

**Approval criteria for Laboratories wishing to test BSE samples in line with the Requirements laid down in the Transmissible Spongiform Encephalopathies (England) Regulations 2008 (SI 2008 No. 1881); the Transmissible Spongiform Encephalopathies (Wales) Regulations 2008 (SI 2008 No. 3154 (W.252); or the Transmissible Spongiform Encephalopathies (Scotland) Amendment (No.2) Regulations 2008 (SSI 2008 No.417;**

Laboratory and test kit requirements

1. Any laboratory wishing to be approved must be approved to the ISO17025 accreditation standard for other tests which they are currently operating in their laboratory (demonstrated by providing the relevant certificate) and commit to adding BSE testing to their scope within 6 months of approval to undertake BSE testing. A copy of the laboratory Quality Manual must be provided to the Veterinary Laboratories Agency (VLA) for review prior to any laboratory inspection being arranged.
2. In order to ensure the independence of any laboratory wishing to be approved for BSE rapid testing of human consumption animals, no laboratory business should be owned or managed by a slaughterhouse, its suppliers or its customers. Any company bidding for work must demonstrate that they are totally independent of any slaughterhouse company or management or of its suppliers or customers.
3. Any laboratory wishing to be approved must demonstrate that bovine samples will be tested for BSE using one of the EU-approved rapid test methods (this means a test listed in Annex X of Regulation (EC) No. 999/2001, as amended. The laboratory will be expected to test successfully a panel of proficiency test samples issued by the VLA before final approval.
4. The test manufacturer's quality assurance system for the rapid test used must be approved by the Community Reference Laboratory at VLA to ensure that the test performance does not change. If there is any doubt, the CRL can be contacted direct (email address [tseeucri@vla.defra.gsi.gov.uk](mailto:tseeucri@vla.defra.gsi.gov.uk)).
5. Any laboratory wishing to be approved must have a quality system which demonstrates that systems are in place to prevent the issue of false negative, false positive, false 'no test' or false 'insufficient to test' results.
6. Any laboratory wishing to be approved must have in place a Business Continuity and Disaster Recovery Plan by carrying out a whole system laboratory hazard / risk analysis, identifying each hazard / risk and the action to be taken to mitigate each one of them.
7. Any laboratory wishing to be approved must permit the VLA to undertake:
  - 7.1. Pre-scheduled and unannounced laboratory inspections (with full access to laboratory systems, records and any other information required, including raw data and testing protocols);
  - 7.2. Confirmatory testing of rapid test samples. Any laboratory wishing to be approved must agree the necessary protocols with the VLA for

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confirmatory testing following an initial reactive BSE result from a rapid test (and for investigation of any initial reactive results which are not confirmed by the VLA);

- 7.3. Any laboratory wishing to be approved must provide a full set of current protocols associated with BSE rapid testing to the VLA. If protocols are amended this must be in discussion with the VLA.
8. Any laboratory wishing to be approved must ensure their laboratory site is in a ready state to be used for such testing in advance of arranging inspection by VLA. There will be no pre-approval visit by VLA to any site that is unequipped or where accommodation or refurbishment is incomplete.
9. Any laboratory wishing to be approved must:
  - 9.1. Test proficiency testing panels which the VLA issues and report results as indicated
  - 9.2. Accept that any recommendations from the VLA will be adopted within an agreed timescale
10. Any laboratory wishing to be approved must allow the VLA or other governmental or EU-based audit teams access to laboratory systems and records in order for them to assess effectiveness of the sample collection, laboratory sampling accuracy, testing and report service methodologies used.
11. Any laboratory wishing to be approved must provide the VLA with projected annual throughput figures. They must also demonstrate that they can test the number of samples per year that they propose to perform. This should include evidence of an achievable maximum daily throughput capability to meet abattoir requirements in the timescale required.
12. Any laboratory wishing to be approved must demonstrate that contingency testing and reporting arrangements are in place in case of laboratory testing failure, or in case an IT systems failure occurs in relation to reporting test results.
13. Any laboratory wishing to be approved must ensure that its laboratory staff are trained in identifying the appropriate target area of the obex to ensure that submitted samples are suitable for testing and to minimise the risk of a false negative. They must provide evidence of competence based training of staff in this area and demonstrate that competencies are reviewed on a regular basis. Named individuals should be identified to authorise the issue of any 'no test' or 'insufficient test' results.
14. Any laboratory wishing to be approved must provide a protocol on multiple testing of 'no-test' results to ensure that there is no need to apply the one before two after (1b2a) rule<sup>1</sup> for cattle subject to a 'no-test' result. The laboratory is also required to store such material until VLA examination is arranged, which may be up to 3 months from date of sample receipt. Further information on these requirements is available from the VLA.
15. Any laboratory wishing to be approved must ensure that all brainstem samples

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<sup>1</sup> See point 6.5 of Annex III Chapter A of Council Regulation 999/2001

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that test negatively are stored frozen for a minimum of 7 days from the date of testing.

16. Any laboratory wishing to be approved must ensure that it has adequate facilities and procedures in place to handle the storage, testing and disposal of Specified Risk Material (SRM) (in accordance with the Animal By-Products Regulations 2005 (or equivalent legislation in Scotland and Wales). They must also ensure that their laboratory staff are trained in the procedures and requirements for handling SRM. The laboratory must conform to disease security and safety guidance described in the Department of Health website on “Transmissible spongiform encephalopathy agents: safe working and the prevention of infection” part 3, which can be found at <http://www.advisorybodies.doh.gov.uk/acdp/tseguidance> with particular reference to the containment level 3 for handling of BSE.
17. Any laboratory wishing to be approved must demonstrate that results (including raw data) from rapid tests, linked to the individual samples submitted can be kept for a minimum of 7 years and be accessed by the VLA or Defra upon request.
18. Any laboratory wishing to be approved must ensure that paperwork received from abattoirs should be kept for a minimum of 7 days in the case of negatively tested samples, or for a minimum of 7 years in the case of positively tested or inconclusive samples, and electronic files are to be kept for a minimum of 7 years in either case, with written permission requested from the NRL before destruction of this electronic data. In the event of animal or sample identification issues, copies of movement cards will be sent to the VLA on demand.
19. Any laboratory wishing to be approved must demonstrate that their internal traceability systems allow the continued use of both the Manual and Electronic sample identification systems already operating in abattoirs, with a minimum of disruption to the industry. (Further details of these systems will be made available by the Food Standards Agency (FSA), upon request).
20. Any laboratory wishing to be approved must have access to an ISO17025-accredited back-up DNA results service, to reconcile the identification of a brain stem sample to the carcass or parts of the body of a tested bovine animal, upon request by the FSA or VLA. The BSE rapid testing laboratory management can make the choice of accredited DNA laboratory to be used.

### IT requirements

21. Any laboratory wishing to be approved must provide evidence of protocols, instructions or other validation and verification systems in place to ensure data quality and sample tracking.
  - Data needs to be validated on entry to the system.
  - Duplicate records must be rejected and exception procedures actioned.
22. Any laboratory wishing to be approved must have an IT system in place for the reporting of test results electronically to the VLA, the FSA, Animal Health (AH) and other Government officials as required. The system must use electronic

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transfer of data that conforms to an agreed schema or format. Results must be available to the VLA, the FSA, AH and other Government officials as required at the same time they are available to the abattoir that has submitted the samples. The system must ensure that results are withheld (and an 'outstanding' status reported) if any essential data is missing from the information submitted with the sample. Where a sample cannot be tested for any reason the system must be able to issue a 'no-test' or an 'insufficient test' result on its results system. Any change to the status of a sample tested should be limited to 'outstanding' results only.

23. Any laboratory wishing to be approved must ensure that complete data for each days' testing is sent electronically to Defra's TSE Surveillance System and the VLA at a preset time after every testing day; this must exclude incomplete records where results have not been released to the abattoir. The system must prevent records from being sent more than once. A summary of the results contained in the data file from each site must also be sent to the VLA each day.
24. Data must be held in a way such that bovine details (such as birth and movement records) related to issued results can be linked on the Cattle Tracing System (CTS) of the British Cattle Movement Service (BCMS). The eartag number (matching that on the animal passport) should be scanned by preference and must be included.
25. A control system must be in place to ensure that the status of 'outstanding' results will only be changed once missing or unclear information has been obtained/clarified, and the results not reported until this data is complete. Any changes made must be auditable.
26. Any laboratory wishing to be approved must have reporting formats and coding systems - compatible with existing VLA & FSA formats and systems. (More information of existing formats and systems is available on request).
27. Any laboratory wishing to be approved must nominate at least one named individual and one named deputy to act as IT liaison with VLA, the FSA and abattoirs for purposes of data validation, error correction, hardware or software issues and data transfer issues.
28. To become approved to slaughter Over Forty Eight Months (OFEM) cattle, abattoirs must run two days worth of official trials backed up by as many dummy runs as they feel is necessary. The IT system put in place by any laboratory seeking approval must ensure that data relating to these trials or dummy samples are not included in the files transferred to Defra's TSE Surveillance System.
29. The results of testing proficiency test samples from the VLA must not be included in the files transferred to Defra's TSE Surveillance System.

### Service requirements

30. Test results must be made available to abattoirs either electronically (through a web based or an e-mail reporting system) or by fax for those plants which do

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not have IT access.

31. Daily reports to the abattoir will need to show at a minimum: a breakdown of all samples tested the previous night; provide details of kill number, kill date, report date, sampling category, barcode number, eartag number and (where available) date of birth. It must highlight any positive, 'no test', 'insufficient test' and 'outstanding' results at the top of the report to ensure the necessary enforcement action by the FSA and AH.
32. Any laboratory wishing to be approved must demonstrate that it is able to provide to an abattoir, by e-mail or by fax, a digital photograph of any sample for which it has issued a 'no test' or 'insufficient test' result because of the poor quality of the sample. The image must also include a description of why such a result has been issued.
33. Any laboratory wishing to be approved must provide the FSA with an Excel spreadsheet of monthly results broken down by testing code within 5 calendar days of the following month.
34. A suitably staffed telephone helpline should be available to abattoirs, the FSA, AH, VLA and Defra to answer queries on results and outstanding results.
35. Abattoirs must only be able to access their own results; the VLA, the FSA, AH and other Government officials as required must be able to access all results.
36. Any laboratory wishing to be approved must ensure that any packaging they supply to abattoirs complies with UN packaging standards (see Chapter 4.1 of ADR 2005 which can be found at :- [http://www.unece.org/trans/danger/publi/adr/adr2005/English/Part4\\_ch4-1.pdf](http://www.unece.org/trans/danger/publi/adr/adr2005/English/Part4_ch4-1.pdf)) and HSE guidance.
  - 36.1. Please note that the testing laboratory may not handle samples that have not been packaged to the required standard. In such a situation a 'no-test' result will be issued and the 'one before, two after' rule will have to be applied. The laboratory must require and ensure that abattoirs submit samples in pots, sealed within tamper-evident serially numbered bags for the collection of samples, supplied by the laboratory where they decide to provide such consumables. Laboratories must inspect all incoming bags against reported bag number, and all samples for evidence of tampering with the tamper-evident bag. Laboratories must immediately notify any evidence of tampering to the FSA.
  - 36.2. Where such consumables are not supplied by the approved laboratory, samples should not be accepted unless the abattoir concerned has used tamper-evident serially numbered bags provided by another consumable supplier.
37. Any laboratory wishing to be approved must demonstrate that they have facilities available to receive, record and refrigerate any samples received outside of opening hours.
38. Any laboratory wishing to be approved must provide a 'dummy results' service, upon request, for abattoirs seeking approval from the FSA to process OFEM

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cattle for human consumption. This service must include a written summary of sample condition and sample packaging issues to the abattoir and the FSA. Dummy data must not enter the “live” results reporting system.

39. Any laboratory wishing to be approved must have systems in place to ensure that any evidence of consistently poor sample taking, packaging or use of inappropriate sample consumables by an abattoir, is notified as soon as possible to FSA and Defra. The laboratory must immediately report to FSA, copied to Defra, any anomaly in sample receipt, such as two brainstems in a pot, an empty pot, an unlabelled pot, a pot with two labels, or missing or unusual sample documentation
40. There should be clear management accountability on the part of the laboratory such that responsibility for the testing services covered falls to named individuals who are available to respond to any service delivery queries on a daily basis. If more than one company or organisation is to form a consortium to deliver the services required, it must be demonstrated that there is the same management accountability as would be expected from a single management structure.
41. The VLA<sup>2</sup> may refuse, amend, suspend or revoke any approval relating to a testing laboratory if there is:
  - a failure of the proficiency testing;
  - an unsatisfactory outcome from a laboratory visit;
  - a major non-compliance with the requirements of ISO 17025 or with any of the criteria set out above; or,
  - a consequential change is required to the approval as a result of any change to statutory legislation.
42. Once approved, a laboratory must notify the VLA of any proposed material change to any procedures, testing, IT, equipment, buildings, management or other factor affecting any of the above criteria, before that approved laboratory makes such changes. VLA reserve the right to suspend or revoke approval if this is not done, or if such a change has a detrimental effect on the performance of that laboratory. The VLA may require additional QA or inspection activities following such changes, to confirm approval before testing can continue.

VLA reserves the right to issue improvement notices where necessary, which must be complied with within the time specified. All documentation provided by a laboratory and correspondence connected with TSE rapid testing laboratory approval will be treated as “Commercial In Confidence”.

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<sup>2</sup> Operating on behalf of the Secretary of State for England, Scottish or Welsh Ministers