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**SUMMARY: Safety and Effectiveness Information  
for the VIDAS *C. difficile* Toxin A II assay**

The VIDAS *C. difficile* Toxin A II assay detects the presence of *C. difficile* toxin A. It is substantially equivalent to the Meridian Premier *C. difficile* Toxin A test as an aid in the diagnosis of *Clostridium difficile* associated disease (CDAD). Safety and effectiveness issues for qualitative enzyme immunoassay such as the VIDAS *C. difficile* Toxin A II assay may include the following:

1. False positive results: In studies comparing the VIDAS *C. difficile* Toxin A II assay to a commercially available EIA with discrepant resolved by cytotoxicity, of the 1,407 negative specimens there were 13 false positive results for a specificity of 99.1%.
2. False negative results: In studies comparing the VIDAS *C. difficile* Toxin A II assay to a commercially available EIA with discrepant resolved by cytotoxicity, of the 136 positive specimens there were 7 false negative results for a sensitivity of 94.9%.
3. Equivocal results: The occurrence of equivocals with the VIDAS CDA 2 test was 2.5% in the studies done to demonstrate the performance of the assay. All equivocals were resolved with the use of the VIDAS *C. difficile* Blocking Reagents in the VIDAS CDB test of the VIDAS *C. difficile* Toxin A II assay.
4. Invalid results: In the studies done to support the VIDAS *C. difficile* Toxin A II assay performance claims, there were no invalid VIDAS results.
5. Precision: In the studies done to support the VIDAS *C. difficile* Toxin A II assay performance claims, the VIDAS CDA 2 test intra-assay precision testing showed coefficients of variation for test values ranging from 2.7 to 31.9 % when utilizing stool precision pools. For the VIDAS CDB test intra-assay precision testing showed coefficients of variation for test values ranging from 19.0 to 39.2 %. When utilizing the same stool precision pools, the VIDAS CDA 2 test inter-assay precision testing gave coefficients of variation for the test values ranging from 8.6 to 30.8% and coefficients of variation for the test values ranging from 9.1 to 33.4% for the VIDAS CDB test.
6. Assay Specificity: A panel of normal human colonic flora was tested for both cross-reactivity and interference for the VIDAS *C. difficile* Toxin A II assay. Cross-reactivity and interference was seen with the *C. sordellii* strain (VPI #9048) when tested at a concentration of  $3 \times 10^8$  organisms/ml and the *C. difficile* toxin producing strains (ATCC #9689 and VPI # 10463) when tested at a concentration of  $1 \times 10^7$  organisms/ml.

The VIDAS *C. difficile* Toxin A II assay must be used according to package insert instructions when testing for the presence of *C. difficile* toxin A. Additional information and references may be found in the package insert.