Technical FAQs about the UC Merced Rapid Saliva Test

January 11, 2021

The saliva test used at UC Merced is a rapid test that detects whether someone is currently infected with the coronavirus. This is a laboratory developed test that uses a high throughput, real time, quantitative polymerase chain reaction (RT-qPCR) protocol run on machines repurposed from the agricultural genetics industry. The saliva samples are processed at the UC Davis Genome Center.

For more information, visit UC Davis's COVID-19 Testing webpage.

Technical FAQs:

- ***How does this test work?***

  This protocol tests for the presence of two viral genes, N1 and N2, in a saliva sample to identify if someone is acutely infected with COVID-19. The test uses a protocol adapted from CDC-designed assays specific to the SARS-CoV-2 virus in order to detect the virus in saliva samples. SARS-CoV-2 RNA is generally detectable in saliva specimens during the acute phase of infection. Detection of the viral genes leads to a positive result.

- ***How accurate is it? What about false positives or false negatives? How sensitive and specific is this test?***

  All tests have a trade-off between the likelihood of false negatives and the likelihood of false positives, which is measured by a test's sensitivity and specificity.

  Sensitivity can be considered in two ways. The limit of detection can be determined by analyzing contrived samples containing known amounts of deactivated virus added in. This test's lower limit of detection was determined to be 15 copies per microliter (µL) of saliva. This represents a low level of virus that is comparable to other tests authorized by the FDA for emergency use. Such low levels have been shown to be rarely infectious in cell culture studies.

  The second way to measure sensitivity is to compare it to clinical samples that have been declared positive or negative by an independent lab. On this basis, this test's sensitivity is currently calculated at 84–88%, which is considered adequately sensitive. This means the test will positively identify 84–88% of those who are actually infected with COVID-19. It will, however, reliably detect people with high viral counts, who are the most likely to be infectious.

  Another way of looking at this test's sensitivity is that about 12–16% of people who are actually infected will receive a "false negative" result from this test because they have low levels of virus. This could be because they are in the short period during early stages of infection when the viral load is just beginning to increase or in the longer period of recovery after the infectious period.

  The test uses the same PCR primers as previously validated for numerous FDA approved tests, and it is therefore considered highly specific for SARS-CoV-2. Consequently, a positive result is therefore diagnostic of COVID-19. False positives are highly unlikely.

- ***Is this test FDA approved?***

  No, this test is not currently authorized by the Food and Drug Administration. This is a laboratory-developed test. The FDA is not currently required to review laboratory-developed tests and until recently has declined to review new requests for emergency use authorizations (EUAs). There is signage to this effect at the testing kiosk. The guidance on EUAs has recently changed and therefore we will be submitting an EUA to the FDA.

- ***How was this test validated?***

  To validate the test, the UC Davis campus testing protocol was compared to a validated saliva-based test from Arizona State University. ASU provided 50 positive and 50 negative samples; the FDA recommends at least 30 of each. The UC Davis test achieved high concordance up to the limit of detection. The test's limit of detection was determined by testing contrived samples containing known amounts of deactivated virus. The lab director for Student Health and Counseling Services approved the validation of this UC Davis rapid saliva test based on the validation data as recommended by FDA.

- ***What genes does the test target? What about the endogenous control?***

  The test targets the N1 and N2 gene of SARS-CoV-2 using primers approved by the FDA. Human RNaseP is used as the endogenous control as approved by FDA.

- ***What is the cycle threshold for this testing process?***

  The cycle threshold (Ct) values will vary by test and machine. The Ct value for our limit of detection as defined by the FDA is 32. However, the test can detect the virus at higher Ct values (lower viral loads). The cut-off for calling a positive is the FDA recommended value of <40. However, we rarely obtain Ct values greater than 35.

- ***Are samples batch tested?***

  Samples are tested in batches of up to 760 as individual samples. Samples are not pooled. The machine is sufficiently high throughput that pooling is not necessary or desirable. Pooling would increase the complexity of the workflow and slow the return of results by at least a day.

- ***I'm concerned about privacy. Who will have access to our results?***

  Saliva samples delivered to the UC Davis Genome Center do not have any identifiable information associated with them. The UC Davis Genome Center receives a sample in a bar-coded tube and reports a result for that barcode to our database.

  From the database, employees from our Student Health Services— all of whom are trained to maintain HIPAA compliance — connect the result to the individual tested.

  If you test positive, you will receive a call from a campus medical provider with information about your results and next steps. You will also be contacted by the campus contact tracing team.

  Positive test results are also reported to the Merced County Public Health Department, in accordance with CDC guidance, state and county requirements and as mandated by law.

- ***What will happen to my saliva sample? Are the samples being used for research?***

  All saliva samples are stored in a cold room for at least a few days in case a sample needs to be rerun.

  All positive samples are then stored frozen in a freezer, for use in quality control and protocol improvement. A few negative samples will be kept as controls.

  Currently the saliva samples are not being used for research. If in the future the UC Davis Genomics Lab team is interested in pursuing research using saliva samples from this testing process, then they will be guided by the Institutional Review Board process, and a consent form for optional research will be made available for testing participants to decide if they want to consent to participating in the research or not.

- ***Why does campus allow an employee or student to access facilities on the same day they get tested, before they have received a negative test result?***

  Our goal is to test asymptomatic members of our campus community frequently, in order to quickly identify individuals who may be contagious and to monitor the infection rates of our community. Participating in this routine testing program is valuable for our community, and we aim to make this process as easy and convenient as possible.

  Routine testing is a public health program aimed to reduce risk, but it does not guarantee that anyone accessing campus facilities is negative for the coronavirus.

  It is important to understand the limitations of a negative test result. Even with rapid, regular testing, someone can get infected and become contagious in between their weekly tests. Through multiple layers of public health precautions and responses, we are doing our best to reduce the number of people who are accessing campus while they are at risk of being infectious and to mitigate potential spread.

  We encourage everyone to act as if those around them are potentially positive for the virus.