

口蹄疫非結構性蛋白抗體 ELISA 之能力測試比對

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摘要

由國內研究團隊共同開發具有高準確度和靈敏度的體外診斷套組 (IVD) 即 Sentinel 阻斷型酵素連結免疫吸附法 (ELISA)，主要用於接種或感染口蹄疫病毒 (FMDV) 非結構性蛋白抗體之檢測，並應用在豬，牛和羊血清之評估試驗，結果顯示其診斷靈敏度和診斷特異性皆可高達 95% 以上。近幾年來，在能力驗證計畫中發現實驗室間的比對從 Sentinel ELISA 與 PrioCHECK 和 UBI 等 FMD-NS 試劑套組所獲得結果的一致性及再現性頗高。另於 2016 年參加英國口蹄疫參考實驗室 Proficiency Test Scheme (PTS) 能力比對測試，其中以 Sentinel ELISA kit 測試牛及豬血清樣品 NSP 抗體檢測結果一致符合。故本試劑套組可檢測豬及牛血清中 O/TW/97 和 O/TW/99 FMDV 及其他血清型之非結構蛋白的抗體，且對豬水疱病病毒和水疱性口炎病毒等抗體無交叉反應，因此具有分析特異性。

Proficiency Testing Scheme of NSP Antibody ELISA Diagnostic Devices for Foot-and-Mouth Disease Virus

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Abstract

A domestic research team has jointly developed a highly accurate and sensitive in-vitro diagnostic kit (IVD) using a blocking enzyme-linked immunosorbent assay (ELISA) and is commercially available as the Sentinel® FMDV NSP Ab ELISA kit. This kit is mainly to be used for the detection of non-structural protein (NSP) antibodies of anti-foot-and-mouth disease virus (FMDV) which can differentiate vaccinated sera from infected sera. After evaluating this ELISA diagnostic kit using pig, cattle, and goat sera, we report diagnostic sensitivities and specificities as high as 95% or more. In recent years, the inter-laboratory validation of the proficiency testing scheme (PTS) has demonstrated high agreement and reproducibility of the results obtained between the Sentinel NSP ELISA, PrioCHECK, and UBI FMD-NS ELISA kits. Our participation in the PTS of the United Kingdom Foot-and-Mouth Disease reference laboratory in 2016 produced similarly satisfactory results with respect to bovine and porcine serum samples tested with the Sentinel® FMDV NSP Ab ELISA kit. Furthermore, the kit can specifically detect antibodies for the NSP of O/TW/97 and O/TW/99 FMDV serotypes as well as other serotypes in swine and bovine sera. We did not observe cross-reactions of the antibodies to swine vesicular disease and vesicular stomatitis viruses which further highlights this assay's specificity.