



Update: OFFLU at OIE, Paris, 14-15
September 2009

Marek Slomka

OIE/FAO/European Community Reference
Laboratory for Avian Virology,
Veterinary Laboratories Agency (VLA), U.K.

**Commercial Diagnostics for AI:
Evaluation / validation data**





The Group:

Me (VLA, UK)

Timm Harder (Deputy, FLI, Germany)

Dennis Senne (USDA, USA)

Sylvie Marche (VAR, Belgium)

Giovanni Cattoli (IZSVe, Italy)

Gwen Dauphin (FAO)

Gavin Smith (Hong Kong)

Veronique Jestin (AFSSA, France)

David Suarez (SEPRL, USA)

Karl Stahl (SVA, Sweden)

Francois Diaz (Observer, OIE)

Conflicts of interest declared

OFFLU forum established on FluLabNet website (EU funded)



Raison d'être:

“One of the problems with rapidly emerging new tests is that methods and protocols may be developed and reported without the test being properly validated”

Our remit:

To investigate *available* of evaluation / validation data for commercial AI diagnostic tests

Information gathering exercise, to seek-out:

1. Peer-reviewed publications
2. Data in public-sector labs
3. Product registration dossiers, eg to USDA
4. Company data



Current product registration requirements for commercial veterinary diagnostic tests

- **In Europe & Asia, there are currently no requirements to formally register commercial veterinary diagnostic kits**
- **Are there any rules? None in Europe & Asia (unlike human diagnostic products)**
- **USDA in N America however does have requirements**

Three types of commercial diagnostic test to investigate:



1) AI RRT PCR

- Validated & robust tests already emerged from public sector (reference) labs
- Some companies following this lead

2) Lateral flow devices (LFDs)

- Driven by diagnostics industry
- Industry validations largely restricted to testing egg-grown AIVs, little with clinical specimens
- Peer-reviewed publications beginning to emerge

3) Antibody detection ELISAs



3) Antibody detection ELISAs: Priority for the Group:

- ELISA as an alternative to HI?
- Poultry surveillance programmes in many countries based on initial serological screening
 - Pan flu A antibody
 - H5 / H7 specific antibodies
- Industry can (must!) provide necessary robustness & stability for reproducible ELISA performance
- Difficult for public sector labs to produce reproducible ELISAs



Antibody detection ELISAs continued....

- ID Vet's validation data for pan A & H5 / H7 antibody ELISAs posted in our forum
- Awaiting peer review by Group members
- Reference laboratory assessments of antibody detection ELISAs continuing in projects, eg FLUTEST

1. We welcome the involvement of the diagnostics industry in these activities
2. Ultimately this will be in a company's interests
3. We wish to identify trustworthy validation data.....
4.but not advertising nor product marketing

Thank you for your attention

OFFLU secretariat

World Organisation for Animal Health (OIE), 12 rue de Prony, 75017 Paris France

- Tel: +33 (0)1 44 15 18 88 • Fax: +33 (0)1 42 67 09 87
- offlu@oie.int • <http://www.offlu.net>

