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# CDC Coronavirus Test Kits Generate 30% False Positive and 20% False Negative Results - Connecticut Pathologist's Newly

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CDC Coronavirus Test Kits Generate 30% False Positive and 20% False Negative Results - Connecticut Pathologist's Newly Published Findings Confirm

Business Wire

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The current CDC nucleic acid test kits for SARS-CoV-2 generate 30% false-positive and 20% false-negative results in the best state public health laboratory, Dr. Sin Hang Lee reported in a peer-reviewed article published in the International Journal of Geriatrics and Rehabilitation, an online journal based in Japan (<http://www.int-soc-clin-geriat.com/info/wp-content/uploads/2020/03/Dr.-Lees-paper-on-testing-for-SARS-CoV-2.pdf>), on July 17, 2020.

Sin Hang Lee, MD, director of Milford Molecular Diagnostics Laboratory, the author of the article ([http://www.dnalymetest.com/images/IJGeriatRehabLee\\_on\\_SARSCoV2\\_test.pdf](http://www.dnalymetest.com/images/IJGeriatRehabLee_on_SARSCoV2_test.pdf)), re-tested 20 reference samples provided by the Connecticut State Department of Public Health Microbiology Laboratory Division to arrive at this conclusion, according to the published article. These reference samples were tested by the State Microbiology Laboratory with the CDC test kit and used as the standard reference to guide local laboratories to develop their own tests for SARS-CoV-2 in clinical specimens from suspected COVID-19 patients, according to the published article titled "Testing for SARS-CoV-2 in cellular components by routine nested RT-PCR followed by DNA sequencing."

Dr. Lee is the first scientist developing a protocol to test the cellular components, instead of the cell-free fluid sample of a swab rinse, for SARS-CoV-2 genomic RNA.

"The virus must grow and replicate in a living cell, and one infected cell may contribute thousands of copies of viral genome equivalents to be tested," explained Dr. Lee.

The Food and Drug Administration (FDA) requires 95% positive and negative agreement with the reference samples for a laboratory-developed test to be acceptable in a request for SARS-CoV-2 molecular diagnostic test to be performed under the Emergency Use Authorization (EUA). But the FDA also states, "False results can be investigated using an additional EUA RT-PCR assay, and/or Sanger sequencing." This indicates that Sanger sequencing is a de facto gold standard in resolving discordant nucleic acid-based test results, said Dr. Lee.

Using Sanger sequencing as a tool for molecular validation, one of the two false-negative samples supplied by the Connecticut State Laboratory was found to contain a mutant with a novel single nucleotide A insertion in the N gene and a wild-type parental SARS-CoV-2, indicating that a newly developed mutant and its parental virus can co-infect the same host, as illustrated in this N gene sequence published in the article.

One of the nine positive SARS-CoV-2 isolates was found to belong to a recently discovered mutant first isolated from a specimen collected in the State of New York on March 17, 2020, Dr. Lee reports in the article.

"Long-term care facilities with exceptionally high COVID-19 death tolls among their residents and hospitals with active nose-and-throat surgery departments

may need to install an extremely sensitive and highly accurate Sanger sequencing-based test for SARS-CoV-2 to protect their residents, patients and staff," said Dr. Lee.

According to Dr. Lee, this manuscript has been peer-reviewed by 5 reviewers and two journal editorial boards before finally accepted for publication under an Open Review process.

Dr. Lee offers to re-test the residues of the respiratory swab samples of the deceased residents of the nursing homes with exceptionally high death tolls for SARS-CoV-2 with his protocol to investigate a possible link between false test results and the high rates of COVID-19 death in these institutions, as widely reported in the news media. Interested parties are encouraged to contact Kevin Moore.

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