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# Lateral flow immunoassay based on upconverting nanoparticles for the diagnosis of *Clostridioides difficile* toxins

**Teppo Salminen, Krista Korpi, Sonja Koskela, Tapio Laaksoaho, Johanna Pyylampi** | Uniogen, Turku, Finland

## BACKGROUND

- Rapid and accurate diagnosis of *C. difficile* infection (CDI) is essential for proper medical intervention and infection control measures.
- We are developing an automated Upcon® immunoassay (UIA) for the rapid, sensitive and selective diagnosis of CDI (**Figure 1**).
- The automated *C. difficile* UIA assay under development is based on the detection of toxin A (ToxA) and toxin B (ToxB) produced by pathogenic *C. difficile* strains.
- Here, the evaluation of the automated ToxA UIA assay is presented.

## RESULTS

- The ToxA UIA assay demonstrated higher sensitivity (in the original 100% stool sample) compared with the commercial POC membrane-based assay:
  - ToxA UIA: **2.5 ng/mL**
  - Commercial POC: **5 ng/mL**
- The ToxA UIA assay showed excellent sensitivity and good specificity with stool samples (**Table 1**).
- The ToxA UIA assay was less complicated and faster to operate with only 1 manual step in comparison to the 5 steps required with the commercial POC assay (**Figure 2**).

***Table 1. The performance of the assays (agreement with PCR).***

| Assay | Sensitivity | Specificity | Manual steps | Turnaround time |
|---|---|---|---|---|
| ToxA UIA | 96%[1] | 89%[2] | 1 | 19 min |
| Commercial POC | 84% | 96% | 5 | 33 min |

[1]Final result after confirmation (one sample re-run due to suspected error in sample handling).
[2]False positives due to negative samples containing high amount of solid material.

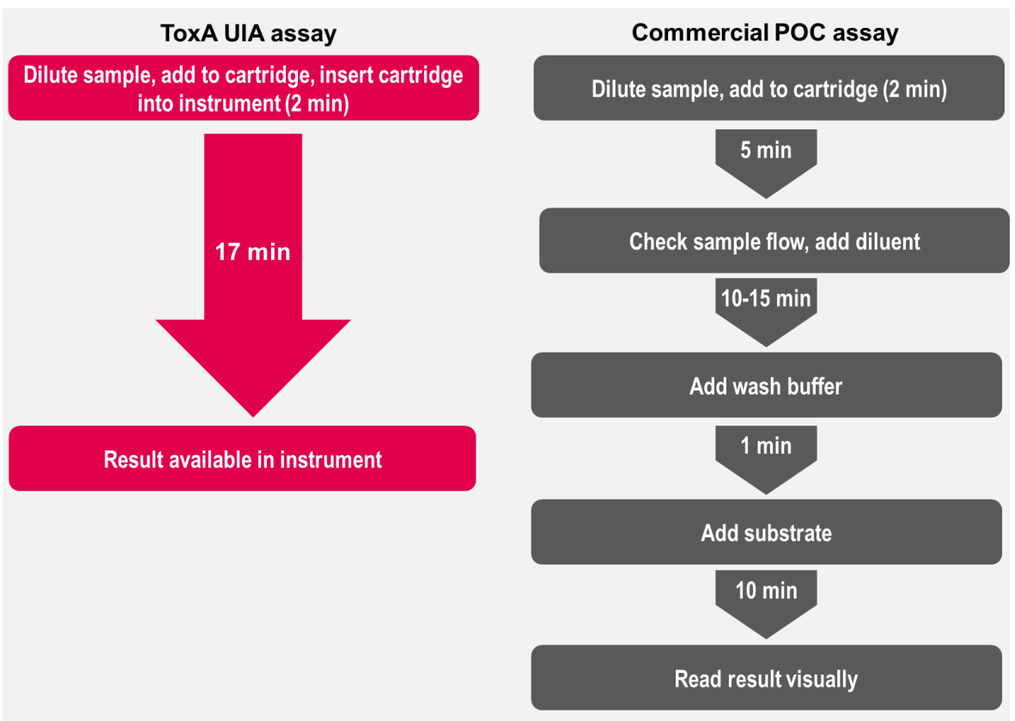


**Figure 2. The workflow of the ToxA UIA and commercial POC assays.** The workflow of the UIA system is simple: the stool sample is diluted in 5% (w/w), added to a cartridge (Figure 1) and run in the instrument. The turnaround time is 19 min with a hands-on-time of <2 min.

## MATERIALS AND METHODS

- The sensitivity and specificity of the ToxA UIA assay was compared with a commercial point-of-care (POC) membrane-based *C. difficile* toxin immunoassay with visual interpretation.
- For the assessment of analytical sensitivity, pooled negative stool samples were diluted, spiked with native ToxA and analyzed using the automated UIA system and the commercial POC immunoassay.
- For the assessment of clinical sensitivity and specificity, a panel of PCR-positive (n=25) and PCR-negative (n=28) samples was tested in the automated UIA system and with the commercial POC immunoassay.

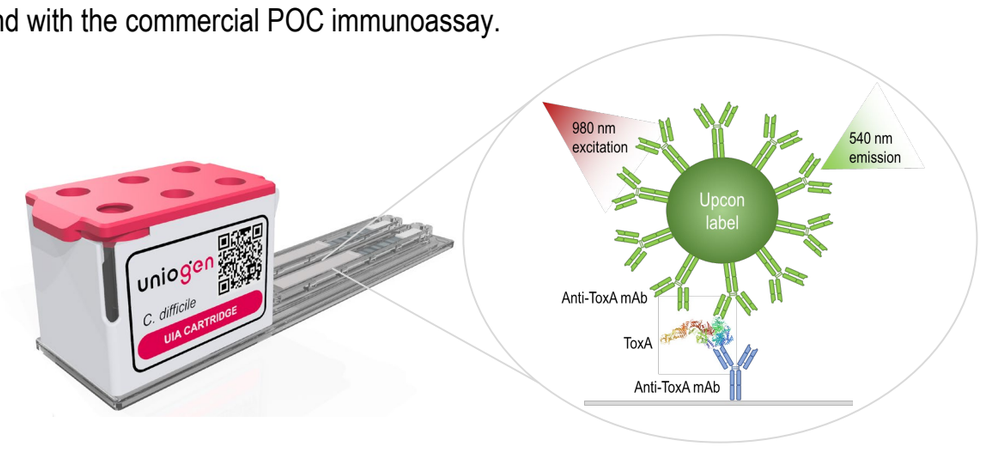


***Figure 1. The C. difficile ToxA Upcon® immunoassay is performed in a cartridge.*** *The assay is based on lateral flow immunoassay utilizing upconverting nanoparticle labels, enabling the development of sensitive immunoassays for POC diagnostics. The Upcon particle generates upconverting luminescence, which minimizes background interference from the sample and enables highly sensitive quantitative measurements.*

## CONCLUSIONS

- Excellent sensitivity due to Uniogen's proprietary Upcon labelling technology combined with platform's walk-away automation and fast turnaround time make the *C. difficile* UIA assay ideally suited for point-of-care diagnostics.
- ToxA UIA and ToxB UIA assays are being further developed to reduce the number of false positives, mainly caused by negative samples containing high amount of solid material.
- The data suggests that the *C. difficile* UIA assay utilizing Uniogen's proprietary Upcon labelling technology provides a promising option for fast and reliable diagnosis of CDI.

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**Contact:**
info@uniogen.com