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[redacted]

Our ref: FOI2023/14953
10 August 2023

Dear [redacted]

REQUEST FOR INFORMATION: Avian Influenza testing

Thank you for your request for information of 28th July about Avian Influenza testing. APHA have handled your request under the Freedom of Information Act 2000 (FOIA).

Your information request and our response are set out below.

“For the various PCR (or other) tests and genomic sequencing methods used for testing for avian influenza in Scotland, can you please provide:

1. The Positive Predictive Value for each PCR (or other) tests currently employed.”

APHA do not normally express the test data in terms of ‘positive predictive values’. However, we know from validation studies of all Polymerase Chain Reaction (PCR) assays used and the data obtained since October 2020 using the same PCR tests on the ongoing clinical samples submitted from the avian influenza outbreak investigations across the UK (including Scotland) that the diagnostic sensitivity of the PCR assays is 100%. In other words, the PCR assays have correctly detected the virus in all true-positive cases which is in complete agreement with the epidemiological findings and clinical presentations of the birds from these infected premises. The assays have not missed any positive cases (no false negative results).

2. “The Scientific study or studies that these values are based on.”

As stated above, the confidence in the use of the PCR (and other) assays is based upon, and is underpinned by, strong validation and continual accumulation of positive results data from the continuing avian influenza epizootic in the UK. Furthermore, experimental studies conducted at APHA-Weybridge using the viruses detected from the outbreak also completely support our faith in the use of the PCR (and other) assays used in all outbreak investigations (including those occurring in Scotland).

Published studies:

Slomka MJ, Reid SM, Byrne AMP, Coward VJ, Seekings J, Cooper JL, Peers-Dent J, Agyeman-Dua E, de Silva D, Hansen RDE, Banyard AC, Brown IH. Efficient and Informative Laboratory Testing for Rapid Confirmation of H5N1 (Clade 2.3.4.4) High-

Pathogenicity Avian Influenza Outbreaks in the United Kingdom. Viruses. 2023 Jun 9;15(6):1344. doi: 10.3390/v15061344. PMID: 37376643; PMCID: PMC10304448.

James J, Billington E, Warren CJ, De Sliva D, Di Genova C, Airey M, Meyer SM, Lewis T, Peers-Dent J, Thomas SS, Lofts A, Furman N, Nunez A, Slomka MJ, Brown IH, Banyard AC. Clade 2.3.4.4b H5N1 high pathogenicity avian influenza virus (HPAIV) from the 2021/22 epizootic is highly duck adapted and poorly adapted to chickens. J Gen Virol. 2023 May;104(5). doi: 10.1099/jgv.0.001852. PMID: 37167079.

3. The Positive Predictive Value for the genomic sequencing methods used.

As for the PCR assays above, we do not normally express the sequencing data in terms of 'positive predictive values', However, we know that our sequencing methods have been completely successful since October 2020 in determining the virus sequence of at least one sample from each infected premises from the ongoing avian influenza epizootic. As for the PCR assays, our sequencing methods have correctly sequenced the virus in all true-positive cases in complete agreement with the epidemiological findings and clinical presentations of the birds from these infected premises. The sequencing methods have not missed any positive cases.

4. The scientific studies these values are based on.

Same answer as provided in point 2 above – continued generation of accurate and robust data from outbreak clinical samples since 2020 backed-up by the use of the same sequencing methods on the samples generated from the experimental infections with outbreak viruses.

Published study

Byrne AMP, James J, Mollett BC, Meyer SM, Lewis T, Czepiel M, Seekings AH, Mahmood S, Thomas SS, Ross CS, Byrne DJF, McMenamy MJ, Bailie V, Lemon K, Hansen RDE, Falchieri M, Lewis NS, Reid SM, Brown IH, Banyard AC. Investigating the Genetic Diversity of H5 Avian Influenza Viruses in the United Kingdom from 2020-2022. Microbiol Spectr. 2023 Jun 26:e0477622. doi: 10.1128/spectrum.04776-22. Epub ahead of print. PMID: 37358418.

5. The scientific studies used to determine that a positive PCR test result combined with positive genomic sequencing confirms active infection (the Positive Predictive Value of the combination)."

The data generated from the PCR testing from the outbreak investigations is used to select positive samples for sequencing from each case. Therefore, the two tests are used in tandem to firstly detect (PCR) and characterise (sequencing) the clinical samples for each case. All samples selected from the PCR testing for sequencing will provide sequencing data.

Published study

Byrne AMP, James J, Mollett BC, Meyer SM, Lewis T, Czepiel M, Seekings AH, Mahmood S, Thomas SS, Ross CS, Byrne DJF, McMenamy MJ, Bailie V, Lemon K,

Hansen RDE, Falchieri M, Lewis NS, Reid SM, Brown IH, Banyard AC. Investigating the Genetic Diversity of H5 Avian Influenza Viruses in the United Kingdom from 2020-2022. Microbiol Spectr. 2023 Jun 26:e0477622. doi: 10.1128/spectrum.04776-22. Epub ahead of print. PMID: 37358418.

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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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.