

FOR IMMEDIATE RELEASE

## ASSURANCE SCIENTIFIC LABORATORIES IS AUTHORIZED BY THE FDA AS ONE OF TWO LABS IN THE U.S. TO TEST EVERLYWELL COVID-19 AT-HOME COLLECTION KIT SPECIMENS

BIRMINGHAM, AL (May 18, 2020) – Assurance Scientific Laboratories has been approved by the FDA as one of two laboratories to test specimens from Everlywell COVID-19 at-home test collection kits. This week, the FDA issued emergency use authorization (EUA) for this test and for the COVID-19 lab testing by Assurance Labs. This test enables individuals to take a nasal sample at home and send in directly to the lab for processing.

"This process will allow expanded access, limit exposure, and preserve valuable Personal Protective Equipment without compromising sample integrity," said Chad Austin, M.D., Co-founder and Owner of Assurance Labs.

"The EUA comes after an exhausting amount of work and collaboration to fulfill requirements set forth by the FDA to ensure that all aspects from ordering, delivery, sample collection, and shipping proved to be safe, accurate, and reproducible," said Ty Thomas, M.D., Co-Founder and Lab Director for Assurance Labs. "We are grateful for the partnership with Everlywell, with whom we have been working alongside since early March."

Assurance Labs began testing for COVID-19 on March 11<sup>th</sup>, making it the first commercial lab in Alabama and one of the first in the country to begin testing for COVID-19. Assurance Labs has increased capacity and can process upwards of 5,000 tests per day. <u>Everlywell</u>, based in Austin, Texas, is a digital health company that offers consumers access to at-home lab tests. They plan to make the at-home COVID-19 test collection kit available online by the end of May.

"Today's action is also another great example of public-private partnerships in which data from a privately funded study was used by industry to support an EUA request, saving precious time as we continue our fight against this pandemic, " said Jeffrey Shuren, M.D., J.D., Director of the FDA's Center for Devices and Radiological Health.

For more information on the FDA's news release about this EUA, visit <u>FDA.gov</u>. Additional announcement as see in the New York Times, <u>https://www.nytimes.com/2020/05/16/health/fda-clears-</u> another-coronavirus-testing-kit-for-use-at-home.html.

## **About Assurance Scientific Laboratories**

Assurance Scientific Laboratories is a highly complex clinical reference lab with a robust R&D department that develops and provides rapid diagnostic services for clinicians, hospital sys-



tems, private entities, long term care facilities, and other reference labs. They specialize in molecular diagnostics and microbiology. Assurance Labs uses PCR for the identification of pathogens that are capable of causing illness. This type of testing is the same that is used to identify COVID-19.

In addition to the COVID-19, they test for over 100 different pathogens and offer several panels including Respiratory Pathogen Panel, UTI with Antibiotic Resistance Markers, Vaginitis, STD, Wound, and GI panels. They also perform culture and Antibiotic Sensitivity Testing. Please visit <u>assurancescientificlabs.com</u>, email <u>clientservices@assurancescientific.com</u> or call 855.319.4459 for additional information.

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