Fauci, FDA, WHO All Now Admit False Results From PCR Tests

January 5, 2021

Screenshot: CBS Face The Nation, YouTube

Zero Hedge – The FDA on Monday joined The WHO and Dr. Fauci in admitting there is a notable risk of false results from the standard PCR-Test used to define whether an individual is a COVID "Case" or not. [Full FDA statement below.]

This matters significantly as it fits perfectly with the 'fake rescue' plan we have previously described would occur once the Biden admin took office.

But before we get to that 'conspiracy', we need a little background on how the world got here…

We have detailed the controversy surrounding America's COVID "casedemic" and the misleading results of the PCR test and its amplification procedure in great detail over the past few months.

As a reminder, "cycle thresholds" (Ct) are the level at which widely used polymerase chain reaction (PCR) test can detect a

sample of the COVID-19 virus.

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The higher the number of cycles, the lower the amount of viral load in the sample; the lower the cycles, the more prevalent the virus was in the original sample.

Numerous epidemiological experts have argued that cycle thresholds are an important metric by which patients, the public, and policymakers can make more informed decisions about how infectious and/or sick an individual with a positive COVID-19 test might be.

However, as JustTheNews reports, health departments across the country are failing to collect that data.

Here are a few headlines from those experts and scientific studies:

1. Experts compiled three datasets with officials from the states of Massachusetts, New York and Nevada that conclude:"Up to 90% of the people who tested positive did not carry a virus."

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2. The Wadworth Center, a New York State laboratory, analyzed the results of its July tests at the request of the NYT: 794 positive tests with a Ct of 40: "With a Ct threshold of 35, approximately half of these PCR tests would no longer be considered positive," said the NYT. "And about 70% would no longer be considered positive with a Ct of 30! "

3. An appeals court in Portugal has ruled that the PCR process is not a reliable test for Sars-Cov-2, and therefore any enforced quarantine based on those test results is unlawful.

4. A new study from the Infectious Diseases Society of America, found that at 25 cycles of amplification, 70% of PCR test "positives" are not "cases" since the virus cannot be cultured, it's dead. And by 35: 97% of the positives are non-clinical.

5. PCR is not testing for disease, it's testing for a specific RNA pattern and this is the key pivot. When you crank it up to 25, 70% of the positive results are not really "positives" in any clinical sense, since it cannot make you or anyone else sick

So, in summary, with regard to our current "casedemic", positive

tests as they are counted today do not indicate a "case" of anything … *Click source below to read more.*

FDA PRESS RELEASE:

Risk of False Results with the Curative SARS-Cov-2 Test for COVID-19: FDA Safety Communication

Date Issued: January 4, 2021

The U.S. Food and Drug Administration (FDA) is alerting patients and health care providers of the risk of false results, particularly false negative results, with the Curative SARS-Cov-2 test. Risks to a patient of a false negative result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

To reduce the risk of false negative results, it is important to perform the test in accordance with its authorization and as described in the authorized labeling, e.g., the Fact Sheet for Healthcare Providers. When the test is not performed in accordance with its authorization or as described in the authorized labeling, there is a greater risk that the results of the test may not be accurate.

Important Recommendations for Health Care Providers, Patients, and Caregivers

- Be aware of the important information regarding the use of the Curative SARS-Cov-2 test, which is described in the test's authorized labeling, including the following:
  - Collection of nasal swabs and oral fluid specimens is limited to symptomatic individuals within 14 days of COVID-19 symptom onset.
  - Specimen collection must be directly observed and directed during the sample collection process by a trained health care worker at the specimen collection site.
  - A negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.
- **Health care providers:** Consider retesting your patients using a different test if you suspect an inaccurate result was given *recently* by the Curative SARS-Cov-2 test. If testing was performed more than two weeks ago, and there is no reason to suspect current SARS-CoV-2 infection, it is not necessary to retest.
- **Patients and caregivers:** Talk to your health care provider if you think you were tested with the Curative SARS-Cov-2 test (the test name is displayed on this test's authorized Fact Sheets and, generally, the Fact Sheets must be provided with test result reports) and you have concerns about your test results.
- Report any problems you experience with the Curative SARS-Cov-2 test to the FDA, including suspected inaccurate results.

Device Description

The Curative SARS-Cov-2 Assay is a real-time RT-PCR test used to detect SARS-CoV-2, the virus that causes COVID-19. This test is authorized for prescription-only use. The test is performed by

collecting a throat swab, nasopharyngeal swab, nasal swab, or oral fluid specimen from an individual suspected of COVID-19 by their health care provider. Under the Emergency Use Authorization, the specimen is then to be processed at the KorvaLabs, Inc., laboratory, and results are returned to the patient.

Consistent with the test's authorized labeling, collection of nasal swabs and oral fluid specimens is limited to individuals who have shown symptoms of COVID-19 within 14 days of onset of the symptoms. Specimen collection must be directly observed and directed during the sample collection process by a trained health care worker at the specimen collection site.

Consistent with the EUA summary, negative results for SARS-CoV-2 RNA from oral fluid specimens should be confirmed by testing of another specimen type authorized for use with this test if clinically indicated.

FDA Actions

The FDA regularly monitors the post-authorization use of tests, including reports of problems with test performance or results, and is providing this information to help educate patients, caregivers, and health care providers and reduce the risk of false results.

The FDA will keep the public informed if significant new information becomes available.

Reporting Problems with a Medical Device

The FDA encourages stakeholders to report adverse events or

suspected adverse events, including problems with test performance or results, through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

Generally, as specified in a test's EUA, device manufacturers and authorized laboratories must comply with applicable Medical Device Reporting (MDR) regulations.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV or call 800-638-2041 or 301-796-7100. SOURCE