Accurate diagnosis of CDI remains challenging as there is no standalone laboratory test with adequate clinical sensitivity and specificity. Thus, many clinical laboratories currently employ a multipletest incorporating a sensitive screening test followed by a specific toxin test. An automated ultrasensitive toxin immunoassay (Singulex Clarity® C. difficile toxins A/B assay) has demonstrated excellent performance compared with cell cytotoxicity neutralization assay (CCNA). In this study, the Clarity assay was evaluated relative to glutamate dehydrogenase (GDH), toxin EIA, toxin B PCR, multipletesting algorithms, and C. difficile culture with ribotyping.

Methods. Residential clinical stool samples (n = 293) were collected from patients with suspected CDI. The samples were tested on-site with GDH (C. DIFF CHEK™-60), PCR (EntericBio realtime® C. difficile assay), a membrane-type toxin EIA (Tox A/B QuikChek™), and culture and ribotyping. In total, 188 samples were tested with GDH and 239 samples were tested by PCR. All PCR-positive samples (n = 148) and prospectively tested GDH samples (n = 97) were tested with the toxin EIA. Culture and ribotyping information were available for 205 samples.

Results. Three of the samples tested gave no result using the Clarity assay and were excluded from the analysis. The Singulex Clarity C. difficile toxins A/B assay had high positive percent agreement (PPA) and low negative percent agreement (NPA) compared with toxin EIA and multipletesting algorithms ending with toxin EIA. The Clarity assay had high NPA and low PPA compared with PCR, GDH, and the multipletest algorithm ending with PCR (figure). Less than 70% of the detected C. difficile PCR positive samples had toxins present. There was no difference in toxin concentration between the ribotypes.

Conclusion. The Clarity assay had strong PPA compared with toxin EIA and strong NPA compared with PCR. The low NPA and PPA compared with toxin EIA and PCR, respectively, may reflect the poor sensitivity of current toxin EIA and low specificity of PCR. The Clarity assay detected 30 different ribotype strains, and less than 70% of samples (by PCR) or strains (by ribotyping) had toxins present. The Clarity assay may be considered for use as a standalone test for CDI diagnosis.