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Celltrion to launch antigen and antibody testing kits in US

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Plans to launch two rapid COVID-19 testing kits, SAMPINUTETM COVID-19 Antigen MIA and DiaTrustTM COVID-19 IgG/IgM Rapid Test

South Korea based Celltrion Group recently announced the launch of two rapid kits for SARS-CoV-2 in the US by the third week of August. SAMPINUTE™ COVID-19 Antigen MIA is an electrochemical immunoassay test for the detection of SARS-CoV-2 antigen from nasopharyngeal swab samples, composed of one-time-use test cartridges and a portable analyzer developed in collaboration with BBB.

DiaTrust™ COVID-19 IgG/IgM Rapid Test is a one-step in-vitro diagnostic test based on immunochromatographic assay designed for the rapid detection of antibodies of the novel coronavirus in healthcare settings in collaboration with Humasis. Both SAMPINUTE™ COVID-19 Antigen MIA (antigen test) and DiaTrust™ COVID-19 IgG/IgM Rapid Test (antibody test) have shown reliable performance and promising clinical trial results. SAMPINUTE™ COVID-19 Antigen MIA has a sensitivity of 94% and a specificity of 100%, with time to results within 10 minutes.

Celltrion requested Emergency Use Authorization (EUA) for SAMPINUTE™ COVID-19 Antigen MIA on July 24th, and for DiaTrust™ COVID-19 IgG/IgM Rapid Test on July 8th. The rapid tests kits are currently under the review of the US Food and Drug Administration's Emergency Use Authorization. Celltrion anticipates the FDA EUA approval and subsequent commercialization in the US market by mid-August.

Celltrion plans to launch the second-generation antibody and antigen tests, in collaboration with the DiaTrust™ COVID-19 IgG/IgM Rapid Test's manufacturer Humasis, for which Celltrion will apply its proprietary COVID-19 antibody-antiviral technology to enhance detection sensitivity during the second half of 2020.