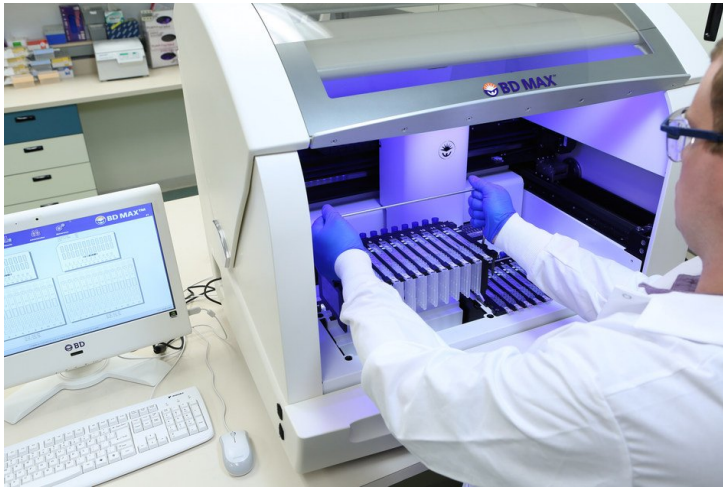


BD launches new molecular diagnostic test for COVID-19

15 April 2020 | News

The test, which is run on the BD MAX™ System, provides additional testing capacity for COVID-19



BD (Becton, Dickinson and Company), a leading global medical technology company, has announced that the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for an additional molecular diagnostic test for COVID-19 that can return results in two to three hours. The new test also has been CE marked to the IVD Directive (98/79/EC).

The test, which is run on the BD MAX™ System, provides additional testing capacity for COVID-19 in the United States and in countries that recognize the CE Mark to test patients and health care workers.

The test is in addition to the other tests already available on the BD MAX™ System from collaborations with BioGX and CerTest and is based on the CDC assay design. The BD MAX™ System, a molecular diagnostic platform, is already in use at thousands of laboratories worldwide, and each unit is capable of analyzing hundreds of samples over a 24-hour period.

The majority of BD MAX™ Systems are installed in hospital laboratories, reducing the added time and complexity of needing to send samples to a reference lab. The system is fully automated, reducing the opportunity for human error and increasing the speed to result, and can process 24 samples simultaneously. The assay is based on the same viral RNA targeting sequences and real-time PCR detection method as the test developed by the U.S. Centers for Disease Control and Prevention (CDC).