

FDA authorizes saliva-based COVID-19 test developed at Yale

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By Michael Greenwood
Yale University

A saliva-based laboratory diagnostic test developed by researchers at the Yale School of Public Health to determine whether someone is infected with the novel coronavirus has been granted an emergency use authorization by the U.S. Food and Drug Administration (FDA). The method, called SalivaDirect, is being further validated as a test for asymptomatic individuals through a program that tests players and staff from the National Basketball Association (NBA). SalivaDirect is simpler, less expensive, and less invasive

than the traditional method for such testing, known as nasopharyngeal (NP) swabbing. Results so far have found that SalivaDirect is highly sensitive and yields similar outcomes as NP swabbing. With the FDA’s emergency use authorization, the testing method is immediately available to other diagnostic laboratories that want to start using the new test, which can be scaled up quickly for use across the nation — and, perhaps, beyond — in the coming weeks, the researchers said. A key component of SalivaDirect, they note, is that the method has been validated with reagents and instruments from multiple vendors. This flexibility enables continued testing if some vendors encounter supply chain issues, as

experienced early in the pandemic. “The preprint on the development and validation of SalivaDirect was recently posted on medRxiv. Development of SalivaDirect as a means of rapidly expanding SARS-CoV-2 testing was spearheaded this spring by Nathan Grubaugh and Anne Wyllie, assistant professor and associate research scientist, respectively, at Yale School of Public Health. After finding saliva to be a promising sample type for SARS-CoV-2 detection, they wanted to improve the method further. “With saliva being quick and easy to collect, we realized it could be a game-changer in COVID-19 diagnostics,” said Wyllie. With testing urgently needed, the Yale team was determined to decrease both testing

times and costs, to make testing widely accessible. “Wide-spread testing is critical for our control efforts. We simplified the test so that it only costs a couple of dollars for reagents, and we expect that labs will only charge about \$10 per sample. If cheap alternatives like SalivaDirect can be implemented across the country, we may finally get a handle on this pandemic, even before a vaccine,” said Grubaugh. One of the team’s goals was to eliminate the expensive saliva collection tubes that other companies use to preserve the virus for detection. In a separate study led by Wyllie and the team at the Yale School of Public Health, and recently published on medRxiv, they found that SARS-CoV-2 is stable in saliva for prolonged periods at warm

temperatures, and that preservatives or specialized tubes are not necessary for collection of saliva. The Jackson Laboratory for Genomic Medicine in Farmington, Connecticut, will partner with Yale to explore how to implement the test for a broader audience. The laboratory already analyzes patient samples for an RNA signature unique to that of SARS-CoV-2, the virus that causes COVID-19. “We must continue to invent and implement new ways to conduct SARS-CoV-2 testing faster, more economically and with greater accessibility, while maintaining acceptable test accuracy,” said Charles Lee, the lab’s director. “This is an important next step toward this goal.” Grubaugh and Wyllie said that they are not

seeking to commercialize the method. Rather, they want the simplified testing method to help those most in need. Testing for SARS-CoV-2 has been a major stumbling block in the fight against the pandemic, with long delays and shortages of testing. Some experts have said that up to 4 million tests are needed per day; SalivaDirect provides one pathway toward that goal, the researchers said. “Using SalivaDirect, our lab can double our testing capacity,” said Professor Chen Liu, chair of Yale Pathology, who oversaw the clinical validation of the study. “Dr. Liu and Yale Pathology Laboratory were instrumental in our application. We look forward to continuing to partner with them,” said Grubaugh.



AP Photo/Don Thompson, File

In this July 12, 2018, file photo, Jane Carson-Sandler, of South Carolina, who was raped by the Golden State Killer in 1976, holds a sign with a message to her attacker in Sacramento, California. She is among survivors who this week plan to confront Joseph James DeAngelo during four days of court hearings before the 74-year-old is sentenced to life in prison.

Victims tell of trauma in rape, murder case

By DonThompson
Associated Press

SACRAMENTO, Calif. — Jane Carson-Sandler said she has served an effective life sentence in the more than four decades since she was one of the first rape victims of a one-time police officer who eventually became known as the Golden State Killer. Now it’s Joseph James DeAngelo’s turn. Carson-Sandler will be among nearly three dozen victims or survivors who plan to confront DeAngelo this week during an extraordinary four days of court hearings before the 74-year-old is sentenced to life in prison. Some plan to tell of their pain, others of their healing. It’s the culmination of a plea deal that will spare him the death penalty for 13 murders and numerous sadistic rapes and burglaries that terrorized California for more than a decade. The perpetrator behind the reign of terror mystified investigators until they used a new form of DNA tracking to arrest him in 2018. “Our wounds heal and our scars remain,” Carson-Sandler said. Certain things always trigger flashbacks to that night in 1976 when DeAngelo confronted her with a butcher knife as she snuggled in bed with her 3-year-old son after her husband left for work at a nearby military base. She can’t go skiing, for fear she’ll see someone in a ski mask like the one DeAngelo wore. The sound of a helicopter is another trigger, because “after the attack the helicopters would fly over

every night with spotlights on the ground, looking for DeAngelo.” DeAngelo pleaded guilty in June to 13 counts of murder and admitted to dozens of rapes that were too old to prosecute. His attorneys did not respond to a request for comment. All told, he admitted to 161 crimes involving 48 people. Testimony from DeAngelo’s Sacramento County rape victims alone will consume a full day Tuesday. Other rape victims will speak Wednesday, and family members of those murdered will speak Thursday before Sacramento County Superior Court Judge Michael Bowman formally sentences DeAngelo on Friday. Kris Pedretti was 15 when DeAngelo attacked her just before Christmas in 1976. “This kid who liked to go shopping and do cartwheels on the lawn, that girl was gone,” she said. She lost her friends, her once profound faith in God, switched schools three times, had two failed marriages, and “did a lot of self-medicating, a lot of poor coping mechanisms.” It wasn’t until DeAngelo’s arrest that she sought therapy and changed her life again. She’s now happily married, is described by other survivors as the “den mother” who helps organize pot luck dinners after each of DeAngelo’s court appearances, and this year she started a Facebook group for sexual assault survivors. It now has more than 300 members. “He didn’t win, I’m not a lost girl. I want to make that clear,” Pedretti said.



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