



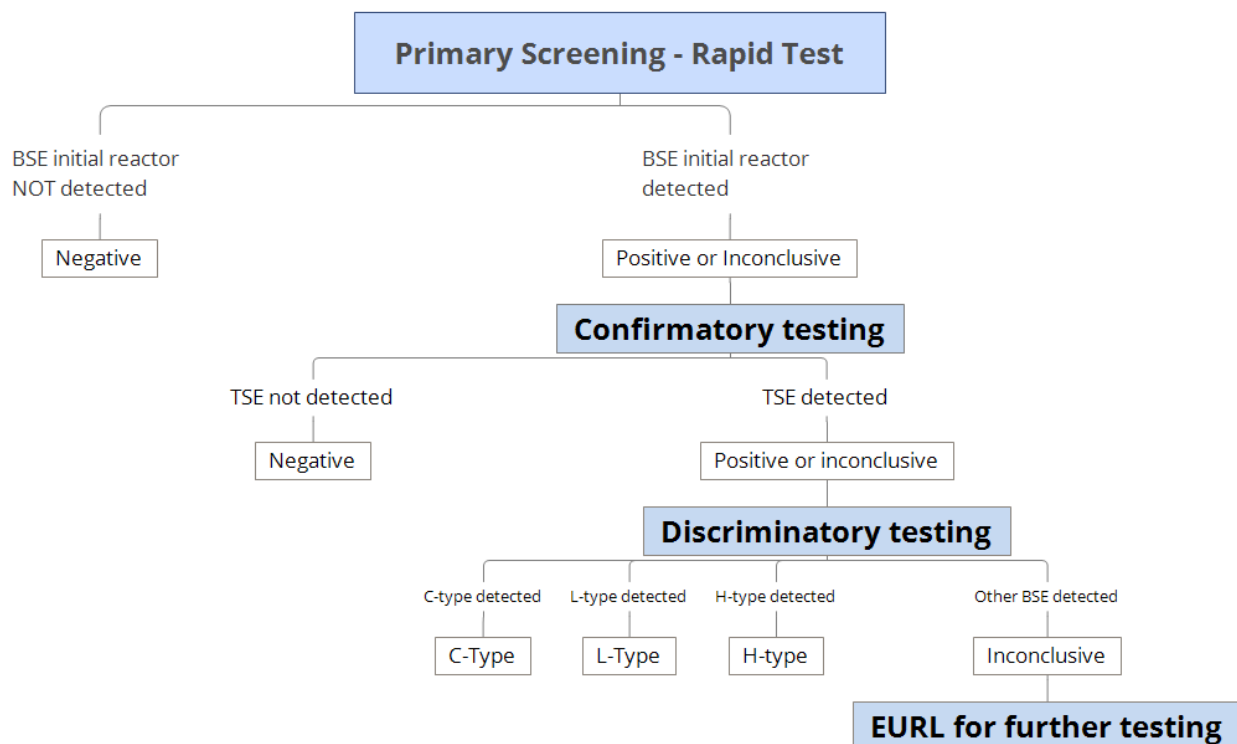
# GUIDELINES FOR THE SUBMISSION OF SAMPLES FOR TSE CONFIRMATORY TESTING

Version 1.0 – February 2019

## 1. INTRODUCTION

The European Union Reference Laboratory (EURL) for Transmissible Spongiform Encephalopathies (TSEs) will be able to confirm suspected TSE cases identified in the Member States (MS) through the active and passive surveillance systems.

The testing protocol for bovine, small ruminants and CWD are reported in Figures 1 -3



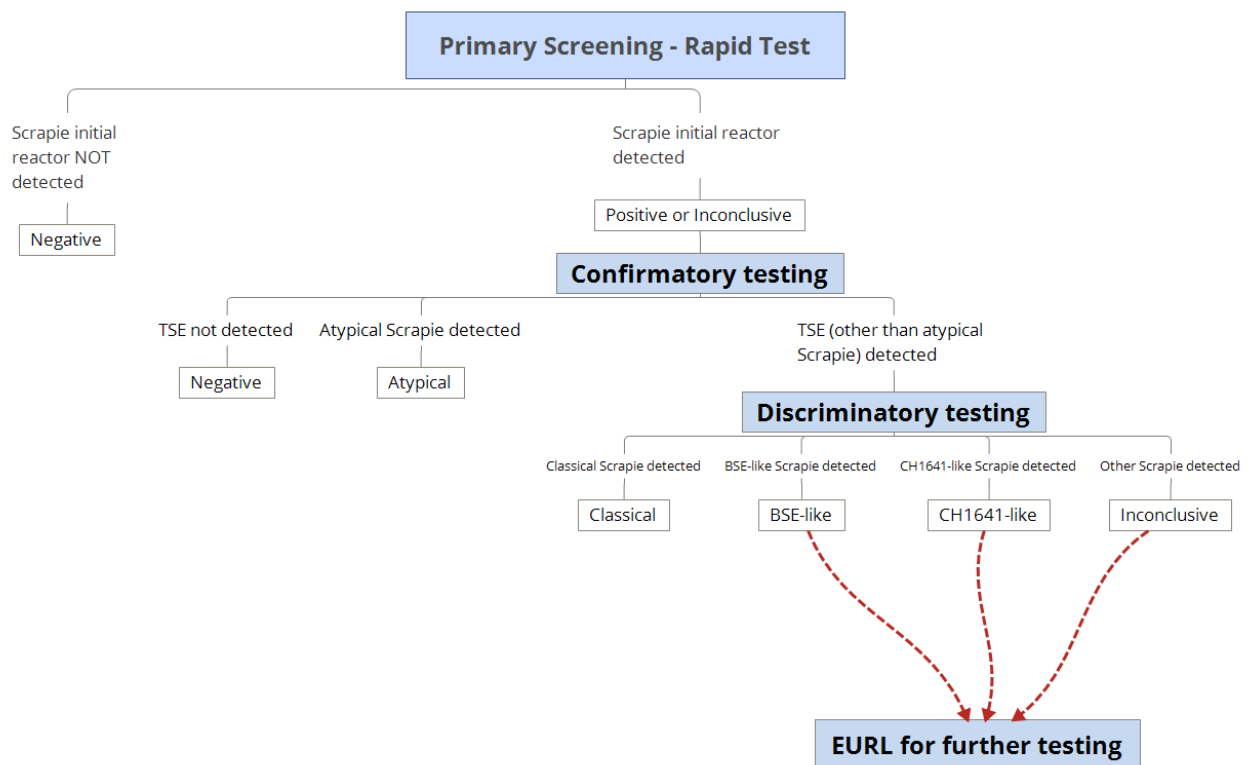
**Figure 1:** Testing protocol for bovine animals. Modified from EFSA (European Food Safety Authority), Monguidi M and Stoicescu A-V, 2018. Guidelines for reporting surveillance data on Transmissible Spongiform Encephalopathies (TSE) in the EU within the framework of Regulation



**TSE EURL**

Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta – Turin  
Istituto Superiore di Sanità - Rome

(EC) No 999/2001. EFSA supporting publication 2018:EN-1380. 48 pp.  
doi:10.2903/sp.efsa.2018.EN-1380

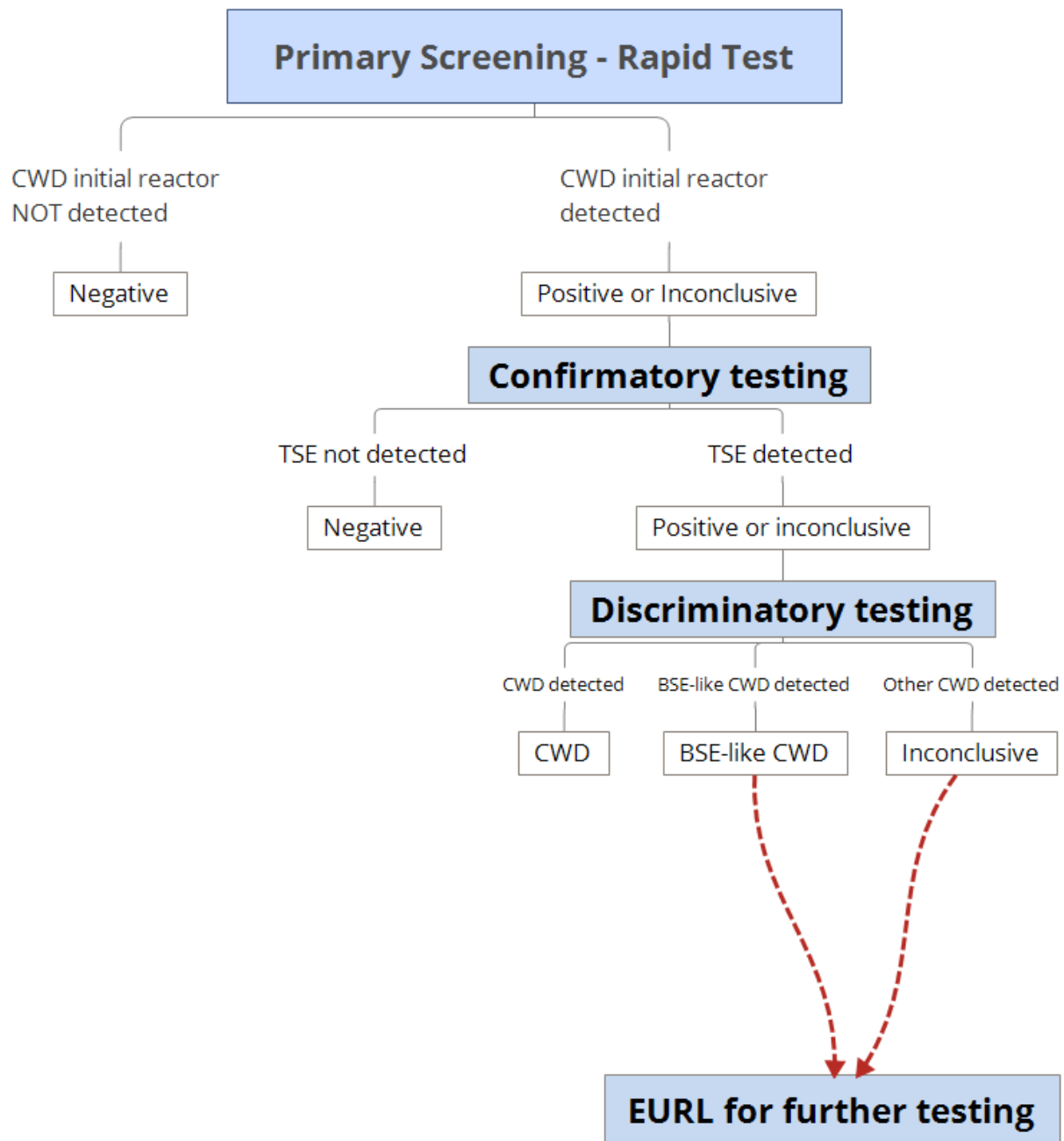


**Figure 2:** Testing protocol for small ruminants. Modified from EFSA (European Food Safety Authority), Monguidi M and Stoicescu A-V, 2018. Guidelines for reporting surveillance data on Transmissible Spongiform Encephalopathies (TSE) in the EU within the framework of Regulation (EC) No 999/2001. EFSA supporting publication 2018:EN-1380. 48 pp. doi:10.2903/sp.efsa.2018.EN-1380



**TSE EURL**

Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta – Turin  
Istituto Superiore di Sanità - Rome



**Figure 3:** Testing protocol for CWD. Modified from EFSA (European Food Safety Authority), Monguidi M and Stoicescu A-V, 2018. Guidelines for reporting surveillance data on Transmissible Guidelines submission Rapid Tests v1 February 2019



## TSE EURL

Istituto Zooprofilattico Sperimentale del  
Piemonte, Liguria e Valle d'Aosta – Turin  
Istituto Superiore di Sanità - Rome

Spongiform Encephalopathies (TSE) in the EU within the framework of Regulation (EC) No 999/2001. EFSA supporting publication 2018:EN-1380. 48 pp. doi:10.2903/sp.efsa.2018.EN-1380

Please follow the submission instructions below to submit the samples at the EURL for confirmatory and discriminatory testing.

## 2. SAMPLING

It is frequently possible to confirm a positive case of TSE using sub-optimal tissue. However, to be able to state conclusively that a case is TSE negative requires more stringent tissue collection and handling. See the 'Sample requirements for TSE testing and confirmation – EURL guidance' document at <ftp://ftp.izsto.it/EURL%20TSE/RAPID%20TESTS/Test%20protocols/>

- **Fresh material for confirmatory Western Blot (WB)**

Fresh, frozen caudal medulla is the optimal tissue requirement for WB confirmatory analysis. The sample should ideally be a **minimum** of 1-2 g. However, a basic diagnostic WB can be performed on as little as 0.5 g of tissue.

The material should be placed in sealed, clearly labelled containers. The containers should then be packaged with sufficient dry ice to remain frozen for the duration of the transit time, and **in accordance with the IATA instructions** (as below).

- **Fixed or paraffin-embedded material for Histopathology (HP) and Immunohistochemistry (IHC) analyses**

For HP and/or IHC there must be good representation and preservation of the appropriate target areas. **If sub-optimal tissue is submitted, only limited diagnosis may be possible.**

The preferred sampling site for testing is the brainstem at the level of the obex, and cerebellum when available. Samples should be submitted, either as formalin fixed tissue or as paraffin-embedded block(s). Detail should be given of the fixative used and any post-fixation treatment of the tissue.



## **TSE EURL**

Istituto Zooprofilattico Sperimentale del  
Piemonte, Liguria e Valle d'Aosta – Turin  
Istituto Superiore di Sanità - Rome

- **Unstained sections**

These can be sent if it is not possible to submit fixed or embedded material.

However, we could encounter difficulties with this type of submission if the bonding agent on the slides is not compatible with our staining protocols, and the likelihood of wash-offs is greatly increased.

### **3. PACKAGING AND LABELLING OF PARCELS**

All material must be packaged to IATA standards. It is recommended that you contact your nearest IATA office which will be able to give you the relevant local information with regard to pathogens, fixatives and dry ice.

The parcel should be clearly addressed to:

**TSE EURL - Istituto Zooprofilattico Sperimentale**

**del Piemonte, Liguria e Valle d'Aosta**

**Palazzina B**

**Via Bologna,148**

**10154 Torino**

**Italy**

Prior to dispatch of any samples, please send an email to [giuseppe.ru@izsto.it](mailto:giuseppe.ru@izsto.it) with a copy to [EURL.TSE@izsto.it](mailto:EURL.TSE@izsto.it) with preliminary information about the sample:

- species
- existing test results
- amount and type of tissue being dispatched
- proposed dispatch date and details



## TSE EURL

Istituto Zooprofilattico Sperimentale del  
Piemonte, Liguria e Valle d'Aosta – Turin

Istituto Superiore di Sanità - Rome

- contact name and email
- If you consider that any pathogen other than TSE might be present in the sample, please discuss this with us BEFORE sending the sample.

It is requested that packages are sent to arrive on a working day (i.e. Monday to Friday), and not at a weekend.

**Please note: All parcels should be dispatched in a way that ensures delivery to TSE EURL. If this is not done, samples will be delayed through Customs clearance, and the sender will be invoiced for the costs incurred by this, and subsequent transport of samples to TSE EURL in Turin.**

#### 4. ACCOMPANYING DOCUMENTATION

All samples must be accompanied by **copies of relevant, current Import and Export Licenses**. You will be advised of any Import documentation required by the TSE EURL following your initial email. It is your responsibility to ensure that all relevant Export documentation is in place before dispatch of any samples.

**A letter with the individual animal and sample details** and reference numbers, together with any relevant background information, should be included in the packaging. This letter should also include an indication of the test requested.

For single/small numbers of cases the EURL currently makes no charge (this service is presently covered by our role as an EU and OIE reference laboratory).

However, if larger numbers of routine confirmatory tests are required over a period of time, this would be undertaken on a contractual basis, and a charge made. Please email the reference laboratory mailbox (EURL.TSE@izsto.it) if you wish to discuss this option.

Under some circumstances transportation charges may be incurred (see above). These will be charged to the submitting laboratory.



## **TSE EURL**

Istituto Zooprofilattico Sperimentale del  
Piemonte, Liguria e Valle d'Aosta – Turin

Istituto Superiore di Sanità - Rome

## **5. QUERIES AND CONTACTS**

If you require any further clarification of these procedures and options, please contact Giuseppe Ru (giuseppe.ru@izsto.it) or the TSE reference laboratory general mailbox ([EURL.TSE@izsto.it](mailto:EURL.TSE@izsto.it))

This document is largely based on a previous one that originally was made available by APHA (UK) as EURL for TSEs. After the transition of the EURL to our consortium, in the documentation that we are making available, some minor changes were needed to update information regarding e.g. logistical aspects, sample flow, contacts and references, or changes carried out by the relevant companies in protocols and nomenclatures.