FDA OKs First Chlamydia, Gonorrhea Tests for Throat, Rectal Swabs

Previously, tests were approved only for use with genital or urine samples.

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The Food and Drug Administration (FDA) has approved the first tests for chlamydia and gonorrhea for use assessing rectal or oral swabs.

The Aptima Combo 2 Assay and the Xpert CT/NG test were previously approved for testing urine, vaginal and cervical samples.

“Prior to today, there were no chlamydia or gonorrhea tests cleared for use on samples from the throat and rectum. The availability of these two tests will fill an unmet public health need, by allowing for more screening,” Tim Stenzel, MD, PhD, director of the Office of In Vitro Diagnostics and Radiological Health in the FDA’s Center for Devices and Radiological Health, said in a press release. “It is best for patients if both of these sexually transmitted infections are caught and treated right away, as significant complications can occur if left untreated. Today’s clearances provide a mechanism for more easily diagnosing these infections.”

The two tests were approved for the new purposes through the premarket notification 510(k) pathway, for which the FDA requires that a device prove at least as safe and effective as an already approved and marketed device. The FDA reviewed data from a collaborative, multisite cross-sectional clinical study of more than 2,500 people that evaluated the accuracy of various commercially available sexually transmitted infection (STI) tests known as nucleic acid amplification assays that test for chlamydia and gonorrhea infections in throat and rectal sites.

This study, together with other information, indicated that the Aptima Combo 2 Assay and the Xpert CT/NG test were indeed safe and effective for testing for chlamydia and gonorrhea outside of the genital area.

STIs have been rising steeplyin the United States in recent years just as the federal response has declined.

To read a press release about the approval, click here.

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