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Korean firm Celltrion receives FDA EUA for COVID-19 Ag rapid test

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Expanded usage scope for use at the Point of Care (POC) and serial testing programs

South Korean firm Celltrion has announced that DiaTrust™ (Celltrion DiaTrust™ COVID-19 Ag Rapid Test) is now launched and available for immediate supply.

DiaTrust™ received the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) approval for their COVID-19 Point of Care (POC) antigen rapid test kit, DiaTrust™ (Celltrion DiaTrust™ COVID-19 Ag Rapid Test). With the recent EUA approval, DiaTrust™ is available for immediate supply and distribution.

DiaTrust™ uses Celltrion's proprietary antibody, which specifically binds to the COVID-19 virus and detects the infection within 15 minutes. Most rapid test kits in the market generally detect only one of the N or S antigens, but DiaTrust™ is characterized by maximizing the sensitivity with a dual antigen (Ag) method that detects both antigens.

Clinical trials with patients within the first seven days of symptom onset showed sensitivity and specificity levels at 93.3% and 99.0%, respectively, showing a high level of accuracy.

Celltrion confirmed the equivalent level of sensitivity of detecting variants from the UK, South Africa, Brazil, California, and New York with clinical studies or in-vitro studies. Clinical trials were conducted in the U.S. when the UK variant was the most prevalent, and clinical trials in Brazil also showed more than 90% sensitivity.