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|  **Application for Authorisation for the Exceptional Private Use of Non-validated Tests for TB in Cattle Herds in Wales** |

**Introduction**

1. This document sets out the terms and conditions that must be in place to enable the Welsh Ministers to authorise the exceptional private use of non-validated tests for TB in a cattle herd affected by a TB breakdown.

2. To have a good understanding of the performance of a new diagnostic technique, it must be validated to the standards required by the World Organisation for Animal Health (OIE)[[1]](#footnote-1), even if the test is not actually listed by the OIE. Where novel tests are under development, this level of evaluation will not yet have been undertaken.

3. The Welsh Government may authorise the private use of a non-validated test(s) in exceptional circumstances as a supplementary approach to managing problem TB breakdowns, subject to the following terms and conditions.

4. Prior to any use of a non-validated test, the keeper and their private veterinary surgeon must complete this application and sign the appropriate declarations which will confirm that they have read, understood and agreed the conditions applicable to the declaration before forwarding the application to the Welsh Government.

5. The completed application will be considered by the Welsh Government TB Team and the keeper and their private veterinary surgeon will be informed of the decision. At least ten working days must be allowed for this decision.

[Nb - The Enferplex (Bovine Serum) Test is an OIE validated test. It is a test not currently approved by the Welsh Government as a “relevant test” in Wales under the Tuberculosis (Wales) Order 2010 (as amended) and is currently the subject of a separate short-term pilot for private use with its own authorisation document. For further details contact BovineTB@gov.wales.]

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| **Details of holding on which non-validated** **test(s) is/are to be performed** |
| Holding Number |       |
| Name of Farm Business/Keeper |       |
| Address of holding |       |
| Name of Private Veterinary Surgeon  |       |
| Address of Veterinary Practice |       |

**Conditions relevant to the Private Veterinary Surgeon:**

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| **Details of non-validated test(s) to be used:** |
| Name of non-validated test (s) to be used: |       |
| Type of samples to be collected: |       |
| Name and address of test manufacturer: |       |
| Published articles/ proof of concept, date of publication, location of publication and author(s): |       |
| Is the test being used in collaboration with the test manufacturer? | Yes:       No:       |
| **Home Office Licence** - Sampling cattle for a non-validated test(s) may be considered a regulated procedure under the Animals Scientific Procedures Act 1986 unless it has been agreed with the Royal College of Veterinary Surgeons (RCVS) that it forms a legitimate part of a disease control intervention that is covered by the Veterinary Surgeons Act.Home Office Licence has been obtained:       A Home Office Licence is not necessary:       [NB- Evidence that a Home Office Licence has been obtained, or that one is not necessary must be provided.] |

1. I have specified above the test(s) to be used, including details of the current known performance of the test given (such as published articles and/or access to proof-of-concept data).

 2. I understand the use of the test(s) proposed ideally should be part of development work in collaboration with the test manufacturer, so that the data generated can contribute to the evidence needed for the candidate test(s) to be validated.

3. As required under Article 15 (3) of The Tuberculosis (Wales) Order 2010 (as amended), I seek prior permission to use the non-validated test(s) listed. I have provided the Welsh Government with a clear plan setting out:

* what animals will be tested
* what type of samples will be taken (e.g. blood, milk, faeces, bulk milk)
* what test(s) will be used, and when
* what will be done with the results, and
* how the Welsh Government and APHA will be kept informed as required
* additional diseases in the herd e.g. Johnes/BVD, which may be affecting the TB status of cattle in the herd, and a plan detailing how these diseases are being, or will be controlled.

4. I understand that:

* The Welsh Government approves the use of the Interferon-gamma test and the IDEXX ELISA antibody test by APHA only, at the Welsh Government’s expense.
* Animals that are reactors or inconclusive reactors to the TB skin test or direct contacts (DCs) awaiting slaughter and those with a positive result to the Interferon-gamma test, the IDEXX ELISA antibody test and/or Enferplex (bovine serum) test (if carried out by APHA)  must not be re-tested with a non-validated test, except where this takes place at the point of slaughter to obtain suitable samples for validation purposes.
* If required by APHA, the Interferon-gamma test and (if appropriate) the IDEXX ELISA test, or the Enferplex (bovine serum) test (if carried out by APHA), must be performed first and any animals which are positive to those tests will be removed before a non-validated test is applied.

4. I will keep APHA informed in a regular and timely manner of all the results received from the use of non-validated tests, within 24 hours if there are any positive results and within 5 days if they are clear. The date of sampling and the positive and negative results will be listed.

**Please sign the declaration near the end of this application**

**Conditions relevant to the keeper:**

1. I understand that:

* the test in question is not validated and has not officially been approved for use by the Welsh Government;
* the test results may be unreliable and difficult to interpret, meaning the test may not offer any certainty about the true infection status of the animal(s);
* APHA is under no obligation to remove the animal(s) nor is the Welsh Government liable to pay compensation for any test-positive animals and, therefore, the removal and slaughter costs will be the responsibility of the farm business;
* any animal that gives a positive result to a non-validated test will be restricted to the premises either until all movement restrictions are lifted or it can be moved under licence direct to slaughter, to an Approved Slaughter Gathering, to a TB Dedicated Sale, or to an Approved Finishing Unit (AFU);
* any animal that gives a positive result to a non-validated test should be kept, where possible, isolated from other animals which have not tested positive to the non-validated test and must be kept isolated from reactors or inconclusive reactors detected during official Welsh Government tests.

2. I am aware that, in a breakdown when an Individual Herd Action Plan is in place, APHA will continue to use severe interpretation and remove all standard inconclusive reactors as Direct Contacts, with compensation, up to the point where the exit strategy applies.

3. I am aware that APHA will continue to use additional testing for TB control purposes, including the Interferon-gamma test (flexible-extended and parallel), the IDEXX ELISA antibody test and the Enferplex (bovine serum) test (if carried out by APHA) and will remove animals reacting positively to tests instructed by APHA.

4. APHA will monitor the results from the use of a non-validated test(s) in this herd and decide whether it is necessary to remove any additional animals as Direct Contacts under the Tuberculosis (Wales) Order 2010 (as amended), with compensation.

5. Where the existing approved tests are required for use by APHA and are applied in accordance with Welsh Government policy, compensation will be payable for the removal of any positive testing (reactor) animals as normal.

6. No compensation will be paid by the Welsh Government for any animal voluntarily killed by the keeper following a positive result to a non-validated test. If APHA decides to remove the animal compulsorily as a Direct Contact, then compensation will be paid.

7. When the herd has satisfied the APHA testing requirements to achieve Officially TB Free (OTF) status and would normally have a TB10 (Withdrawal of Notice Prohibiting Movement of Animals) there are two options for the keeper.

**Either Option 1:**

1. The herd movement restrictions will be maintained while animals positive to the non-validated test(s) remain on the holding until the outcome of the six month post-breakdown test (6M) procedure detailed below is completed.
2. Movement of bovine animals onto the holding will be allowed with a general licence.
3. Movements of bovine animals off the holding will be allowed under licence to slaughter directly or via an approved slaughter gathering, to an Approved Finishing Unit (AFU) directly or via a TB Dedicated Sale (‘orange market’).
4. The use of the non-validated test(s) approved here can continue during this period and up to the 6M test. All test results must continue to be notified to APHA.
5. At the 6M test, all non-validated test positive animals remaining in the herd must be clear (or have negative test results) to all of the following:

* the Single Intradermal Comparative Cervical Test (the skin test) interpreted as a Single Intradermal Test. Any animal with a positive reaction to bovine tuberculin, irrespective of the avian reaction, will be removed by APHA with compensation
* a flexible extended Interferon-gamma test
* an IDEXX ELISA antibody test.

If the animal fails any of these tests it is removed with full compensation.

1. Normal TB breakdown procedures will apply if a non-validated test positive animal fails the skin test, or reacts positively to a flexible-extended Interferon-gamma test, or an IDEXX ELISA antibody test, or if another animal in the herd fails the skin test. The general licence to move cattle on will be revoked.
2. All restrictions on movement off are totally removed, and the approval to carry out non-validated testing is withdrawn, if all non-validated test positive animals and the other eligible cattle in the herd pass the approved testing regime.

**Or Option 2:**

1. At any time after the herd has satisfied the normal requirements to achieve OTF status and before the 6M test, the keeper can arrange for the movement off under licence of all non-validated test positive animals to private slaughter, or to an AFU and have the approval to carry out non-validated testing withdrawn.
2. Once all of these animals have been moved off the holding and the approval has been withdrawn, herd movement restrictions will be lifted.

**A decision as to which option you wish to pursue must be taken after the clear**

 **test which, under normal breakdown circumstances, would result in the herd achieving OTF status.**

8. Animals testing positive to a non-validated test cannot be moved off the premises other than direct to slaughter, to an Approved Slaughter Gathering, to a TB Dedicated Sale, or to an AFU, until the herd movement restrictions are finally removed, after the 6M test. Culling of non-validated test positive animals will be a voluntary decision by the owner and the costs and risks of such slaughter and removal will be borne by the owner.

9. Under the Tuberculosis (Wales) Order 2010 (as amended), where an APHA veterinarian considers any cow to be a TB suspect animal they can serve a notice to restrict the use of the cow’s milk.

10. Should any current non-validated test/s become validated the use of the test privately will be subject to approval by the Welsh Government.

11. I will notify the Welsh Government in writing if I decide no longer to use the above named non-validated test(s) on animals in my herd.

12. The Welsh Government may decide at any time to cease approval of the use of the non-validated test(s), providing reasons in writing to the keeper.

13. If any of the conditions specified in this document are breached then the Welsh Government may immediately revoke this agreement.

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| **Note: All involved in this agreement must ensure that GDPR requirements are met with regards to all information captured, stored and shared.** |

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| **Keeper declaration:** I confirm that I have read and agree the above terms and conditions for the use of a non-validated test(s) |
| Signed |       | Date:       |
| Name in capitals |       |
| Partner or business owner |       |
| Address of business |       |
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| **Private Veterinary Surgeon declaration:**  I confirm that I approve the use of the named non-validated test/s in this herd, until such time as I am notified by the keeper in writing that he/she is intending no longer to use the test/s, or I confirm in writing that the approval has been rescinded. |
| Signed |       | Date:       |
| Name in capitals |       |
| VMD Veterinary practice number |       |
| RCVS number for the Veterinary Surgeon |       |
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**Please send the completed application to the Welsh Government TB Team at the address below:**

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| TB Team, OCVOGovernment BuildingsPicton TerraceCarmarthenSA31 3BT  |  |

**For any queries, please use these contact details:**

Tel: 08004961439

Email: BovineTB@gov.wales

**If approved, a copy of this application form will be returned to you, authorised by the Welsh Government:**

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| **The Welsh Government declaration:** I confirm that I authorise the use of the non-validated TB tests specified below in this herd subject to the terms and conditions for the use detailed in this document. |
| Non-validated test(s) authorised |       |
| Signed |        Date:       |
| Name in capitals |        |
| Title  | Head of Bovine TB Branch OCVO |  |

1. OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter 1.1.6 – Principles and methods of validation of diagnostic assays for infectious diseases (version adopted in May 2013): <http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.06_VALIDATION.pdf> [↑](#footnote-ref-1)