Evaluation of a New Commercial TaqMan PCR Assay for Direct Detection of the *Clostridium difficile* Toxin B Gene in Clinical Stool Specimens[▽]

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The ProGastro Cd assay (Prodesse, Inc., Waukesha, WI) is a new commercial TaqMan PCR assay that detects *tcdB*. The ProGastro Cd assay was compared to the Wampole *Clostridium difficile* toxin B test (TOX-B test; TechLab, Blacksburg, VA), a cell culture cytotoxicity neutralization assay (CCCNA), and to anaerobic toxigenic bacterial culture, as the “gold standard,” for 285 clinical stool specimens. Assays were independently performed according to manufacturers’ directions. A 1.0-ml sample was removed from the stool specimen, of which 20 μ l was used for extraction on the NucliSENS easyMAG platform (bioMérieux, Inc., Durham, NC) for the Prodesse ProGastro Cd assay and 200 μ l of the stool filtrate was used for the TOX-B CCCNA. Anaerobic toxigenic culture was done by heating an additional 1.0 ml of the stool sample to 80°C for 10 min before inoculation onto modified cycloserine, cefoxitin, and fructose agar with horse blood (Remel, Lenexa, KS) and into a prereduced chopped meat glucose broth (BBL, BD Diagnostics, Sparks, MD). The prevalence of toxin-producing strains of *C. difficile* was 15.7% ($n = 44$) as determined by anaerobic toxigenic culture. The sensitivity, specificity, and positive and negative predictive values of the Prodesse ProGastro Cd assay compared to the TOX-B test were 83.3%, 95.6%, 69.4%, and 98%, respectively. Compared to toxigenic culture, the sensitivity, specificity, and positive and negative predictive values of the Prodesse ProGastro Cd assay were 77.3%, 99.2%, 94.4%, and 95.9%, respectively, and those of the TOX-B test were 63.6%, 99.2%, 93.3%, and 93.6%, respectively. Although no statistical difference (Fisher’s exact test) was detected ($P = 0.242$) between the sensitivities of the Prodesse ProGastro Cd assay and a standard CCCNA compared to anaerobic culture for the detection of toxigenic *C. difficile*, the Prodesse ProGastro Cd assay did detect more toxigenic *C. difficile* isolates than the CCCNA.

The severity of disease associated with *Clostridium difficile* infection (CDI) can vary from asymptomatic colonization or mild gastroenteritis to severe manifestations, such as colitis, pseudomembrane formation, and toxic megacolon (2, 3, 7). The increased recognition of CDI-associated morbidity and mortality with the apparent rise of hypervirulent *C. difficile* epidemic strains (BI/NAP1/027) necessitates a dependable diagnostic assay for the detection of toxigenic *C. difficile* as fast as possible (7, 8).

A large number of diagnostic methods are available for the detection of toxigenic *C. difficile* in stool samples. Individual laboratories must balance the performance characteristics with test complexity, costs, and time to results. The cell culture cytotoxicity neutralization assay (CCCNA), once considered a “gold standard,” has been replaced in most laboratories by more rapid technologies. Rapid traditional methods for detection of toxins A and B, i.e., lateral flow devices and enzyme immunoassay methods, are quicker, less complex, and less expensive, but their performances differ with regard to sensitivity and specificity (1, 10, 12, 13, 15–17, 21). Although time-con-

suming, the most sensitive and specific method is anaerobic culture with selective media for *C. difficile* followed by testing of recovered isolates for cytotoxin production (1, 6, 12, 15–17, 21). A few real-time PCR assays have been evaluated in routine clinical laboratories for direct detection of toxin A and/or toxin B directly in stool, but only three PCR assays have been directly compared to anaerobic toxigenic culture (1, 4, 12, 15, 17–20). The only consensus on testing methods is that a rapid, sensitive, and specific assay that differentiates between toxigenic and nontoxigenic *C. difficile* isolates is the preferred tool to assist clinicians in their decision-making process.

The real-time PCR assay manufactured by Prodesse, Inc. (Waukesha, WI), is performed on stool after extraction with the NucliSENS easyMAG platform (bioMérieux, Inc., Durham, NC). The PCR assay uses TaqMan chemistry and consists of proprietary primers specific to the toxin B gene (*tcdB*) as well as an internal control (IC), incorporated into every reaction, that is amplified on the Cepheid SmartCycler II (Sunnyvale, CA). The IC, added on initial processing of the stool sample, acts as a general process control and monitors for the presence of PCR inhibitors. In this study, we compared the ProGastro Cd assay (Prodesse, Inc., Waukesha, WI) to the Wampole *C. difficile* toxin B test (TOX-B test; TechLab, Blacksburg, VA) for a Prodesse (Waukesha, WI)-sponsored clinical trial. In addition, both assays were also compared to an anaerobic

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toxigenic culture method that was not a component of the sponsored clinical trial.

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MATERIALS AND METHODS

Patients and specimens. This study was approved by the Johns Hopkins University School of Medicine Institutional Review Board. Only liquid or soft stool samples were accepted for routine *C. difficile* testing. Samples were eligible if they were obtained from symptomatic patients (≥ 2 years of age) of the Johns Hopkins Hospital, a 900-bed tertiary-care university medical institution. Participants could contribute a second sample, provided the samples were collected more than 7 days after the initial specimen.

Specimen processing and stool clarification. The stools were held at 4°C upon completion of the standard-of-care diagnostic assays until processing for nucleic acid extraction, TOX-B CCCNA, and toxigenic culture. Samples were well mixed in a biological safety cabinet and then split; a stool specimen (1.0 ml) was placed into a sterile polystyrene culture tube (12 by 75 mm) for nucleic acid extraction and cytotoxin processing, and an additional stool specimen (1.0 ml) was transferred to a sterile glass test tube for culture. Samples for the ProGastro Cd assay were initially clarified in a process that included dilution and separation of solids. Using a cold block, clarification began with each individual well-mixed sample (100 μ l) being transferred using a disposable transfer pipette with a wide bore tip to its own 1.5-ml microcentrifuge tube containing 400 μ l of Stool Transport and Recovery (STAR) buffer (Roche Applied Science, Indianapolis, IN). A 1:5 dilution of stool-STAR buffer was created using a disposable transfer pipette. When necessary, thick samples were additionally diluted with STAR buffer using 100- μ l increments. Solutions were vortexed to homogeneity. The solution was centrifuged at 13,000 rpm for 1 min. Taking care to avoid any particulate matter, the supernatant was placed into a new 1.5-ml microcentrifuge tube by using a fine-tip transfer pipette. At this point, the clarified stool (stool supernatant) no longer needed to be kept on a cold block and could be stored at 2 to 8°C for up to 7 days.

ProGastro Cd assay PCR extraction and PCR. The working concentration of the IC (10 μ l) was added to each sample vessel in the easyMAG disposable plastic tray and then the clarified stool sample (20 μ l) was added. Samples were mixed well, with the use of a new pipette tip for each sample, and we attentively avoided creation of air bubbles and contamination of neighboring sample vessels. Remaining clarified stool samples were stored at -70°C. The negative control was made similarly except that 20 μ l of STAR buffer was used in place of clarified stool. The assay uses an additional positive control and negative control called matrix controls to test the extraction procedure. In place of the clarified stool, the negative matrix control and positive matrix control were made using 20 μ l of the single-use negative and positive matrix control solutions, respectively, provided by the manufacturer. The automated extraction was performed using the NucliSENS easyMAG platform (bioMérieux, Inc., Durham, NC) according to the manufacturer's protocol, using high-affinity magnetic silica to extract nucleic acid. The eluate (purified nucleic acids) was stored in 1.5-ml microcentrifuge tubes at 5°C if used on that day; otherwise, the eluate was frozen at -70°C until use the following day. Within 1 h of thawing the master mix and the frozen eluate from the extraction, PCR was performed using the SmartCycler I-Core module (Cepheid, Sunnyvale, CA). A Cepheid cooling block was used to set up the PCRs. After the single-use intermediate stock of positive control was thawed, 5 μ l of the positive control was added to 45 μ l of molecular-grade water in a 1.5-ml microcentrifuge tube. Extracted eluate (5 μ l) from each sample and three of the controls (negative, negative matrix, and positive matrix) was added to 20 μ l of master mix in the SmartCycler reaction tubes. The previously diluted positive control (not extracted, 5 μ l) was added in a similar manner to a separate SmartCycler tube containing master mix. Remaining master mix and samples were frozen at -70°C. The Cepheid microcentrifuge, which is adapted to fit only the SmartCycler tubes, was used to centrifuge tubes for 5 to 10 s. Tubes were returned to the cooling block before they were loaded into the SmartCycler. The clinical samples were placed in the I-Core sites, with the last four being filled by the controls (positive control, positive matrix control, negative control, and negative matrix control). The ProGastro Cd assay (Prodesse, Inc., Waukesha, WI) was run on the SmartCycler by using the manufacturer's software settings for the PCR protocol and interpretation of the results.

Wampole *C. difficile* TOX-B CCCNA. The Wampole *C. difficile* TOX-B test (TechLab, Blacksburg, VA) was performed using the manufacturer's protocol. In brief, 0.2 ml of evenly suspended specimen in diluent (1:10 dilution), phosphate-

buffered saline containing preservative and phenol red provided by the manufacturer, was vortexed (10 s) and centrifuged. The supernatant was filtered (0.45- μ m membrane), and fecal filtrate was inoculated into tissue culture (1/50 dilution) containing human foreskin fibroblasts (Diagnostic Hybrids, Athens, OH). CCCNA plates were incubated (37°C $\pm$ 2°C) and reviewed at 24 h and 48 h.

Toxigenic culture and toxin testing of recovered isolates. Specimens were processed for anaerobic bacterial culture by using a spore selection step by heating the stool (1.0 ml) on a dry heat block (80°C) for 10 min. After being cooled for 5 min (room temperature), the stool was inoculated onto a modified cycloserine, cefoxitin, and fructose agar with horse blood (CCFA-HB) (reference number R01266; Remel, Lenexa, KS) and into a prereduced chopped meat glucose (CMG) broth (catalog number 297307; BBL, BD Diagnostics, Sparks, MD). After 48 h of anaerobic incubation at 35°C, the CCFA-HB plates were examined for colonies morphologically resembling *C. difficile* as described in a publication by Stamper et al. (17). Suspicious colonies were identified using standard phenotypic culture methods. CMG broths were incubated at 35°C for 48 to 72 h and then subcultured onto prereduced *Brucella* blood agar plates (Anaerobe Systems, Morgan Hill, CA). CMG broth subculture isolates were identified using standard phenotypic culture methods.

C. difficile isolates were incubated at 35°C for 48 h in CMG, a glucose-rich medium promoting toxin production, and tested for cytotoxin B by evenly suspending 0.2 ml of CMG in diluent (1:10 dilution). The suspension was then filtered (0.45- μ m membrane) and inoculated into tissue culture plates (human foreskin fibroblasts). The same procedure for the direct CCCNA testing of stool as described above was used to determine cytotoxicity.

Data analysis. Per the sponsor's protocol, the Prodesse ProGastro Cd assay was compared to the Wampole *C. difficile* TOX-B test. Both assays were compared to anaerobic toxigenic culture as a separate evaluation distinct from the trial. For this evaluation, a true positive was defined as being anaerobic culture positive for a toxin B-producing strain of *C. difficile*. Descriptive statistics and tests for strength of association were performed with Stata 9.2 (Stata Corporation, College Station, TX).

RESULTS

In 10 weeks, 285 samples from 271 participants (4.9% duplicate samples from the same patients) were tested. The mean time from sample collection to extraction by the easyMAG platform for PCR and time from sample collection to testing by the TOX-B test were 20.6 h and 21.7 h, respectively. The PCRs of five samples were initially inhibited, and one resolved as a negative upon repeat PCR testing. An additional five samples were positive for the TOX-B test because of a nonspecific cytotoxin effect; four of these resolved upon repeat TOX-B testing. The four inhibited PCR tests and one nonspecific cytotoxin-positive case were excluded from analysis. There were 25 concordantly positive results and 239 that were concordantly negative by the Prodesse ProGastro Cd assay and the TOX-B test, for an overall agreement of 94.3% (264/280). The performance characteristics of the Prodesse ProGastro Cd assay compared to the TOX-B test are displayed in Table 1.

The overall agreements of the ProGastro Cd assay and the TOX-B test with anaerobic toxigenic culture were 95.7% and 93.6%, respectively. The performance characteristics of each assay compared to anaerobic toxigenic culture as the reference standard or gold standard are presented in Table 2. Seven samples were negative by both the Prodesse ProGastro Cd assay and the TOX-B test but were positive for toxigenic *C. difficile* by anaerobic culture. The sensitivity, specificity, and positive and negative predictive values of the Prodesse ProGastro Cd assay were 77.3%, 99.2%, 94.4%, and 95.9%, respectively, and those for the TOX-B test were 63.6%, 99.2%, 93.3%, and 93.6%, respectively. There was no statistical difference between the sensitivities of the ProGastro Cd assay and TOX-B test for detection of toxigenic *C. difficile* directly in

TABLE 1. Direct comparison of the Prodesse ProGastro Cd assay to the Wampole TOX-B test (CCCNA)

Prodesse ProGastro Cd assay result ^a	No. of samples with TOX-B (cytotoxic activity) result	
	Positive	Negative
Positive	25	11
Negative	5	239
Total ^b	30	250

^a The sensitivity was 83.3% (95% CI, 70.0% to 96.7%), the specificity was 95.6% (95% CI, 93.1% to 98.1%), the positive predictive value was 69.4% (95% CI, 54.4% to 84.5%), and the negative predictive value was 98.0% (95% CI, 96.2% to 99.7%).

^b Total, 280 samples. Five samples were excluded from analysis (four samples inhibited PCR; one sample had a nonspecific cytotoxin present).

stool ($P = 0.242$) with anaerobic toxigenic culture as the reference method.

DISCUSSION

Specimen processing, easyMAG extraction, and testing by the Prodesse ProGastro Cd assay took 3 to 4 h before the results were reported. This time was considerably shorter than the 24 to 48 h for TOX-B test results and much shorter than the 3 to 5 days to results from anaerobic toxigenic culture.

The initial performance of the ProGastro Cd assay compared to the TOX-B test performed directly from stool was adequate. The ProGastro Cd assay performed better than the TOX-B test when using toxigenic anaerobic culture as the reference standard, but the difference between the two assays was not statistically significant. Only four samples were positive by either the ProGastro Cd assay or the TOX-B assay but were negative by the corresponding anaerobic toxigenic culture (Table 2). However, none of these four samples negative by anaerobic toxigenic culture was concordantly positive by both the ProGastro Cd assay and the TOX-B test (Table 3).

In our study, using a CCCNA directly on stools, the TOX-B test performed as previously reported with toxigenic anaerobic culture as the reference standard, with comparable sensitivities ranging from 56% to 85% (1, 5, 6, 12, 17, 21). The two samples which were TOX-B positive but toxigenic anaerobic culture

TABLE 3. Review of testing of stool samples positive by the ProGastro Cd assay and the TOX-B test (CCCNA) from which no toxigenic *C. difficile* was isolated^a

Sample no.	Result		
	Prodesse ProGastro Cd assay (PCR)	Wampole TOX-B test (CCCNA)	Anaerobic culture ^b
4171	Positive	Negative	Negative
4246	Positive	Negative	CLBU
4034	Negative	Positive	Negative
4230	Negative	Positive	CLSP

^a Tested at Johns Hopkins Hospital Laboratory (Baltimore, MD). CLBU, *Clostridium butyricum*; CLSP, *Clostridium* species, not *C. difficile*/*C. innocuum*/*C. sordellii*.

^b Approximately 1.0 ml of stool sample was heated at 80°C for 10 min before toxigenic anaerobic culture was performed using CCFA-HB and prereduced CMG. Isolates of *Clostridium* species were tested for toxin B production by the TOX-B test.

negative were negative by culture attempts on selective media and nonselective media (direct plating of the stool onto the CCFA-HB agar plate and also from the enriched CMG). It is possible that toxin B was present but that the *C. difficile* bacteria and spores were killed by the heat in the spore enrichment step. This explanation seems unlikely, given the fact that toxin is labile and there was no bacterial DNA that was amplified in this specimen. No other potential toxin-producing *Clostridium* species was found. Of five specimens initially testing negative by the ProGastro Cd assay but positive by the TOX-B test, two were described above and three had toxigenic *C. difficile* isolates that were recovered. No direct PCR of the isolates was done at the Johns Hopkins Hospital Laboratory, but further evaluation of whether the assay's PCR primers can detect *tcdB* in all *C. difficile* isolates should be considered (9).

Two samples tested positive by the ProGastro Cd assay but negative by CCCNA directly on stool and negative by toxigenic culture (CCFA-HB and CMG enrichment). There could have been low numbers of toxigenic *C. difficile* bacteria that failed to produce toxin in concentrations detectable by TOX-B, and the spores failed to survive the spore selection process, whether because of increased temperature or toxicity of the *C. difficile*. In this case, too, no other potential toxin-producing *Clostridium* species was found on the prereduced *Brucella* blood agar

TABLE 2. Comparison of the Prodesse ProGastro Cd assay and the Wampole TOX-B test (CCCNA) to toxigenic anaerobic culture

Assay result	Toxigenic anaerobic culture result ^a					
	No. of samples with result		% Assay performance (95% confidence interval)			
	Positive	Negative	Sensitivity	Specificity	PPV	NPV
Prodesse ProGastro Cd assay						
Positive	34	2				
Negative	10	234				
Total ^b	44	236	77.3 (64.9–90.0)	99.2 (98.0–100)	94.4 (87.0–99.9)	95.9 (93.4–98.4)
TechLab Wampole TOX-B CCCNA						
Positive	28	2				
Negative	16	234				
Total ^b	44	236	63.6 (49.4–77.9)	99.2 (98.0–100)	93.3 (84.4–99.9)	93.6 (90.6–96.6)

^a Approximately 1 ml of stool sample was heated at 80°C for 10 min before toxigenic anaerobic culture was performed using CCFA-HB and prereduced CMG. *C. difficile* isolates were tested for toxin B production by TOX-B. PPV, positive predictive value; NPV, negative predictive value.

^b Total, 280 samples. Five samples were excluded from analysis after retesting (four samples, inhibited PCR; one sample, nonspecific cytotoxin present).

TABLE 4. Comparison of published real-time PCR assays for toxigenic *C. difficile* detection

Study authors, yr (reference)	Target (assay design)	Extraction/PCR	IC	No. of samples	Sensitivity (%)	Specificity (%)	Reference method	FDA cleared
S. D. Bélanger et al., 2003 (4)	<i>tcdA</i> and <i>tcdB</i> (in-house)	Manual/SmartCycler	No	56	97 ^a	100	CCCNA ^a	No
F. Barbut et al., 2009 (1)	<i>tcdB</i> (BD GeneOhm)	Manual/SmartCycler	Yes	300	93.9	97.7	Anaerobic toxigenic culture	Yes
L. R. Peterson et al., 2007 (12)	<i>tcdB</i> (in-house)	MagnaPure LC/LightCycler	Yes	370	93.3	97.4	Anaerobic toxigenic culture	No
L. M. Sloan et al., 2008 (15)	<i>tcdC</i> (in-house)	MagnaPure LC/LightCycler	No	200	86	97	Anaerobic toxigenic culture	No
P. D. Stamper et al., 2009 (17)	<i>tcdB</i> (BD GeneOhm)	Manual/SmartCycler	Yes	401	83.6	98.2	Anaerobic toxigenic culture	Yes
P. D. Stamper et al. (this study)	<i>tcdB</i> (Prodesse)	easyMAG NucliSENS/SmartCycler	Yes	280	77.3	99.2	Anaerobic toxigenic culture	Yes
R. J. van den Berg et al., 2005 (18)	<i>tcdB</i> (in-house)	MagnaPure LC iCycler IQ	Yes	367	87 ^b	96	CCCNA ^b	No
R. J. van den Berg et al., 2006 (19)	<i>tcdB</i> (in-house)	MagnaPure LC iCycler IQ	Yes	85	100 ^b	94	CCCNA ^b	No
R. J. van den Berg et al., 2007 (20)	<i>tcdB</i> (in-house) ^c	MagnaPure LC iCycler IQ	Yes	540	87.1 ^b	96.5	CCCNA ^b	No

^a CCCNA was used as the reference method to resolve samples with discrepant results. True prevalence was extrapolated.

^b Anaerobic toxigenic culture only was used to resolve discrepant samples. True prevalence was extrapolated.

^c Real-time PCR assay was published in reference 19.

plate. Nine of the 11 specimens initially testing positive by the ProGastro Cd assay but negative by the TOX-B test were positive for toxigenic *C. difficile*. No further analysis of these samples was performed, as they were true positives missed by the TOX-B test.

The sensitivity of the TOX-B test performed directly on stool specimens compared to toxigenic culture was 64%, which confirms previous studies indicating that CCCNA is an imperfect gold standard when evaluating very sensitive methods for diagnosis of CDI. Neither the ProGastro Cd assay PCR nor the TOX-B CCCNA was as sensitive as anaerobic culture.

Table 4 summarizes the literature to date on the performance of real-time PCR methods. Study details and comparative reference methods are included and are briefly summarized in the following paragraphs.

Four analytical real-time PCR studies (4, 18, 19, 20) using three real-time PCR assays were performed using CCCNA as the reference standard, with anaerobic culture performed (18, 19, 20) only for discrepant results. Determination or estimation of the true prevalence of toxigenic *C. difficile* in the population studied would be difficult, because only discrepant results were studied, and this is an underestimation of the true prevalence of toxigenic *C. difficile* (4, 5, 12, 17). The sensitivities of these real-time PCR assays using a less-sensitive reference standard could possibly overestimate the assays' sensitivity, because the true prevalence of toxigenic *C. difficile* was underestimated.

In four previous studies comparing real-time PCR to anaerobic toxigenic culture as in our current study, culture was the most sensitive method for detection of toxin B-producing strains of *C. difficile* for CDI diagnosis (1, 12, 15, 17). While culturing every clinical sample is impractical, toxigenic anaerobic culture should be considered in evaluation studies of new assays as the most-sensitive method to detect toxigenic *C. difficile*, as well as for epidemiologic purposes, to define infection control practices, and most importantly, in clinically relevant cases in which other toxin B assays test negative.

The real-time PCR methods using anaerobic toxigenic culture as the comparator have sensitivities ranging from 77.3% to 93.9%. For the two in-house-developed assays on a LightCycler (Roche Applied Science, Indianapolis, IN) (12, 15), Peterson et al. (12) reported a sensitive real-time PCR using SYBR green chemistry on a highly conserved region of *tcdB* (sensitivity and specificity of 93.3% and 97.4%, respectively). The in-house TaqMan assay developed by Sloan et al. (15) performed similarly, with a sensitivity of 86% and a specificity of 97%. Interestingly, the assay developed by Sloan et al. (15) on the LightCycler indirectly detects toxins A and/or B by amplifying the *tcdC* gene and, using melt curve analysis, can identify base pair deletions associated with epidemic strains. Barbut et al. (1) and Stamper et al. (17) found that the BD GeneOhm assay, a test based on proprietary *tcdB* primers with molecular beacons on the SmartCycler, was comparable in performance, with sensitivities of 94% and 84%, respectively, and with a specificity of 98%. The Prodesse ProGastro Cd assay, which is a TaqMan PCR using the SmartCycler, was the least sensitive of the assays (77.3%) but the most specific (99.2%). However, there were no statistical differences (Fisher's exact test) between the sensitivities ($P = 0.215$) and the specificities ($P = 0.513$) of the various published assays which used anaerobic toxigenic culture as the reference method.

Potential limitations of real-time PCR have been discussed previously in a publication by Stamper et al. (17). These include practical concerns regarding clinical specificity, since with molecular assays, it is the gene encoding the toxin and not the toxin itself that is detected. In addition, there is the theoretical concern that, over time, genetic drift of *tcdB* may occur or that pathogenic *tcdA*-positive, *tcdB*-negative toxigenic *C. difficile* strains may evolve, resulting in false-negative results (9, 11, 14). To date, the emergence of new pathogenic genotypes affecting the clinical performance of the toxin B PCR assays is undocumented.

Although less sensitive than the in-house-developed assays,

the ProGastro Cd assay is available in a format more applicable to laboratories unable to validate and maintain analyte-specific reagents. The anticipated cost of the ProGastro Cd assay is \$25.00 per test, which compares favorably to the price for another FDA-approved test for toxigenic *C. difficile*, the BD GeneOhm assay, which has a listed price of \$49.50 per test. Recently FDA cleared and not yet peer reviewed, the Cepheid Gene Xpert assay is estimated to cost \$45.00 per test, whereas a validated in-house analyte-specific molecular amplified diagnostic test ("home brew") costs approximately \$12.20 per test. As performed at our institution, the CCCNA toxin test costs \$13.00 and anaerobic toxigenic culture costs \$22.

In summary, the Prodesse ProGastro Cd assay is an FDA-cleared real-time PCR assay that has a shorter turnaround time than cytotoxin testing. Compared to toxigenic culture, the PCR assay is more sensitive than the TOX-B test and appears to be competitively priced relative to other commercial real-time PCR platforms.

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