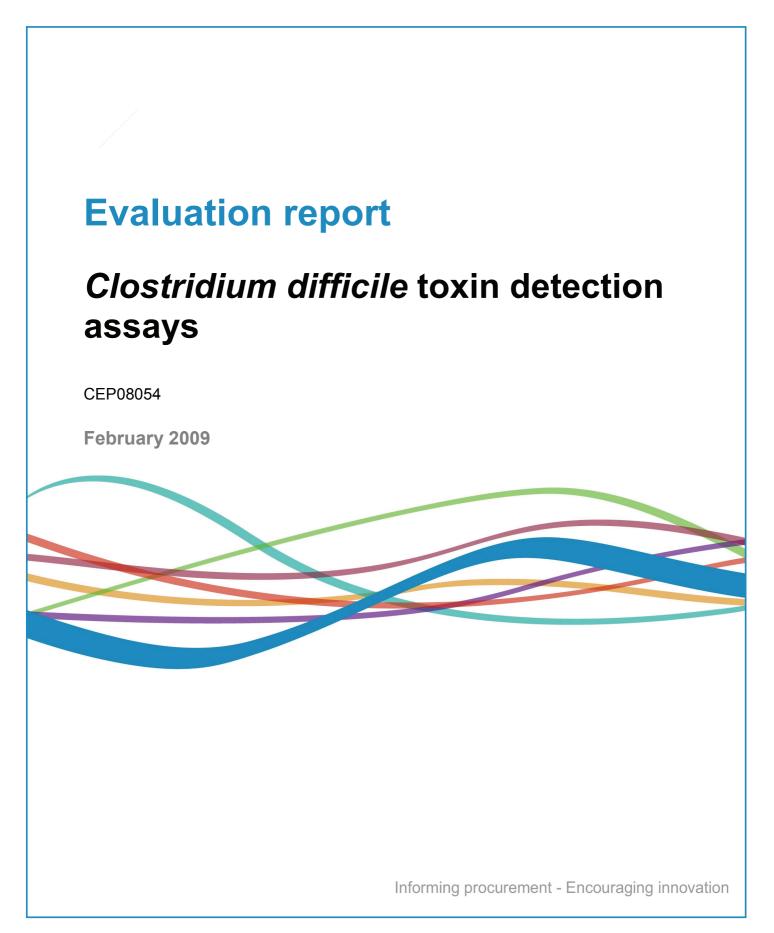
## **NHS** Purchasing and Supply Agency

**Centre for Evidence-based Purchasing** 



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# Summary

### The product

The *Clostridium difficile* toxin A & B detection assay is a test for the presence of the toxins that are present in *C. difficile* infection (CDI). It is available as a cytotoxin assay, an enzyme-linked immunoassay, or as a membrane-bound assay.

#### **Field of use**

The detection of *C. difficile* toxin in a patient's stool sample is used as an indicator of CDI.

#### **Methods**

Six hundred faecal samples submitted from Leeds, Bradford and Sheffield to the Microbiology Department at Leeds Teaching Hospitals NHS Trust were tested for the presence of *C. difficile* toxin using nine commercial toxin detection assays, and the gold standard cytotoxin assay. All samples were cultured. Samples which were cytotoxin negative but culture positive were further investigated by cytotoxin assay (cytotoxigenic culture).

### **Technical performance**

In this report we present data on the comparative sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for six immunoassays and three membrane-bound assays for *C. difficile* toxins in comparison with two gold standard methods (the cytotoxin assay and cytotoxigenic culture).

#### **CEP verdict**

None of the assays tested had a particularly high sensitivity. *Premier Toxin A* + *B*, *Techlab Toxin A/B II*, *Remel ProSpecT*, and *Vidas C. difficile Toxin A & B* performed best, with sensitivities between 90 % and 92 % against the gold standard cytotoxin assay.

The most specific assays relative to the gold standard cytotoxin assay were *Remel Xpect* (98.8 %) and *Techlab Tox A/B Quik Chek* (98.6 %). These two assays also had the highest PPV, with estimates above 50% when the prevalence is 2% (*i.e.* similar to that seen when testing faecal samples from the community), rising to just over 85% when the prevalence is 10% (*i.e.* similar to that seen when testing faecal samples from the seen when testing faecal samples from the seen when testing faecal samples from the testing faecal samples from the seen when testing faecal samples from the seen when testing faecal samples from the seen when testing faecal samples from hospitals).

There is no single assay that is clearly superior in terms of both sensitivity and specificity. However, five assays (*Remel Xpect, Techlab Tox A/B Quik Chek, Premier* 

# Summary

*Toxin A* + *B*, *Vidas C. difficile Toxin A* & *B* and *Techlab Toxin A/B II*) appear to be superior to the other four.

The poor PPVs of toxin detection kits, especially in the context of widespread testing, raises doubts about their appropriateness when used as single tests for the laboratory detection of *C. difficile* toxins.

# Table1. Summary table of results for comparison of commercial *C. difficile* toxin detection kits with cytotoxin assay

Assay	Sensitivity % (95% CI*)	Specificity % (95% CI*)	PPV**	NPV**
	. ,	. ,		
Premier Toxin A+B	91.7 (84.7- 96.1)	97.1 (95.1-98.4)	78.0	99.1
Vidas <i>C. difficile</i> Toxin A &B	89.8 (82.5- 94.8)	96.7 (94.6-98.0)	75.3	98.8
GA Clostridium difficile Antigen	76.8 (67.7- 84.4)	90.9 (88.0-93.3)	48.6	97.3
Ridascreen toxin A/B	66.7 (56.9- 75.4)	95.1 (92.6-96.7)	60.1	96.3
Techlab Toxin A/B II	90.7 (83.6-95.5)	95.7 (93.4-97.3)	70.1	98.9
Remel ProSpecT	89.8 (82.5- 94.8)	92.6 (89.8-94.7)	57.5	98.8
Remel Xpect	77.8 (68.8- 85.2)	98.8 (97.2-99.5)	87.5	97.6
Techlab Tox A/B Quik Chek	84.3 (76.0- 90.6)	98.6 (96.9-99.4)	86.8	98.3
Premier Immunocard A+B	77.8 (68.8- 85.2)	92.8 (90.1-94.9)	54.7	97.4
Note * CI = Confide	nce interval			

Note CI = Confidence interval

\*\* PPV and NPV data quoted for a 10% prevalence of Toxin positive stools in the population tested

### Introduction

#### Background

*Clostridium difficile* infection (CDI) is of increasing concern within the NHS, and accurate laboratory diagnosis is crucial in enabling correct treatment of infected patients and appropriate infection control precautions, and in establishing accurate epidemiological data.

Laboratory diagnosis of CDI relies on detection of *C. difficile* toxins. The accepted gold standard test is a cytotoxin assay, demonstrating that a supernatant of faeces can kill a monolayer of cells, and that this effect is lost if the cells are protected by an antibody which neutralises *C. difficile* toxin. An alternative gold standard test is *C. difficile* culture followed by cytotoxin assay (known as cytotoxigenic culture); this assay detects the presence of *C. difficile* strains that have the capacity to produce toxin(s), as opposed to the presence in a sample of toxins *per se*. A number of commercial toxin detection kits are also available. Kits that target both toxins (A and B) are able to detect recently emerged strains that are negative for toxin A and positive for toxin B.

Laboratory reports of toxin positive faecal samples in England have continued to increase markedly in the past decade. This probably reflects a true increase in the incidence of CDI, although the fact that many laboratories have switched from cytotoxin testing to kit methods is likely to have increased the number of false positive results obtained. This appears to be reflected in recently published evidence of low positive predictive values [1]. False-positive and false-negative results have major implications for patient care, including unnecessary treatment and isolation in the former case, and increased risk of cross-infection by *C. difficile* in the latter.

This report presents the findings of an evaluation of commercially available enzyme immunoassays (EIAs) and membrane-based assays for detection of *C. difficile* toxins A and B in human faecal specimens. Assays which do not detect both toxins are excluded.

### **Methods**

#### Protocol

Faecal samples submitted from Leeds, Bradford and Sheffield to the Microbiology Department at Leeds Teaching Hospitals NHS Trust were for *C. difficile* cytotoxin testing were selected for inclusion in the evaluation. All samples included were diarrhoeal, < 48 hours old, and had been stored at 2-5°C [2]. The number of positive samples was increased by selecting samples from patients who had a high likelihood of CDI (*i.e.* previously diagnosed CDI; n=2) or who had been confirmed as toxin positive at another centre (Sheffield; n=13). Investigators were blinded to the status of all samples included in this evaluation. In total, 600 specimens were included in the evaluation.

Commercially available *C. difficile* toxin detection assays were obtained directly from the suppliers, together with any necessary supplementary equipment. The mini Vidas analyser was supplied by Biomérieux for the evaluation of the *Vidas C. difficile toxin A & B* assay, and the DS2 instrument was supplied by Launch Diagnostics for the evaluation of the *Premier toxin A + B* assay. All other manual EIAs were performed using an automated washer (Wellwash, Labsystems) and microplate reader (230s, Organon Teknika) (appendix 3). The manufacturer's operational instructions were followed for all kits included in the evaluation.

Туре	Assay	Supplier
Well-type EIAs	Premier Toxin A+B	Meridian, Launch
	Toxin A/B II	Techlab, Bioconnections
	Ridascreen toxin A/B	Biopharm
	Remel ProSpecT	Oxoid
	GA Clostridium difficile Antigen	The Binding Site
Automated immunoassay	Vidas Tox A/B	Vidas
Membrane assays	Remel Xpect	Remel, Oxoid
	Tox A/B Quik Chek	Techlab
	Immunocard Stat	Meridian, Launch

Table 2. C. difficile toxin detection assays included in this evaluat
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Each specimen was tested by each of the kits and by cytotoxin assay, and was cultured on CCEYL\* (following alcohol shock). For the cytotoxin assay 20µl of supernatant from a 1:5 dilution of faeces in phosphate buffered saline was added to both *C. sordelli* antitoxin protected and non-protected Vero cell monolayers. Cell

## **Methods**

cultures were incubated at  $37^{\circ}$ C in a CO<sub>2</sub> incubator and examined, using an inverted microscope, for cell rounding at 24 and 48 hours.

All assays were performed on the same day for each batch of samples included in the evaluation. *C. difficile* isolates that grew from cytotoxin-negative samples were tested for the production of toxin in culture supernatants that had been incubated for 48 hours (cytotoxigenic culture). Isolates were sub-cultured onto Fresh Blood agar (FBA) and incubated at 35°C for 7 days before harvesting of spores for storage in 10% glycerol broth at -70°C. All isolates were ribotyped following the protocol from the *Clostridium difficile* Riboyping Network for England (CDRNE) laboratory. Specimens were stored at 4°C for one week (in case re-testing was required) and then frozen at -20°C.

The automated systems (VIDAS and DS2 Premier Toxin A+B) gave a printed result as; positive, negative or equivocal. These results were calculated by the instrument using manufacturer set algorithms.

The manual EIA assays provided a cut-off value and in two cases (Ridascreen toxin A/B and GA Clostridium difficile antigen) a correction factor. For the Techlab Toxin A/B II and Remel ProSpecT assays the cut-off was fixed by the manufacturer and any OD value above this figure was recorded as positive; below this figure as negative. If the OD matched the cut-off it was recorded as equivocal. For the two assays with correction factors, the cut-off value had to be calculated each time the assay was performed. The OD of the negative control was added to the correction factor. Any value higher than 1.1 x cut-off was recorded as positive; below 0.9 x cut-off was recorded as negative. Any value between 0.9 and 1.1 x cut-off was recorded as equivocal.

The membrane assays were read visually by three people. Results were recorded as positive (line or colour change), negative (no line or colour change) or equivocal (if unclear). Where operators couldn't agree, the majority result was recorded.

Specimens with equivocal results were retested and if a result was still equivocal then it was recorded as such. Specimens which were discordant when tested in the assays under evaluation, were retested in duplicate on the same specimen, where sufficient specimen was available, to exclude the possibility of technical error.

<sup>\*</sup> Brazier's CCEY agar base (Bioconnections) was supplemented with 8mg/l cefoxitin and 250mg/l cycloserine, 2% lysed horse blood (E & O Laboratories) and 5mg/l lysozyme (Sigma). Egg yolk was not added as a supplement

## **Methods**

### Analysis

Sensitivity, specificity, positive predictive values (PPVs) and negative predictive values (NPVs) were calculated for each test, using either the cytotoxin assay (n = 596)\*\* or cytotoxigenic culture as the gold standard (n = 600). In addition, PPVs and NPVs were calculated for different prevalence values of *C. difficile* toxin positivity in the population (appendix 4).

\*\* Four false positive cytotoxin samples (according to the results of cytotoxigenic culture) were removed from the analysis. Using cytotoxigenic culture assay as a gold standard assumes that a negative culture result was always accurate.

### Sensitivity relative to cytotoxin assay

Assay	No of		Initial reaction			Sensitivity %	
	positives tested	Positive	Negative	Equivocal	Invalid	(95 % Cl*)	
Premier Toxin A+B	108	99	9	0	0	91.7 (84.7- 96.1)	
Vidas <i>C. difficile</i> Toxin A &B	108	97	2	9	0	89.8 (82.5- 94.8)	
GA Clostridium difficile Antigen	108	83	25	0	0	76.8 (67.7- 84.4)	
Ridascreen toxin A/B	108	72	36	0	0	66.7 (56.9- 75.4)	
Techlab Toxin A/B II	108	98	10	0	0	90.7 (83.6-95.5)	
Remel ProSpecT	108	97	11	0	0	89.8 (82.5- 94.8)	
Remel Xpect	108	84	17	7	0	77.8 (68.8- 85.2)	
Techlab Tox A/B Quik Chek	108	91	17	0	0	84.3 (76.0- 90.6)	
Premier Immunocard A+B	108	84	15	0	9	77.8 (68.8- 85.2)	

#### Table 3. Sensitivity vs cytotoxin assay

Four assays (*Premier Toxin A* + *B*, *Vidas C. difficile Toxin A* & *B*, *Techlab Toxin A*/*B II*, and *Remel ProSpecT*) had sensitivities of 90 - 92 % and were not significantly different from each other. They had, however, significantly higher sensitivities than those observed with the other five assays. The *Ridascreen toxin A*/*B* assay was the least sensitive, with an estimated sensitivity (67 %) significantly lower than those for the other eight assays (appendix 4).

### Specificity relative to cytotoxin assay

Assay	No of Initial reaction					Specificity %
	negatives tested	Negative	Positive	Equivocal	Invalid	(95 % Cl*)
Premier Toxin A+B	488	474	14	0	0	97.1 (95.1-98.4)
Vidas <i>C. difficile</i> Toxin A &B	488	472	5	11	0	96.7 (94.6-98.0)
GA Clostridium difficile Antigen	488	444	44	0	0	90.9 (88.0-93.3)
Ridascreen toxin A/B	488	464	23	1	0	95.1 (92.6-96.7)
Techlab Toxin A/B II	488	467	21	0	0	95.7 (93.4-97.3)
Remel ProSpecT	488	452	36	0	0	92.6 (89.8-94.7)
Remel Xpect	488	482	5	1	0	98.8 (97.2-99.5)
Techlab Tox A/B Quik Chek	488	481	5	1	1	98.6 (96.9-99.4)
Premier Immunocard A+B	488	453	4	0	31	92.8 (90.1-94.9)

#### Table 4. Specificity vs cytotoxin assay

The *Remel Xpect* and *Techlab Tox A/B Quik Chek* assays were the most specific (98.8 % and 98.6 % respectively), and not significantly different from each other. These two assays had specificities that were either significantly higher or at least showed some evidence (0.1 > p > 0.05) of being higher than the other seven assays (appendix 4).

The *GA Clostridium difficile antigen*, *Remel ProSpecT*, and *Premier Immunocard A* + *B* assays had the lowest specificity (approximately 91 - 93%). The estimated specificities of these three assays were not significantly different, but they were on the whole significantly lower than specificities for the other assays (appendix 4).

The remaining four assays (*Premier Toxin A* + *B*, *Vidas C. difficile Toxin A* & *B*, *Ridascreen toxin A*/*B*, and *Techlab Toxin A*/*B II*) had specificities of approximately 95% - 97%, which were not significantly different from each other (appendix 4).

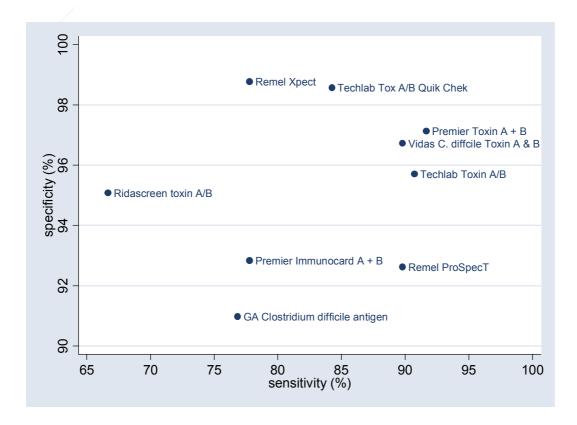
#### Discordant results relative to the cytotoxin assay

The number of initial and repeat discordant results (*i.e.* those not in agreement with the gold standard cytotoxin assay) found for each of the commercial assays is shown in table 5. All nine *C. difficile* toxin detection kits tested gave discordant results (n = 23-69). The majority of these discordant results (mean 68.6%; range 48.9-93.3%) remained unaltered on repeat testing.

Assay	Number of initial discordant results*	Number of repeat discordant results*	% repeatability of discordant results
Premier Toxin A + B	23	18	78.3
Vidas C. difficile Toxin A & B	27	21	77.7
GA Clostridium difficile Antigen	69	54	78.3
Ridascreen toxin A/B	60	41	68.3
Techlab Toxin A/B II	31	16	51.6
Remel ProSpecT	47	23	48.9
Remel Xpect	30	28	93.3
Techlab Tox A/B Quik Chek	24	21	87.5
Premier Immunocard A + B	59	32	54.2
Note: *This includes samples where	e an equivocal or failure w	as reported.	

#### Table 5. Discordant results vs cytotoxin assay

Figure 1. Scatter plot of estimated specificity against sensitivity (cytoxin assay comparator)



### Sensitivity relative to cytotoxigenic culture

Assay	No of						
	positives tested	Positive	Negative	Equivocal	Invalid	(95 % Cl*)	
Cytotoxin	125	108	17	0	0	86.4 (79.1-91.9)	
Premier Toxin A+B	125	101	24	0	0	80.8 (72.3-87.3)	
Vidas <i>C. difficile</i> Toxin A &B	125	100	16	9	0	80.0 (71.9- 86.6)	
GA Clostridium difficile Antigen	125	86	39	0	0	68.8 (59.9-76.8)	
Ridascreen toxin A/B	125	75	50	0	0	60.0 (50.9- 68.7)	
Techlab Toxin A/B II	125	100	25	0	0	80.0 (71.9- 86.6)	
Remel ProSpecT	125	102	23	0	0	81.6 (73.7- 87.9)	
Remel Xpect	125	86	31	8	0	68.8 (59.9- 76.8)	
Techlab Tox A/B Quik Chek	125	93	32	0	0	74.4 (65.8- 81.78	
Premier Immunocard A+B	125	86	29	0	10	68.8 (59.9- 76.8)	

#### Table 6. Sensitivity vs cytotoxigenic culture

**Note:** \* CI = confidence interval.

Sensitivities relative to cytotoxigenic culture were lower than sensitivities relative to the cytotoxin assay, although the same four assays (*Premier Toxin A + B, Vidas C. difficile Toxin A & B, Techlab Toxin A/B II,* and *Remel ProSpecT*) were most sensitive. The *Ridascreen toxin A/B* assay remained the least sensitive assay, with an estimated sensitivity of 60%, significantly lower than for the other eight assays (appendix 4).

### Specificity relative to cytotoxigenic culture

Assay	No of		Initial I	reaction		Specificity %		
	negatives tested	Negative	Positive	Equivocal	Invalid	(95 % CI*)		
Cytotoxin	475	471	4	0	0	99.2 (97.9-99.8)		
Premier Toxin A+B	475	463	12	0	0	97.5 (95.5-98.6)		
Vidas <i>C. difficile</i> Toxin A &B	475	462	2	11	0	97.3 (95.2-98.5)		
GA Clostridium difficile Antigen	475	434	41	0	0	91.4 (88.4-93.7)		
Ridascreen toxin A/B	475	454	20	1	0	95.6 (93.2-97.2)		
Techlab Toxin A/B II	475	456	19	0	0	96.0 (93.7-97.5)		
Remel ProSpecT	475	443	32	0	0	93.3 (90.6- 95.4)		
Remel Xpect	475	472	3	0	0	99.4 (98.2- 99.9)		
Techlab Tox A/B Quik Chek	475	470	3	1	1	98.9 (97.6- 99.7)		
Premier Immunocard A+B	475	442	2	0	31	93.0 (90.4- 95.2)		
Note: * CI = confide	ence interval.							

#### Table 7. Specificity vs cytotoxigenic culture

Specificities relative to cytotoxigenic culture were higher than specificities relative to the cytotoxin assay, although the relative performance of the commercial assays was similar for both reference methods (appendix 4).

### Discordant results relative to cytotoxigenic culture

The number of initial and repeat discordant results (*i.e.* those not in agreement with cytotoxigenic culture) found for each of the commercial assays is shown in table 8. All nine *C. difficile* toxin detection kits tested gave discordant results (n = 29-65). The majority of these discordant results (mean 66.5%; range 28.1-95.0%) remained unaltered on repeat testing.

Number of initial discordant results*	Number of repeat discordant results*	% repeatability of discordant results
31	26	83.9
30	21	70.0
65	50	76.9
52	33	63.5
29	14	48.3
32	9	28.1
40	38	95.0
33	29	87.9
46	18	39.1
	discordant results* 31 30 65 52 29 32 40 33	discordant results*discordant results*3126302165505233291432940383329

#### Table 8. Discordant results vs cytotoxigenic culture

Note: \*This includes samples where an equivocal or failure was reported.

### Positive predictive value

Positive predictive values for the commercial assays were calculated for a range of *C. difficile* prevalences from 2% to 10%, using both the cytotoxin assay (table 9) and cytotoxigenic culture (table 10) as reference.

	Positive predictive value (%)					
Prevalence:	2%	4%	6%	8%	10%	
Premier Toxin A + B	39.5	57.1	67.1	73.5	78.0	
Vidas C. difficile Toxin A & B	35.9	53.3	63.6	70.4	75.3	
GA Clostridium difficile antigen	14.8	26.2	35.2	42.6	48.6	
Ridascreen toxin A/B	21.7	36.1	46.4	54.1	60.1	
Techlab Toxin A/B II	30.1	46.8	57.4	64.7	70.1	
Remel ProSpecT	19.9	33.7	43.7	51.4	57.5	
Remel Xpect	56.3	72.5	80.1	84.6	87.5	
Techlab Tox A/B Quik Chek	54.6	71.1	79.0	83.7	86.8	
Premier Immunocard A + B	18.1	31.1	40.9	48.5	54.7	

#### Table 9. Positive predictive value vs cytotoxin assay

#### Table 10. Positive predictive value vs cytotoxigenic culture

	Positive predictive value (%)				
Prevalence:	2%	4%	6%	8%	10%
Cytotoxin	67.7	81.1	86.8	89.9	92.0
Premier Toxin A + B	39.5	571	67.1	73.5	78.0
Vidas C. difficile Toxin A & B	37.3	54.9	65.1	71.7	76.4
GA Clostridium difficile antigen	14.0	24.9	33.7	40.9	47.0
Ridascreen toxin A/B	21.7	36.1	46.4	54.1	60.1
Techlab Toxin A/B II	29.0	45.5	56.1	63.5	69.0
Remel ProSpecT	19.8	33.5	43.6	51.3	57.4
Remel Xpect	69.0	82.0	87.5	90.5	92.4
Techlab Tox A/B Quik Chek	59.1	74.7	81.9	86.0	88.7
Premier Immunocard A + B	16.8	29.2	38.7	46.3	52.4

### Negative predictive value

Negative predictive values for the commercial assays were calculated for a range of *C. difficile* prevalences from 2% to 10%, using both the cytotoxin assay (table 11) and cytotoxigenic culture (table 12) as reference.

	Negative predictive value (%)				
Prevalence:	2%	4%	6%	8%	10%
Premier Toxin A + B	99.8	99.6	99.5	99.3	99.1
Vidas C. difficile Toxin A & B	99.8	99.6	99.3	99.1	98.8
GA Clostridium difficile antigen	99.5	99.0	98.4	97.8	97.3
Ridascreen toxin A/B	99.3	98.6	97.8	97.0	96.3
Techlab Toxin A/B II	99.8	99.6	99.4	99.2	98.9
Remel ProSpecT	99.8	99.5	99.3	99.1	98.8
Remel Xpect	99.5	99.1	98.6	98.1	97.6
Techlab Tox A/B Quik Chek	99.7	99.3	99.0	98.6	98.3
Premier Immunocard A + B	99.5	99.0	98.5	98.0	97.4

#### Table 11. Negative predictive value vs cytotoxin assay

#### Table 12. Negative predictive value vs cytotoxigenic culture

	Negative predictive value (%)				
Prevalence:	2%	4%	6%	8%	10%
Cytotoxin	99.7	99.4	99.1	98.8	98.5
Premier Toxin A + B	99.6	99.2	98.8	98.3	97.9
Vidas C. difficile Toxin A & B	99.6	99.2	98.7	98.2	97.8
GA Clostridium difficile antigen	99.3	98.6	97.9	97.1	96.3
Ridascreen toxin A/B	99.2	98.3	97.4	96.5	95.6
Techlab Toxin A/B II	99.6	99.1	98.7	98.2	97.7
Remel ProSpecT	99.6	99.2	98.8	98.3	97.9
Remel Xpect	99.4	98.7	98.0	97.3	96.6
Techlab Tox A/B Quik Chek	99.5	99.0	98.4	97.8	97.2
Premier Immunocard A + B	99.3	98.6	97.9	97.2	96.4

### Ribotyping

The three most common ribotypes of *C. difficile* isolated during this evaluation were 106 (25.2%), 027 (19.6%) and 005 (5.6%).

#### Kit and sample storage conditions

All of the kits evaluated in this study need to be stored at 2-8°C. They should be removed from the fridge/cold room, and allowed to warm to room temperature before use. Once diluted the wash buffer should be stored at 2-8°C, and allowed to warm to room temperature before use.

Faecal samples should be stored at 2-8°C and tested within 48 hours.

#### **Facilities required**

The VIDAS *C. difficile* toxin A & B kit requires the use of a VIDAS or mini VIDAS machine, available from Biomérieux.

The Premier Toxin A + B kit and the TechLab Toxin A/B II kit can be performed manually or on the DS2 instrument from Magellan Biosciences, available from Launch Diagnostics.

Manual EIAs can be performed without the use of any dedicated instruments; however, considerable time and manpower can be saved when using an automatic plate washer. Whilst some kits supply a colour card to enable determination of positive and negative results most laboratories will use an automated plate reader, with results based on optical density readings of the control and test wells. Automated plate washer/reader combinations may need to be validated locally to ensure optimum performance.

The Premier Toxin A + B, VIDAS *C. difficile* toxin A & B and the TechLab Toxin A/B II kits all required a centrifugation step. The laboratory would therefore require a centrifuge capable of 3500g, 25000g and 5000g, respectively, to use these three kits. This extra equipment might increase the laboratory's energy consumption and overhead costs.

The GA Clostridium difficile Antigen kit and the TechLab Toxin A/B II kit could be incubated either directly on the bench or on an orbital shaker, to reduce incubation time.

The TechLab Toxin A/B II kit may also be used with the Faecal Quik-Prep device to simplify sample preparation. This would need to be purchased separately from the manufacturer as it does not come with the toxin detection kit.

#### Consumables

All of the kits had an initial dilution step included in the method. This requires a small (2ml) tube, which is generally not supplied with the kit. The Remel Xpect kit is the only kit to supply the initial dilution tube.

To aid the initial dilution step the Remel Xpect and ProSpecT, Premier Immunocard and TechLab Tox A/B Quik Chek kits all include graduated plastic pastettes. Where these are not supplied adjustable positive-displacement pipettes will be required.

#### **Operational time required**

Each kit has a different operational time due to the different lengths of incubation and number of steps in the assay. All assays, however, require an initial dilution of the faecal sample. The membrane assays generally have the shortest operational time ranging from approximately 16 (Premier Immunocard) to 26 minutes (Techlab Tox A/B Quik Chek). The VIDAS *C. difficile* toxin A & B assay and the Premier Toxin A + B kit have operational times of approximately 1 hour, with an actual 'hands-on' time of approximately 10-15 minutes. The manual EIA kits have operational times ranging from approximately 1 hour (TechLab Toxin A/B II) to 1 hour 45 minutes (Ridascreen toxin A/B).

#### Level of skill required

The enzyme immunoassays should be performed by skilled laboratory personnel to ensure correct optimum performance. The membrane assays are much simpler to use and do not require any accessory equipment, thereby making them potential point of care tests (assuming adequate sensitivity and specificity can be achieved).

#### **Clarity of instructions**

Each kit is supplied with a kit insert containing instructions for use. Most instructions are comprehensive. Ridascreen toxin A/B instructions are limited to the test procedure only; detailed performance characteristics for this kit can be obtained separately. Easy-to-use illustrated quick reference guides are also supplied with the Remel and TechLab kits.

#### Ease of use

The VIDAS and DS2 instruments indicate a positive, negative or equivocal result, making results easy to interpret. The manual EIA assays provide an optical density (OD) reading that needs to be interpreted to determine if a result is positive, negative or equivocal. The Remel ProSpecT and TechLab Toxin A/B II use the same cut-off value for each test run, making result interpretation easy, *i.e.* any OD above 0.08

indicates a positive result. The GA Clostridium difficile Antigen kit and the Ridascreen assay both require a correction factor to be added to the OD value obtained for the negative control to give the cut-off value for each batch of tests. The batch specific calculated cut-off value is then multiplied by a constant to define the threshold values for positive, negative or equivocal results. The membrane assays are straightforward to interpret visually, depending on a colour change, and do not need to be interpreted by qualified laboratory staff, making them potentially suitable for use at the point of care.

Kits with fewer wash steps (TechLab Toxin A/B II has the lowest number of washes; n=1) are simpler and quicker to use than those with numerous wash steps (GA Clostridium difficile Antigen has the highest number of washes; n=4).

Graduated pastettes included with some kits (Remel Xpect and ProSpecT, Premier Immunocard and TechLab Tox A/B Quik Chek) make the initial dilution step more convenient, removing the need for additional positive displacement pipettes.

#### Quality

For quality control, positive and negative controls should be performed at the same time as the samples for the manual EIAs and the Premier Toxin A + B. These controls are included in the kits along with their expected value ranges. When control values fall outside of the expected range the batch should be repeated.

The controls for the VIDAS are also supplied with the kit but do not need to be performed on each run. They are performed every two weeks, with the results stored on the instrument to validate subsequent sample results. A QC panel should also be assayed on the instrument every month. This is not included in the kit but can be purchased separately.

The membrane assays have both an internal and external quality control. Each membrane will show two reactions, one for the control and one for the test. If the control fails to change colour, the test must be recorded as invalid and repeated. Each kit is also supplied with a positive and negative control which should be performed at least once per box of tests

Toxin detection kits are intended to allow more rapid diagnosis of CDI, and were introduced as alternatives to the slower cytotoxin assay, which also needs a cell culture line to be maintained. More rapid diagnosis can provide guidance on the need for prompt treatment or further diagnostic testing (for other causes of diarrhoea), helping to optimise the use of isolation facilities, and minimise consequential healthcare resource usage.

There is, however, a hidden cost to toxin detection kits associated with the greater number of inaccurate results they produce relative to the cytotoxin assay. An economic assessment of these hidden costs was beyond the scope of this study, but they might be substantially higher than the kit acquisition costs. For example, a missed true positive might result in transmission of CDI because of failure to isolate a patient, with attendant costs for each additional case of approximately £4000 (1996 prices), mainly driven by increased length of hospital stay [5]. A missed diagnosis might also mean that the patient fails to receive appropriate treatment, increasing the risk of clinical complications. A false positive result might result in unnecessary treatment and, of particular concern, exposure of the patient to an increased risk of cross-infection by C. difficile if cases are cohort nursed. A UK study found that significantly more microbiology (but not total) laboratory tests were carried out on CDI cases than on elderly medical control patients without CDI [5]. Nevertheless, laboratory costs were found to represent only approximately 5% of the total additional costs attributable to CDI [5]. These observations highlight that total health costs must be assessed in cost-effectiveness analyses of diagnostic methods given the potentially large financial burden due to incorrect diagnosis.

CDI surveillance data indicate marked increases in the past decade. This probably reflects a true increase in the incidence of CDI, notably associated with the introduction and spread of new epidemic strains. However, the fact that many laboratories have switched from cytotoxin testing to kit methods is likely to have increased the number of false positive results obtained. This evaluation and a recent meta-analysis of studies reporting on the accuracy of six toxin detection kits both found that the PPV of toxin detection kits is poor (<50% in some circumstances)[3]. NPVs are relatively high (typically >95%), driven by the high likelihood in general that samples are truly toxin-negative. Crucially, however, as the prevalence of CDI decreases then the PPV reduces markedly. In the community setting, only 2% of diarrhoeal samples tested may be positive for *C. difficile* toxin [4]. Another key problem with low sensitivity tests that also have suboptimal specificity is that repeat testing, while increasing the likelihood of obtaining a true positive result, also increases the chance of a false positive.

The poor PPV of toxin detection kits, especially in the context of widespread testing, raises doubts about their acceptability as single tests for the detection of *C. difficile* toxins, and the cost-effectiveness of their use as replacements for cytotoxin testing. It should be acknowledged that the cytotoxin test is not standardised and requires

access to a continuous cell line; such cell lines are now typically not held in most diagnostic microbiology laboratories, although the required expertise is not demanding. Two-step approaches to CDI diagnosis, *e.g.* rapid detection of toxin, bacterium, or toxin gene, with subsequent confirmation of toxin presence, will increase laboratory costs, but these might be offset by reduced total healthcare costs for CDI. A two-step approach will also increase the time for a final result, but this may be acceptable, particularly if interim results are made available. Further work is required to assess the cost-effectiveness of toxin detection kits, cytotoxin testing, and two-step diagnostic approaches.

# Purchasing

#### **Purchasing procedures**

The Trust Operational Purchasing Procedures Manual provides details of the procurement process [6].

European Union procurement rules apply to public bodies, including the NHS, for all contracts worth more than £90,319 (from January 1<sup>st</sup> 2008) [7]. The purpose of these rules is to open up the public procurement market and ensure the free movement of goods and services within the EU. In the majority of cases, a competition is required and decisions should be based on best value.

NHS Supply Chain (NHS SC) offers national contracts or framework agreements for some products, goods and services. Use of these agreements is not compulsory and NHS organisations may opt to follow local procedures.

#### **Purchasing options**

The kits are not currently available through NHS Supply Chain. Volume-dependent discounts are generally available, and consideration should be given to the use of regional contracting (*eg* through local collaborative procurement hubs) where usage volume is significant.

#### Sustainable procurement

The UK Government launched its current strategy for sustainable development, *Securing the Future* [8] in March 2005. The strategy describes four priorities in progressing sustainable development:

- sustainable production and consumption working towards achieving more with less
- natural resource protection and environmental enhancement protecting the natural resources and habitats upon which we depend
- sustainable communities creating places where people want to live and work, now and in the future
- climate change and energy confronting a significant global threat.

The strategy highlights the key role of public procurement in delivering sustainability.

This section identifies relevant sustainability issues and provides some guidance on how these can be incorporated into procurement decision making processes.

# Purchasing

Energy consumption associated with the cytotoxin assay is based upon use of a centrifuge to spin down the diluted sample, and incubators, both to maintain cell lines and to incubate the test sample, plus the consumable waste generated; the latter includes waste growth media, 96-well tissue culture trays, pipette tips and dilution tubes.

Manual EIA assays incur different energy costs compared with the cytotoxin assay, including those due to test production and use of automated plate washers and readers. Some of these assays also require a centrifugation step, whilst others require the use of an orbital shaker. A tube and a plastic pastette for the initial dilution step are included in some of the kits (see operational considerations for details), so reducing the consumables the laboratory has to purchase separately. Extra consumables waste may be generated by these EIA kits due to the packaging of the kit, and the disposal of buffers and reagents that are supplied, in excess, with each kit.

Automated EIA assays are performed using an instrument that completes all the stages of the assay except the initial dilution and centrifugation steps. Other energy costs are similar to those seen with manual EIA assays, if they are used with automated plate washers and readers. The consumables waste produced by these assays is similar to that produced by the manual EIA assays.

Membrane assays do not require any electrical equipment for their performance and therefore have the lowest energy consumption of all the assays (over and above production energy costs). All of the membrane assays provide a tube and plastic pastette for the initial dilution step, reducing the consumables the laboratory has to purchase separately. These assays do, however, produce more waste than the cytotoxin assay and the EIA assays, due to the disposal of the used membranes and individual test packaging.

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						Compositor
Assay	Sensitivity % (95% Cl, if available)	Specificity % (95% Cl, if available)	PPV (95% CI, if available)	NPV (95% Cl, if available)	Prevalence of toxin positive stool in population tested %	Comparator
Premier Toxin A+B	94.7 (88.1-98.3)	97.3 (95.4-98.5)	87.4 (81.0-93.8)	98.9 (97.5-99.7)	16.6	Cytotoxin testing
Video O						
Vidas <i>C. difficile</i> Toxin A &B	88.3 (81.2-93.5)	99.8 (99.2-99.9)	98.1 (93.5-99.8)	98.4 (97.3-99.8)	N/A	Cytotoxin testing
GA						
Clostridium difficile Antigen	93.5	100	N/A	N/A	29.3	Cytotoxin testing
Ridascreen toxin A/B	91.7	100	100	98.5	16.7	Composite of Culture, PCR, Cytotoxin testing
Techlab Toxin						Cytotoxin
A/B II	92.2	100	100	98.6	15.5	testing
Remel ProSpecT	90.3 (84.7-94.4)	96.2 (94.3-97.5)	N/A	N/A	27.5	Cytotoxin testing
Romol Vacat	86.3 (70 8 01 2)	96.2	84.1	96.8	23.1	Cytotoxin
Remel Xpect	(79.8-91.3)	(94.5-97.5)	(77.4-89.4)	(95.2-98.0)	23.1	testing
Techlab Tox A/B Quik Chek	90.2 (84.1-94.2)	99.7 (98.8-99.9)	98.6 (94.4-99.8)	97.9 (96.4-98.7)	18.2	Cytotoxin testing
Premier Immunocard A+B*	93.1 (87.1-98.9)	98.9 (97.6-100)	97.1 (92.9-100)	97.2 (94.5-99.5)	28.8	Cytotoxin testing

### Table 13. Manufacturers' performance claims (from kit inserts)

### Table 14. Suppliers

Supplier	Test kit	Type of assay
Biomérieux UK Ltd Grafton Way Basingstoke RG22 6HY +44 (0) 1256461881 www.biomerieux.com	Vidas <i>C. difficile</i> Toxin A & B	Automated Immunoassay
Biopharm Quadratech Diagnostics Ltd PoBox 167 Epsom Surrey KT18 7YL +44 (0) 2087867811 www.quadratech.co.uk	Ridascreen toxin A/B	Well-type EIA
Inverness Medical UK Pepper Road	Toxin A/B II	Well Type EIA
Hazel Grove Stockport SK7 5BW +44 (0) 161 483 5884 www.invernessmedical.com	Tox A/B Quik Chek	Membrane based assay
Launch Diagnostics Ltd Ash House Ash Road	Premier Toxin A+B (performed on the DS2)	Well type EIA
New Ash Green Kent DA3 8JD +44 (0) 1474874426 www.launchdiagnostics.com	Premier Immunocard A+B	Membrane based assay
Oxoid (part of Thermofisher Scientific)	Remel ProSpecT	Well type EIA
Wade Road Basingstoke Hants RG24 8PW +44 (0) 1256841144 www.oxoid.com	Remel Xpect	Membrane based assay
The Binding Site Limited PO Box 11712 Birmingham B14 4ZB England + 44 (0) 121 436 1000 www.bindingsite.co.uk	GA Clostridium difficile Antigen	Well type EIA

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### Table 15. Equipment used during evaluation

Equipment	Manufacturer	Supplied by
Mini-Vidas	Biomérieux	Biomérieux UK Ltd Grafton Way Basingstoke RG22 6HY +44 (0) 1256461881 www.biomerieux.com
DS2	Magellan Biosciences	Launch Diagnostics Ltd Ash House Ash Road New Ash Green Kent DA3 8JD +44 (0) 1474874426 www.launchdiagnostics.com
Wellwash 4	Labsystems (Now part of Thermo Fisher Scientific)	In-house equipment at Leeds Teaching Hospitals NHS Trust
Microwell plate reader 230S	Organon Teknika	In-house equipment at Leeds Teaching Hospitals NHS Trust

# Statistical analysis of nine commercial kits for *C. difficile* toxin detection verses two gold standard methods

#### Introduction

Each of the nine *C. difficile* toxin detection assays: Premier Toxin A + B, Vidas C. diffcile Toxin A & B, GA Clostridium difficile antigen, Ridascreen toxin A/B, Techlab Toxin A/B II, Remel ProSpecT, Remel Xpect, Techlab Tox A/B Quik Chek, and Premier Immunocard A + B, wasn tested on 600 samples. Two reference methods were used to determine the true status of these samples, a cytotoxin assay and cytotoxigenic culture.

#### Methods

The estimated sensitivity ( $\hat{p}_{sens}$ ) and specificity ( $\hat{p}_{spec}$ ) were calculated for each assay based on the initial result, and any repeat or confirmatory testing has been ignored. The equivocal results and failed samples were assumed to be negative when estimating sensitivity and positive when estimating specificity. This provides what can be considered a worst case situation, with the estimated sensitivity and specificity being lower than they would be if samples with these results were ignored. Exact binomial 95% confidence intervals (95% CI) were calculated to provide the range in which the true estimate will lie with reasonable certainty. Estimates have been expressed as percentages, rather than proportions.

The difference in both sensitivity and specificity between each pair of assays was determined using M<sup>c</sup>Nemar's test for paired proportions. This was done separately for the 108 cytotoxin positive and 488 cytotoxin assay negative samples. Exact binomial p values were calculated due to the potentially small numbers of discordant samples.

While both sensitivity and specificity are invariant quantities, the positive and negative predictive values of diagnostic tests depend crucially on the prevalence ( $\pi$ ) of *C. difficile* in the stool samples being tested. Therefore, the positive predictive vale (*PPV*) and negative predictive value (*NPV*) have been calculated for each assay's estimated sensitivity and specificity using equations 1 and 2, for a range of prevalences.

$$PPV = \frac{\pi \cdot \hat{p}_{sens}}{\left(\pi \cdot \hat{p}_{sens}\right) + \left(\left(1 - \pi\right) \cdot \left(1 - \hat{p}_{spec}\right)\right)} \qquad \dots (1)$$

$$NPV = \frac{(1-\pi)\cdot\hat{p}_{spec}}{\left((1-\pi)\cdot\hat{p}_{spec}\right) + \left(\pi\cdot(1-\hat{p}_{sens})\right)} \qquad \dots (2)$$

#### Results

The estimated difference in sensitivities and pair-wise comparisons for each of the nine assays against the two "standards" are given in Tables 13-16.

	each pair of comparative	assays		
	Ass	says	Estimated difference (95% CI)	P value
1	Premier Toxin A + B	Vidas C. difficile Toxin A & B	1.85 (-3.51 to 7.21)	0.69
	Premier Toxin A + B	GA Clostridium difficile antigen	14.81 (6.27 to 23.36)	0.0004
	Premier Toxin A + B	Ridascreen toxin A/B	25.00 (15.91 to 34.09)	<0.0001
	Premier Toxin A + B	Techlab Toxin A/B	0.93 (-4.05 to 5.91)	1.0000
	Premier Toxin A + B	Remel ProSpecT	1.85 (-3.51 to 7.21)	0.69
	Premier Toxin A + B	Remel Xpect	13.89 (5.95 to 21.82)	0.0003
	Premier Toxin A + B	Techlab Tox A/B Quik Chek	7.41 (0.92 to 13.90)	0.02
	Premier Toxin A + B	Premier Immunocard A + B	13.89 (5.50 to 22.28)	0.0007
	Vidas C. difficile Toxin A & B	GA Clostridium difficile antigen	12.96 (5.20 to 20.72)	0.0005
	Vidas C. difficile Toxin A & B	Ridascreen toxin A/B	23.15 (14.27 to 32.03)	<0.0001
	Vidas C. difficile Toxin A & B	Techlab Toxin A/B	-0.93 (-5.91 to 4.05)	1.0000
	Vidas C. difficile Toxin A & B	Remel ProSpecT	0.00 (-5.37 to 5.37)	1.0000
	Vidas C. difficile Toxin A & B	Remel Xpect	12.04 (4.46 to 19.61)	0.001
	Vidas C. difficile Toxin A & B	Techlab Tox A/B Quik Chek	5.56 (-0.40 to 11.51)	0.07
	Vidas C. difficile Toxin A & B	Premier Immunocard A + B	12.04 (4.46 to 19.61)	0.001
	GA Clostridium difficile antigen	Ridascreen toxin A/B	10.19 (1.59 to 18.78)	0.02
	GA Clostridium difficile antigen	Techlab Toxin A/B	-13.89 (-22.71 to -5.07)	0.002
	GA Clostridium difficile antigen	Remel ProSpecT	-12.96 (-21.19 to -4.74)	0.001
	GA Clostridium difficile antigen	Remel Xpect	-0.93 (-10.92 to 9.07)	1.0000
	GA Clostridium difficile antigen	Techlab Tox A/B Quik Chek	-7.41 (-16.33 to 1.51)	0.12
	GA Clostridium difficile antigen	Premier Immunocard A + B	-0.93 (-9.33 to 7.48)	1.0000
	Ridascreen toxin A/B	Techlab Toxin A/B	-24.07 (-33.06 to -15.08)	<0.0001
	Ridascreen toxin A/B	Remel ProSpecT	-23.15 (-32.03 to -14.27)	<0.0001
	Ridascreen toxin A/B	Remel Xpect	-11.11 (-20.68 to -1.55)	0.02
	Ridascreen toxin A/B	Techlab Tox A/B Quik Chek	-17.59 (-26.96 to -8.22)	0.0002
	Ridascreen toxin A/B	Premier Immunocard A + B	-11.11 (-20.29 to -1.94)	0.02
	Techlab Toxin A/B II	Remel ProSpecT	0.93 (-4.05 to 5.91)	1.0000
	Techlab Toxin A/B II	Remel Xpect	12.96 (5.70 to 20.22)	0.0001
	Techlab Toxin A/B II	Techlab Tox A/B Quik Chek	6.48 (0.25 to 12.71)	0.04
	Techlab Toxin A/B II	Premier Immunocard A + B	12.96 (4.74 to 21.19)	0.001
	Remel ProSpecT	Remel Xpect	12.04 (3.98 to 20.09)	0.002
	Remel ProSpecT	Techlab Tox A/B Quik Chek	5.56 (-1.57 to 12.68)	0.15
	Remel ProSpecT	Premier Immunocard A + B	12.04 (4.46 to 19.61)	0.001
	Remel Xpect	Techlab Tox A/B Quik Chek	-6.48 (-13.30 to 0.34)	0.07
	Remel Xpect	Premier Immunocard A + B	0.00 (-9.44 to 9.44)	1.0000
			0, 40, (4, 00, 1, 44, 70)	0 4 4

Premier Immunocard A + B

Table 13.	Estimated difference in sensitivity against the cytotoxin assay fo	r
each pair	of comparative assays	

6.48 (-1.83 to 14.79)

0.14

Techlab Tox A/B Quik Chek

# Table 14. Estimated difference in sensitivity against cytotoxigenic culture foreach pair of comparative assays

Δο	says	Estimated difference (95% CI)	P value
Cytotoxin assay	Premier Toxin A + B	5.60 (-0.31 to 11.51)	0.0654
Cytotoxin assay	Vidas C. difficile Toxin A & B	6.40 (-0.16 to 12.96)	0.0574
Cytotoxin assay	GA Clostridium difficile antigen	17.60 ( 9.10 to 26.10)	< 0.0001
Cytotoxin assay	Ridascreen toxin A/B	26.40 (16.97 to 35.83)	< 0.0001
Cytotoxin assay	Techlab Toxin A/B	6.40 ( 0.29 to 12.51)	0.0386
Cytotoxin assay	Remel ProSpecT	4.80 (-2.22 to 11.82)	0.2101
Cytotoxin assay	Remel Xpect	17.60 ( 9.42 to 25.78)	< 0.0001
Cytotoxin assay	Techlab Tox A/B Quik Chek	12.00 ( 4.70 to 19.30)	0.0007
Cytotoxin assay	Premier Immunocard A + B	17.60 ( 9.42 to 25.78)	< 0.0001
Premier Toxin A + B	Vidas C. difficile Toxin A & B	0.80 (-4.70 to 6.30)	1.0000
Premier Toxin A + B	GA Clostridium difficile antigen	12.00 (4.33 to 19.67)	0.002
Premier Toxin A + B	Ridascreen toxin A/B	20.80 (12.55 to 29.05)	< 0.0001
Premier Toxin A + B	Techlab Toxin A/B	0.80 (-3.50 to 5.10)	1.0000
Premier Toxin A + B	Remel ProSpecT	-0.80 (-6.30 to 4.70)	1.0000
Premier Toxin A + B	Remel Xpect	12.00 (5.09 to 18.91)	0.0003
Premier Toxin A + B	Techlab Tox A/B Quik Chek	6.40 (0.77 to 12.03)	0.02
Premier Toxin A + B	Premier Immunocard A + B	12.00 (4.70 to 19.30)	0.0007
Vidas C. difficile Toxin A & B	GA Clostridium difficile antigen	11.20 (4.04 to 18.36)	0.001
Vidas C. difficile Toxin A & B	Ridascreen toxin A/B	20.00 (11.52 to 28.48)	<0.0001
Vidas C. difficile Toxin A & B	Techlab Toxin A/B	0.00 (-5.23 to 5.23)	1.0000
Vidas C. difficile Toxin A & B	Remel ProSpecT	-1.60 (-7.35 to 4.15)	0.75
Vidas C. difficile Toxin A & B	Remel Xpect	11.20 (4.04 to 18.36)	0.001
Vidas C. difficile Toxin A & B	Techlab Tox A/B Quik Chek	5.60 (-0.31 to 11.51)	0.07
Vidas C. difficile Toxin A & B	Premier Immunocard A + B	11.20 ( 4.04 to 18.36)	0.001
GA Clostridium difficile antigen	Ridascreen toxin A/B	8.80 (0.98 to 16.62)	0.03
GA Clostridium difficile antigen	Techlab Toxin A/B	-11.20 (-19.09 to -3.31)	0.004
GA Clostridium difficile antigen	Remel ProSpecT	-12.80 (-20.60 to -5.00)	0.0009
GA Clostridium difficile antigen	Remel Xpect	0.00 (-8.80 to 8.80)	1.0000
GA Clostridium difficile antigen	Techlab Tox A/B Quik Chek	-5.60 (-13.52 to 2.32)	0.19
GA Clostridium difficile antigen	Premier Immunocard A + B	0.00 (-7.45 to 7.45)	1.0000
Ridascreen toxin A/B	Techlab Toxin A/B	-20.00 (-28.15 to -11.85)	<0.0001
Ridascreen toxin A/B	Remel ProSpecT	-21.60 (-29.61 to -13.59)	<0.0001
Ridascreen toxin A/B	Remel Xpect	-8.80 (-17.29 to -0.31)	0.04
Ridascreen toxin A/B	Techlab Tox A/B Quik Chek	-14.40 (-22.79 to -6.01)	0.0005
Ridascreen toxin A/B	Premier Immunocard A + B	-8.80 (-16.96 to -0.64)	0.04
Techlab Toxin A/B II	Remel ProSpecT	-1.60 (-6.83 to 3.63)	0.73
Techlab Toxin A/B II	Remel Xpect	11.20 (4.87 to 17.53)	0.0001
Techlab Toxin A/B II	Techlab Tox A/B Quik Chek	5.60 (0.20 to 11.00)	0.04
Techlab Toxin A/B II	Premier Immunocard A + B	11.20 (4.04 to 18.36)	0.001
	Remel Xpect	12.80 (5.36 to 20.24)	0.0004
	Techlab Tox A/B Quik Chek	7.20 (0.46 to 13.94)	0.04
Remel ProSpecT	Premier Immunocard A + B	12.80 (5.74 to 19.86)	0.0001
Remel Xpect	Techlab Tox A/B Quik Chek	-5.60 (-11.51 to 0.31)	0.07
Remel Xpect	Premier Immunocard A + B	0.00 (-8.15 to 8.15)	1.0000
Techlab Tox A/B Quik Chek	Premier Immunocard A + B	5.60 (-1.59 to 12.79)	0.14

# Table 15. Estimated difference in specificity against the cytotoxin assay for each pair of comparative assays

AssaysEstimated difference (95% C1)P valuePremier Toxin A + BVidas C. difficile Toxin A & B0.41 ( $2.66$ to -1.84)0.85Premier Toxin A + BRidascreen toxin A/B2.05 ( $4.45$ to -0.35)0.10Premier Toxin A + BTechlab Toxin A/B2.05 ( $4.45$ to -0.35)0.10Premier Toxin A + BTechlab Toxin A/B2.05 ( $4.45$ to -0.35)0.26Premier Toxin A + BRemel ProSpecT4.51 ( $7.16$ to 1.86)0.0005Premier Toxin A + BRemel Xpect-1.64 ( $0.06$ to -3.34)0.06Premier Toxin A + BTechlab Tox A/B Quik Chek-1.43 ( $0.21$ to -3.08)0.09Vidas C. difficile Toxin A & BGA Clostridium difficile antigen5.74 ( $8.74$ to 2.74)0.0001Vidas C. difficile Toxin A & BTechlab Toxin A/B1.64 ( $4.04$ to -0.76)0.20Vidas C. difficile Toxin A & BRemel Xpect-2.05 ( $-0.25$ to -3.85)0.002Vidas C. difficile Toxin A & BRemel ProSpecT4.10 ( $7.00$ to 1.19)0.005Vidas C. difficile Toxin A & BPremier Immunocard A + B3.89 ( $6.77$ to 1.02)0.007GA Clostridium difficile antigenRidascreen toxin A/B-4.10 ( $-1.08$ to $-7.87$ )0.003GA Clostridium difficile antigenRemel Xpect-7.79 ( $5.07$ to $-10.50$ )<0.0001GA Clostridium difficile antigenRemel Xpect-7.79 ( $5.07$ to $-10.50$ )<0.0017GA Clostridium difficile antigenRemel Xpect-7.79 ( $5.07$ to $-10.50$ )<0.0017GA Clostridium difficile antigenRemel Xpect-7.79 ( $5.07$ to $-10.50$	-	-	Estimated difference (050/ 01)	Dualus
Premier Toxin A + B         GA Clostridium difficile antigen         6.15 (9.08 to 3.21)         <0.0001           Premier Toxin A + B         Ridascreen toxin A/B         2.05 (4.45 to -0.35)         0.10           Premier Toxin A + B         Techlab Toxin A/B         1.43 (3.80 to -0.93)         0.26           Premier Toxin A + B         Remel ProSpecT         4.51 (7.16 to 1.86)         0.0005           Premier Toxin A + B         Remel Xpect         -1.64 (0.06 to -3.34)         0.06           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.43 (0.21 to -3.08)         0.09           Premier Toxin A + B         Premier Immunocard A + B         4.30 (7.05 to 1.56)         0.002           Vidas C. difficile Toxin A & B         GA Clostridium difficile antigen         5.74 (8.74 to 2.74)         0.001           Vidas C. difficile Toxin A & B         Remel Xpect         -2.05 (-0.25 to -3.85)         0.02           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.10 (7.00 to 1.19)         0.005           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.10 (-1.08 to -7.12)         0.007           GA Clostridium difficile antigen         Redascreen toxin A/B         4.10 (-1.08 to -7.87)         0.003           GA Clostridium difficile antigen         Techlab Toxin A/B         4.10 (-1.08 to -7.87)			Estimated difference (95% CI)	P value
Premier Toxin A + B         Ridascreen toxin A/B         2.05 ( 4.45 to -0.35)         0.10           Premier Toxin A + B         Techlab Toxin A/B         1.43 ( 3.80 to -0.93)         0.26           Premier Toxin A + B         Remel ProSpecT         4.51 (7.16 to 1.86)         0.0005           Premier Toxin A + B         Remel Xpect         -1.64 ( 0.06 to -3.34)         0.06           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.43 ( 0.21 to -3.08)         0.09           Vidas C. difficile Toxin A & B         GA Clostridium difficile antigen         5.74 ( 8.74 to 2.74)         0.0001           Vidas C. difficile Toxin A & B         Ridascreen toxin A/B         1.64 ( 4.04 to -0.76)         0.20           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.10 ( 7.00 to 1.19)         0.005           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.10 ( 7.00 to 1.19)         0.005           Vidas C. difficile Toxin A & B         Remel Xpect         -2.05 (-0.25 to -3.85)         0.02           Vidas C. difficile Toxin A & B         Remel Xpect         -2.05 (-0.25 to -3.85)         0.007           GA Clostridium difficile antigen         Ridascreen toxin A/B         -4.10 (-1.08 to -7.12)         0.007           GA Clostridium difficile antigen         Rechala Toxin A/B         -7.79 (-5.07 to -10.50			( ,	
Premier Toxin A + B         Techlab Toxin A/B         1.43 ( 3.80 to -0.93)         0.26           Premier Toxin A + B         Remel ProSpecT         4.51 ( 7.16 to 1.86)         0.0005           Premier Toxin A + B         Remel Xpect         -1.64 ( 0.06 to -3.34)         0.06           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.43 ( 0.21 to -3.08)         0.09           Vidas C. difficile Toxin A & B         GA Clostridium difficile antigen         5.74 ( 8.74 to 2.74)         0.00011           Vidas C. difficile Toxin A & B         Ridascreen toxin A/B         1.64 ( 4.04 to -0.76)         0.20           Vidas C. difficile Toxin A & B         Techlab Toxin A/B         1.02 ( 3.46 to -1.41)         0.47           Vidas C. difficile Toxin A & B         Remel Xpect         -2.05 (-0.25 to -3.85)         0.02           Vidas C. difficile Toxin A & B         Techlab Tox A/B Quik Chek         -1.84 ( 0.01 to -3.70)         0.05           Vidas C. difficile antigen         Ridascreen toxin A/B         -4.10 (-1.08 to -7.12)         0.007           GA Clostridium difficile antigen         Remel Xpect         -7.79 (-5.07 to -10.50)         -0.0001           GA Clostridium difficile antigen         Remel ProSpecT         -1.64 ( 1.72 to -5.00)         0.37           GA Clostridium difficile antigen         Remel ProSpecT         -		-	· · · · · · · · · · · · · · · · · · ·	
Premier Toxin A + B         Remel ProSpecT         4.51 (7.16 to 1.86)         0.0005           Premier Toxin A + B         Remel Xpect         -1.64 (0.06 to -3.34)         0.06           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.43 (0.21 to -3.08)         0.09           Premier Toxin A + B         Premier Immunocard A + B         4.30 (7.05 to 1.56)         0.002           Vidas C. difficile Toxin A & B         GA Clostridium difficile antigen         5.74 (8.74 to 2.74)         0.0001           Vidas C. difficile Toxin A & B         Ridascreen toxin A/B         1.02 (3.46 to -1.41)         0.47           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.10 (7.00 to 1.19)         0.005           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.10 (7.00 to 1.90)         0.007           Vidas C. difficile Toxin A & B         Remel Xpect         -2.05 (-0.25 to -3.85)         0.02           Vidas C. difficile Toxin A & B         Premier Immunocard A + B         3.89 (6.77 to 1.02)         0.007           GA Clostridium difficile antigen         Techlab Toxin A/B         -4.10 (-1.08 to -7.12)         0.007           GA Clostridium difficile antigen         Remel ProSpecT         -1.64 (1.72 to -5.00)         0.37           GA Clostridium difficile antigen         Remel Xpect         -7.79 (-5.07 t				
Premier Toxin A + B         Remel Xpect         -1.64 (0.06 to -3.34)         0.06           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.43 (0.21 to -3.08)         0.09           Vidas C. difficile Toxin A & B         GA Clostridium difficile antigen         5.74 (8.74 to 2.74)         0.0001           Vidas C. difficile Toxin A & B         Red Clostridium difficile antigen         5.74 (8.74 to 2.74)         0.0001           Vidas C. difficile Toxin A & B         Reclab Toxin A/B         1.64 (4.04 to -0.76)         0.20           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.10 (7.00 to 1.19)         0.005           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.10 (7.00 to 1.19)         0.007           GA Clostridium difficile antigen         Ridascreen toxin A/B         -1.84 (0.01 to -3.70)         0.05           Vidas C. difficile Toxin A & B         Techlab Tox A/B Quik Chek         -1.84 (0.01 to -3.70)         0.007           GA Clostridium difficile antigen         Ridascreen toxin A/B         -4.10 (-1.08 to -7.12)         0.007           GA Clostridium difficile antigen         Remel ProSpecT         -1.64 (1.72 to -5.00)         0.37           GA Clostridium difficile antigen         Remel ProSpecT         -1.64 (1.72 to -5.43)         0.34           Ridascreen toxin A/B         Techlab T				
Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.43 (0.21 to -3.08)         0.09           Premier Toxin A + B         Premier Immunocard A + B         4.30 (7.05 to 1.56)         0.002           Vidas C. difficile Toxin A & B         GA Clostridium difficile antigen         5.74 (8.74 to 2.74)         0.0001           Vidas C. difficile Toxin A & B         Ridascreen toxin A/B         1.64 (4.04 to -0.76)         0.20           Vidas C. difficile Toxin A & B         Techlab Toxin A/B         1.02 (3.46 to -1.41)         0.47           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.10 (7.00 to 1.19)         0.005           Vidas C. difficile Toxin A & B         Techlab Tox A/B Quik Chek         -1.84 (0.01 to -3.70)         0.05           Vidas C. difficile Toxin A & B         Techlab Tox A/B Quik Chek         -1.84 (0.01 to -3.70)         0.007           GA Clostridium difficile antigen         Techlab Tox A/B         -4.10 (-1.08 to -7.12)         0.007           GA Clostridium difficile antigen         Techlab Toxin A/B         -4.10 (-1.08 to -7.12)         0.001           GA Clostridium difficile antigen         Remel ProSpecT         -1.64 (1.72 to -5.00)         0.37           GA Clostridium difficile antigen         Remel ProSpecT         -1.64 (1.72 to -5.03)         0.0001           GA Clostridium difficile antigen				
Premier Toxin A + BPremier Immunocard A + B $4.30(7.05 \text{ to } 1.56)$ $0.002$ Vidas C. difficile Toxin A & BGA Clostridium difficile antigen $5.74(8.74 \text{ to } 2.74)$ $0.0001$ Vidas C. difficile Toxin A & BRidascreen toxin A/B $1.64(4.04 \text{ to } 0.76)$ $0.20$ Vidas C. difficile Toxin A & BTechlab Toxin A/B $1.02(3.46 \text{ to } -1.41)$ $0.47$ Vidas C. difficile Toxin A & BRemel ProSpecT $4.10(7.00 \text{ to } 1.19)$ $0.005$ Vidas C. difficile Toxin A & BRemel Xpect $-2.05(-0.25 \text{ to } -3.85)$ $0.02$ Vidas C. difficile Toxin A & BTechlab Toxin A/B $-1.84(0.01 \text{ to } -3.70)$ $0.05$ Vidas C. difficile Toxin A & BTechlab Toxin A/B $-4.10(-1.08 \text{ to } -7.12)$ $0.007$ GA Clostridium difficile antigenRidascreen toxin A/B $-4.10(-1.08 \text{ to } -7.12)$ $0.007$ GA Clostridium difficile antigenRemel ProSpecT $-1.64(1.72 \text{ to } -5.00)$ $0.37$ GA Clostridium difficile antigenRemel Xpect $-7.79(-5.07 \text{ to } -10.50) < 0.0001$ GA Clostridium difficile antigenTechlab Toxin A/B $-0.61(1.68 \text{ to } -2.91)$ $0.003$ GA Clostridium difficile antigenTechlab Toxin A/B $-0.61(1.68 \text{ to } -2.91)$ $0.001$ GA Clostridium difficile antigenTechlab Toxin A/B $-0.61(1.68 \text{ to } -2.91)$ $0.001$ GA Clostridium difficile antigenTechlab Toxin A/B $0.61(1.68 \text{ to } -2.91)$ $0.001$ Ridascreen toxin A/BRemel ProSpecT $2.46(5.19 \text{ to } -5.63)$ $0.0003$ Ridascreen toxin A/B				
Vidas C. difficile Toxin A & BGA Clostridium difficile antigen $5.74$ ( $8.74$ to $2.74$ ) $0.0001$ Vidas C. difficile Toxin A & BRidascreen toxin A/B $1.64$ ( $4.04$ to $-0.76$ ) $0.20$ Vidas C. difficile Toxin A & BTechlab Toxin A/B $1.02$ ( $3.46$ to $-1.41$ ) $0.47$ Vidas C. difficile Toxin A & BRemel ProSpecT $4.10$ ( $7.00$ to $1.19$ ) $0.005$ Vidas C. difficile Toxin A & BRemel Xpect $-2.05$ ( $-0.25$ to $-3.85$ ) $0.02$ Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek $-1.84$ ( $0.01$ to $-3.70$ ) $0.05$ Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek $-1.84$ ( $0.01$ to $-3.70$ ) $0.007$ GA Clostridium difficile antigenRidascreen toxin A/B $-4.10$ ( $-1.08$ to $-7.12$ ) $0.007$ GA Clostridium difficile antigenRemel ProSpecT $-1.64$ ( $1.72$ to $-5.00$ ) $0.37$ GA Clostridium difficile antigenRemel ProSpecT $-1.64$ ( $1.72$ to $-5.00$ ) $0.301$ GA Clostridium difficile antigenRemel Xpect $-7.79$ ( $-5.07$ to $-10.50$ ) $<0.0001$ GA Clostridium difficile antigenPremier Immunocard A + B $-1.84$ ( $1.74$ to $-5.43$ ) $0.344$ Ridascreen toxin A/BTechlab Toxin A/B $-0.61$ ( $1.68$ to $-2.91$ ) $0.70$ Ridascreen toxin A/BRemel ProSpecT $2.46$ ( $5.19$ to $-0.28$ ) $0.003$ Ridascreen toxin A/BRemel ProSpecT $3.07$ ( $5.96$ to $0.19$ ) $0.004$ Ridascreen toxin A/BRemel ProSpecT $3.07$ ( $5.96$ to $0.19$ ) $0.04$ Ridascreen toxin A/BRemel ProSp				
Vidas C. difficile Toxin A & BRidascreen toxin A/B1.64 ( 4.04 to -0.76)0.20Vidas C. difficile Toxin A & BTechlab Toxin A/B1.02 ( 3.46 to -1.41)0.47Vidas C. difficile Toxin A & BRemel ProSpecT4.10 ( 7.00 to 1.19)0.005Vidas C. difficile Toxin A & BRemel ProSpecT-2.05 (-0.25 to -3.85)0.02Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek-1.84 ( 0.01 to -3.70)0.05Vidas C. difficile Toxin A & BPremier Immunocard A + B3.89 ( 6.77 to 1.02)0.007GA Clostridium difficile antigenRidascreen toxin A/B-4.10 (-1.08 to -7.12)0.007GA Clostridium difficile antigenRemel ProSpecT-1.64 ( 1.72 to -5.00)0.37GA Clostridium difficile antigenRemel ProSpecT-1.64 ( 1.72 to -5.00)0.001GA Clostridium difficile antigenRemel Xpect-7.79 (-5.07 to -10.50)<0.0001			4.30 ( 7.05 to 1.56)	
Vidas C. difficile Toxin A & BTechlab Toxin A/B $1.02(3.46 \text{ to} -1.41)$ $0.47$ Vidas C. difficile Toxin A & BRemel ProSpecT $4.10(7.00 \text{ to} 1.19)$ $0.005$ Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek $-2.05(-0.25 \text{ to} -3.85)$ $0.02$ Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek $-1.84(0.01 \text{ to} -3.70)$ $0.05$ Vidas C. difficile Toxin A & BPremier Immunocard A + B $3.89(6.77 \text{ to} 1.02)$ $0.007$ GA Clostridium difficile antigenRidascreen toxin A/B $-4.10(-1.08 \text{ to} -7.12)$ $0.007$ GA Clostridium difficile antigenRemel ProSpecT $-1.64(1.72 \text{ to} -5.00)$ $0.37$ GA Clostridium difficile antigenRemel ProSpecT $-7.79(-5.07 \text{ to} -10.50)$ $<0.0001$ GA Clostridium difficile antigenRemel ProSpecT $-7.9(-5.07 \text{ to} -10.40)$ $<0.0001$ GA Clostridium difficile antigenTechlab Toxin A/B $-1.84(1.74 \text{ to} -5.43)$ $0.34$ Ridascreen toxin A/BTechlab Toxin A/B $-0.61(1.68 \text{ to} -2.91)$ $0.70$ Ridascreen toxin A/BRemel ProSpecT $2.46(5.19 \text{ to} -0.28)$ $0.003$ Ridascreen toxin A/BRemel Xpect $-3.69(-1.54 \text{ to} -5.63)$ $0.0003$ Ridascreen toxin A/BTechlab Tox A/B Quik Chek $-3.48(-1.29 \text{ to} -5.67)$ $0.0001$ Ridascreen toxin A/BRemel ProSpecT $2.46(5.19 \text{ to} -2.81)$ $0.002$ Ridascreen toxin A/BRemel ProSpecT $3.07(5.96 \text{ to} -3.94)$ $0.004$ Techlab Toxin A/BPremier Immunocard A + B $2.25(5.26  $	Vidas C. difficile Toxin A & B	GA Clostridium difficile antigen	5.74 ( 8.74 to 2.74)	
Vidas C. difficile Toxin A & B         Remel ProSpecT         4.10 (7.00 to 1.19)         0.005           Vidas C. difficile Toxin A & B         Remel Xpect         -2.05 (-0.25 to -3.85)         0.02           Vidas C. difficile Toxin A & B         Techlab Tox A/B Quik Chek         -1.84 (0.01 to -3.70)         0.05           Vidas C. difficile Toxin A & B         Premier Immunocard A + B         3.89 (6.77 to 1.02)         0.007           GA Clostridium difficile antigen         Ridascreen toxin A/B         -4.10 (-1.08 to -7.12)         0.003           GA Clostridium difficile antigen         Techlab Tox A/B Quik Chek         -4.10 (1.08 to -7.12)         0.001           GA Clostridium difficile antigen         Remel ProSpecT         -1.64 (1.72 to -5.00)         0.37           GA Clostridium difficile antigen         Remel Xpect         -7.79 (-5.07 to -10.50)         <0.0001	Vidas C. difficile Toxin A & B	Ridascreen toxin A/B	1.64 ( 4.04 to -0.76)	0.20
Vidas C. difficile Toxin A & BRemel Xpect $-2.05(-0.25$ to $-3.85)$ $0.02$ Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek $-1.84(0.01$ to $-3.70)$ $0.05$ Vidas C. difficile Toxin A & BPremier Immunocard A + B $3.89(6.77$ to $1.02)$ $0.007$ GA Clostridium difficile antigenRidascreen toxin A/B $-4.10(-1.08$ to $-7.12)$ $0.007$ GA Clostridium difficile antigenTechlab Toxin A/B $-4.71(-1.56$ to $-7.87)$ $0.003$ GA Clostridium difficile antigenRemel ProSpecT $-1.64(1.72$ to $-5.00)$ $0.37$ GA Clostridium difficile antigenRemel ProSpecT $-7.79(-5.07$ to $-10.50)$ $<0.0001$ GA Clostridium difficile antigenPremier Immunocard A + B $-1.84(1.74$ to $-5.43)$ $0.34$ Ridascreen toxin A/BTechlab Toxin A/B $-0.61(1.68$ to $-2.91)$ $0.70$ Ridascreen toxin A/BRemel ProSpecT $2.46(5.19$ to $-0.28)$ $0.08$ Ridascreen toxin A/BRemel Xpect $-3.69(-1.54$ to $-5.83)$ $0.0003$ Ridascreen toxin A/BRemel ProSpecT $2.46(5.19$ to $-0.76)$ $0.15$ Techlab Toxin A/BRemel ProSpecT $3.07(5.96$ to $0.19)$ $0.04$ Techlab Toxin A/BPremier Immunocard A + B $2.25(5.26$ to $-0.76)$ $0.15$ Techlab Toxin A/B IIRemel ProSpecT $3.07(5.96$ to $-4.94)$ $0.004$ Techlab Toxin A/B IIRemel Xpect $-3.07(-1.05$ to $-5.10)$ $0.002$ Techlab Toxin A/B IIPremier Immunocard A + B $2.87(5.90$ to $-0.16)$ $0.06$ Remel ProSpecTRemel X	Vidas C. difficile Toxin A & B	Techlab Toxin A/B	1.02 ( 3.46 to -1.41)	0.47
Vidas C. difficile Toxin A & B Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek Premier Immunocard A + B-1.84 ( 0.01 to -3.70)0.05GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigen Ca Clostridium difficile antigen Ca Clostridium difficile antigen Ca Clostridium difficile antigen Remel ProSpecT-4.10 (-1.08 to -7.12) -4.10 (-1.08 to -7.12)0.007GA Clostridium difficile antigen GA Clostridium difficile antigen Ca Clostridium difficile antigen Ca Clostridium difficile antigen Ca Clostridium difficile antigen Premier Immunocard A + B-4.71 (-1.56 to -7.87) -1.64 ( 1.72 to -5.00) -0.00010.37GA Clostridium difficile antigen GA Clostridium difficile antigen Premier Immunocard A + B-7.79 (-5.07 to -10.40) -0.61 ( 1.68 to -2.91) -0.700.0001GA Clostridium difficile antigen Ridascreen toxin A/BTechlab Toxin A/B Remel ProSpecT-0.61 ( 1.68 to -2.91) -0.61 ( 1.68 to -2.91) -0.700.003Ridascreen toxin A/BRemel ProSpecT2.46 ( 5.19 to -0.28) -0.0030.08Ridascreen toxin A/BRemel Xpect-3.69 (-1.54 to -5.83) -0.00030.003Ridascreen toxin A/BPremier Immunocard A + B2.25 ( 5.26 to -0.76) -0.150.15Techlab Toxin A/B IIRemel ProSpecT3.07 (-1.05 to -5.10) -0.0040.004Techlab Toxin A/B IIRemel Xpect-3.07 (-1.05 to -5.10) -0.0040.004Techlab Toxin A/B IIPremier Immunocard A + B2.87 (5.90 to -0.16) -0.0000.06Remel ProSpecTRemel Xpect-6.15 (-3.60 t	Vidas C. difficile Toxin A & B	Remel ProSpecT	4.10 (7.00 to 1.19)	0.005
Vidas C. difficile Toxin A & BPremier Immunocard A + B3.89 ( 6.77 to 1.02)0.007GA Clostridium difficile antigenRidascreen toxin A/B-4.10 (-1.08 to -7.12)0.007GA Clostridium difficile antigenTechlab Toxin A/B-4.71 (-1.56 to -7.87)0.003GA Clostridium difficile antigenRemel ProSpecT-1.64 ( 1.72 to -5.00)0.37GA Clostridium difficile antigenRemel Xpect-7.79 (-5.07 to -10.50)<0.0001	Vidas C. difficile Toxin A & B	Remel Xpect	-2.05 (-0.25 to -3.85)	0.02
GA Clostridium difficile antigen GA Clostridium difficile antigen Remel ProSpecT-4.10 (-1.08 to -7.12) -4.71 (-1.56 to -7.87) 0.003 -7.79 (-5.07 to -10.50)0.003 0.37GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigen CA Clostridium difficile antigen Premier Immunocard A + B-1.64 (1.72 to -5.00) -7.79 (-5.07 to -10.50) <0.0001	Vidas C. difficile Toxin A & B	Techlab Tox A/B Quik Chek	-1.84 (0.01 to -3.70)	0.05
GA Clostridium difficile antigen GA Clostridium difficile antigen Techlab Tox A/B Quik Chek-4.71 (-1.56 to -7.87) -1.64 (1.72 to -5.00) 0.370.003GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigen Premier Immunocard A + B-1.64 (1.72 to -5.00) -7.79 (-5.07 to -10.50) <0.0001GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigen Premier Immunocard A + B-7.58 (-4.77 to -10.40) -0.601 (1.68 to -2.91) 0.700.0001Ridascreen toxin A/B Ridascreen toxin A/BTechlab Toxin A/B Remel ProSpecT-0.61 (1.68 to -2.91) 2.46 (5.19 to -0.28) 0.080.08Ridascreen toxin A/B Ridascreen toxin A/BRemel ProSpecT2.46 (5.19 to -0.28) 0.00030.0003Ridascreen toxin A/B Ridascreen toxin A/BTechlab Tox A/B Quik Chek Premier Immunocard A + B-3.69 (-1.54 to -5.83) 2.25 (5.26 to -0.76)0.15Techlab Toxin A/B II Techlab Toxin A/B IIRemel ProSpecT3.07 (-1.05 to -5.10) 0.0020.004Techlab Toxin A/B II Techlab Tox A/B Quik Chek-2.87 (-0.80 to -4.94) 0.0040.004Techlab Toxin A/B II Premier Immunocard A + B2.87 (5.90 to -0.16) 0.060.06Remel ProSpecT Remel Xpect-6.15 (-3.60 to -8.70) -0.0001-0.0001Remel ProSpecT Remel ProSpecTTechlab Tox A/B Quik Chek -5.94 (-3.35 to -8.53) -0.0001	Vidas C. difficile Toxin A & B	Premier Immunocard A + B	3.89 (6.77 to 1.02)	0.007
GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigenRemel ProSpecT-1.64 (1.72 to -5.00)0.37GA Clostridium difficile antigen GA Clostridium difficile antigenRemel Xpect-7.79 (-5.07 to -10.50)<0.0001	GA Clostridium difficile antigen	Ridascreen toxin A/B	-4.10 (-1.08 to -7.12)	0.007
GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigenRemel Xpect Techlab Tox A/B Quik Chek Premier Immunocard A + B $-7.79(-5.07 \text{ to } -10.50)$ $<0.0001$ GA Clostridium difficile antigenTechlab Tox A/B Quik Chek Premier Immunocard A + B $-7.58(-4.77 \text{ to } -10.40)$ $<0.0001$ GA Clostridium difficile antigenPremier Immunocard A + B $-1.84(1.74 \text{ to } -5.43)$ $0.34$ Ridascreen toxin A/BTechlab Toxin A/B $-0.61(1.68 \text{ to } -2.91)$ $0.70$ Ridascreen toxin A/BRemel ProSpecT $2.46(5.19 \text{ to } -0.28)$ $0.08$ Ridascreen toxin A/BRemel Xpect $-3.69(-1.54 \text{ to } -5.83)$ $0.0003$ Ridascreen toxin A/BTechlab Tox A/B Quik Chek $-3.48(-1.29 \text{ to } -5.67)$ $0.0009$ Ridascreen toxin A/BTechlab Tox A/B Quik Chek $-3.48(-1.29 \text{ to } -5.67)$ $0.0009$ Ridascreen toxin A/BRemel ProSpecT $3.07(5.96 \text{ to } 0.19)$ $0.04$ Techlab Toxin A/B IIRemel ProSpecT $3.07(-1.05 \text{ to } -5.10)$ $0.002$ Techlab Toxin A/B IIRemel Xpect $-3.07(-1.05 \text{ to } -5.10)$ $0.004$ Techlab Toxin A/B IIPremier Immunocard A + B $2.87(5.90 \text{ to } -0.16)$ $0.06$ Remel ProSpecTRemel Xpect $-6.15(-3.60 \text{ to } -8.70)$ $<0.0001$ Remel ProSpecTRemel Xpect $-6.15(-3.60 \text{ to } -8.70)$ $<0.0001$ Remel ProSpecTPremier Immunocard A + B $-0.20(2.81 \text{ to } -3.22)$ $1.0000$ Remel ProSpecTPremier Immunocard A + B $-0.20(2.81 \text{ to } -3.49)$ <t< td=""><td>GA Clostridium difficile antigen</td><td>Techlab Toxin A/B</td><td>-4.71 (-1.56 to -7.87)</td><td>0.003</td></t<>	GA Clostridium difficile antigen	Techlab Toxin A/B	-4.71 (-1.56 to -7.87)	0.003
GA Clostridium difficile antigen GA Clostridium difficile antigenTechlab Tox A/B Quik Chek Premier Immunocard A + B $-7.58(-4.77 \text{ to } -10.40)$ $<0.0001$ Ridascreen toxin A/BTechlab Toxin A/B $-1.84(1.74 \text{ to } -5.43)$ $0.34$ Ridascreen toxin A/BTechlab Toxin A/B $-0.61(1.68 \text{ to } -2.91)$ $0.70$ Ridascreen toxin A/BRemel ProSpecT $2.46(5.19 \text{ to } -0.28)$ $0.08$ Ridascreen toxin A/BRemel Xpect $-3.69(-1.54 \text{ to } -5.83)$ $0.0003$ Ridascreen toxin A/BTechlab Tox A/B Quik Chek $-3.48(-1.29 \text{ to } -5.67)$ $0.0009$ Ridascreen toxin A/BPremier Immunocard A + B $2.25(5.26 \text{ to } -0.76)$ $0.15$ Techlab Toxin A/B IIRemel ProSpecT $3.07(5.96 \text{ to } 0.19)$ $0.04$ Techlab Toxin A/B IIRemel Xpect $-3.07(-1.05 \text{ to } -5.10)$ $0.002$ Techlab Toxin A/B IITechlab Tox A/B Quik Chek $-2.87(-0.80 \text{ to } -4.94)$ $0.004$ Techlab Toxin A/B IIPremier Immunocard A + B $2.87(5.90 \text{ to } -0.16)$ $0.06$ Remel ProSpecTRemel Xpect $-6.15(-3.60 \text{ to } -8.70)$ $<0.0001$ Remel ProSpecTTechlab Tox A/B Quik Chek $-5.94(-3.35 \text{ to } -8.53)$ $<0.0001$ Remel ProSpecTPremier Immunocard A + B $-0.20(2.81 \text{ to } -3.22)$ $1.0000$ Remel ProSpecTPremier Immunocard A + B $-0.20(2.81 \text{ to } -3.22)$ $1.0000$ Remel XpectTechlab Tox A/B Quik Chek $0.20(1.47 \text{ to } -1.06)$ $1.0000$ Remel XpectPremier Immunocard A + B $-0.20(2.81 \text{ to } -3.4$	GA Clostridium difficile antigen	Remel ProSpecT	-1.64 (1.72 to -5.00)	0.37
GA Clostridium difficile antigen         Premier Immunocard A + B         -1.84 (1.74 to -5.43)         0.34           Ridascreen toxin A/B         Techlab Toxin A/B         -0.61 (1.68 to -2.91)         0.70           Ridascreen toxin A/B         Remel ProSpecT         2.46 (5.19 to -0.28)         0.08           Ridascreen toxin A/B         Remel Xpect         -3.69 (-1.54 to -5.83)         0.0003           Ridascreen toxin A/B         Techlab Tox A/B Quik Chek         -3.48 (-1.29 to -5.67)         0.0009           Ridascreen toxin A/B         Premier Immunocard A + B         2.25 (5.26 to -0.76)         0.15           Techlab Toxin A/B         Premier Immunocard A + B         2.25 (5.26 to -0.76)         0.15           Techlab Toxin A/B II         Remel ProSpecT         3.07 (5.96 to 0.19)         0.04           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.002           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (-0.80 to -4.94)         0.004           Techlab Toxin A/B II         Premier Immunocard A + B         2.87 (5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	GA Clostridium difficile antigen	Remel Xpect	-7.79 (-5.07 to -10.50)	<0.0001
Ridascreen toxin A/B         Techlab Toxin A/B         -0.61 ( 1.68 to -2.91)         0.70           Ridascreen toxin A/B         Remel ProSpecT         2.46 ( 5.19 to -0.28)         0.08           Ridascreen toxin A/B         Remel Xpect         -3.69 (-1.54 to -5.83)         0.0003           Ridascreen toxin A/B         Techlab Tox A/B Quik Chek         -3.48 (-1.29 to -5.67)         0.0009           Ridascreen toxin A/B         Premier Immunocard A + B         2.25 ( 5.26 to -0.76)         0.15           Techlab Toxin A/B II         Remel ProSpecT         3.07 ( 5.96 to 0.19)         0.04           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.002           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.002           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.004           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (-0.80 to -4.94)         0.004           Techlab Toxin A/B II         Premier Immunocard A + B         2.87 ( 5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	GA Clostridium difficile antigen	Techlab Tox A/B Quik Chek	-7.58 (-4.77 to -10.40)	<0.0001
Ridascreen toxin A/B         Techlab Toxin A/B         -0.61 ( 1.68 to -2.91)         0.70           Ridascreen toxin A/B         Remel ProSpecT         2.46 ( 5.19 to -0.28)         0.08           Ridascreen toxin A/B         Remel Xpect         -3.69 (-1.54 to -5.83)         0.0003           Ridascreen toxin A/B         Techlab Tox A/B Quik Chek         -3.48 (-1.29 to -5.67)         0.0009           Ridascreen toxin A/B         Premier Immunocard A + B         2.25 ( 5.26 to -0.76)         0.15           Techlab Toxin A/B II         Remel ProSpecT         3.07 ( 5.96 to 0.19)         0.04           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.002           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.002           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.004           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (-0.80 to -4.94)         0.004           Techlab Toxin A/B II         Premier Immunocard A + B         2.87 ( 5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	GA Clostridium difficile antigen	Premier Immunocard A + B	-1.84 ( 1.74 to -5.43)	0.34
Ridascreen toxin A/B         Remel Xpect         -3.69 (-1.54 to -5.83)         0.0003           Ridascreen toxin A/B         Techlab Tox A/B Quik Chek         -3.48 (-1.29 to -5.67)         0.0009           Ridascreen toxin A/B         Premier Immunocard A + B         2.25 (5.26 to -0.76)         0.15           Techlab Toxin A/B II         Remel ProSpecT         3.07 (5.96 to 0.19)         0.04           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.002           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.004           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (-0.80 to -4.94)         0.004           Techlab Toxin A/B II         Premier Immunocard A + B         2.87 (5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	Ridascreen toxin A/B	Techlab Toxin A/B	-0.61 ( 1.68 to -2.91)	0.70
Ridascreen toxin A/B         Techlab Tox A/B Quik Chek         -3.48 (-1.29 to -5.67)         0.0009           Ridascreen toxin A/B         Premier Immunocard A + B         2.25 (5.26 to -0.76)         0.15           Techlab Toxin A/B II         Remel ProSpecT         3.07 (5.96 to 0.19)         0.04           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.002           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (-0.80 to -4.94)         0.004           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	Ridascreen toxin A/B	Remel ProSpecT	2.46 (5.19 to -0.28)	0.08
Ridascreen toxin A/B         Premier Immunocard A + B         2.25 (5.26 to -0.76)         0.15           Techlab Toxin A/B II         Remel ProSpecT         3.07 (5.96 to 0.19)         0.04           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.002           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (-0.80 to -4.94)         0.004           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	Ridascreen toxin A/B	Remel Xpect	-3.69 (-1.54 to -5.83)	0.0003
Techlab Toxin A/B II         Remel ProSpecT         3.07 (5.96 to 0.19)         0.04           Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.002           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (-0.80 to -4.94)         0.004           Techlab Toxin A/B II         Premier Immunocard A + B         2.87 (5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	Ridascreen toxin A/B	Techlab Tox A/B Quik Chek	-3.48 (-1.29 to -5.67)	0.0009
Techlab Toxin A/B II         Remel Xpect         -3.07 (-1.05 to -5.10)         0.002           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (-0.80 to -4.94)         0.004           Techlab Toxin A/B II         Premier Immunocard A + B         2.87 (5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	Ridascreen toxin A/B	Premier Immunocard A + B	2.25 ( 5.26 to -0.76)	0.15
Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (-0.80 to -4.94)         0.004           Techlab Toxin A/B II         Premier Immunocard A + B         2.87 (5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	Techlab Toxin A/B II	Remel ProSpecT	3.07 (5.96 to 0.19)	0.04
Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.87 (-0.80 to -4.94)         0.004           Techlab Toxin A/B II         Premier Immunocard A + B         2.87 (5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	Techlab Toxin A/B II	Remel Xpect	-3.07 (-1.05 to -5.10)	0.002
Techlab Toxin A/B II         Premier Immunocard A + B         2.87 (5.90 to -0.16)         0.06           Remel ProSpecT         Remel Xpect         -6.15 (-3.60 to -8.70)         <0.0001	Techlab Toxin A/B II	Techlab Tox A/B Quik Chek		0.004
Remel ProSpecT         Techlab Tox A/B Quik Chek         -5.94 (-3.35 to -8.53)         <0.0001           Remel ProSpecT         Premier Immunocard A + B         -0.20 (2.81 to -3.22)         1.0000           Remel Xpect         Techlab Tox A/B Quik Chek         0.20 (1.47 to -1.06)         1.0000           Remel Xpect         Premier Immunocard A + B         5.94 (8.39 to 3.49)         <0.0001	Techlab Toxin A/B II	Premier Immunocard A + B		0.06
Remel ProSpecT         Techlab Tox A/B Quik Chek         -5.94 (-3.35 to -8.53)         <0.0001           Remel ProSpecT         Premier Immunocard A + B         -0.20 (2.81 to -3.22)         1.0000           Remel Xpect         Techlab Tox A/B Quik Chek         0.20 (1.47 to -1.06)         1.0000           Remel Xpect         Premier Immunocard A + B         5.94 (8.39 to 3.49)         <0.0001	Remel ProSpecT		· · · · ·	< 0.0001
Remel ProSpecT         Premier Immunocard A + B         -0.20 (2.81 to -3.22)         1.0000           Remel Xpect         Techlab Tox A/B Quik Chek         0.20 (1.47 to -1.06)         1.0000           Remel Xpect         Premier Immunocard A + B         5.94 (8.39 to 3.49)         <0.0001				
Remel Xpect         Techlab Tox A/B Quik Chek         0.20 (1.47 to -1.06)         1.0000           Remel Xpect         Premier Immunocard A + B         5.94 (8.39 to 3.49)         <0.0001		Premier Immunocard A + B		
Remel Xpect         Premier Immunocard A + B         5.94 (8.39 to 3.49)         <0.0001				

# Table 16. Estimated difference in specificity against cytotoxigenic culture foreach pair of comparative assays

Assays         Estimated difference (98% CI)         P value           Cytotoxin assay         Premier Toxin A + B         1.68 (3.54 to -0.17)         0.0768           Cytotoxin assay         GA Clostridium difficile antigen         7.79 (10.68 to 4.90)         <0.0001           Cytotoxin assay         Ridascreen toxin A/B         3.58 (5.83 to 1.33)         0.0002           Cytotoxin assay         Techlab Toxin A/B         3.16 (5.33 to 0.99)         0.0026           Cytotoxin assay         Remel ProSpecT         5.89 (8.45 to 3.34)         <0.0001           Cytotoxin assay         Remel ProSpecT         5.89 (8.45 to 3.34)         <0.0001           Cytotoxin assay         Techlab Tox A/B Quik Chek         0.21 (1.96 to 1.51)         1.0000           Cytotoxin assay         Premier Immunocard A + B         6.11 (8.69 to 3.52)         <0.0002           Premier Toxin A + B         GA Clostridium difficile antigen         6.11 (8.69 to 3.52)         <0.0001           Premier Toxin A + B         Ridascreen toxin A/B         1.47 (3.90 to -0.95)         0.1360           Premier Toxin A + B         Remel ProSpecT         4.21 (6.87 to 1.55)         0.0012           Premier Toxin A + B         Remel Xpect         -1.89 (-0.21 to -3.56)         0.0225           Premier Toxin A + B         Rechal Tox A/B Quik Chek	^	-	Estimated difference (95% CI)	P value
Cytotoxin assay         Vidas C. difficile Toxin A & B         1.89 (3.80 to -0.01)         0.0490           Cytotoxin assay         GA Clostridium difficile antigen         7.79 (10.68 to 4.90)         <0.0001			· · · · · · · · · · · · · · · · · · ·	
Cytotoxin assay         GA Clostridium difficile antigen         7.79 (10.68 to 4.90)         <0.0001           Cytotoxin assay         Ridascreen toxin A/B         3.56 (5.33 to 1.33)         0.0009           Cytotoxin assay         Techlab Toxin A/B         3.16 (5.33 to 1.99)         0.0026           Cytotoxin assay         Remel ProSpecT         5.89 (8.45 to 3.34)         <0.0001				
Cytotoxin assay         Ridascreen toxin A/B         3.58 (5.83 to 1.33)         0.0009           Cytotoxin assay         Techlab Toxin A/B         3.16 (5.33 to 0.99)         0.0026           Cytotoxin assay         Remel ProSpecT         5.89 (8.45 to 3.34)         <0.0001				
Cytotoxin assay         Techlab Toxin A/B         3.16 (5.33 to 0.99)         0.0026           Cytotoxin assay         Remel ProSpecT         5.89 (8.45 to 3.34)         <0.0001			· · · · ·	
Cytotoxin assay         Remel ProSpecT         5.89 (8.45 to 3.34)         <0.0001           Cytotoxin assay         Remel Xpect         -0.21 (1.09 to -1.51)         1.0000           Cytotoxin assay         Techlab Tox A/B Quik Chek         0.21 (1.66 to -1.24)         1.0000           Cytotoxin assay         Premier Immunocard A + B         6.11 (8.69 to 3.52)         <0.0002				
Cytotoxin assay         Remel Xpect         -0.21 (1.09 to -1.51)         1.0000           Cytotoxin assay         Techlab Tox A/B Quik Chek         0.21 (1.66 to -1.24)         1.0000           Cytotoxin assay         Premier Immunocard A + B         6.11 (8.69 to 3.52)         <0.0002			· · · · · ·	
Cytotoxin assay         Techlab Tox A/B Quik Chek         0.21 (1.66 to -1.24)         1.0000           Cytotoxin assay         Premier Immunocard A + B         6.11 (8.69 to 3.52)         <0.0002			· · · · ·	
Cytotoxin assay         Premier Immunocard A + B         6.11 ( 8.69 to 3.52)         <0.0002           Premier Toxin A + B         Vidas C. difficile Toxin A & B         0.21 ( 2.40 to -1.98)         1.0000           Premier Toxin A + B         Ridascreen toxin A/B         1.89 ( 4.32 to -0.53)         0.1360           Premier Toxin A + B         Techlab Toxin A/B         1.89 ( 4.32 to -0.53)         0.1360           Premier Toxin A + B         Remel ProSpecT         4.21 ( 6.87 to 1.55)         0.0012           Premier Toxin A + B         Remel ProSpecT         4.21 ( 6.87 to 1.55)         0.0023           Premier Toxin A + B         Remel ProSpecT         4.21 ( 6.87 to 1.55)         0.0023           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.89 (-0.21 to -3.68)         0.0025           Vidas C. difficile Toxin A & B         Ridascreen toxin A/B         1.86 ( 3.99 to -0.62)         0.0686           Vidas C. difficile Toxin A & B         Redel ProSpecT         4.00 ( 6.89 to 1.11)         0.0349           Vidas C. difficile Toxin A & B         Remel Xpect         -2.11 (-0.36 to -3.85)         0.0129           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 ( 6.89 to 1.11)         0.0554           Vidas C. difficile Toxin A & B         Premier Immunocard A + B         4.21 ( 7.07 to 1.35)         <			· · · · · ·	
Premier Toxin A + B         Vidas C. difficile Toxin A & B         0.21 ( 2.40 to -1.98)         1.0000           Premier Toxin A + B         GA Clostridium difficile antigen         6.11 ( 9.09 to 3.12)         <0.0001			· · · · ·	
Premier Toxin A + B         GA Clostridium difficile antigen         6.11 (9.09 to 3.12)         <0.0001           Premier Toxin A + B         Ridascreen toxin A/B         1.88 (4.32 to -0.53)         0.1360           Premier Toxin A + B         Techlab Toxin A/B         1.47 (3.90 to -0.95)         0.2649           Premier Toxin A + B         Remel ProSpecT         4.21 (6.87 to 1.55)         0.0012           Premier Toxin A + B         Remel Xpect         -1.89 (-0.21 to -3.58)         0.0225           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.47 (0.22 to -3.17)         0.0923           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.48 (0.91 to 2.88)         0.00015           Vidas C. difficile Toxin A & B         Ridascreen toxin A/B         1.26 (3.65 to -1.13)         0.3449           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 (6.89 to 1.11)         0.0054           Vidas C. difficile Toxin A & B         Remel Xpect         -2.11 (-0.36 to -3.85)         0.0029           GA Clostridium difficile antigen         Ridascreen toxin A/B         -4.21 (-1.71 to -7.25)         0.0055           GA Clostridium difficile antigen         Ridascreen toxin A/B         -4.21 (-1.71 to -7.25)         0.0038           GA Clostridium difficile antigen         Ridascreen toxin A/B         -4.21 (			· · · · · · · · · · · · · · · · · · ·	
Premier Toxin A + B         Ridascreen toxin A/B         1.89 (4.32 to -0.53)         0.1360           Premier Toxin A + B         Techlab Toxin A/B         1.47 (3.90 to -0.95)         0.2649           Premier Toxin A + B         Remel ProSpecT         4.21 (6.87 to 1.55)         0.0012           Premier Toxin A + B         Remel Xpect         -1.89 (-0.21 to -3.58)         0.0225           Premier Toxin A + B         Premier Immunocard A + B         4.42 (7.24 to 1.60)         0.0015           Vidas C. difficile Toxin A & B         Ridascreen toxin A/B         1.68 (3.99 to -0.62)         0.1860           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 (6.89 to 1.11)         0.0054           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 (6.89 to 1.11)         0.0054           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 (6.89 to 1.11)         0.0054           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 (6.89 to 1.11)         0.0055           GA Clostridium difficile antigen         Ridascreen toxin A/B         4.21 (7.07 to 1.35)         0.0029           GA Clostridium difficile antigen         Ridascreen toxin A/B         4.21 (7.07 to 1.35)         0.0035           GA Clostridium difficile antigen         Remel Xpect         -8.00 (-5.21 to -10.79)				
Premier Toxin A + B         Techlab Toxin A/B         1.47 ( 3.90 to -0.95)         0.2649           Premier Toxin A + B         Remel ProSpecT         4.21 ( 6.87 to 1.55)         0.0012           Premier Toxin A + B         Remel Xpect         -1.89 (-0.21 to -3.58)         0.0225           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.47 ( 0.22 to -3.17)         0.0923           Premier Toxin A + B         Premier Immunocard A + B         4.42 ( 7.24 to 1.60)         0.0015           Vidas C. difficile Toxin A & B         Ridascreen toxin A/B         1.68 ( 3.99 to -0.62)         0.1686           Vidas C. difficile Toxin A & B         Remel Xpect         -2.11 (-0.36 to -3.85)         0.0129           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 ( 6.89 to 1.11)         0.00574           Vidas C. difficile Toxin A & B         Remel Xpect         -2.11 (-0.36 to -3.43)         0.0574           Vidas C. difficile Toxin A & B         Premier Immunocard A + B         4.21 (7.07 to 1.35)         0.0029           GA Clostridium difficile antigen         Remel ProSpecT         -1.89 (1.48 to -5.27)         0.2976           GA Clostridium difficile antigen         Remel ProSpecT         -1.89 (1.48 to -5.27)         0.2976           GA Clostridium difficile antigen         Remel ProSpecT         -2.32 ( 5.09 to -				
Premier Toxin A + B         Remel ProSpecT         4.21 ( 6.87 to 1.55)         0.0012           Premier Toxin A + B         Remel Xpect         -1.89 (-0.21 to -3.58)         0.0225           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.47 ( 0.22 to -3.17)         0.0923           Premier Toxin A + B         Premier Immunocard A + B         4.42 ( 7.24 to 1.60)         0.00115           Vidas C. difficile Toxin A & B         GA Clostridium difficile antigen         5.89 ( 8.91 to 2.88)         0.0001           Vidas C. difficile Toxin A & B         Recel ProSpecT         4.00 ( 6.89 to 1.13)         0.3449           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 ( 6.89 to 1.11)         0.0055           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 ( 6.89 to 1.33)         0.0574           Vidas C. difficile Toxin A & B         Remel Xpect         -2.11 (-0.36 to -3.43)         0.0574           Vidas C. difficile Toxin A & B         Premier Immunocard A + B         4.21 ( 7.07 to 1.35)         0.0038           GA Clostridium difficile antigen         Ridascreen toxin A/B         -4.63 (-1.42 to -7.85)         0.0038           GA Clostridium difficile antigen         Remel ProSpecT         -1.89 ( 1.48 to -5.27)         0.2976           GA Clostridium difficile antigen         Remel ProSpecT				
Premier Toxin A + B         Remel Xpect         -1.89 (-0.21 to -3.58)         0.0225           Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.47 (0.22 to -3.17)         0.0923           Vidas C. difficile Toxin A & B         GA Clostridium difficile antigen         5.89 (8.91 to 2.88)         0.00015           Vidas C. difficile Toxin A & B         Ridascreen toxin A/B         1.68 (3.99 to -0.62)         0.1686           Vidas C. difficile Toxin A & B         Rechlab Toxin A/B         1.26 (3.65 to -1.13)         0.3449           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 (6.89 to 1.11)         0.00574           Vidas C. difficile Toxin A & B         Remel Xpect         -2.11 (-0.36 to -3.85)         0.0129           Vidas C. difficile Toxin A & B         Techlab Tox A/B Quik Chek         -1.88 (0.06 to -3.43)         0.0574           Vidas C. difficile Toxin A & B         Techlab Tox A/B Quik Chek         -1.88 (0.06 to -3.43)         0.0296           GA Clostridium difficile antigen         Ridascreen toxin A/B         -4.21 (-1.71 to -7.25)         0.0055           GA Clostridium difficile antigen         Remel Xpect         -8.00 (-5.21 to -10.79)         <0.0001				
Premier Toxin A + B         Techlab Tox A/B Quik Chek         -1.47 (0.22 to -3.17)         0.0923           Premier Toxin A + B         Premier Immunocard A + B         4.42 (7.24 to 1.60)         0.0015           Vidas C. difficile Toxin A & B         GA Clostridium difficile antigen         5.89 (8.91 to 2.88)         0.0001           Vidas C. difficile Toxin A & B         Ridascreen toxin A/B         1.68 (3.99 to -0.62)         0.1686           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 (6.89 to 1.11)         0.0044           Vidas C. difficile Toxin A & B         Remel ProSpecT         4.00 (6.89 to 1.11)         0.00574           Vidas C. difficile Toxin A & B         Remel ProSpecT         -2.11 (-0.36 to -3.85)         0.0129           Vidas C. difficile Toxin A & B         Techlab Tox A/B Quik Chek         -1.68 (0.06 to -3.43)         0.0574           Vidas C. difficile antigen         Ridascreen toxin A/B         -4.21 (7.07 to 1.35)         0.0029           GA Clostridium difficile antigen         Techlab Tox A/B Quik Chek         -1.89 (1.48 to -5.27)         0.2976           GA Clostridium difficile antigen         Remel ProSpecT         -1.89 (1.48 to -5.21)         0.20976           GA Clostridium difficile antigen         Techlab Toxin A/B         -0.42 (1.89 to -2.74)         0.8450           Ridascreen toxin A/B		•		
Premier Toxin A + BPremier Immunocard A + B $4.42$ ( $7.24$ to $1.60$ ) $0.0015$ Vidas C. difficile Toxin A & BGA Clostridium difficile antigen $5.89$ ( $8.91$ to $2.88$ ) $0.0001$ Vidas C. difficile Toxin A & BRidascreen toxin A/B $1.68$ ( $3.99$ to $-0.62$ ) $0.1686$ Vidas C. difficile Toxin A & BTechlab Toxin A/B $1.26$ ( $3.65$ to $-1.13$ ) $0.3449$ Vidas C. difficile Toxin A & BRemel ProSpecT $4.00$ ( $6.89$ to $1.11$ ) $0.0054$ Vidas C. difficile Toxin A & BRemel Xpect $-2.11$ ( $-0.36$ to $-3.85$ ) $0.0129$ Vidas C. difficile Toxin A & BPremier Immunocard A + B $4.21$ ( $7.07$ to $1.35$ ) $0.0029$ GA Clostridium difficile antigenRidascreen toxin A/B $-4.21$ ( $-1.17$ to $-7.25$ ) $0.0055$ GA Clostridium difficile antigenRemel Xpect $-8.00$ ( $-5.21$ to $-10.79$ ) $<0.0001$ GA Clostridium difficile antigenRemel Xpect $-8.00$ ( $-5.21$ to $-10.79$ ) $<0.0001$ GA Clostridium difficile antigenRemel Xpect $-8.00$ ( $-5.21$ to $-10.44$ ) $<0.0001$ GA Clostridium difficile antigenTechlab Toxin A/B $-0.42$ ( $1.89$ to $-2.74$ ) $0.8450$ Ridascreen toxin A/BTechlab Toxin A/B $-0.42$ ( $1.89$ to $-2.74$ ) $0.8450$ Ridascreen toxin A/BRemel ProSpecT $2.32$ ( $5.09$ to $-0.46$ ) $0.1081$ Ridascreen toxin A/BRemel ProSpecT $2.32$ ( $5.09$ to $-0.46$ ) $0.1081$ Ridascreen toxin A/BRemel ProSpecT $2.32$ ( $5.65$ to $-0.591$ ) $0.0001$ Ridascreen toxin A/BRemel ProSp				
Vidas C. difficile Toxin A & BGA Clostridium difficile antigen $5.89$ ( $8.91$ to $2.88$ ) $0.0001$ Vidas C. difficile Toxin A & BRidascreen toxin A/B $1.68$ ( $3.99$ to $-0.62$ ) $0.1686$ Vidas C. difficile Toxin A & BTechlab Toxin A/B $1.26$ ( $3.65$ to $-1.13$ ) $0.3449$ Vidas C. difficile Toxin A & BRemel ProSpecT $4.00$ ( $6.89$ to $1.11$ ) $0.0054$ Vidas C. difficile Toxin A & BRemel ProSpecT $-2.11$ ( $-0.36$ to $-3.85$ ) $0.0129$ Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek $-1.68$ ( $0.06$ to $-3.43$ ) $0.0574$ Vidas C. difficile Toxin A & BPremier Immunocard A + B $4.21$ ( $-1.77$ to $1.35$ ) $0.0029$ GA Clostridium difficile antigenRidascreen toxin A/B $-4.21$ ( $-1.77$ to $-7.25$ ) $0.0055$ GA Clostridium difficile antigenRemel ProSpecT $-1.89$ ( $1.48$ to $-5.27$ ) $0.2976$ GA Clostridium difficile antigenRemel ProSpecT $-1.89$ ( $1.48$ to $-5.27$ ) $0.2001$ GA Clostridium difficile antigenRemel Xpect $-8.00$ ( $-5.21$ to $-10.79$ ) $<0.0001$ GA Clostridium difficile antigenPremier Immunocard A + B $-1.68$ ( $1.98$ to $-5.34$ ) $0.4030$ Ridascreen toxin A/BRemel ProSpecT $2.32$ ( $5.09$ to $-0.46$ ) $0.1081$ Ridascreen toxin A/BRemel ProSpecT $2.32$ ( $5.09$ to $-0.46$ ) $0.1081$ Ridascreen toxin A/BRemel ProSpecT $2.37$ ( $-1.67$ to $-5.91$ ) $0.0001$ Ridascreen toxin A/BRemel ProSpecT $2.37$ ( $-1.67$ to $-5.91$ ) $0.0001$ Ridascreen toxin A				
Vidas C. difficile Toxin A & BRidascreen toxin A/B $1.68 (3.99 to -0.62)$ $0.1686$ Vidas C. difficile Toxin A & BTechlab Toxin A/B $1.26 (3.65 to -1.13)$ $0.3449$ Vidas C. difficile Toxin A & BRemel ProSpecT $4.00 (6.89 to 1.11)$ $0.0054$ Vidas C. difficile Toxin A & BRemel Xpect $-2.11 (-0.36 to -3.43)$ $0.0574$ Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek $-1.68 (0.06 to -3.43)$ $0.0574$ Vidas C. difficile Toxin A & BPremier Immunocard A + B $4.21 (7.07 to 1.35)$ $0.0029$ GA Clostridium difficile antigenRidascreen toxin A/B $-4.63 (-1.42 to 7.85)$ $0.0038$ GA Clostridium difficile antigenRemel ProSpecT $-1.89 (1.48 to -5.27)$ $0.2976$ GA Clostridium difficile antigenRemel Xpect $-8.00 (-5.21 to -10.79)$ $<0.0001$ GA Clostridium difficile antigenTechlab Toxin A/B $-0.42 (1.89 to -5.34)$ $0.4030$ Ridascreen toxin A/BTechlab Toxin A/B $-0.42 (1.89 to -2.74)$ $0.8450$ Ridascreen toxin A/BRemel ProSpecT $2.32 (5.09 to -0.46)$ $0.1081$ Ridascreen toxin A/BRemel ProSpecT $2.32 (5.09 to -0.46)$ $0.1081$ Ridascreen toxin A/BRemel ProSpecT $2.74 (5.64 to -0.17)$ $0.0001$ Ridascreen toxin A/BRemel ProSpecT $2.74 (5.64 to -0.17)$ $0.0660$ Remal ProSpecT $2.74 (5.64 to -0.17)$ $0.0604$ $-6.11 (-3.59 to -8.62)$ $0.00043$ Techlab Toxin A/BPremier Immunocard A + B $2.95 (6.06 to -0.17)$ $0.0649$ <t< td=""><td></td><td></td><td></td><td></td></t<>				
Vidas C. difficile Toxin A & BTechlab Toxin A/B $1.26 (3.65 to -1.13)$ $0.3449$ Vidas C. difficile Toxin A & BRemel ProSpecT $4.00 (6.89 to 1.11)$ $0.0054$ Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek $-2.11 (-0.36 to -3.85)$ $0.0129$ Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek $-1.68 (0.06 to -3.43)$ $0.0574$ Vidas C. difficile Toxin A & BPremier Immunocard A + B $4.21 (7.07 to 1.35)$ $0.0029$ GA Clostridium difficile antigenRidascreen toxin A/B $-4.21 (-1.17 to -7.25)$ $0.0038$ GA Clostridium difficile antigenRemel ProSpecT $-1.89 (1.48 to -5.27)$ $0.2976$ GA Clostridium difficile antigenRemel ProSpecT $-8.00 (-5.21 to -10.79)$ $<0.0001$ GA Clostridium difficile antigenTechlab Toxin A/B $-0.42 (1.89 to -5.34)$ $0.4030$ Gidascreen toxin A/BTechlab Toxin A/B $-0.42 (1.89 to -5.34)$ $0.4030$ Ridascreen toxin A/BRemel ProSpecT $2.32 (5.09 to -0.46)$ $0.1081$ Ridascreen toxin A/BRemel ProSpecT $2.32 (5.09 to -0.46)$ $0.1081$ Ridascreen toxin A/BRemel ProSpecT $2.32 (5.65 to -0.59)$ $0.1189$ Ridascreen toxin A/BRemel ProSpecT $2.74 (5.64 to -0.17)$ $0.06001$ Ridascreen toxin A/BRemel ProSpecT $2.74 (5.64 to -0.17)$ $0.0601$ Ridascreen toxin A/BRemel ProSpecT $2.74 (5.64 to -0.17)$ $0.0004$ Remel Doxin A/BRemel ProSpecT $2.74 (5.64 to -0.17)$ $0.0660$ Rechlab Toxin A/B <td< td=""><td></td><td></td><td></td><td></td></td<>				
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Vidas C. difficile Toxin A & BRemel Xpect $-2.11(-0.36 \text{ to } -3.85)$ $0.0129$ Vidas C. difficile Toxin A & BTechlab Tox A/B Quik Chek $-1.68(0.06 \text{ to } -3.43)$ $0.0574$ Vidas C. difficile Toxin A & BPremier Immunocard A + B $4.21(7.07 \text{ to } 1.35)$ $0.0029$ GA Clostridium difficile antigenRidascreen toxin A/B $-4.21(-1.17 \text{ to } -7.25)$ $0.0055$ GA Clostridium difficile antigenTechlab Toxin A/B $-4.63(-1.42 \text{ to } -7.85)$ $0.0038$ GA Clostridium difficile antigenRemel ProSpecT $-1.89(1.48 \text{ to } -5.27)$ $0.2976$ GA Clostridium difficile antigenRemel ProSpecT $-8.00(-5.21 \text{ to } -10.49)$ $<0.0001$ GA Clostridium difficile antigenTechlab Toxin A/B $-0.42(1.89 \text{ to } -3.34)$ $0.4030$ Ridascreen toxin A/BTechlab Toxin A/B $-0.42(1.89 \text{ to } -3.74)$ $0.8450$ Ridascreen toxin A/BRemel ProSpecT $2.32(5.09 \text{ to } -0.46)$ $0.1081$ Ridascreen toxin A/BRemel Xpect $-3.79(-1.67 \text{ to } -5.91)$ $0.0001$ Ridascreen toxin A/BRemel ProSpecT $2.74(5.64 \text{ to } -0.17)$ $0.6660$ Techlab Toxin A/BPremier Immunocard A + B $2.53(5.65 \text{ to } -0.59)$ $0.1189$ Ridascreen toxin A/BRemel ProSpecT $2.74(5.64 \text{ to } -0.17)$ $0.0660$ Techlab Toxin A/B IIRemel ProSpecT $2.74(5.64 \text{ to } -0.17)$ $0.0660$ Techlab Toxin A/B IIPremier Immunocard A + B $2.95(6.06 \text{ to } -0.17)$ $0.0649$ Remel ProSpecTRemel Xpect $-6.11(-3.59 \text{ to } -8.62$				
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Vidas C. difficile Toxin A & BPremier Immunocard A + B $4.21(7.07 \text{ to } 1.35)$ $0.0029$ GA Clostridium difficile antigenRidascreen toxin A/B $-4.21(-1.17 \text{ to } -7.25)$ $0.0055$ GA Clostridium difficile antigenTechlab Toxin A/B $-4.63(-1.42 \text{ to } -7.85)$ $0.0038$ GA Clostridium difficile antigenRemel ProSpecT $-1.89(1.48 \text{ to } -5.27)$ $0.2976$ GA Clostridium difficile antigenRemel Xpect $-8.00(-5.21 \text{ to } -10.79)$ $<0.0001$ GA Clostridium difficile antigenTechlab Tox A/B Quik Chek $-7.58(-4.72 \text{ to } -10.44)$ $<0.0001$ GA Clostridium difficile antigenPremier Immunocard A + B $-1.68(1.98 \text{ to } -5.34)$ $0.4030$ Ridascreen toxin A/BTechlab Toxin A/B $-0.42(1.89 \text{ to } -2.74)$ $0.8450$ Ridascreen toxin A/BRemel ProSpecT $2.32(5.09 \text{ to } -0.46)$ $0.1081$ Ridascreen toxin A/BRemel Xpect $-3.79(-1.67 \text{ to } -5.91)$ $0.0001$ Ridascreen toxin A/BTechlab Tox A/B Quik Chek $-3.37(-1.16 \text{ to } -5.58)$ $0.0015$ Ridascreen toxin A/BTechlab Tox A/B Quik Chek $-3.37(-1.16 \text{ to } -5.58)$ $0.0015$ Ridascreen toxin A/BPremier Immunocard A + B $2.53(5.65 \text{ to } -0.59)$ $0.1189$ Techlab Toxin A/B IIRemel Xpect $-3.37(-1.16 \text{ to } -5.08)$ $0.0043$ Techlab Toxin A/B IIRemel Xpect $-3.37(-1.34 \text{ to } -5.40)$ $0.0043$ Techlab Toxin A/B IIPremier Immunocard A + B $2.95(6.06 \text{ to } -0.17)$ $0.0669$ Remel ProSpecTRemel Xpect <td< td=""><td></td><td></td><td></td><td></td></td<>				
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GA Clostridium difficile antigen         Techlab Toxin A/B         -4.63 (-1.42 to -7.85)         0.0038           GA Clostridium difficile antigen         Remel ProSpecT         -1.89 (1.48 to -5.27)         0.2976           GA Clostridium difficile antigen         Remel Xpect         -8.00 (-5.21 to -10.79)         <0.0001				
GA Clostridium difficile antigen GA Clostren Ga Clost on 0.001 Remel ProSpecT Remel Xpect Chil Clost to -0.80				
GA Clostridium difficile antigen GA Clostridium difficile antigen GA Clostridium difficile antigenRemel Xpect-8.00 (-5.21 to -10.79)<0.0001GA Clostridium difficile antigen GA Clostridium difficile antigenTechlab Tox A/B Quik Chek Premier Immunocard A + B-7.58 (-4.72 to -10.44)<0.0001				
GA Clostridium difficile antigen         Techlab Tox A/B Quik Chek         -7.58 (-4.72 to -10.44)         <0.0001           GA Clostridium difficile antigen         Premier Immunocard A + B         -1.68 (1.98 to -5.34)         0.4030           Ridascreen toxin A/B         Techlab Toxin A/B         -0.42 (1.89 to -2.74)         0.8450           Ridascreen toxin A/B         Remel ProSpecT         2.32 (5.09 to -0.46)         0.1081           Ridascreen toxin A/B         Remel ProSpecT         2.379 (-1.67 to -5.91)         0.0001           Ridascreen toxin A/B         Techlab Tox A/B Quik Chek         -3.37 (-1.16 to -5.58)         0.0015           Ridascreen toxin A/B         Premier Immunocard A + B         2.53 (5.65 to -0.59)         0.1189           Techlab Toxin A/B         Premier Immunocard A + B         2.53 (5.65 to -0.17)         0.0660           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.40)         0.0004           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.08)         0.0043           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.95 (-0.82 to -5.08)         0.0043           Techlab Toxin A/B II         Premier Immunocard A + B         2.95 (6.06 to -0.17)         0.0649           Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.		•		
GA Clostridium difficile antigenPremier Immunocard A + B $-1.68 (1.98 \text{ to} -5.34)$ $0.4030$ Ridascreen toxin A/BTechlab Toxin A/B $-0.42 (1.89 \text{ to} -2.74)$ $0.8450$ Ridascreen toxin A/BRemel ProSpecT $2.32 (5.09 \text{ to} -0.46)$ $0.1081$ Ridascreen toxin A/BRemel Xpect $-3.79 (-1.67 \text{ to} -5.91)$ $0.0001$ Ridascreen toxin A/BTechlab Tox A/B Quik Chek $-3.37 (-1.16 \text{ to} -5.58)$ $0.0015$ Ridascreen toxin A/BPremier Immunocard A + B $2.53 (5.65 \text{ to} -0.59)$ $0.1189$ Techlab Toxin A/B IIRemel ProSpecT $2.74 (5.64 \text{ to} -0.17)$ $0.0660$ Techlab Toxin A/B IIRemel Xpect $-3.37 (-1.34 \text{ to} -5.40)$ $0.0004$ Techlab Toxin A/B IITechlab Tox A/B Quik Chek $-2.95 (-0.82 \text{ to} -5.08)$ $0.0043$ Techlab Toxin A/B IIPremier Immunocard A + B $2.95 (6.06 \text{ to} -0.17)$ $0.0669$ Remel ProSpecTRemel Xpect $-6.11 (-3.59 \text{ to} -8.62)$ $<0.0001$ Remel ProSpecTTechlab Tox A/B Quik Chek $-5.68 (-3.09 \text{ to} -8.28)$ $<0.0001$ Remel ProSpecTPremier Immunocard A + B $0.21 (3.25 \text{ to} -2.83)$ $1.0000$ Remel ProSpecTPremier Immunocard A + B $0.21 (3.25 \text{ to} -2.83)$ $1.0000$ Remel XpectTechlab Tox A/B Quik Chek $0.42 (1.64 \text{ to} -0.80)$ $0.6875$ Remel XpectPremier Immunocard A + B $0.21 (3.25 \text{ to} -3.84)$ $<0.0001$				
Ridascreen toxin A/B         Techlab Toxin A/B         -0.42 (1.89 to -2.74)         0.8450           Ridascreen toxin A/B         Remel ProSpecT         2.32 (5.09 to -0.46)         0.1081           Ridascreen toxin A/B         Remel Xpect         -3.79 (-1.67 to -5.91)         0.0001           Ridascreen toxin A/B         Techlab Tox A/B Quik Chek         -3.37 (-1.16 to -5.58)         0.0015           Ridascreen toxin A/B         Premier Immunocard A + B         2.53 (5.65 to -0.59)         0.1189           Techlab Toxin A/B II         Remel ProSpecT         2.74 (5.64 to -0.17)         0.0660           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.40)         0.0004           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.08)         0.0043           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.95 (-0.82 to -5.08)         0.0043           Techlab Toxin A/B II         Premier Immunocard A + B         2.95 (6.06 to -0.17)         0.0649           Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.0001				
Ridascreen toxin A/B         Remel ProSpecT         2.32 (5.09 to -0.46)         0.1081           Ridascreen toxin A/B         Remel Xpect         -3.79 (-1.67 to -5.91)         0.0001           Ridascreen toxin A/B         Techlab Tox A/B Quik Chek         -3.37 (-1.16 to -5.58)         0.0015           Ridascreen toxin A/B         Premier Immunocard A + B         2.53 (5.65 to -0.59)         0.1189           Techlab Toxin A/B         Premier Immunocard A + B         2.53 (5.64 to -0.17)         0.0660           Techlab Toxin A/B II         Remel ProSpecT         2.74 (5.64 to -0.17)         0.0660           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.40)         0.0004           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.08)         0.0043           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.95 (-0.82 to -5.08)         0.0043           Techlab Toxin A/B II         Premier Immunocard A + B         2.95 (6.06 to -0.17)         0.0649           Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.0001				
Ridascreen toxin A/B         Remel Xpect         -3.79 (-1.67 to -5.91)         0.0001           Ridascreen toxin A/B         Techlab Tox A/B Quik Chek         -3.37 (-1.16 to -5.58)         0.0015           Ridascreen toxin A/B         Premier Immunocard A + B         2.53 (5.65 to -0.59)         0.1189           Techlab Toxin A/B II         Remel ProSpecT         2.74 (5.64 to -0.17)         0.0660           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.40)         0.0004           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.08)         0.0043           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.95 (-0.82 to -5.08)         0.0043           Techlab Toxin A/B II         Premier Immunocard A + B         2.95 (6.06 to -0.17)         0.0649           Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.0001				
Ridascreen toxin A/B         Techlab Tox A/B Quik Chek         -3.37 (-1.16 to -5.58)         0.0015           Ridascreen toxin A/B         Premier Immunocard A + B         2.53 (5.65 to -0.59)         0.1189           Techlab Toxin A/B II         Remel ProSpecT         2.74 (5.64 to -0.17)         0.0660           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.40)         0.0004           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.95 (-0.82 to -5.08)         0.0043           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.95 (6.06 to -0.17)         0.0669           Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.0001		•	· · · · · · · · · · · · · · · · · · ·	
Ridascreen toxin A/B         Premier Immunocard A + B         2.53 (5.65 to -0.59)         0.1189           Techlab Toxin A/B II         Remel ProSpecT         2.74 (5.64 to -0.17)         0.0660           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.40)         0.0004           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.95 (-0.82 to -5.08)         0.0043           Techlab Toxin A/B II         Premier Immunocard A + B         2.95 (6.06 to -0.17)         0.0669           Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.0001				
Techlab Toxin A/B II         Remel ProSpecT         2.74 (5.64 to -0.17)         0.0660           Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.40)         0.0004           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.95 (-0.82 to -5.08)         0.0043           Techlab Toxin A/B II         Premier Immunocard A + B         2.95 (6.06 to -0.17)         0.0669           Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.0001				
Techlab Toxin A/B II         Remel Xpect         -3.37 (-1.34 to -5.40)         0.0004           Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.95 (-0.82 to -5.08)         0.0043           Techlab Toxin A/B II         Premier Immunocard A + B         2.95 (6.06 to -0.17)         0.0649           Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.0001				
Techlab Toxin A/B II         Techlab Tox A/B Quik Chek         -2.95 (-0.82 to -5.08)         0.0043           Techlab Toxin A/B II         Premier Immunocard A + B         2.95 (6.06 to -0.17)         0.0649           Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.0001		•	. , , , , , , , , , , , , , , , , , , ,	
Techlab Toxin A/B II         Premier Immunocard A + B         2.95 (6.06 to -0.17)         0.0649           Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.0001		•	· · · · · · · · · · · · · · · · · · ·	
Remel ProSpecT         Remel Xpect         -6.11 (-3.59 to -8.62)         <0.0001           Remel ProSpecT         Techlab Tox A/B Quik Chek         -5.68 (-3.09 to -8.28)         <0.0001			· · · · · · · · · · · · · · · · · · ·	
Remel ProSpecT         Techlab Tox A/B Quik Chek         -5.68 (-3.09 to -8.28)         <0.0001           Remel ProSpecT         Premier Immunocard A + B         0.21 ( 3.25 to -2.83)         1.0000           Remel Xpect         Techlab Tox A/B Quik Chek         0.42 ( 1.64 to -0.80)         0.6875           Remel Xpect         Premier Immunocard A + B         6.32 ( 8.79 to 3.84)         <0.0001				0.0649
Remel ProSpecT         Premier Immunocard A + B         0.21 (3.25 to -2.83)         1.0000           Remel Xpect         Techlab Tox A/B Quik Chek         0.42 (1.64 to -0.80)         0.6875           Remel Xpect         Premier Immunocard A + B         6.32 (8.79 to 3.84)         <0.0001	•			
Remel Xpect         Techlab Tox A/B Quik Chek         0.42 (1.64 to -0.80)         0.6875           Remel Xpect         Premier Immunocard A + B         6.32 (8.79 to 3.84)         <0.0001	-			
Remel Xpect         Premier Immunocard A + B         6.32 (8.79 to 3.84)         <0.0001	•			
		Techlab Tox A/B Quik Chek		0.6875
Techlab Tox A/B Quik ChekPremier Immunocard A + B5.89 (8.38 to 3.41)<0.0001		Premier Immunocard A + B	6.32 ( 8.79 to 3.84)	<0.0001
	Techlab Tox A/B Quik Chek	Premier Immunocard A + B	5.89 (8.38 to 3.41)	<0.0001

### Evaluation report: *Clostridium difficile* toxin detection assays

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