Animal & Plant Health Agency

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Lind Gold
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Our ref: FOI2024/05608
08 April 2024

Dear Lind Gold,

REQUEST FOR INFORMATION: Brucella Canis test validation

Thank you for your request for information of 10th March about Brucella Canis test validation. APHA have handled your request under the Freedom of Information Act 2000 (FOIA).

Your information request and our response are set out below.

“I have become aware that another type of Indirect ELISA that underwent validation also looked to see if their test reported false positives for dogs infected with a range of infectious diseases. These diseases included: Leishmania chagasi, Ehrlichia canis, Babesia canis, Leptospira species, Neospora canis and canine distemper virus (CDV) infection.

This study can be found here:

De Oliveira, MZD., et al. 2011. Validation of an ELISA method for the serological diagnosis of canine brucellosis due to Brucella canis. Research in Veterinary Science. 90(3): 425 - 431 Available from: https://www.sciencedirect.com/science/article/pii/S0034528810002407?via=ihub

It was noted that one of their tests (US - antigen), showed evidence of cross-reactivity with a range of diseases. Ten dogs from each disease group were tested for evidence of cross-reactivity and the following (number/%) tested positive for Brucella canis:

* Eight (80%) dogs with leptospirosis
* Three (30%) dogs with ehrlichiosis
* Seven (70%) dogs with babesiosis
* Three (30%) dogs with leishmaniasis
* Three (30%) dogs with neosporosis
* Three (10%) dogs with distemper

It was particularly noticeable that some of these infected dogs also so strongly cross-reacted on the Brucella canis US-antigen based indirect ELISA result that they also had a positive result on the Brucella canis test that was not close to the threshold for the test.

As an owner of an overseas dog, I was particularly interested to note that some of these are recognised to be common diseases that overseas dogs may be infected with or have been infected with.

I realise that this is not the same indirect ELISA as the one offered by yourselves at APHA Weybridge, but it has led me to the importance of ensuring that the validation work for these tests should include a population of dogs that are similar to the dogs that it is intended to use the tests on and that these validation trials should identify common diseases that an overseas dog imported into the UK may have been infected with.

Therefore, I would like the following information:

Indirect ELISA:

1. “When the APHA indirect ELISA was initially validated, what population were the 'uninfected' control group drawn from? What % of these were UK originating dogs, what % were Western Europe originating dogs, what % were Eastern European originating dogs, what % from elsewhere in the world, and what % were unknown?”

The uninfected group were drawn from dogs from UK origin with no identified risk factors.

2. “How was the 'high confidence that uninfected' status determined?”

The disease is of low prevalence within the UK population.

3. “What validation data have you specifically done to ensure that the indirect ELISA does NOT cross-react with the common diseases that an imported dog may be infected with/previously infected with and still retain antibodies for? In particular, I would like to know for: Leishmaniasis, Ehrlichiosis, Babesia, Anaplasmosis, Distemper, Hepatozoon Canis, Bordetella Bronchiseptica, Giardiasis, and Heart worm.”

This information is not held by APHA.

4. “As raw food feeding is an endemic feeding approach in the UK linked to several gram negative bacteria, I would also like to know what validation data you have specifically done to demonstrate that your indirect ELISA does not cross-react with the following pathogens: E Coli, Salmonella, Campylobacter?”

This information is not held by APHA.

5. “Finally, could you give me a list of the pathogens that you HAVE checked for evidence of cross-reactivity?”

This information is not held by APHA.

6. “For (3) (4) and (5) please state whether this study was in vivo or in vitro.”

This information is not held by APHA.

SAT:

1. “You report the sensitivity and specificity values for the SAT but never mention your validation data. Did APHA validate this data or was this test validated elsewhere and the APHA adopt the methodology?”

This data was validated by APHA.

2. “If you did not validate this test, please signpost me to the source of the specificity and sensitivity data that you report?”

See the response to SAT 1, above.

3. “If you did validate your version of the SAT, what population were the 'uninfected' control group drawn from? What % of these were UK originating dogs, what % were Western Europe originating dogs, what % were Eastern European originating dogs, what % from elsewhere in the world, and what % were unknown?”

The uninfected group were drawn from dogs from UK origin with no identified risk factors.

4. “How was the 'high confidence that uninfected' status determined?”

This information is not held by APHA.

5. What validation data have you specifically done to ensure that the SAT does NOT cross-react with the common diseases that an imported dog may be infected with/previously infected with and still retain antibodies for? In particular, I would like to know for: Leishmaniasis, Ehrlichiosis, Babesia, Anaplasmosis, Distemper, Hepatozoon Canis, Bordetella Bronchiseptica, Giardiasis, and Heart worm.

This information is not held by APHA.

6. As raw food feeding is an endemic approach to feeding in the UK but linked to several gram negative bacteria, I would also like to know what validation data you have specifically done to demonstrate that your indirect SAT does not cross-react with the following pathogens: E Coli, Salmonella, Campylobacter?

This information is not held by APHA.

7. Finally, could you give me a list of the pathogens that you HAVE checked for evidence of cross-reactivity.

This information is not held by APHA.

8. For (5) (6) and (7) please state whether this study was in vivo or in vitro.

This information is not held by APHA.

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.