Evaluation of the Quidel Solana *C. difficile* Assay at a UK reference laboratory using residual clinical sample material

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Introduction

- Current recommendations for the microbiological diagnosis of *Clostridioides difficile* infection (CDI) advocate the use of a nucleic acid amplification test (NAAT) as an optional third line method or for front line screening. The Quidel Solana *C. difficile* assay utilises approximately 30 minutes of helicase-dependent amplification (HDA) for detection of the *tcdA* gene. This study describes an evaluation of the test with residual clinical material at the Public Health Wales UK Anaerobe Reference Unit.

Materials and methods

- Eighty seven GDH positive stool samples were retrieved from -80°C storage (stored up to 7 months) for processing on the Solana platform retrospectively. Results from testing using the TechLab C. diff Chek – 60 (GDH) and Tox A/B Quik Chek immunoassays and PCR ribotyping (where available) were documented. PCR ribotyping was accomplished by capillary gel electrophoresis using an ABI 3500 sequencer.

Figure 1: The Solana instrument – a compact (23cm x 23cm x 15cm) and robust amplification and detection platform capable of producing results for 12 samples with minimal hands-0n and sample processing time

- Solana *C. difficile* testing was undertaken using the heat station, lysis and dilution buffers and lyophilised reagents provided. Samples were run in batches of between one and 12 specimens on the Solana platform (figure 1).

- The Luminex xTAG® gastrointestinal pathogen panel (GPP) was utilised for samples with discordant Solana HDA and GDH/toxin A/B results and for all toxin A/B negative samples.

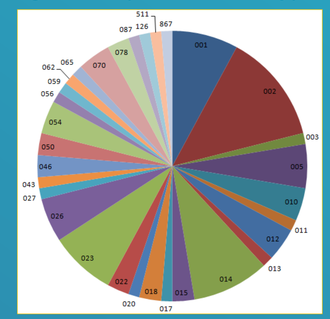
Results

- Sixty three samples were both GDH and toxin A/B positive with the remaining 24 samples GDH positive but toxin A/B negative. Over 30 *C. difficile* PCR ribotypes were represented within the sample cohort (figure 2).

	Solana (GPP) positive	**Solana (GPP) negative**
Toxin A/B Quik Chek positive	61/63 (1/2)	2/63 (1/2)
Toxin A/B Quik Chek negative	8/24 (11/24)	16/24 (13/24)

Table 1: Solana and discrepant sample test result summary

Figure 2: represented ribotypes



- A breakdown of the TechLab, Solana and GPP results is included (table 1). Twelve samples demonstrated discrepant Quik Chek and Solana results.
- Three of four toxin A/B Quik Chek positive/Solana PCR negative samples were negative using the GPP assay. One was a low level GPP positive. Two of these were culture negative, one grew a toxin negative strain and one grew a toxin positive strain.
- Eight GDH positive/toxin A/B negative Solana PCR positive samples were also GPP positive. Three additional samples gave extremely weak GPP signals and were negative on Quick Check toxin A/B and Solana testing.

Conclusions

- The Solana *C. difficile* assay was rapid and simple to use. The concordance of the Solana results with toxin A/B immunoassay and GPP testing was good and warrants further prospective testing.

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