



TSE EURL  
Istituto Zooprofilattico Sperimentale del  
Piemonte, Liguria e Valle d'Aosta – Torino  
  
Istituto Superiore di Sanità – Roma

PROFICIENCY TESTING FOR VETERINARY LABORATORIES

Results Tabulation for BSE Confirmatory Immunoblot - Scheme: WB19 Distribution date: 08-09-15 October 2019

| BLOT             | Test Method used                                                        | Kit Batch Number                  | Expiry Date    | Gel Type                                                        | Batch    | Expiry date     | Positive Control result         | NegativeCon<br>trol result      | Positive Cut<br>Off value | Method details                                          | Sample No. WB1901 |                  |                 | Sample No. WB1902 |                  |                | Sample No. WB1903 |                  |                 | Sample No. WB1904 |                  |                 | Sample No. WB1905 |                  |                |
|------------------|-------------------------------------------------------------------------|-----------------------------------|----------------|-----------------------------------------------------------------|----------|-----------------|---------------------------------|---------------------------------|---------------------------|---------------------------------------------------------|-------------------|------------------|-----------------|-------------------|------------------|----------------|-------------------|------------------|-----------------|-------------------|------------------|-----------------|-------------------|------------------|----------------|
|                  |                                                                         |                                   |                |                                                                 |          |                 |                                 |                                 |                           |                                                         | Result            | Characterisation | Interpretation  | Result            | Characterisation | Interpretation | Result            | Characterisation | Interpretation  | Result            | Characterisation | Interpretation  | Result            | Characterisation | Interpretation |
| Intended ID Lab. |                                                                         |                                   |                |                                                                 |          |                 |                                 |                                 |                           |                                                         | positive          | ////             | strong positive | negative          | ////             | negative       | positive          | ////             | medium positive | positive          | ////             | medium positive | negative          | ////             | negative       |
| 378              | PrioWESTERN BSE kit (Prionics Check Western)                            | W190101G                          | 13/05/2020     | NuPage, Invitrogen                                              | 18090571 | 04/01/2020      | 0                               | 0                               | 0                         | 0                                                       | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 157              | PrioWESTERN BSE KIT, Applied Biosystems by Thermo Fisher Scientific     | W180301G                          | 29.10.2019     | NuPAGE 12% Bis-Tris Gel, Invitrogen by Thermo Fisher Scientific | 18112870 | 28.03.2020      | positive                        | negative                        | -                         | 0                                                       | positive          | #RIF1            | strong positive | negative          | #RIF1            | negative       | positive          | #RIF1            | strong positive | positive          | #RIF1            | strong positive | negative          | #RIF1            | negative       |
| 092              | ThermoFisher PrioWestern                                                | W190101G                          | 13-May-2020    | 12% Bis-Tris                                                    | 19012371 | 23-May-2020     | Positive                        | negative                        | N.A                       | 00-14-0308                                              | positive          |                  |                 | negative          |                  |                | positive          |                  |                 | positive          |                  |                 | negative          |                  |                |
| 221              | Immunoblotting developed in house                                       | 0                                 | 0              | Pre-cast gel Invitrogen                                         | 19070370 | 31/10/2020      | medium positive                 | negative                        | 0                         | SOP 100G019 (6/2)                                       | positive          | #RIF1            | strong positive | negative          | #RIF1            | negative       | positive          | #RIF1            | strong positive | positive          | #RIF1            | strong positive | negative          | #RIF1            | negative       |
| 717              | modified WB                                                             | W190101G                          | 13/05/2020     | NUPAGE 12% Bis-Tris                                             | 19041771 | 01/02/2020      | positive                        | negative                        | N.A.                      | modified WB based on Prionics with 9A2 instead of 6H4   | positive          | 0                | strong positive | negative          | 0                | negative       | positive          | 0                | medium positive | positive          | 0                | medium positive | negative          | 0                | negative       |
| 932              | Bio-Rad TeSeE Western blot kit                                          | 8M0043                            |                | Criterion XT 12010 Bis-Tris Gel                                 |          |                 | positive                        | negative                        |                           | western blot                                            | 0                 | 3 bands          | BSE             | negative          | negative         | negative       | positive          | 3 bands          | BSE             | positive          | 3 bands          | BSE             | negative          | negative         | negative       |
| 991              | TeSeE Western Blot                                                      | 8M0043                            | 27.04.2020     | BioRad-Criterion XT                                             | 64301361 | 10.09.2020      | 0                               | 0                               | 0                         | kit for confirmation of suspected TSE positive samples  | positive          |                  | medium positive | negative          |                  | negative       | positive          |                  | medium positive | positive          |                  | medium positive | negative          |                  | negative       |
| 642              | APHA Biorad Hybrid Western Blot                                         | BioRad TeSeE WB kit 8M0043        | 27/04/2020     | 12% Criterion                                                   | 64276416 | 12/03/2020      | Positive                        | NA                              | NA                        | SOP SE198 Ed 7.                                         | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | medium positive | positive          |                  | medium positive | negative          |                  | negative       |
| 117              | BIORAD WESTERN BLOT                                                     | 8M0043                            | 27/04/2020     | CRITERION XT PRECAST GEL                                        | 64255539 | 05/02/2020      | 0                               | 0                               | 0                         | 0                                                       | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 342              | Confirmatory Immunoblot                                                 | W190101G (Prionics Check Western) | 13 May 2020    | NuPAGE invitrogen                                               | 18100371 | 1 February 2020 | positive                        | negative                        | 0                         | 0                                                       | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 55               | TeSeE WESTERN BLOT BIO-RAD                                              | 8M0043                            | 27/04/2020     | 0                                                               | 0        | 0               | Positive                        | Negative                        | 0                         | 0                                                       | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 322              | TeSeE Western Blot BioRad                                               | 8M0043                            | 27/04/2020     | 0                                                               | 0        | 0               | Positive                        | Negative                        | 0.219                     | 0                                                       | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 224              | In house Sha31 Immunoblot                                               | 43466                             | 31/12/2019     | Bio-Rad TGX Gels                                                | 64267210 | 25/03/2025      | positive                        | 0                               | negative                  | 0                                                       | positive          |                  | 0               | negative          |                  | 0              | positive          |                  | 0               | positive          |                  | 0               | negative          |                  | 0              |
| 564              | TeSeE Western Blot kit (BioRad)                                         | 9F0044                            | 20/11/2020     | XT Precast Criterion 12% Bis-Tris 18W gels                      | 64281983 | 04/06/2020      | Positive, internal control BP32 | Negative, internal control BN29 | 0                         | LCY SOP: PESIG/EET-3D Western Blot Confirmación TeSeE   | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 561              | SAF western blot                                                        | Prionics W190101G                 | 13/05/2020     | NuPage                                                          | 18090571 | 04/01/2020      | positive                        | negative                        | 0                         | SAF western blot                                        | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 860              | BIO-RAD TeSeE-based Hybrid WB BIO-RAD ref: 3551169, R-Biopharm AG R8008 | BIO-RAD 8M0043                    | 27-04-2020     | NuPage 12% BT                                                   | 19070370 | 31-10-2020      | 3 bands                         | no signal                       | 0                         | Confirmatory test based on the BIO-RAD kit              | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 909              | Western blot-Bio Rad                                                    | 8M0043                            | 27/04/2020     | Criterion TM XT Precast Gel                                     | 64222538 | 10/09/2019      | strong positiv                  | negative                        | 1700                      | Western blot                                            | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | medium positive | positive          |                  | strong positive | negative          |                  | negative       |
| 648              | OIE SAF Immunoblot                                                      | Not applicable                    | Not applicable | Self Cast Gel                                                   | 0        | Not applicable  | Positive                        | Negative                        | Not applicable            | OIE SAF Immunoblot (in house)                           | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 495              | BioRad TeSeE Western Blot                                               | 8M0043                            | 27/04/2020     | NuPage 12% BisTris                                              | 19041771 | 15/08/2020      | positive                        | negative                        | 0                         | 0                                                       | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 605              | Bio-Rad TeSeE Western Blot                                              | 8M0043                            | 27/04/2020     | Criterion XT                                                    | 64273802 | 23/04/2020      | POS+++ (1:10)                   | NEG-                            | N/A                       | SOP BSE_01                                              | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | medium positive | positive          |                  | medium positive | negative          |                  | negative       |
| 899              | Biorad TeSeE western blot                                               | 9FD44                             | 20/11/2020     | Criterion XT precast gel 12% Bis-Tris                           | 64296813 | 20/08/2020      | COI valid                       | no control                      | 0                         | Protocol corresponding to the recommendation of the kit | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | strong positive | negative          |                  | negative       |
| 704              | Biorad TeSeE Western Blot kit                                           | 8M0043                            | 27/04/2020     | Biorad Criterion XT 12% Bis-Tris                                | 64261048 | 27/02/2020      |                                 |                                 |                           | 0                                                       | positive          |                  | medium positive | negative          |                  | negative       | positive          |                  | strong positive | positive          |                  | medium positive | negative          |                  | negative       |
| 615              | BioRad TeSeE Western Blot                                               | 8M0043                            | 24/04/2020     | In-house made                                                   | 0        | 0               | Positive                        | Negative                        | 0                         | 0                                                       | positive          |                  | strong positive | negative          |                  | negative       | positive          |                  | weak positive   | positive          |                  | medium positive | negative          |                  | negative       |

| 1st Alternative Test |                                                                   |                  |             |                              |          |             |                                 |                                 |                        |                                                                | Sample No. WB1901 |                  |                 | Sample No. WB1902 |                  |                | Sample No. WB1903 |                  |                 | Sample No. WB1904 |                  |                 | Sample No. WB1905 |                  |                |
|----------------------|-------------------------------------------------------------------|------------------|-------------|------------------------------|----------|-------------|---------------------------------|---------------------------------|------------------------|----------------------------------------------------------------|-------------------|------------------|-----------------|-------------------|------------------|----------------|-------------------|------------------|-----------------|-------------------|------------------|-----------------|-------------------|------------------|----------------|
|                      | Test Method used                                                  | Kit Batch Number | Expiry Date | Gel Type                     | Batch    | Expiry date | Positive Control result         | Negative Control result         | Positive Cut Off value | Method details                                                 | Result            | Characterisation | Interpretation  | Result            | Characterisation | Interpretation | Result            | Characterisation | Interpretation  | Result            | Characterisation | Interpretation  | Result            | Characterisation | Interpretation |
| Intended             |                                                                   |                  |             |                              |          |             |                                 |                                 |                        |                                                                | positive          | ////             | strong positive | negative          | ////             | negative       | positive          | ////             | medium positive | positive          | ////             | medium positive | negative          | ////             | negative       |
| ID Lab.              |                                                                   |                  |             |                              |          |             |                                 |                                 |                        |                                                                |                   |                  |                 |                   |                  |                |                   |                  |                 |                   |                  |                 |                   |                  |                |
| 378                  | HerdChek BSE Scrapie Antigen kit (IDEXX)                          | CR046            | 04/03/2020  | 0                            | 0        | 0           | 3.723/3.715                     | 0.017/0.017                     | 0.137                  | 0                                                              | positive          | 3,655            | strong positive | negative          | 0,007            | negative       | positive          | 3,652            | strong positive | positive          | 3,895            | strong positive | negative          | 0,008            | negative       |
|                      | PrioSTRIP BSE KIT, Applied Biosystems by Thermo Fisher Scientific | S180101G         | 25.04.2020  | 0                            | 0        | 0           | 6279                            | 0                               | 96                     | 0                                                              | positive          | 6514             | strong positive | negative          | 0                | negative       | positive          | 3841             | medium positive | positive          | 4198             | medium positive | negative          | 0                | negative       |
| 157                  | HerdChek iDEXX                                                    | CR046            | 04/03/2020  | 0                            | 0        | 0           | >3.5; 3.472                     | 0.011; 0.014                    | 0.133                  | 0                                                              | positive          | over 3.5         | strong positive | negative          | 0.022            | negative       | positive          | over 3.5         | strong positive | positive          | 3.398            | strong positive | negative          | 0.04             | negative       |
| 55                   |                                                                   |                  |             |                              |          |             |                                 |                                 |                        |                                                                |                   |                  |                 |                   |                  |                |                   |                  |                 |                   |                  |                 |                   |                  |                |
| 564                  | Prionics Check Western Blot                                       | W190101G         | 13/05/2020  | NuPAGE 12% Bis-Tris 17w gels | 18100371 | 01/02/2020  | Positive, internal control BP92 | Negative, internal control BN29 | 0                      | LCV SOP: PESIG/EET-01 Western Blot Prionics                    | positive          | 0                | strong positive | negative          | 0                | negative       | positive          | 0                | medium positive | positive          | 0                | medium positive | negative          | 0                | negative       |
|                      |                                                                   |                  |             |                              |          |             |                                 |                                 |                        |                                                                |                   |                  |                 |                   |                  |                |                   |                  |                 |                   |                  |                 |                   |                  |                |
| 860                  | BIO-RAD TeSeE SAP Combi test 3551192                              | 9C0073           | 15-01-2020  | 0                            | 0        | 0           | 3.104                           | 0.025                           | 0.235                  | Purification NSP robot; Detection: Evolis 5C Microplate System | positive          | 3.311            | strong positive | negative          | 0.028            | negative       | positive          | 3.46             | strong positive | positive          | 3.409            | strong positive | negative          | 0.034            | negative       |
| 704                  | Combi kit                                                         | 9F0074           | 10/04/2020  | 0                            | 0        | 0           | 0                               | 0                               | 0                      | 0                                                              | positive          | 3.309            | medium positive | negative          | 0.02             | negative       | positive          | 3.786            | strong positive | positive          | 3.332            | medium positive | negative          | 0.017            | negative       |

| 2nd Alternative Test |                                                     |                  |             |          |       |             |                         |                         |                        |                               | Sample No. WB1901 |                  |                 | Sample No. WB1902 |                  |                | Sample No. WB1903 |                  |                 | Sample No. WB1904 |                  |                 | Sample No. WB1905 |                  |                |
|----------------------|-----------------------------------------------------|------------------|-------------|----------|-------|-------------|-------------------------|-------------------------|------------------------|-------------------------------|-------------------|------------------|-----------------|-------------------|------------------|----------------|-------------------|------------------|-----------------|-------------------|------------------|-----------------|-------------------|------------------|----------------|
|                      | Test Method used                                    | Kit Batch Number | Expiry Date | Gel Type | Batch | Expiry date | Positive Control result | NegativeCon trol result | Positive Cut Off value | Method details                | Result            | Characterisation | Interpretation  | Result            | Characterisation | Interpretation | Result            | Characterisation | Interpretation  | Result            | Characterisation | Interpretation  | Result            | Characterisation | Interpretation |
| Intended             |                                                     |                  |             |          |       |             |                         |                         |                        |                               | positive          | ////             | strong positive | negative          | ////             | negative       | positive          | ////             | medium positive | positive          | ////             | medium positive | negative          | ////             | negative       |
| ID Lab.              |                                                     |                  |             |          |       |             |                         |                         |                        |                               |                   |                  |                 |                   |                  |                |                   |                  |                 |                   |                  |                 |                   |                  |                |
| 157                  | BSE Scrapie Antigen Test Kit, IDA, IDEXX Herd Check | A6368            | 26.12.2019  | 0        | 0     | 0           | 3.999; 3.999            | 0.020; 0.018            | 0.139                  | Ultra short protocol was used | positive          | 3.999            | strong positive | negative          | 0.022            | negative       | positive          | 3.999            | strong positive | positive          | 3.999            | strong positive | negative          | 0.025            | negative       |

Comments provided by Pier Luigi Acutis, IZSPLVA - Turin (pierluigi.acutis@izsto.it)

Sample WB1903 = WB1904; Sample WB1902=WB1905.

WB1901 - BSE positive tissue homogenate - strong positive  
All Labs reported the correct result.

WB1902 - BSE negative tissue homogenate.  
All Labs reported the correct result.

WB1903 - BSE positive tissue homogenate - medium positive  
All Labs reported the correct result.

WB1904 - BSE positive tissue homogenate - medium positive  
All Labs reported the correct result.

WB1905 - BSE negative tissue homogenate  
All Labs reported the correct result.

In summary all laboratories have passed this PT round. Well done.

Date: 10/02/2020  
Giuseppe Ru, Director of TSE EURL