Validation of a Commercial Enzyme Immunoassay for Detection of Clostridium difficile Toxins in Horse Feces

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The Clostridium difficile TOX A/B II ELISA is a reliable and practical diagnostic tool for C. difficile–associated disease in horses. Authors’ address: Large Animal Clinic, University Teaching Hospital, Department of Clinical Studies, Ontario Veterinary College, University of Guelph, Guelph, Ontario N1G 2W1, Canada; e-mail: medinac@uoguelph.ca (Medina-Torres). © 2008 AAEP.

1. Introduction
Clostridium difficile has been implicated in acute equine diarrhea. Accurate diagnosis is important for adequate therapeutic intervention. The cell cytotoxicity assay (CTA), considered the “gold standard,” is not readily available for routine testing. Enzyme immunoassays are typically used because of low cost and technical requirements and short turnaround time. The C. difficile TOX-A/B II ELISA has been validated in humans and pigs, but its performance was inadequate for dogs. The test is widely used in horses; however, it has not been validated, and its performance is unclear. The objective of this study was to evaluate the performance of the TOX-A/B II ELISA and validate its use in horses.

2. Materials and Methods
Fecal samples were collected from horses with acute diarrhea, and the ELISA and CTA tests were performed in parallel.

3. Results
Of 72 samples tested, 19 (26.4%) were CTA positive. Sixteen (84.2%) CTA-positive and two (3.8%) CTA-negative samples were positive on the ELISA. Using the McNemar’s test, no significant difference was observed between tests. The ELISA had a sensitivity of 84%, a specificity of 96%, and positive and negative predictive values of 89% and 94%, respectively. Good agreement between the ELISA and the CTA was observed ($\kappa = 0.82$).

4. Discussion
Performance of the test was adequate, as indicated by its high level of agreement with the CTA. Results of this study indicate that the TOX-A/B II ELISA is an adequate diagnostic tool and a reliable, practical test for the clinical diagnosis of C. difficile–associated disease in horses.

Footnote

*C. difficile TOX-A/B II ELISA, TECHLAB, Blacksburg, VA 24060-6358.