Abbott gains CE mark for Alinity m system, assays

March 19, 2019—<u>Abbott</u> announced it has received the CE mark for its Alinity m automated molecular diagnostics system and assays.

Alinity m features the company's proprietary ReadiFlex technology for true random access, a universal sample rack, and a time to first result of less than 115 minutes. The system can provide 300 results in about eight hours and can have up to 20 assays on board at one time. Alinity m may also reduce the lab equipment footprint of four to six instruments down to one, the company reports.

"Molecular laboratories are playing an increasingly important role in providing critical test results, and we're struggling to keep up with demand," Martin Obermeier, MD, CEO, Medical Center for Infectious Diseases in Berlin, said in a press release from Abbott. "Alinity m will significantly improve the way we operate laboratories by letting staff run any sample at any time, without the need to group samples, allowing us to focus on giving physicians the information they need to make accurate, timely clinical decisions."

Alinity m STI assays include virologic testing for HIV-1, hepatitis B virus, and hepatitis C virus; sexual health-related testing for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis*, and *Mycoplasma genitalium*, or CT/NG/TV/MG panel; and high-risk human papillomavirus testing.

In the United States, Alinity m is in development and not commercially available for diagnostic use.