduct of diagnostic tests

In the framework of this proficiency test, predefined reference brain tissue samples must be tested for the presence of BSE-specific prion antigens by means of an ELISA test. The procedures for the ELISA tests must be fully described in the SOPs of the participating laboratories.

III.2. Reference samples

III.2.1. BSE-specific prion antigens reference brain tissue samples

Replicates of four reference brain tissue samples, one free from detectable BSE-specific prion antigens ($n = 1$; coded 'PT2010BSETSEBr1') and three containing detectable BSE-specific prion antigens ($n = 3$; coded 'PT2010BSETSEBr2', 'PT2010BSETSEBr3', and 'PT2010BSETSEBr4'), were used. In total 56 aliquots, prepared by the BSE reference laboratory of the Veterinary and Agrochemical Research Center (CODA-CERVA), were distributed to the participating laboratories. Each reference brain tissue sample was accompanied with a certificate containing the assigned value "status of the sample = golden standard". The assigned value for each reference brain tissue sample was obtained by the BSE reference laboratory of the CODA-CERVA by testing the negative brain tissue sample and positive brain tissue samples respectively four times and one time before the proficiency test (pre-verification). Each reference brain tissue sample was also tested once after the proficiency test (post-verification) to confirm the stability and the status of the brain tissue samples. Consequently, these reference brain tissue samples were considered as reliable samples to evaluate the ability to identify the absence or presence of BSE-specific prion antigens in brain tissue of bovine origin.

III.3. Classification of results, level of agreement and threshold for qualification

III.3.1. Classification of results

Results provided by the participating laboratories are categorized as *success* (positive result when the reference sample is truly positive, negative result when the reference sample is truly negative, non-interpretable result when the reference sample is truly non-interpretable) or *failure* (positive result when the reference sample is truly negative or non-interpretable, negative result when the reference sample is truly positive or non-interpretable, non-interpretable result when the reference sample is truly negative or positive).

III.3.2. Level of agreement

The level of agreement achieved by the participating laboratories is expressed as the percentage of success for all 7 samples (aliquots) for BSE-specific prion antigens carried out for this proficiency test.

III.3.3. Threshold for qualification

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

IV. Results

For confidentiality reasons, the participating laboratories are quoted anonymously and the concordance table is safely kept at the Operational Unit: CVD-ERA of CODA-CERVA.

IV.1. Reference samples

IV.1.1. Allocation of reference brain tissue samples to participating laboratories

All participating laboratories were given:

- i. 4 aliquots of reference brain tissue sample free from detectable BSE-specific prion antigens: PT2010BSETSEBr1 samples (n=4);
- ii. 3 aliquots of reference brain tissue samples containing detectable BSE-specific prion antigens: PT2010BSETSEBr1 sample (n = 1), PT2010BSETSEBr2 sample (n = 1), and PT2010BSETSEBr3 sample (n = 1).

IV.1.2. Transfer and start of the analyses

The 7 aliquots of reference brain tissue samples were available on 26 October 2010 for each of the eight participating laboratories (56 aliquots in total) at the reception desk of the CODA-CERVA. All the participating laboratories collected the samples themselves on the same day. The analyses were carried out on 26 (LAB2, LAB4, LAB6, LAB7, and LAB8) and 27 (LAB3 and LAB5) October 2010. No information about the start of the analysis was provided by LAB1.

IV.2. Dates at which results were returned to the CVD-ERA

Results from the participating laboratories have been received on 29 (LAB1 and LAB2) October and 3 (LAB5, LAB7, and LAB8) and 4 (LAB3, LAB4, and LAB6) November 2010.

IV.3. Compliance with the procedure

All participating laboratories have provided a duly dated and signed copy of the results.

IV.4. Level of agreement

Six participating laboratories reached 100% of agreement for the detection of BSE-specific prion antigens in reference brain tissue samples. Two participating laboratories reached 85.7% of agreement for the detection of BSE-specific prion antigens in reference brain tissue samples (Table 1).

Table 1. Agreement between results generated by the participating laboratories (LABNR) and the status of reference brain tissue samples. The purpose of the proficiency test is to detect BSE-specific prion antigens in reference brain tissue samples by ELISA.

Success while screening the samples (0 = Failure, 1 = Success)								
Variable	LABNR							
	1 (N=7)	2 (N=7)	3 (N=7)	4 (N=7)	5 (N=7)	6 (N=7)	7 (N=7)	8 (N=7)
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
0	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)
1	7 (100.0)	7 (100.0)	6 (85.7)	7 (100.0)	7 (100.0)	6 (85.7)	7 (100.0)	7 (100.0)

IV.5. Variability among participating laboratories

The responses of the eight participating laboratories that provided their results for the reference brain tissue samples are displayed in Table 2.

Table 2. The responses (RESULT) of the participating laboratories (LABNR) with the identification (SAMPLE) of the reference brain tissue samples, the position (LABPOSIT) of the reference brain tissue samples in the box, and the results (STATUS) obtained by repeated screening by the BSE reference laboratory of CODA-CERVA.

	LABNR	LABPOSIT	SAMPLE	STATUS	RESULT	SUCCESS
1	1	1	PT2010BSETSENB1	NEG	NEG	1
2	1	2	PT2010BSETSEPB1	POS	POS	1
3	1	3	PT2010BSETSENB1	NEG	NEG	1
4	1	4	PT2010BSETSEPB2	POS	POS	1
5	1	5	PT2010BSETSENB1	NEG	NEG	1
6	1	6	PT2010BSETSEPB3	POS	POS	1
7	1	7	PT2010BSETSENB1	NEG	NEG	1
8	2	1	PT2010BSETSENB1	NEG	NEG	1
9	2	2	PT2010BSETSENB1	NEG	NEG	1
10	2	3	PT2010BSETSEPB1	POS	POS	1
11	2	4	PT2010BSETSENB1	NEG	NEG	1
12	2	5	PT2010BSETSEPB2	POS	POS	1
13	2	6	PT2010BSETSENB1	NEG	NEG	1
14	2	7	PT2010BSETSEPB3	POS	POS	1



(CONTINUED)

	LABNR	LABPOSIT	SAMPLE	STATUS	RESULT	SUCCESS
15	3	1	PT2010BSETSEPBr3	POS	NI	0
16	3	2	PT2010BSETSENBBr1	NEG	NEG	1
17	3	3	PT2010BSETSENBBr1	NEG	NEG	1
18	3	4	PT2010BSETSEPBr1	POS	POS	1
19	3	5	PT2010BSETSENBBr1	NEG	NEG	1
20	3	6	PT2010BSETSEPBr2	POS	POS	1
21	3	7	PT2010BSETSENBBr1	NEG	NEG	1
22	4	1	PT2010BSETSENBBr1	NEG	NEG	1
23	4	2	PT2010BSETSEPBr3	POS	POS	1
24	4	3	PT2010BSETSENBBr1	NEG	NEG	1
25	4	4	PT2010BSETSENBBr1	NEG	NEG	1
26	4	5	PT2010BSETSEPBr1	POS	POS	1
27	4	6	PT2010BSETSENBBr1	NEG	NEG	1
28	4	7	PT2010BSETSEPBr2	POS	POS	1
29	5	1	PT2010BSETSENBBr1	NEG	NEG	1
30	5	2	PT2010BSETSEPBr2	POS	POS	1
31	5	3	PT2010BSETSEPBr3	POS	POS	1
32	5	4	PT2010BSETSENBBr1	NEG	NEG	1
33	5	5	PT2010BSETSENBBr1	NEG	NEG	1
34	5	6	PT2010BSETSEPBr1	POS	POS	1
35	5	7	PT2010BSETSENBBr1	NEG	NEG	1
36	6	1	PT2010BSETSENBBr1	NEG	NEG	1
37	6	2	PT2010BSETSEPBr3	POS	NI	0
38	6	3	PT2010BSETSENBBr1	NEG	NEG	1
39	6	4	PT2010BSETSEPBr2	POS	POS	1
40	6	5	PT2010BSETSENBBr1	NEG	NEG	1
41	6	6	PT2010BSETSENBBr1	NEG	NEG	1
42	6	7	PT2010BSETSEPBr1	POS	POS	1



(CONTINUED)

	LABNR	LABPOSIT	SAMPLE	STATUS	RESULT	SUCCESS
43	7	1	PT2010BSETSENB1	NEG	NEG	1
44	7	2	PT2010BSETSEPB1	POS	POS	1
45	7	3	PT2010BSETSENB1	NEG	NEG	1
46	7	4	PT2010BSETSEPB3	POS	POS	1
47	7	5	PT2010BSETSEPB2	POS	POS	1
48	7	6	PT2010BSETSENB1	NEG	NEG	1
49	7	7	PT2010BSETSENB1	NEG	NEG	1
50	8	1	PT2010BSETSENB1	NEG	NEG	1
51	8	2	PT2010BSETSEPB3	POS	POS	1
52	8	3	PT2010BSETSENB1	NEG	NEG	1
53	8	4	PT2010BSETSEPB1	POS	POS	1
54	8	5	PT2010BSETSENB1	NEG	NEG	1
55	8	6	PT2010BSETSENB1	NEG	NEG	1
56	8	7	PT2010BSETSEPB2	POS	POS	1

V. Discussion

The purpose of this proficiency test is to assess performances of participating laboratories when analyzing reference brain tissue samples of bovine origin for the detection of BSE-specific prion antigens by ELISA test.

Six participating laboratories (LAB1, LAB2, LAB4, LAB5, LAB7, and LAB8) provided responses that were in full agreement with the true status of the reference brain tissue samples.

Two participating laboratories (LAB3 and LAB6) reached 85.7% of agreement for the detection of BSE-specific prion antigens. LAB3 and LAB6 misclassified sample PT2010BSETSEPB3 which is considered as a weak positive reference brain tissue sample.

VI. Conclusions

According to the procedure currently in force, the performances of a participating laboratory is satisfactory if at least 90% of the results provided by this laboratory are in agreement with the status of the reference brain tissue samples (Section III.3.3. of this Report). Consequently, six participating laboratories achieved a satisfactory performance for the detection of BSE-specific prion antigens by ELISA test and two participating laboratories (LAB3 and LAB6) didn't achieved 90% for the detection of BSE-specific prion antigens by ELISA test.

Head CVD-ERA
Yves Van der Stede



Appendix:

Name of the participating Laboratories

Chemiphar
CODA-CERVA
DGZ (Drongen)
Ecca
Eurofins
LLuCS (Laboratoire Luxembourgeois de Contrôle Sanitaire)
LMVE (Laboratoire de Médecine Vétérinaire de l'État)
Quality Partner