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FDA approves diagnostic tests for chlamydia and gonorrhoea

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FDA clears first diagnostic tests for extragenital testing for chlamydia and gonorrhea

The U.S. Food and Drug Administration cleared for marketing two tests that can detect the presence of the bacteria Chlamydia trachomatis and Neisseria gonorrhoeae, which cause the sexually-transmitted infections, respectively, chlamydia and gonorrhea, through diagnostic testing of extragenital specimens.

The Aptima Combo 2 Assay and the Xpert CT/NG are the first devices cleared for extragenital diagnostic testing of these infections via the throat and rectum. These tests were previously only cleared for testing urine, vaginal and endocervical samples.

The FDA granted clearance of Aptima Combo 2 Assay to Hologic, Inc.

The FDA granted clearance of the Xpert CT/NG to Cepheid.

In its evaluation of the devices, the FDA reviewed clinical data collected through a cross-sectional study coordinated by the Antibacterial Resistance Leadership Group, which is funded and supported by the National Institute of Allergy and Infectious Diseases. The study was a collaborative, multi-site clinical study of more than 2,500 patients that evaluated the diagnostic accuracy of multiple commercially available nucleic acid amplification tests for detection of Neisseria gonorrhoeae and Chlamydia trachomatis from throat and rectal sites. The results of this study, along with other information reviewed by the FDA, demonstrated that the Aptima Combo 2 Assay and the Xpert CT/NG for extragenital specimens are safe and effective for extragenital testing for chlamydia and gonorrhea.