

## TGen North Clinical Laboratory COVID-19 Testing & Submission Guidelines

### 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 includes fever, coughing, sneezing, and difficulty breathing.

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

TGen has developed a real-time reverse-transcription polymerase chain reaction (RT-PCR) assay designed to detect the virus that causes COVID-19 in respiratory specimens, such as nasopharyngeal or oropharyngeal swabs and nasal wash specimens collected from individuals suspected of having COVID-19.

### What type of samples does TGen accept?

TGen accepts respiratory specimens including nasopharyngeal swabs, combined mid-turbinate nasal and oropharyngeal swabs, aspirates, and nasal washes in viral transport media or sterile saline.

### How should samples be collected?

Collection should be conducted with a sterile swab. Specimen collection with a flocked swab is preferred. When options are limited, collection by a foam swab or spun synthetic swab is also acceptable but may not be sufficient to rule out infection. Only use swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit testing. Additional CDC guidance on specimen collection and handling can be found [here](#).

### What are the storage and shipping guidelines?

Specimens should be stored at 2-8°C and shipped overnight on ice packs or stored frozen and shipped on dry ice if specimen shipment will occur more than 72 hours after specimen collection.

### What are the requirements to submit a sample?

Specimens should be labeled with the patient's name, date of birth, ID number (e.g., medical record number) and the date the specimen was collected, and be accompanied by a completed laboratory requisition form. Specimens for clinical testing must be received in a sterile, leak-proof collection tube with 2-3 mL of viral transport media or 1-3 mL of sterile saline. Specimens must be packaged in a secured biohazard (or Ziploc) bag with the requisition form in an outside pocket or in a separate bag, which is then placed with the specimen to avoid contamination of the form if leakage occurs.

### Where do I send my samples?

Specimens should be packed in accordance with UN 3373, Category B Biological Substance, and shipped via FedEx or UPS directly to TGen North Clinical Laboratory (TNCL) 3051 W Shamrell Blvd, Suite 106, Flagstaff, AZ 86005. Receipt via a courier is also accepted.

### What is the turn-around time?

Our turn-around time is 48 hours from sample receipt to reporting of laboratory results.

### How do I receive my results?

Laboratory reports will be returned to the submitting agency listed on the requisition form through secure email or fax. Verbal results can be communicated to the ordering provider or delegated party by TNCL Data Management Team or Partner Management Coordinator. All clinical results must be interpreted by a licensed healthcare provider.

### Does TNCL have reporting requirements?

TNCL will follow Communicable Disease Reporting requirements for Federal and State Public Health Agencies and will report all laboratory results to the appropriate entity.

Visit the [FDA website](#) for further details on diagnostic testing for SARS-CoV-2.

Please contact TNCL's Partnership Management Coordinator ([hyaglom@tgen.org](mailto:hyaglom@tgen.org)) to receive a copy of our laboratory requisition form and for any additional information (e.g. capacity, testing costs, and assay performance).

## TGen North Clinical Laboratory (TNCL) Technical Information Sheet

### **What is the TGen's SARS CoV-2 RT-PCR Assay?**

The TGen SARS-CoV-2 RT-PCR Assay is a real-time reverse-transcription polymerase chain reaction (RT-PCR) assay targeting 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 the SARS-CoV-2 in respiratory specimens, such as nasopharyngeal or oropharyngeal swabs and nasopharyngeal wash/aspirate or nasal aspirate specimens collected from individuals suspected of being exposed to COVID-19 or who meet the clinical and/or epidemiological criteria.

### **What is the sensitivity and specificity of the assay?**

The sensitivity and specificity of the TGen SARS CoV-2 RT-PCR Assay is equivalent to CDC's revised assay. The TGen assay is an EUA validated test, was designed, and subsequently validated, not to cross react with any known human viruses. As part of the assay's analytical validation, 20/20 samples consisting of collection medium spiked with SARS-CoV-2 RNA at 3.13 genome copies per ml and 20/20 spiked at 6.25 viral genome copies per ml tested positive by the assay.

### **What could cause false positive results?**

False positives occur very rarely and are generally the result of a sample processing or reporting error.

### **What could cause false negative results?**

False negative results could occur for a number of reasons, including specimen method of collection, degradation of the patient sample (i.e. increased time between collection and testing), low viral load in the patient specimen, severity of illness, prior treatment with antivirals, or human error (i.e. during processing or reporting).

### **How does TNCL mitigate the risks of false positive and false negative results?**

The TGen SARS-CoV-2 RT-PCR Assay has been designed to minimize the likelihood of false positive and false negative test results. The TNCL has incorporated a living Quality Management system that not only includes numerous quality controls, but constantly evaluates potential for errors, redesigns processes and training to prevent such errors and improves overall quality assurance. Laboratory technicians employed by TNCL's high complexity CLIA laboratory meet CMS requirements. The laboratory uses automation, a laboratory information management system and barcoded sample tracking to minimize handling errors and sample swaps. Furthermore, each sample is interrogated by two different assays, targeting different SARS-CoV-2 genes, both of which must match in order to yield a reported result.

### **How should laboratory results be interpreted?**

Laboratory test results should always be considered in the context of clinical observations and the patient's recent exposures when making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines. If results are inconsistent with a patient's exposure history and other clinical findings, re-testing should be considered in consultation with public health authorities.

Please contact TNCL's Partnership Management Coordinator ([hyaglom@tgen.org](mailto:hyaglom@tgen.org)) for any additional information.