

## Unyvero System gets de novo clearance

**June 2018**—Curetis has been granted de novo clearance by the FDA to market the Unyvero System and Lower Respiratory Tract Infection Application Cartridge in the U.S. The sample-to-answer Unyvero System with the Unyvero LRT Application Cartridge provide rapid infectious disease testing directly from aspirate samples in less than five hours. With 29 multiplexed PCR assays, the system can detect more than 30 Gram-positive and Gram-negative bacterial organisms known to cause lower respiratory tract infections, as well as 10 genetic markers for antibiotic resistance, including carbapenem and third-generation cephalosporins.

[Curetis USA](#), 619-452-3644