○○○ **Chair: Prof.Vincenzo Caporale**

THE USE OF DIAGNOSTIC KITS AND NON-STRUCTURAL PROTEIN TESTS FOR FOOT AND MOUTH DISEASE IN CATTLE AND IN OTHER SUSCEPTIBLE SPECIES: CONSTRAINTS AND CHALLENGES

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During the past decade there has been an increased application of tests that detect foot-and-mouth disease virus (FMDV) antibodies to non-capsid proteins (NCP) to assess FMD past/present infection/circulation irrespective of vaccination. Main objectives for its application include: substantiate absence of viral activity in support of the application to OIE for the FMD free status where vaccination is practised; detection and removal of vaccinates in which virus is circulating or has established persistent infection after applying emergency vaccination upon occurrence of an outbreak; confirmation of suspect cases of FMD; input for animal movement; outbreak alert; and screening infection prior to the evaluation of population immunity. In overall, NCP tests have the advantage over structural protein assays that the vaccination status of the animal and/or serotype of virus eventually involved do not have to be known.

The widespread use brought into play new kits and in house tests. A major challenge that will determine the success of a reliable and comparable application of the tests in support of control programs and by trading partners is to ensure the equivalence of results and their interpretation. To this aim, the following aspects should be adjusted: a) approaches used to estimate performance characteristics of the different assays, appropriate for the target population, and their comparative assessment; b) ensuring the quality of testing in different laboratories; c) ensuring batch quality; d) guarantee that positive results are not derived from traces of NCP in vaccine preparation; e) definition of testing algorithms, including guidelines to follow-up positive results; f) definition and development of adequate tools to enable studies on quality control of individual methods and comparative performance of different assays.

Other factors, not necessarily inherent to the test, affect the reliability with which disease freedom can be substantiated by serology, and are related to the survey design.

Progress has been made by OIE and other international organizations in defining guidelines to enable confident NCP test application, including: designation of PANAFTOSA`s test system as index, allowing the definition of the required standards of diagnostic performance; elaboration of validation schemes and registration charts. Guidelines to carry out serosurveillance to substantiate freedom form viral circulation/infection are provided in the OIE *Code*.

Additionally some efforts have been made to support/implement harmonization exercises' as well as to standardize tools to determine the equivalence of tests through serum panels. These activities were focused mainly for cattle, and more work needs to be done for other species.

This paper examines the efforts that are being undertaken for equivalent use and interpretation of NCP testing, the constraints that have been overcome and future challenges that are being addressed to respond to the international requirements for defining freedom from infection/circulation, within the guidelines specified by the OIE.