Comparison of the Sensitivity and Specificity of the Commercial Non-Structural Protein ELISA Kits Available in Thailand for Detecting the Antibodies to the Foot and Mouth Disease Virus

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INTRODUCTION and OBJECTIVE

INTRODUCTION

To control and prevent foot and mouth disease (FMD), the Non-Structural-Protein (NSP) ELISA test kit is used to detect antibodies to the NSP of FMD virus (FMDV) to distinguish between vaccinated animals and naturally infected animals with FMDV. Currently, various NSP ELISA test kits are available in Thailand. Therefore, the efficiency of the kits should be studied before selecting the appropriate kit.

OBJECTIVE

This study aimed to compare the efficiency of detecting antibodies to NSP of FMDV using six commercial NSP ELISA test kits.

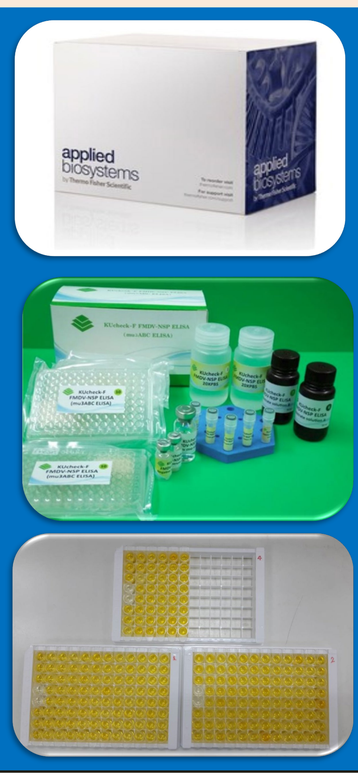
MATERIAL and METHOD

Table 1. Details of the characteristics of the NSP ELISA kits used in the study

Test kit	Manufacturer	Testing format	Animals that can be tested	Positive interpretation criteria
Biovet®	Biovet Inc., Canada	Blocking ELISA	cattle, buffaloes, goats, sheep and pigs	The PI value depends on the status and type of animals.
ID Screen®	IDvet, France	Blocking ELISA	cattle, buffaloes, goats, sheep and pigs	S/N% ≤ 50%
VDPro®	MEDIAN Diagnostic Inc., South Korea	Blocking ELISA	cattle, buffaloes, goats, sheep and pigs	S/N value ≤ 0.6
IDEXX®	IDEXX Laboratories Inc., USA	Blocking ELISA	cattle, buffaloes, goats, sheep and pigs	cattle, buffaloes, goats, sheep: S/P% ≤ 35%, pigs: S/P% ≤ 55%
PrioCHECK®	Prionics Lelystad B.V., Netherlands	Blocking ELISA	cattle, buffaloes, goats, sheep and pigs	PI ≥ 50%
KUcheck-F	Kasetsart University, Thailand	Indirect ELISA	cattle, buffaloes, goats and pigs	COD ≥ 0.2

Note
- %S/N = (OD test sample / OD negative control) × 100
- S/P ratio (sample to positive ratio) = (OD test sample - Average of OD negative control) / (Average of OD positive control - Average of OD negative control)
- Percent Inhibition; % PI = (OD_{450} test sample) × 100 / OD_{450} Max
- COD (corrected optical density) It is the measurement of light absorption.

- The 400 positive sera from cattle, buffalo and swine from the outbreak areas and the Bureau of Veterinary Biologics, the sera were confirmed for FMDV infection by ELISA Typing or RT-PCR.
- The 400 negative sera were brought from Japan and Australia, which have been certified FMD-free by WOAH.
- The sera were used to examine the sensitivity and specificity of the test kits using ANOVA at 95% confidence level, concordance with Cohen's kappa analysis and diagnostic accuracy of the assay.



RESULTS and CONCLUSION

Table 2. The sensitivity and specificity values of the six NSP ELISA test kits.

Test kit	Animal type	Sensitivity (%)	95% CI (SE)	Specificity (%)	95% CI (SP)
Biovet®	Cattle	99.22 (383/386)	97.75–99.84	99.00 (99/100)	94.55–99.97
	Pigs	100 (14/14)	76.84–100	100 (300/300)	98.78–100
	Total	99.25 (397/400)	97.82–99.85	99.75 (399/400)	98.62–99.99
ID Screen®	Cattle	99.48 (384/386)	98.14–99.94	100 (100/100)	96.38–100
	Pigs	100 (14/14)	76.84–100	100 (300/300)	98.78–100
	Total	99.50 (398/400)	98.21–99.94	100 (400/400)	99.08–100
VDPro®	Cattle	97.67 (377/386)	95.62–98.93	100 (100/100)	96.38–100
	Pigs	92.86 (13/14)	66.13–99.82	100 (300/300)	98.78–100
	Total	97.50 (390/400)	94.45–98.79	100 (400/400)	99.08–100
IDEXX®	Cattle	97.93 (378/386)	95.96–99.10	100 (100/100)	96.38–100
	Pigs	100 (14/14)	76.84–100	100 (300/300)	98.78–100
	Total	98.00 (392/400)	96.10–99.13	100 (400/400)	99.08–100
PrioCHECK®	Cattle	98.45 (380/386)	96.65–99.43	100 (100/100)	96.38–100
	Pigs	100 (14/14)	76.84–100	100 (300/300)	98.78–100
	Total	98.50 (394/400)	96.76–99.45	100 (400/400)	99.08–100
KUcheck-F	Cattle	98.96 (382/386)	97.37–99.72	92.00 (92/100)	84.84–96.48
	Pigs	100 (14/14)	76.84–100	99.00 (297/300)	97.11–99.79
	Total	99.00 (396/400)	97.46–99.73	97.25 (389/400)	95.13–98.62

Note: "Total" is calculated from the cumulative number of serum samples used in the testing.

Table 3. The Cohen's kappa statistics and diagnostic accuracy of the six NSP ELISA kits

Test kit	Cohen's kappa	95% CI (Cohen's kappa)	Diagnostic accuracy (%)	95% CI (Diagnostic accuracy)
Biovet®	0.99	0.98–1.00	99.50	98.72–99.86
ID Screen®	1.00	0.99–1.00	99.75	99.10–99.97
VDPro®	0.98	0.96–0.99	98.75	97.71–99.40
IDEXX®	0.98	0.97–0.99	99.00	98.04–99.57
PrioCHECK®	0.99	0.97–1.00	99.25	98.37–99.72
KUcheck-F	0.96	0.94–0.98	98.12	96.93–98.95

Discussion & Conclusion

Currently, there are commercially available NSP ELISA test kits in Thailand. The examination and evaluation of the effectiveness of these test kits is a key step in selecting the appropriate kit for the control and prevention of FMD in the country.

The study of six kits showed that the sensitivity was 97.50%-99.00%, specificity was 97.25%-100.00%, concordance was 0.96-0.99, and accuracy was 98.12%-99.75%. The results indicate that all six test kits were statistically similar and significant on sensitivity and specificity. In addition, the kits were found to have concordance and accuracy within the reliable criteria. This concludes that all kits could be used interchangeably. Therefore, the findings of this study can be used as decision-making data for selecting and purchasing a diverse range of effective kits.

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