FDA clears Aptima BV, Aptima CV/TV molecular assays

June 12, 2019—Hologic announced FDA clearance for its Aptima BV assay for identifying bacterial vaginosis and Aptima CV/TV assay for identifying *Candida vaginitis* and *Trichomonas vaginalis*.

“Vaginitis is one of the most common reasons women visit a health care provider, and Hologic’s new molecular assays have the potential to transform how these infections are diagnosed in that very first appointment,” Edward Evantash, MD, medical director and vice president of medical affairs, Hologic, said in a company press release. “The improved sensitivity and specificity of Hologic’s molecular assays over traditional methods in determining the underlying cause of vaginitis not only means identifying the right infection, but enabling the right treatment and, in turn, reducing the potential for recurrent or persistent infections.”

With these two FDA clearances, Hologic now offers 16 FDA-cleared assays that detect more than 20 pathogens. Aptima assays are run on the company’s Panther system.