



TGen North Clinical Laboratory (TNCL) rRT-PCR Specimen and Shipping Guidelines

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 type 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 should samples be collected?

For nasopharyngeal specimens: 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.

For saliva specimens: Saliva should be allowed to collect in the mouth before slowly guiding saliva into an empty, sterile collection device or Spectrum™ collection kit.

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?

Specimen tubes are required to 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. Nasopharyngeal specimens 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 (ultimately packaged in the secured biohazard/Ziploc bag) to protect the requisition form should the collection device leak.

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, 3051 W Shamrell Blvd, Suite 106, Flagstaff, AZ 86005. Receipt via a courier is also accepted.

What are TGen's operating hours?

The laboratory accepts and processes samples Monday through Friday from 8-5 pm. We do not operate on weekends or federal holidays.

What is the turnaround time?

Our turnaround time is 24-48 hours from sample receipt to reporting of laboratory results. Anticipated delays will be communicated with submitting agency.

How will 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.

For more information

Please contact us at tncl@tgen.org for any additional information (e.g. capacity, to receive a copy of our laboratory requisition form, to order collection kits, testing costs, assay performance, etc.).