

**P2267 Do the results of membrane and well-based EIAs for the diagnosis of Clostridium difficile infection (CDI) correlate?**

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**Background:** Although CDI test algorithms have been rigorously studied, little published evidence is available on comparisons between membrane and well-based methods. One small study indicated that the toxin component of membrane assays may have decreased sensitivity compared with a well-based EIA.

**Materials/methods:** Selected samples from two UK hospitals were tested using three reference methods: cell-cytotoxicity neutralisation assay (CCNA), cytotoxigenic culture (CTC) and culture. Two CDI test algorithms were also used: well-based CHEK-60 (glutamate-dehydrogenase (GDH))/TOXABII (toxins A&B), and membrane-based *QUIK CHEK COMPLETE (QCC)*. Algorithms and single component tests were compared with all reference methods and to each other. Clinical data relating to patient outcomes were also collected.

**Results:** 693 samples were tested on all assays, with 119 (17.2%) CCNA positives; classified as CDI cases. The QCC and the CHEK-60/TOXABII algorithm had a positive and negative agreement of 85.6% and 98.7%, respectively and were not significantly different ( $p=0.21$ ). However, both tests yielded results that were significantly different versus the GDH/CCNA algorithm (positive and negative agreements: 77.1%/99.0%,  $p=0.0003$  and 85.6%/99.5%,  $p=0.003$  for QCC and C60/TOXABII, respectively). The two GDH assays had comparable sensitivity and specificity when compared with the reference methods, and 94.1% positive agreement between themselves. The QCC toxin component had a non-significantly decreased sensitivity compared with the TOXABII assay; positive agreement 85.6% ( $p=0.21$ ).

Of the TOXABII negative/CCNA positive samples, 13/18 (72.2%) were weak positive on CCNA, suggesting low faecal concentrations of toxin; only 14/27 (51.9%) were weak CCNA positives for QCC negative/CCNA positives. The mortality rate in CDI patients with a weak positive CCNA result was numerically lower than those with a definitively positive CCNA result (7.1% vs 13.1%;  $p=0.5$ ).

**Conclusions:** Both commercial algorithms have reduced sensitivity compared with CCNA. There was a non-significantly reduced sensitivity of the QCC toxin component compared with the TOXABII assay. In the well-based test, the majority of missed toxin positives related to low faecal toxin concentrations, but the latter only account for half of the cases missed by the QCC, suggesting some other cause. Further work to investigate the possible reasons for these discrepancies is on-going.