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Letters to the Editor

Tox-A Test for *Clostridium difficile*

In recent articles (1, 4), the results of studies comparing several of the *Clostridium difficile* toxin enzyme-linked immunosorbent assays (ELISAs) with tissue culture assay were presented and points were made concerning the low specificity and high rate of indeterminate results with the Tox-A Test. We point out that the Tox-A Tests used in those studies were labeled "For Investigational Use Only" and that they are not the same test that has been approved for in vitro diagnostic use.

The approved Tox-A Test exhibits higher specificity and fewer indeterminate results than those in these two articles. This statement is based on the results from a number of studies performed at various locations around the country. In our clinical trials, which were performed at six different locations and which involved the analysis of 1,130 specimens, the Tox-A Test exhibited a sensitivity and specificity of 91.9 and 97.4%, respectively, and the predictive positive and negative values were 84.5 and 98.7%, respectively, when the test was compared with tissue culture and/or toxigenic culture. The overall correlation of the Tox-A Test with tissue culture assay and/or toxigenic culture was 96.7%, and the indeterminate rate was 1.7%.

In studies presented at the 93rd ASM General Meeting last year (2, 3), the Tox-A Test was compared with other *C. difficile* toxin ELISAs, including the Baxter EIA, the Analytab (Cytoclone) EIA, and the Premier test. The results showed that the Tox-A Test exhibited performance characteristics similar to those of the other ELISAs. Specificities of 98.3 and 100% were reported for the Tox-A Test in those studies. In one of the studies, indeterminate rates of 5.1, 0.5, and 2.6% were reported for Cytoclone, Premier, and the Tox-A Test, respectively. The results from a reference laboratory that routinely uses the Tox-A Test indicated a sensitivity of 80.3% and a specificity of 98.0% compared directly with tissue culture assay when used with more than 400 specimens. In addition, the predictive positive and negative values were 87.5 and 96.7%, respectively; the overall correlation was 95.4%; and the indeterminate rate was 3.0%.

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Tracy D. Wilkins, President
David M. Lyerly, Vice President
TechLab
VPI Research Park
Blacksburg, Virginia 24060

Author's Reply

Because most laboratories cannot evaluate each new product that reaches the marketplace, they are dependent upon laboratories with sufficient staff and interest to perform and report their findings of new product evaluations. These evaluations are dependent upon manufacturers supplying their products to the investigators. Most manufacturers attempt to supply investigators with products that are as close as possible to those which they will market. However, products may not perform in these evaluations as well as the manufacturer would hope. When this occurs, three choices are left to the manufacturer: (i) do nothing to the product and hope for the best, especially if it has received Food and Drug Administration approval, (ii) modify the product to improve its performance characteristics, or (iii) abandon the product. Without published, critical evaluations of the product the first strategy would be much more common than many of us would like to think. Because of critical evaluations, the second strategy is frequently followed.

Recently published abstracts indicate that improvements have been made to the TechLab Tox-A Test for detection of *C. difficile* toxin A. It is clear that the manufacturer deemed the second strategy to be more appropriate than the first strategy. For this, it should be commended. My coauthors and I await with interest published data in refereed journals corroborating these findings.

Peter H. Gilligan
Associate Director
Clinical Microbiology/Immunology Laboratories
University of North Carolina Hospitals
Chapel Hill, North Carolina 27599

Additional Data on Clinical Isolates of *Campylobacter mucosalis*

Figura et al. (3) reported the first isolation of *Campylobacter mucosalis* from children with enteritis. We disputed this identification (5), indicating that phenotypic tests were unreliable and that molecular studies must be done for positive identification of *C. mucosalis*. Dr. Figura (3) indicated that these presumed *C. mucosalis* strains had been deposited at the National Collection of Type Cultures (NCTC), London, as NCTC 12407 and NCTC 12408. We obtained strain NCTC 12408, but strain NCTC 12407 was not available from NCTC. Dr. Figura was unable to supply us with these strains (2a).

The Red Cross Hospital microbiology laboratory uses filtration and incubation in both a microaerophilic and an H_2-enhanced (Oxoid BR 38; no catalyst) microaerophilic atmosphere for the isolation of bacterial pathogens (4). In a