In a recent report published by the FDA, the Hologic assays are the most sensitive fully-automated, high-throughput molecular SARS-CoV-2 assays available.¹

The Panther® platform offers scalability, the potential to grow and full automation required to respond in these unprecedented times.

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* The Aptima and Panther Fusion SARS-CoV-2 assays:
  - These tests have not been FDA cleared or approved;
  - These tests have been authorized by FDA under an EUA for use by authorized laboratories;
  - These tests have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
  - These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

† The Panther Fusion SARS-CoV-2 assay is available for EUA use in the United States, Australia, New Zealand, and Canada. EUA does not apply to the European Union. The Aptima SARS-CoV-2 assay is available for EUA use in the United States.

‡ In development and not for sale.