APC Health, a Houston Area CLIA Certified High-complexity Laboratory, Receives Authorization for the Highly Accurate Non-Invasive COVID-19, SalivaDirect™

Game-changing test developed by Yale School of Public Health offers ease of collection, accuracy, and rapid turnaround at lower cost.

PEARLAND, Texas, Nov. 16, 2020 /PRNewswire/ -- APC Health is pleased to announce that the company's high-complexity CLIA-certified lab operating out of Pearland, Texas has been authorized to perform saliva-based SalivaDirect™ SARS-CoV-2 test effective immediately.

Developed by the Yale School of Public Health, SalivaDirect™ uses a high-complexity protocol that requires a certified lab and trained technicians to conduct the testing. It provides analytical sensitivity of 99% and is accurate 94% of the time. The new non-invasive COVID-19 test is ideal for large-scale testing and offers many advantages over traditional testing methods.

This real-time reverse transcription-polymerase chain reaction (rRT-PCR) test for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva skips the time-consuming, difficult, and expensive viral ribonucleic acid (RNA) extraction step used in standard nasal swab assays. Unlike invasive and uncomfortable nasopharyngeal (NP) swab tests, SalivaDirect™ only requires a small saliva sample without any expensive preservatives which lowers costs. No special collection kit is needed, making it even more cost-effective and scalable.

"We are delighted to be authorized by Yale University to offer SalivaDirect™ at our lab in Pearland, Texas. With this test, we can significantly increase access to highly accurate, cost-effective, and scalable testing SARS-CoV-2 in our community. We are committed to serving high-risk segments such as seniors by providing a better option to existing invasive, high-cost COVID-19 tests," said Rohan Nath, Founder and CEO of APC Health.

Recognizing the benefits of SalivaDirect™, APC Health completed a rigorous validation process to offer this ground-breaking test. It signed an agreement with the Yale School of Public Health on October 30, 2020, to provide the test to urgent care clinics, senior living facilities, dentists, medical practices, and businesses in the Greater Houston area with a need for COVID-19

testing. For more information on how to start using SalivaDirect™ at their location, users can email info@apchealth.net.

About APC Health LLC

Founded in 2015, APC Health is a high-complexity CLIA-certified diagnostic lab that specializes in PCR technology using QuantStudio5, BioFire, and ABI 7500 devices. It provides a comprehensive respiratory panel that tests for 13 viruses, including Influenza A/B and RSV, STI, UTI, wound-care, and women's health panels. In addition to PCR-based testing, the lab provides urine drug toxicology testing using LC-MS technology. The privately-owned company is in-network with most leading healthcare insurance companies.

About SalivaDirect™

SalivaDirect™ has not been FDA cleared or approved. The FDA authorized the test under an emergency use authorization (EUA) for use by authorized laboratories on August 15, 2020. The test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/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.

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