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Evaluation of Two Molecular Assays for the Detection of *Clostridium difficile*

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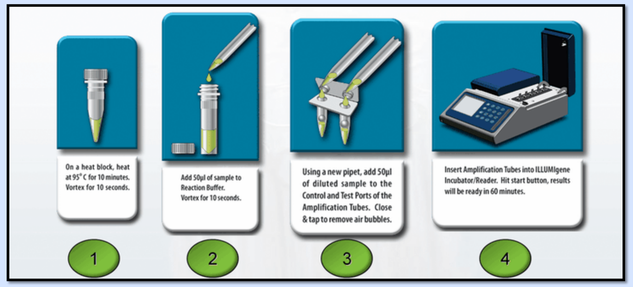
Introduction

Clostridium difficile causes potentially serious cases of infectious diarrhea and is a common hospital acquired infection (HAI), with nearly half a million individuals being infected each year. Recently, several nucleic acid amplification techniques have been developed to improve sensitivity for detecting *C. difficile*. We compared the Meridian *illumigene*® *C. difficile* and the recently FDA-cleared Focus Simplexa™ *C. difficile* Direct assays to standard culture methods. The *illumigene*® assay uses loop-mediated isothermal DNA amplification (LAMP) targeting the PaLoc gene locus, whereas Simplexa™ uses real-time PCR targeting the toxin B gene. Both assays were found to detect more *C. difficile* than toxigenic culture; however, the Simplexa™ Direct assay was more sensitive than culture and *illumigene*®.

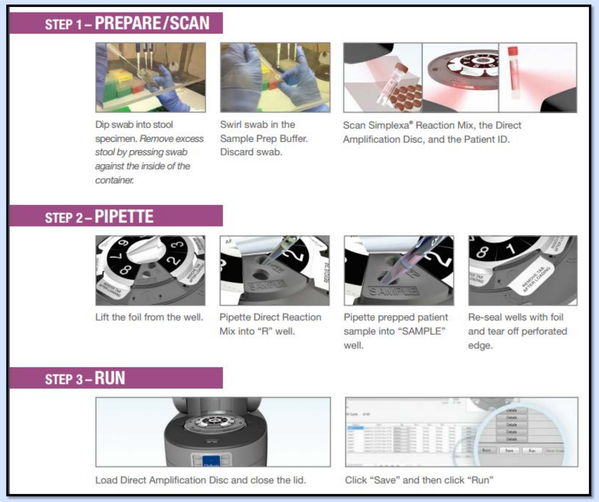
Methods

- In this study, 410 unformed stool specimens were received in the laboratory and tested prospectively with the *illumigene*® and Simplexa™ *C. difficile* assays according to manufacturers' instructions.
- Aliquots of all specimens were sent to a reference laboratory for toxigenic culture by standard methods.
- Results of the molecular assays were compared to each other as well as to culture.

***illumigene*® *C. difficile* Assay Test Procedure**



Simplexa™ *C. difficile* Direct Assay Test Procedure



Results

Performance of *illumigene*® and Simplexa™ *C. difficile* Assays

	Simplexa™ Positive	Simplexa™ Negative
illumigene® Positive	67[a]	2[c]
illumigene® Negative	13[b]	328[d]

[a] – 9 were negative by culture
[b] – 11 were culture positive, 2 were culture negative
[c] – Both were culture negative
[d] – 3 were culture positive

Performance of Simplexa™ *C. difficile* Assay vs Culture

	Simplexa™	
Culture	Positive	Negative
Positive	69	3
Negative	11	327

Performance of *illumigene*® *C. difficile* Assay vs Culture

	illumigene®	
Culture	Positive	Negative
Positive	58	14
Negative	11	327

Sensitivity and Specificity[a]

	illumigene®	Simplexa™
Sensitivity	81 %	96 %
Specificity	97 %	97 %

[a] – with culture as the gold-standard

Conclusions

- The two molecular assays were in agreement 395/410 or 96 % of the time.
- The molecular assays detected 9 positive samples that were negative by culture.
- Culture detected 3 positive samples that were negative by both molecular assays.
- The Simplexa™ assay detected 13 positive samples negative by the *illumigene*® assay – 11 confirmed by culture, 2 were not.
- The *illumigene*® assay detected 2 positive samples that were negative by the Simplexa™ assay; however both were negative by culture.
- Overall, the Simplexa™ assay was more sensitive than the *illumigene*® assay, but both were more sensitive than toxigenic culture.
- This Simplexa™ *C. difficile* Direct Assay is a sensitive and simple method to detect the presence of *C. difficile* in stool.