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## Validation of the PrioCHECK<sup>®</sup> African Swine Fever Virus Ab Kit

*CHASSAING E.*<sup>1</sup>, *ROGE J.*<sup>1</sup>, *LEYVA BACA I.*<sup>1</sup>, *ŠTEINGOLDE*<sup>2</sup>, *DONESCU D.*<sup>3</sup>, *MOINE S.*<sup>1</sup>

<sup>1</sup> Thermo Fisher Scientific, Lyon, France; <sup>2</sup> Institute of Food Safety - Animal Health and Environment - BIOR, Riga, Latvia; <sup>3</sup> Institute of Diagnostic and Animal Health - IDAH, Bucharest, Romania

### INTRODUCTION

African Swine Fever (ASF) is a highly contagious and mortal disease caused by a double-stranded DNA virus: the ASF virus (ASFV). The recent epidemic in Asia has demonstrated its capacity for a global spread and massive culling of pigs leading to a sharp rise in pork prices negatively impacting pig commerce for production and human consumption. Recent outbreaks and cases have been reported in Poland, Latvia, Romania and Italy, evidencing a high risk for the epidemic to spread throughout the rest of Europe. Hence, there is a continuous need for development of reliable, and cost-effective diagnostic tools for ASF. The current study contains diagnostic evaluation and performance of a new ELISA for the detection of antibodies from ASFV infected animals. A large panel of reference samples (n=1090) sourced from three independent laboratories based on western and eastern Europe is presented here. This study aims to demonstrate that the assay validation met the standards defined by the World Organization for Animal Health (WOAH).

### METHOD

The immuno-assay is an Indirect ELISA designed to capture the antibodies directed against the p30 envelope protein of ASFV. The procedure uses ready to use reagents that allows a run time of less than two hours. First, prediluted porcine sera is incubated on the antigen-coated plated. Then a peroxidase labeled secondary antibody against the host species binds to the targeted antibody. The complex is then revealed by addition of a colorimetric substrate and the optical density (OD) is measured. ODs are then converted into percentage of positivity (PP) using ODs obtained with the kit's positive and negative controls. Samples are then classified as positive or negative by comparison of their PP value with the threshold of the kit. Diagnostic performances were evaluated on 1090 serum samples: 590 positive and 500 negative, from domestic pigs and wild boars. Samples statuses were determined by reference methods approved by WOAH. The experiments were performed in three laboratories: the Institute of Food Safety, Animal Health and Environment (BIOR) in Latvia - the Institute for Diagnosis and Animal Health (IDAH) in Romania - and Thermo Fisher Scientific Research and Development facilities in France. Diagnostic sensitivity and specificity were estimated with Wilson 95% interval of confidence. ROC analysis and area under the curve were calculated to assess the separation of the populations and the pertinence of the threshold value. Reproducibility between sites was evaluated with the use of 20 serum samples.

### RESULTS

Overall Diagnostic Sensitivity was assessed to 98.6% (Wilson 95% confidence interval: 97.1 - 99.3). Overall Diagnostic Specificity was assessed to 98.6% (Wilson 95% confidence interval: 97.3 - 99.3). There was no cross reactivity with other swine common viruses. Between-site reproducibility: No status shift was observed between the three laboratories.

### CONCLUSION

The assay meets the sensitivity and specificity recommendations of WOAH for the diagnosis of ASF. The PrioCHECK<sup>™</sup> African Swine Fever Virus Ab Kit constitute a highly performant tool for the screening and monitoring of potentially infected animals.