Proficiency Testing Schemes; Results from 2016 & 2017

Anna Lüdi, Ginette Wilsden, Clare Browning, Hannah Baker, Valerie Mioulet, Britta Wood, Ashley Gray, Lissie Henry, Jemma Wadsworth, Julie Maryan, Sarah Belgrave, Donald King

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Purpose of Proficiency Testing Scheme (PTS)

- To assist National FMD Laboratories to develop/improve accurate and reproducible FMD diagnostic tests
  - Achieved by feedback, training and consultation

- Quality Assurance requirements to support ISO/IEC 17025

- Harmonisation amongst laboratories
  - Achieved by presenting results on how reference laboratories compare, distribution of reagents and protocols
The Scheme

3 panels for FMDV
- Panel 1 – outbreak scenario
- Panel 2 – can your diagnostic assay detect the latest strains?
- Panel 3 – serology
  - Panel 3a - outbreak scenario
  - Panel 3b - QA

Quality Assurance
- Virology - all strains are isolated from field strains and sequenced
- Serology - all sera are from experimental studies
- 10x testing has occurred for all diagnostic test types

NOTE – Swine Vesicular Disease Virus samples/panels will not be discussed
Participants in 2016 and 2017

74 countries in total
Panel 1
Outbreak scenarios of vesicular diseases

Supplied as infectious and non-infectious specimens

Based on the scenarios provided (Panel 1a-b), use your **national contingency plan or similar document** to identify the appropriate tests and testing sequence. Please provide a flow chart in English to show the testing and decision tree adopted for evaluating these samples (the original contingency plan is not necessary). This panel is primarily intended to evaluate your overall diagnostic procedure and interpretation of these suspect cases, rather than focusing on the performance of individual test methods. Therefore, it may **not be necessary to use all of your assays to test these samples**. If downstream characterisation methods, (such as viral sequencing) are part of your contingency plan, please use and report the results of these assays.

Tests used – Virus Isolation, Antigen ELISA, rRT-PCR and sequence
Panel 1
Take home messages

Continued improvement – 2017 PTS all correct results for virus isolation, rRT-PCR and antigen ELISA

Use the scenarios to guide your diagnostic testing
Panel 2
Quality assurance to ensure recent FMDV strains are detected

Supplied as non-infectious

This panel of viruses represents recent FMDV isolates that pose a current threat to the EU and elsewhere. The aim of the evaluation is to make sure these latest strains can be detected. Please use appropriate methods to test these virological samples. Note that some of these samples may not contain viruses.

Tests used – Antigen ELISA and rRT-PCR
## Panel 2
### Strains Selected

<table>
<thead>
<tr>
<th>Year</th>
<th>Strain</th>
<th>Lineage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>O/MOR/1/2015</td>
<td>O/ME-SA/Ind-2001d</td>
</tr>
<tr>
<td></td>
<td>A/PAK/12/2015</td>
<td>A/ASIA/Iran-05&lt;sup&gt;FAR-11&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Asia 1/TUR/12/2015</td>
<td>Asia 1/ASIA/Sindh-08</td>
</tr>
<tr>
<td>2017</td>
<td>O/EGY/18/2016</td>
<td>O/EA-3</td>
</tr>
<tr>
<td></td>
<td>A/IRN/8/2016</td>
<td>A/ASIA/G-VII</td>
</tr>
<tr>
<td></td>
<td>SAT 2/OMN/4/2015</td>
<td>SAT 2/VII&lt;sup&gt;Alx-12&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
To Consider

What strains and lineages are endemic in your area?
What is the risk from surrounding pools?
To Consider

What strains and lineages are endemic in your area?
What is the risk from surrounding pools?

FMD-free (without vaccination)
Sporadic
Endemic
Overall Conclusions

Continued Improvements

- The antigen ELISA shows less cross-reactivity than in the past
- More laboratories are determining serotypes as PanFMD rather than negative
- For 2017 all laboratories correctly identified FMDV samples as FMDV
  - However, four laboratories incorrectly identified a negative sample as inconclusive/positive
Panel 3 – FMDV serology

ELISAs being used

- NSP: 62
- VNT: 24
- PrioCHECK: 18
- IZSLER: 16
- in-house LPBE: 14
- in-house SPCE: 11
- IDVet: 5
Panel 3 – FMDV serology

Non-structural protein ELISAs being used

<table>
<thead>
<tr>
<th>Product</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>PrioCHECK</td>
<td>42%</td>
</tr>
<tr>
<td>IDVET</td>
<td>20%</td>
</tr>
<tr>
<td>IZSLER</td>
<td>8%</td>
</tr>
<tr>
<td>IDEXX</td>
<td>6%</td>
</tr>
<tr>
<td>Other</td>
<td>3%</td>
</tr>
<tr>
<td>In-house</td>
<td>2%</td>
</tr>
</tbody>
</table>
Panel 3a
Continuation of outbreak scenarios

During the outbreak described in scenario 1 (Panels 1a and b), some animals were vaccinated with a high potency, purified monovalent vaccine. Three sera have been collected after vaccination from farms within the 10km surveillance zone surrounding the outbreaks. Please test them and define whether the samples are from infected animals, and if not, whether or not there is any evidence of vaccine-induced immunity. Note you should use information from Panels 1a and b to limit the range of testing that you need to carry out.
Panel 3a
Take home messages

Continued improvement – compared to 2016, more laboratories correctly chose the ELISA for serological testing

Although individual serotypes were correctly identified for each assay, some laboratories included multiple serotypes in overall conclusions.

Use the scenarios to guide your diagnostic testing
You have been asked to carry out post-vaccination monitoring for a country where FMD is endemic. Cattle have been vaccinated with serotype Asia 1 (Asia-1 Shamir) vaccine or A (A22) vaccine; however, there is concern that there may have been an outbreak in the area and the vaccination history is not clear. Please test the samples and comment as to whether the samples are from infected animals, and if not, whether or not there is any evidence of vaccine-induced immunity.
Panel 3b
Take home messages

*Continued improvement – for 2017 all laboratories correctly identified NSP-specific antibodies*

- However, four laboratories incorrectly identified a negative sample as inconclusive/positive

*Although individual serotypes were correctly identified for each assay, some laboratories included multiple serotypes in overall conclusions*

- Question of cross reactivity?

Use the scenarios to guide diagnostic testing.
More on cross-reactivity
See poster by Alison Morris
Acknowledgement

- World Reference Laboratory
- Central Service Unit
- Proficiency Testing Scheme Advisory Board

Contact for PTS – Anna.Ludi@pirbright.ac.uk
2019 PTS and beyond

From January 1\textsuperscript{st} 2019 the European Union PTS will be carried out by by \textit{anses} and \textit{sciensano}.

There is currently no budget for the FAO/self-funded PTS for 2019.

\textit{However}, final decisions have not yet been made.

Your feedback as participants would be useful to determine a way forward…