Animal & Plant Health Agency

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Roger Meacock
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10 December 2024

Dear Roger Meacock,

REQUEST FOR INFORMATION: PCR tests

Thank you for your request for information of 11th November about PCR tests. APHA have handled your request under the Freedom of Information Act 2000 (FOIA).

Your information request and our response are set out below.

“Who regulates and authorises the use of PCR tests for use in veterinary practice given that it is a medical instrument and the VMD say they have nothing to do with this procedure?”

Tests for APHA use (including PCR) are validated according to WOAH (World Organisation of Animal Health) standards and guidelines and then performed under the requirements of ISO17025 standards (covers biological, microbiological and biochemical testing and measurement, relating to the examination of plant material, animal health, food, drugs and pharmaceuticals). In this country compliance with ISO 17025 is overseen by UKAS (UK Accreditation Service). APHA has an internal test validation system, also overseen and audited by UKAS, based on peer review and sign off of test validation data (by specialist scientists not involved in the development or routine delivery of the tests) demonstrating the use of a test for a particular diagnostic application. Validation is generally based on testing of panels of samples of known disease status (positive and negative) to ensure the test produces the correct result and perform to an acceptable standard under routine laboratory conditions.

You may wish to know, the VMD focus on Veterinary Medicinal Products Regulation and veterinary medicines, not diagnostics.

“On what basis are PCR tests used by APHA to determine clinical decisions given that Dr Kary Mullis specifically said they shouldn't be used for field diagnosis, and given the high risk of false positive results using a PCR test what does APHA do to ensure major restrictions such as movement restriction orders and/or culling are based on reliable information? What are the PCR test protocols used for PCR tests currently in use by APHA?”

PCR (or other laboratory tests) are not used to make veterinary clinical decisions in isolation – the tests results are used to inform veterinary surgeons as part of wider diagnostic and clinical decision making.

The following information is not recorded information held by APHA and therefore falls outside of the scope of the FOI Act. It does not form part of our FOI response to your request. However, to assist you with your enquiries, APHA has provided you with the following;

Karry Mullis was the inventor of PCR, but these comments were made decades ago early in the development of the technique and technology and testing has evolved considerably. This is a common occurrence as the use of a technology moves from a research technique to one suitable for routine testing. PCR is now widely accepted, and adopted for front-line diagnostic and laboratory testing across many disciplines of science and diagnostic testing (human, veterinary, plant). The recent widespread use of PCR in the COVID pandemic is a good example of this. APHA (in common with other testing laboratories) have procedures to prevent issues such as false positives, false negatives and contamination with experimental controls built into the testing process to highlight any issues with the testing process. APHA uses many different PCR tests (around 30-40) as part of its wider testing portfolio (of around 500 tests) for a wide variety of diseases (such as avian influenza, TB, Brucella, Classical Swine Fever, TB on tissue samples, Salmonella etc.). PCR offers features and attributes which make it a useful tool in many diagnostic situations but is rarely used in isolation and as previously mentioned, all diagnostic tests are used as part of diagnosis, incorporating clinical signs, epidemiology and veterinary expertise.

“It would be good to get your comments on PCR testing in general, and specifically with regards to any in use that might impact farmers and owners more for diseases such as HPAI, TB etc where significant restrictions or culls might be initiated on the back of such tests.”

The following information is not recorded information held by APHA and therefore falls outside of the scope of the FOI Act.

As described above, PCR is a useful tool in allowing APHA to detect and identify animal and plant disease threats, but it is not the answer or best test for all diagnostic situations. APHA utilise a large variety of other techniques and methods from ELISA to microbial culture, from microscope-based tests to high throughput DNA sequencing. The use of any test is validated, checked and approved prior to routine use in APHA laboratories. The validation only applies to a specific use of the technique (species, sample type, disease etc) and its use for other diseases, sample types etc requires further validation. However, the use of PCR has proved very valuable across the APHA allowing faster testing (allowing rapid response and decision making for potential notifiable diseases), identification of different strains of organisms and testing for diseases for which limited other tests are available.

Please note that FOI requests are for recorded information only. Requests which are not for recorded information, but instead ask questions, such as explanations on policy or explanations on decision making will not be responded to under the legislation and will be treated as routine correspondence. APHA has assisted you with your routine enquiries within this letter but have made clear they do not fall under the FOI Act.

Information disclosed in response to this FOI request is releasable to the public. In keeping with the spirit and effect of the FOIA and the government's Transparency Agenda, this letter and the information disclosed to you may be placed on GOV.UK, together with any related information that will provide a key to its wider context. No information identifying you will be placed on the GOV.UK website.

An Annex is attached which explains the copyright that applies to the information being released to you and contact details should you be unhappy with the service you have received.

If you have any queries about this letter, please contact the Access to Information Team at the email address below or postal address at the top of this letter.

Yours sincerely

Access to Information Team
enquiries@apha.gov.uk

Annex

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Complaints

If you are unhappy with the service you have received in relation to your request, you may make a complaint or appeal against our decision under section 17(7) of the FOIA within 40 working days of the date of this letter. Please write to the Access to Information Team at the address at the top of this letter or email enquiries@apha.gov.uk and the team will arrange for an internal review of your case.

If you are not content with the outcome of the internal review, section 50 of the FOIA gives you the right to apply directly to the Information Commissioner's Office (ICO) for a decision. Please note that generally the ICO cannot make a decision unless you have first exhausted APHA's own complaints procedure.

The ICO can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Please click here for further contact details.