BD gets FDA 510(k) clearance for vaginal panel on BD Cor system

March 16, 2023—<u>BD</u> announced it has received FDA 510(k) clearance for its BD Vaginal Panel on the BD Cor system.

The BD Vaginal Panel is the first microbiome-based PCR assay that uses a single swab and test to simultaneously detect organisms associated with *bacterial vaginosis*, *vulvovaginal candidiasis*, and *Trichomonas vaginalis* and reports a positive or negative result for each condition separately. If a test is positive for *vulvovaginal candidiasis*, the panel provides separate results for *C. glabrata* and *C. krusei*.

The 510(k) clearance for this panel on the BD Cor is the first high-throughput version of the test.