

APHA Briefing Note 47/22

Use of Influenza Antigen Tests for Detecting Avian Influenza

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Purpose

To provide OVs and all Veterinary Surgeons who work with avian species with information regarding the use of Influenza Antigen Tests to detect avian influenza.

To ensure that all veterinary surgeons are clear on the legislative requirements for reporting avian notifiable disease.

To ensure that veterinary surgeons are aware of their responsibilities in terms of interpretation of antigen test results and disease reporting.

Background

APHA recognises the tremendous effort of veterinary surgeons in GB to help control the outbreak of Highly Pathogenic Avian Influenza (HPAI). This includes veterinary surgeons assisting APHA directly and also those working privately to identify and control disease. We would like to take this opportunity to thank you all for your commitment and level of vigilance for this disease.

HPAI is a notifiable disease which has significant impact on animal health and welfare and on trade, as well as potential zoonotic impacts. That is why there is a national reference and official laboratory approach for investigation of this disease in GB. Suspicion of HPAI must always be reported to APHA and any resulting diagnostic testing carried out by the official laboratory as instructed by APHA.

APHA is aware of the increasing use of 'penside' rapid antigen tests to investigate the presence or absence of AI in a variety of situations, as screening tests but also in cases where notifiable disease is suspected.

The manufacturers of at least one of these tests is claiming 100% specificity and 100% sensitivity for Avian Influenza Virus Type A antigen (subtypes H1-H15). This message further increases the clear risk that veterinary surgeons and bird owners/keepers may use the test to 'rule out' disease when the test gives a negative result. There is a significant risk that there may be a failure to report disease as a result of a negative test, even when there is other evidence to support suspicion of disease.

It is very unlikely that any laboratory assay can be 100% sensitive and 100% specific. Even the international standard real time PCRs for avian influenza are considered >99% for both parameters and these are well validated with proven utility using a wide range of sample types at scale.

The sensitivity and specificity of rapid antigen testing methods is inferior to the international standard real time PCRs specified in the WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. The amount of virus present in a clinical sample will vary by sample type but in oropharyngeal or cloacal swabs (sample of choice with relevance to a private setting) the sensitivity of detection in the rapid antigen tests can often be below that typically found in swabs from birds infected with H5Nx HPAI (Slomka et al 2012; Soliman et al 2010). This is supported by APHAs PCR data in the current outbreak. Therefore, a rapid test does not reliably rule out AI. Furthermore, the specificity of some rapid tests has been shown to be lower than real time PCR and they can occasionally produce false positive results.

Rapid antigen tests are not necessarily specific for HPAI, many are for the detection of Influenza A antigen. However, any positive result must be treated as suspicious of AI and reported immediately to APHA.

The Avian Influenza and Influenza of Avian Origin in Mammals Orders in England, Scotland and Wales are clear that in all of the following situations, a person must **immediately** notify APHA:

- if they have in their possession or charge a bird or bird carcase that they suspect may have or know has Al
- if they examine or inspect a bird or bird carcase or analyse a sample from any bird or bird carcase and suspect the presence of AI in the bird or carcase or detect antibodies to AI in the bird or carcase.

The precise wording in the legislation can be found using the links in the 'Information' Section below.

Failure to report suspicion of avian notifiable disease within GB to APHA is an offence. This includes any delay caused by carrying out a rapid antigen test prior to reporting when there is already reason to suspect disease.

If an antigen test is used as a screening test, (for example during the current AI outbreak, a pathologist may wish to routinely carry out an antigen test routinely on all avian carcase submissions where AI is not suspected), the results must be interpreted with caution.

A negative antigen test should not be interpreted as indicating freedom from AI and any decisions must be made according to the full picture. This includes any findings subsequent to the negative test result e.g. a change in clinical presentation, PME findings. If disease is suspected at any point, it must be reported immediately, irrespective of any negative antigen test result. APHA will decide whether further investigation is required, including any official laboratory testing.

A rapid antigen test must not be used to confirm or negate existing suspicion of disease or to inform the decision to report that suspicion to APHA. This also applies to serological tests for AI.

Delay in reporting disease suspicion whilst carrying out further testing is an offence, as is failure to report disease suspicion because a non-official test gives a negative result.

Action

Veterinary Surgeons are asked to carefully consider the use of influenza tests during the current AI outbreak. Inappropriate use or failure to consider tests results within the wider context could lead to failure to identify AI promptly and compromise the control measures that are in place within GB.

Veterinary surgeons, their clients and anyone who suspects avian notifiable disease must report suspicion immediately to APHA. Reporting must not be delayed whilst carrying out a rapid antigen test or any other test. Negative results must never be used as part of the decision-making process as to whether to report clinical or PME suspicion.

Veterinary surgeons are asked to ensure that their colleagues and clients are aware of the legislative requirements and their responsibilities for reporting suspicion of notifiable avian disease.

Further Information

Legislation:

England: <u>The Avian Influenza and Influenza of Avian Origin in Mammals (England) (No.2)</u> <u>Order 2006 (as amended) (legislation.gov.uk)</u>

Wales: The Avian Influenza and Influenza of Avian Origin in Mammals (Wales) (No 2) Order 2006 (legislation.gov.uk)

Scotland: <u>The Avian Influenza and Influenza of Avian Origin in Mammals (Scotland) Order 2006 (legislation.gov.uk)</u>

Papers:

- Soliman M, Selim A, Coward VJ, Hassan MK, Aly MM, Banks J, Slomka MJ. Evaluation of two commercial lateral flow devices (LFDs) used for flockside testing of H5N1 highly-pathogenic avian influenza infections in backyard gallinaceous poultry in Egypt. J Mol Genet Med. 2010 Oct 13;4:247-51. doi: 10.4172/1747-0862.1000043. PMID: 21139668; PMCID: PMC2981883.
- Slomka MJ, To TL, Tong HH, Coward VJ, Mawhinney IC, Banks J, Brown IH. Evaluation of lateral flow devices for identification of infected poultry by testing swab and feather specimens during H5N1 highly pathogenic avian influenza outbreaks in Vietnam. Influenza Other Respir Viruses. 2012 Sep;6(5):318-27. doi: 10.1111/j.1750-2659.2011.00317.x. Epub 2011 Dec 12. PMID: 22151025; PMCID: PMC5779812.