Extragenital tests to detect chlamydia, gonorrhea cleared for marketing

May 29 2019

(HealthDay)—The U.S. Food and Drug Administration has cleared for

marketing two tests that detect the presence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* with diagnostic testing of extragenital specimens.

The Aptima Combo 2 Assay and the Xpert CT/NG were previously cleared for testing urine, vaginal, and endocervical samples; this most recent approval allows for extragenital diagnostic testing via the throat and rectum. Tim Stenzel, M.D., Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA Center for Devices and Radiological Health, said the availability of these two tests for use in the throat and rectum fills an "unmet public health need, by allowing for more screening. Today's clearances provide a mechanism for more easily diagnosing these infections."

To determine marketing approval of the devices, the FDA reviewed clinical data from a cross-sectional, collaborative, multisite clinical study of more than 2,500 patients. Researchers concluded that the Aptima Combo 2 Assay and Xpert CT/NG are safe and effective for extragenital testing for chlamydia and gonorrhea.

Clearance of the Aptima Combo 2 Assay was granted to Hologic, and clearance of the Xpert CT/NG was granted to Cepheid.

More information: More Information