Hologic to launch second assay for novel coronavirus

April 30, 2020—<u>Hologic</u> plans to launch an Aptima molecular assay to detect the SARS-CoV-2 virus that will run on its Panther system, which provides initial results in about three hours and processes more than 1,000 coronavirus tests in a 24-hour period.

The company expects to begin distributing next week a research use only version of its Aptima SARS-CoV-2 test to hospital, public health, and reference laboratories certified under CLIA to perform high-complexity tests and plans to provide its laboratory customers about 3 million RUO tests initially. Hologic expects to begin producing in late May at least 1 million assays per week and increase its production capacity further in the coming months.

The company will apply for FDA emergency use authorization for the Aptima SARS-CoV-2 test and register a CE mark for diagnostic use.

The Panther Fusion SARS-CoV-2 assay, Hologic's first COVID-19 test, received emergency use authorization in March.