



To whom it may concern:

**SYNBIOTICS** is a leading developer, manufacturer and marketer of diagnostic products dedicated to the worldwide companion and food animal industries. SYNBIOTICS produces highly sensitive and highly specific antigen (**FluDETECT<sup>®</sup>**: rapid Influenza Type A Antigen Test Kit) and antibody (ProFLOK<sup>®</sup> AIV plus) tests **for on-site surveillance and early detection of Type A influenza** in commercial poultry flocks. Because of the current epidemiological situation in Mexico, we have prepared the following summary regarding our rapid Ag test and its potential use as a useful tool to participate in the assessment, control and eventually eradication of the recent influenza outbreak.

**What are the claims of FluDETECT<sup>®</sup> ?**

**FluDETECT** is an in-vitro, rapid immuno-migration assay designed to aid in the qualitative detection of Influenza type A virus in tracheal and cloacal samples from symptomatic birds or flocks. This assay detects all 16 subtypes of Influenza type A virus. Positive results should be submitted to a reference lab for confirmation and sub type determination. Negative results indicate that no detectable Influenza type A virus is present.

**Can FluDETECT<sup>®</sup> be used on swine?**

This is not part of the product claim; however, data has been generated by outside parties in the field demonstrating the performance of FluDETECT<sup>®</sup> when used on swine samples.

*USA: The test is licensed for Poultry only.*

**What are the reported field performances?**

A field trial in Mexico has been published at the IPVS 2008 and AMVEC 2008.

Publication: "Antigen Detection for SIV Disease in Pigs using a Commercial Rapid Test and Virus Isolation in a Non-Vaccinated Farm in Mexico" - *Sanchez, M. Diana; Carreon, N. Rosalba; Palacios, A. Juan* - Proceedings of the **International Pig Veterinary Society 2008**, Durban, South Africa

Summary: 100 nasal swabs were sampled in pigs with clinical symptoms and tested with FluDETECT<sup>®</sup>. Viral Isolation was used as the gold standard.

**Specificity: 97.3%** (n=92 samples)

**Sensitivity: 100%** (n=8 samples)

If you want to have access to the abstract of the proceeding and have difficulties to locate it, we will be happy to help.

**What strains were tested and what is the detection limit reported?**

*Non published data from U of MN VDL – Dr Marie Gramer*

The following strains of virus suspension were tested according the kit insert

- Positive Control swine influenza virus H1N1 reference strain at  $10^8$  TCID<sub>50</sub>/ml = positive
- Positive Control swine influenza virus H1N1 reference strain  $10^3$  TCID<sub>50</sub>/ml = positive
- Positive Control swine influenza virus H1N1 reference strain  $10^2$  TCID<sub>50</sub>/ml = positive
- Positive Control swine influenza virus H1N1 reference strain  $10^1$  TCID<sub>50</sub>/ml = positive
- undiluted H1N1 field strain = positive
- undiluted H?N? field strain = positive

- undiluted H1N? field strain = positive
- undiluted H1N? field strain = positive
- undiluted H3N2 field strain = positive
- undiluted H3N2 field strain = positive
- SIV grinding media (uninfected, negative control) = negative

**Where can I get FluDETECT?**

You can request product availability in either of our locations:

*USA: The test is licensed for Poultry at USDA approved locations only.*

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I hope this information might be helpful with your interests in our innovative diagnostic products.

Do not hesitate to contact us for additional information or requests.

Best regards

Stephan

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