Diagnostic testing for the novel coronavirus SARS-CoV-2 is undertaken using 3 approaches: whole genome sequencing, real-time reverse transcriptase PCR (rRT-PCR), and serology. Sequencing was used primarily in the early days of the outbreak for initial identification of this novel virus and is largely a tool of viral discovery. Currently, almost all diagnostic testing for SARS-CoV-2 is done using rRT-PCR. Serologic tests that detect prior infection are now being developed and are discussed in another fact sheet. In rare circumstances, viral cultures can also be used, but they are not normal tools in clinical practice and are not covered here.

A person in the United States can be tested for SARS-CoV-2 by a physician's order when that person has symptoms consistent with COVID-19, the disease caused by the SARS-CoV-2 virus. Recent updates to guidance include prioritization of cases. The CDC recommends that physicians use their best judgment in determining if a patient meets testing criteria and that fever, acute respiratory illness, and shortness of breath are typical symptoms. The priorities of testing are:

1. Hospitalized patients and healthcare facility workers: ensuring proper care for already hospitalized patients, preventing healthcare provider infection, and mitigating risk of healthcare-associated infections.
2. Patients in at-risk populations: patients in long-term care facilities, patients over the age of 65, patients with comorbidities (diabetes, cardiovascular disease, chronic lung disease), and first responders with symptoms.
3. Community testing: critical infrastructure (essential) workers with symptoms, any individuals with symptoms who are not in categories 1 or 2, healthcare facility workers without symptoms, first responders with symptoms, and individuals with mild symptoms in communities experiencing high numbers of COVID-19 hospitalizations (COVID-19 hotspots).

These priorities are in place to manage use of testing reagents and materials, as these are limited at this time. At the time of publication, individuals who are not healthcare providers, critical workers, or first responders who do not have symptoms are not a priority for testing.

**PCR Testing**

Protocols for rRT-PCR testing developed by several countries and entities, including Germany, Hong Kong, China CDC, Thailand, and Japan, have been posted to the WHO website, and the protocol for testing in the United States has been posted to CDC's site. Charité Universitätsmedizin Berlin developed the first assay and protocol.

**US Protocol:** rRT-PCR tests for SARS-CoV-2 infection in the United States are being run at the CDC in Atlanta for jurisdictions that do not have local testing available. The CDC has published a list of diagnostic rRT-PCR tests that have Emergency Use Authorization (EUA) approval.

- rRT-PCR **primers and probes** have been published by CDC.
- Materials and reagents required to run the rRT-qPCR tests are listed [here](#).

Commercial, hospital-based, and academic rRT-PCR tests kits are now widely available.

**Genetic Sequencing**

Now that the virus has been identified, most sequencing is being undertaken to characterize the virus and monitor for viral mutation, not for clinical diagnosis. However, some sequencing is also being done to generate real-time epidemiologic information. For example, sequencers from Oxford Nanopore are being used in China as part of the ARTIC project to develop "an end-to-end system for processing samples from viral outbreaks, to generate real-time epidemiological information that is interpretable and actionable by public health bodies." The ARTIC network has released a set of materials to assist in sequencing (using Oxford Nanopore equipment). China CDC has also been sequencing samples via Oxford Nanopore products (specifically MinION) to investigate clusters in this outbreak. In the United Kingdom, the COVID-19 Genomics UK Consortium (COG-UK) was recently established to sequence the genomes of SARS-CoV-2. Worldwide efforts to sequence samples and establish phylogenies of the virus can be found on NextStrain, sponsored by GISAID.

**Biosafety Practices**

Characterization of viral agents recovered in cultures of SARS-CoV-2 specimens should be conducted only in a Biosafety Level 3 (BSL-3) laboratory using BSL-3 practices. CDC further states that standard biosafety work practices should be used for pathologic examination, molecular analysis, electron microscopic studies, routine examination of cultures, routine staining and microscopic analysis of fixed smears, final packaging of specimens for transport, and inactivated specimens. Class II biosafety cabinets should be used to perform sample collection that may create aerosols or droplets. If a Class II biosafety cabinet is not available, then precautions such as using PPE, splash shield, centrifuge safety cups, and sealed centrifuge rotors should be maintained.
Regulatory Considerations

The Food and Drug Administration launched a landing page to provide information to the public and to product developers on the agency's response to the SARS-CoV-2 outbreak. The page includes an information for diagnostic test sponsors interested in applying for an Emergency Use Authorization.

References


