## ORANGE COUNTY OPERATIONAL AREA EMERGENCY OPERATIONS CENTER

## FOR IMMEDIATE RELEASE

## PRESS RELEASE # 029

Date: 3-26-20 Time: 17:00 hours

## OC HEALTH CARE AGENCY CAUTIONS AGAINST USE OF COVID-19 TESTS NOT APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION

County Health Officer Dr. Nichole Quick today warned residents against the use of testing kits that have not been approved by the U.S. Food and Drug Administration (FDA) for diagnosis of COVID-19.

"These non-approved tests can produce false results and lead to unintended negative consequences for the individual and the broader community," said Dr. Quick. "For example, a false negative result from a non-approved testing kit may lead an individual who in fact has COVID-19 to think they are healthy and not capable of spreading the virus. We want to ensure our community members are getting accurate information about their health, and accurate information drives appropriate medical care."

The most accurate, FDA-approved testing available to-date is polymerase chain reaction, also known as PCR testing. PCR can detect small amounts of the virus in a specimen from a patient. This is the test used by the OC Health Care Agency's (HCA) Public Health Laboratory and by commercial labs reporting to the HCA.

There are currently no FDA-approved COVID-19 serology tests available in the United States. Serology testing may detect if an individual's body is starting to develop antibodies against a particular virus.

Orange County residents should understand that:

- There is currently no Centers for Disease Control and Prevention guidance on how to interpret or take public health action in response to a positive or negative COVID-19 serology result.
- Any company that claims FDA approval or authorization for a serology test is misleading the public.

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• No COVID-19 serology test kits have been reviewed by the FDA or received Emergency Use Authorization.

For general information about COVID-19, please call the OC Health Care Agency's (HCA) Health Referral Line at (800) 564-8448, visit <a href="http://www.ochealthinfo.com/novelcoronavirus">http://www.ochealthinfo.com/novelcoronavirus</a>, or follow the HCA on Facebook (@ochealthinfo) and Twitter (@ochealth).

For non-medical questions, contact the County of Orange Public Information Hotline at (714) 628-7085.

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