

What is COVID-19?

COVID-19 is the disease caused by the SARS-CoV-2 virus. COVID-19 is spread person-to-person through respiratory droplets and can cause mild to severe respiratory illness. Symptoms associated with COVID-19 include fever, coughing, sneezing, loss of taste and/or smell, and difficulty breathing.

What type of COVID-19 molecular testing is currently offered at TGen?

TGen has developed a real-time reverse-transcription polymerase chain reaction (rRT-PCR) assay that targets conserved regions of the N and S genes in the SARS-CoV-2 genome. The assay is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory (e.g., nasopharyngeal/oropharyngeal swabs, nasopharyngeal wash/aspirate, nasal aspirate) or saliva specimens collected from individuals suspected of being exposed to COVID-19 or who meet the clinical and/or epidemiological criteria.

What types of samples does TGen accept?

TGen accepts 1) respiratory specimens (e.g., nasopharyngeal/oropharyngeal swabs, nasopharyngeal wash/aspirate, nasal aspirate) in viral transport media or sterile saline, or 2) saliva specimens collected in empty, sterile collection devices or via a Spectrum™ collection kit.

How specific is TGen's rRT-PCR assay?

As of February 2021, the genomic targets we use in this test are an exact match to the 99.8% of all published SARS-CoV-2 genomes (422,291). This means that the test is effective in detecting essentially all strains of SARS-CoV-2. As more information becomes available about new strains and variants, we will continue to evaluate our test to ensure it is still effective despite new mutations.

What is the limit of detection (LoD) for TGen's rRT-PCR assay?

3.13 genomes/μL. This means that the assay can reliably detect very small quantities of virus in a sample. This number is comparable to the LoD reported by the CDC.

How comparable are saliva and respiratory specimens for use in detecting SARS-CoV-2?

Using internal data, TGen determined the overall concordance between co-collected saliva and nasopharyngeal swab specimens to be 92.4%, with 84.2% concordance for positive samples and 100% concordance for negative samples. Furthermore, our data suggest that concordance is improved if sampling takes place soon after COVID-19 diagnosis or symptom onset. Other studies (e.g. Wyllie et al., 2020) have also found saliva to be an acceptable specimen for the detection of SARS-CoV-2. Considering our internal data and the available literature, we approve the use of saliva as an alternative specimen to nasopharyngeal swabs for SARS-CoV-2 diagnostics.

False negatives

Due to the high sensitivity of our test, the probability of a false negative result is very low. However, variability in viral load over the course of infection can cause a patient at the beginning/end of an infection to produce a sample with viral quantities that are too low to detect. Additionally, inhibitory substances present in the sample due to non-compliance with the testing instructions (e.g., 30 minutes without drinking, eating, tobacco use, etc.) could cause a false negative or invalid result. However, our protocols specify that any sample suspected of containing inhibitory substances (e.g., food, tobacco, etc.) will be rejected, and samples with unavoidable contamination (e.g., blood) will undergo additional purification prior to testing.

While current genome sequencing efforts indicate that the TGen assay is not impacted by the current genetic variants of SARS-Cov-2, future variation may impact assay performance, potentially leading to false negative results. TGen continues to be involved in genomic sequencing of the SARS-CoV-2 virus, in part to support the detection of novel variants.

False positives

Our laboratory developed test design is 99.9% specific to SARS-CoV-2. This specificity validation includes testing for cross-reactivity to closely related organisms. At TGen, we pride ourselves on our daily decontamination processes, in addition to increased-prevalence, line-stop verification protocols that are actively in place to minimize false positive PCR test results.

For more information

Please contact clientsupport@tgen.org for further information about COVID-19 testing at TNCL.