BioSpectrum the business of Bio & Health Sciences

Cepheid gets FDA nod for Xpert® CT/NG Test

30 May 2019 | News

On-Demand Same-Day Extragenital Testing for Chlamydia and Gonorrhea fills critical unmet need in fight against rising rates of Chlamydial and Gonorrheal Infection

Cepheid announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for testing throat and rectal specimens with its Xpert® CT/NG test. The test provides fast and accurate molecular detection of chlamydia and gonorrhea, making same-day consultation and treatment possible.

Xpert CT/NG test is an automated *in vitro* diagnostic test for qualitative detection and differentiation of DNA from *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*. In addition to the new extragenital specimens, Xpert CT/NG is indicated for use with urine, vaginal, and endocervical specimens from symptomatic and asymptomatic patients.

"Xpert CT/NG is the most sophisticated test in its class, yet it can be performed on-demand by virtually any laboratory to maximize the medical impact of the results. Adding throat and rectal sample types addresses a critical unmet need allowing for more complete patient screening," said David H. Persing, M.D., Ph.D., Cepheid's Chief Medical and Technology Officer. "Considering the increasing rates of chlamydial and gonorrheal infection, this is particularly important for public health screening programs, to capture patients who previously would have gone undiagnosed if only genital specimens were tested.It is not uncommon for patients to have an infection only in their throat or rectum, which may be asymptomatic. Same day consultation and treatment is critical for patient management so patients are not lost to follow up."

The Xpert CT/NG test is performed on the Cepheid GeneXpert® Systems. The test's capability to detect DNA from organisms in both genital and extragenital specimens allows for improved screening and detection in patients to ensure infections can be treated in the same day.