BioSpectrum ASIA EDITION
the business of Bio & Health Sciences

FDA provides EUA to PerkinElmer for COVID-19 testing

25 March 2020 | News

PerkinElmer's RT-PCR test is marketed as an in vitro diagnostic (IVD) device

PerkinElmer, Inc., a global leader committed to innovating for a healthier world, has announced that the U.S. Food and Drug Administration (FDA) has provided Emergency Use Authorization (EUA) for the Company's New Coronavirus RT-PCR test.

Clinical laboratories certified under Clinical Laboratory Improvement Amendments (CLIA) can immediately begin using this kit to detect SARS-CoV-2, the virus that causes COVID-19.

PerkinElmer's RT-PCR test is marketed as an in vitro diagnostic (IVD) device by meeting the requirements of the European In Vitro Diagnostic Directive (IVDD) and is available in over 30 countries worldwide.

Despite the challenging environment, our employees have demonstrated unwavering commitment over the past two months to combat this global pandemic," said Prahlad Singh, president and chief executive officer, PerkinElmer. "The breadth of PerkinElmer's total workflow solution puts us in a unique position to rapidly address the needs of our clinical diagnostics customers."