FDA clears QIAstat-Dx syndromic testing system

May 22, 2019—Qiagen launched its QIAstat-Dx (formerly Stat-Dx DiagCore) syndromic testing system after receiving 510(k) clearance from the Food and Drug Administration. The company also launched its multiplex QIAstat-Dx Respiratory Panel for the simultaneous qualitative detection and identification of more than 20 viral and bacterial pathogens.

QIAstat-Dx is designed for an expanding test menu with the potential ability to process up to 48 targets simultaneously. The system features a hands-on time of less than one minute, and results are available in about one hour. Sample processing is built in, all reagents are onboard, and the workflow is designed to be intuitive. Cartridges are processed in a scalable, proprietary, and fully integrated platform that can be configured from one to four modules.

“DiagCore has been enthusiastically received in Europe and other regions of the world for its rapid, clear insights in clinics and other near-patient settings, as well as its cost-efficiency. We now look forward with the launch of QIAstat-Dx to similar success in the U.S. QIAstat-Dx will provide physicians with results to aid in the appropriate diagnosis and treatment for each patient. We are developing a deep menu of additional multiplex panels, such as tests for gastrointestinal syndromes and meningitis infections,” Thierry Bernard, senior vice president and head of molecular diagnostics, Qiagen, said in a press release.