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FDA Quietly Recalls Thousands of Unreliable COVID-19 Tests

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The Food and Drug Administration (FDA) recalled more than 77,000 COVID-19 tests because their results were highly unreliable.

"The FDA has identified this as a Class I recall, the most serious type of recall," begins the agency's recall notice. "Use of these devices may cause serious injuries or death."

According to the FDA, the Innova SARS-CoV-2 Antigen Rapid Qualitative Test "used a nasal swab sample and test strip to detect specific proteins, called antigens, from the SARS-CoV-2 virus. If the nasal sample had SARS-CoV-2 antigens, a colored test line should have appeared on the test strip, indicating that the person may have COVID-19."

As uncomfortable as having one's nostrils swabbed may be, however, the danger of "serious injuries or death" arises from the fact that the test produced both false negatives and false positives.

A false negative might delay diagnosis of COVID-19, by which time the patient may have developed serious symptoms or even died. In addition, the individual might have unknowingly spread the virus.

A false positive, by contrast, might lead to an incorrect diagnosis of what actually ails a patient, preventing proper treatment. It could also — thanks to tyrannical government policies — prevent someone from working, traveling, or otherwise going about normal life despite being perfectly healthy. And if, on the assumption that he had COVID-19, he were housed with others who did have it, he might well contract it after all.

An unreliable COVID-19 test, then, is nothing to sneeze at. That is undoubtedly why the FDA took pains to state, "The test has not been authorized, cleared, or approved by FDA for commercial distribution in the United States." Like the various vaccines, it was only approved for emergency use.

How widely were these tests used? The FDA says healthcare providers and "organizers of large testing programs, such as on college campuses," employed them. At least 77,339 tests were recalled, "but perhaps far more were used and unaccounted for," Brian C. Joondeph, M.D., noted in an American Thinker article. The test, after all, has been around since February 2020.

Joondeph discovered something curious about the test's manufacturer:

> Who makes this recalled test? Innova Medical Group, headquartered in Pasadena, Calfornia [*sic*], is a wholly-owned subsidiary of Pasaca Capital, Inc. Pasaca is a private equity firm, also headquartered in Pasadena, whose founder and CEO, Charles Huang, Ph.D., received his undergraduate degree in economics from Wuhan University, China, where he grew up.

All roads in the COVID story seem to lead to Wuhan.

Joondeph also found that "while the FDA stopped the Innova … test in the U.S., across the pond in the U.K., they are doubling down by clearing its use and extending its authorization." There's no definitive answer as to why the Brits are so intent on employing a faulty test, but Joondeph suggests that Huang may have "connections with … Downing Street power brokers" as a result of obtaining his advanced degrees from a prestigious Scottish university.

Of course, this isn't the first unreliable COVID-19 test to come to light. When the virus first appeared in the United States, the Centers for Disease Control and Prevention (CDC) distributed test kits that the agency knew to be wrong a third of the time. What's more, the frequent failures were caused by contamination that had occurred in the CDC's own laboratories.

Even the supposedly more reliable PCR tests have their problems, from generating false positives (as many as 90 percent, according to the *New York Times*) to being unable to differentiate between COVID-19 and the flu. In fact, the CDC recently withdrew its request for emergency-use authorization for PCR tests specifically because they can't tell the two viruses apart.

One might expect that something as significant as the recall of a coronavirus test would be big news. But the FDA recalled the Innova test in June, and nary a peep was heard about it from the mainstream media, which instead feels compelled to report such hugely important stories as Britney Spears' conservatorship battles. Why? Is it, asked Joondeph, because the test is unimportant now that it has "produced the desired results," i.e., vastly inflated COVID-19 case counts? "Was it ever about the virus?" he wondered. "Or was it just to further a political agenda?"