Official websites use .gov A .gov website belongs to an official government organization in the United States. Secure .gov websites use HTTPS A lock ( ) or https:// means you've safely connected to the .gov website. Share sensitive information only on official, secure websites. This overview describes current information on the types of tests used to detect SARS-CoV-2 infection and their intended uses. This information is intended for use by healthcare providers, public health professionals, and those organizing and implementing testing in non-healthcare settings. Information for the general public on COVID-19 testing is also available. People who are tested for COVID-19 should receive clear information on: Individuals tested are required to receive patient fact sheets as part of the test's Emergency Use Authorization (EUA). SARS-CoV-2 co-infection with another pathogen, including a respiratory virus, bacterium, or fungus, has been documented, particularly in hospitalized patients.(10,11) Detection of a different respiratory pathogen does not rule out SARS-CoV-2 infection. Testing for other causes of respiratory illness, in addition to testing for SARS-CoV-2, may be considered, depending on: More information on coinfection and recommendations on antimicrobial stewardship or systematic approaches to using antimicrobials can be found on CDC's Testing Guidance for Clinicians When SARS-CoV-2 and Influenza Viruses are Co-circulating and the Infectious Diseases Society of America (IDSA) COVID-19 Real-Time Learning Network. Several markers of inflammation and abnormal coagulation are associated with severe COVID-19 illness.(12,13) Studies found that hospitalized patients with COVID-19 may have coagulation abnormalities including increased D-dimer concentration, a modest decrease in platelet count, and a prolongation of the prothrombin time.(13) One study that compared markers of inflammation in patients with and without COVID-19 observed modestly lower leukocyte, lymphocyte, and platelet counts and higher hemoglobin values in patients with COVID-19.(12) This study also noted that serum albumin, neutrophil to lymphocyte ratio, and red cell distribution width were each

associated with disease severity.(12) Viral tests, including nucleic acid amplification tests (NAATs, such as PCR tests), antigen tests and other tests (such as breath tests) are used as diagnostic tests to detect current infection with SARS-CoV-2, determine the need for prevention measures like isolation, and inform an individual's medical care. Viral tests can also be used as screening tests. Viral tests: Positive viral test results indicate current, or sometimes recent, infection and the person with COVID-19 should follow CDC recommendations for isolation. Negative viral test results mean the test did not detect the virus, but this doesn't rule out that you could have an infection. These results represent a snapshot of the time around specimen collection and could change if the same test was performed again in one or more days. Negative antigen test results should be repeated following FDA guidance. Antibody (or serology) tests are used to test for the presence of antibodies from previous infection or vaccination and can aid in fulfilling the case definition for multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A).2 Antibody testing does not diagnose current infection. Antibody testing is primarily used for public health surveillance and epidemiologic purposes. Antibody tests detect specific antibodies that target different parts (nucleocapsid or spike protein) of the virus. Detection of anti-nucleocapsid antibody indicates SARS-CoV-2 infection, while anti-spike protein antibody may be induced by COVID-19 vaccination or by SARS-CoV-2 infection. This should be considered when choosing whether to test for antibodies originating from past infection versus those from vaccination.

FDA continually monitors the accuracy of COVID-19 tests. Their website provides up-to-date information on the impact of viral mutations on COVID-19 tests. See FDA's list of In Vitro Diagnostics Emergency Use Authorizations for more information about the performance and interpretation of specific authorized tests. Diagnostic testing is intended to identify current infection. It is performed when a person has signs or symptoms consistent with COVID-19 or is asymptomatic but has recent known or

suspected exposure to someone with COVID-19. Screening testing is intended to identify people with COVID-19 who are asymptomatic or do not have any known, suspected, or reported exposure to someone with COVID-19. Public health surveillance testing is conducted to specifically monitor population-level burden of disease, or to characterize the incidence and prevalence of SARS-CoV-2 infection. Surveillance testing is primarily used to gain information at a population level, rather than an individual level, and involves testing of de-identified specimens. Surveillance testing results are not reported back to the individual. As such, surveillance testing cannot be used for an individual's healthcare decision-making or individual public health actions, such as isolation. Examples of public health surveillance testing are genomic surveillance and wastewater surveillance. When choosing which test to use, it is important to understand the purpose of the testing (diagnostic or screening), test performance in context of current COVID-19 incidence, need for rapid results, and other considerations (See Table 1). Positive predictive values (probability that the person testing positive is actually infected) and negative predictive values (probability that the person testing negative is actually not infected) of NAAT and antigen tests vary depending upon the pretest probability. Pretest probability considers both the prevalence of COVID-19 in the community and the clinical context of the individual being tested. CDC provides general information on sensitivity, specificity, and positive and negative predictive values for antigen tests and antibody tests. For information on a specific test, refer to FDA's website. Table 1 summarizes some characteristics of NAATs and antigen tests to consider for a testing program. Laboratories that perform screening or diagnostic testing for SARS-CoV-2 must have a CLIA certificate and meet regulatory requirements. Tests that have received an EUA from FDA for point-of-care (POC) use can be performed with a CLIA certificate of waiver. Vaccination does not affect the results of someone's SARS-CoV-2 diagnostic or screening tests (NAAT, antigen or other diagnostic tests). The main effect of vaccination on SARS-CoV-2 testing is related to antibody testing. Because

mRNA COVID-19 vaccines use the SARS-CoV-2 spike protein to generate an immune response, a positive serologic (antibody) test for spike protein IgM/IgG could indicate either previous infection or vaccination. Antibody testing is not currently recommended to assess a person’s protection against SARS-CoV-2 infection or severe COVID-19 following COVID-19 vaccination or prior infection, or to assess the need for vaccination in an unvaccinated person. Antibody testing can be used in the diagnosis of Multisystem Inflammatory Syndrome in Children (MIS-C) or Multisystem Inflammatory Syndrome in Adults (MIS-A). To evaluate for evidence of previous infection in a vaccinated individual, use an antibody test specifically evaluating IgM/IgG to the nucleocapsid protein. For example, specific antibody tests can be used for public health surveillance. Intended Use Intended Use Diagnose current infection Diagnose current infection Diagnose current infection Diagnose current infection Analyte Detected Analyte Detected Viral ribonucleic acid (RNA) Viral ribonucleic acid (RNA) Viral antigens Viral antigens Specimen Type(s) Specimen Type(s) Nasal, Nasopharyngeal, Oropharyngeal, Sputum, Saliva Nasal, Nasopharyngeal, Oropharyngeal, Sputum, Saliva Nasal, Nasopharyngeal Nasal, Nasopharyngeal Sensitivity Sensitivity Varies by test, but generally high for laboratory-based tests and moderate-to-high for point-of-care (POC) tests Varies by test, but generally high for laboratory-based tests and moderate-to-high for point-of-care (POC) tests Less sensitive than NAATs. Varies by test and depending on the course of infection+* Less sensitive than NAATs. Varies by test and depending on the course of infection+* Specificity Specificity High High High High Test Complexity Test Complexity Varies by test Varies by test Relatively easy to use Relatively easy to use Authorized for Use at the Point-of-Care Authorized for Use at the Point-of-Care Most are not, some are Most are not, some are Most are, some are not Most are, some are not Turnaround Time Turnaround Time Most 1–3 days; some are rapid with results in 15 minutes Most 1–3 days; some are rapid with results in 15 minutes Ranges from 15 minutes to 30 minutes

Ranges from 15 minutes to 30 minutes Cost/Test Cost/Test ~$75-$100/test ~$75-$100/test ~$5-$50/test ~$5-$50/test Advantages Advantages Most sensitive test method available Short turnaround time for NAAT POC tests, but few available Usually does not need to be repeated to confirm results Most sensitive test method available Short turnaround time for NAAT POC tests, but few available Usually does not need to be repeated to confirm results Short turnaround time (approximately 15 minutes) ◊ Cost-effective Some can be performed at-home, or anywhere else Short turnaround time (approximately 15 minutes) ◊ Cost-effective Some can be performed at-home, or anywhere else Disadvantages Disadvantages Longer turnaround time for lab-based tests (1–3 days) Higher cost per test After an infection has ended, and the risk of transmission has passed, people may have detectable RNA and test positive for up to 90 days Longer turnaround time for lab-based tests (1–3 days) Higher cost per test After an infection has ended, and the risk of transmission has passed, people may have detectable RNA and test positive for up to 90 days Negative tests should be confirmed by NAAT or repeated as recommended by FDA Less sensitive (more false negative results) compared to NAATs, especially among asymptomatic people and with some variants Negative tests should be confirmed by NAAT or repeated as recommended by FDA Less sensitive (more false negative results) compared to NAATs, especially among asymptomatic people and with some variants * As noted in the labeling for authorized over-the-counter antigen tests: negative results should be treated as presumptive (meaning that they are preliminary results). Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Please see FDA guidance on the use of at-home COVID-19 antigen tests. † The decreased sensitivity of antigen tests might be offset if the POC antigen tests are repeated more frequently. ◊ Refers to point-of-care antigen tests only. Social determinants of health may influence access to testing. For example, travel time may limit access to, and use of, testing

services for those who have limited access to transportation and who live in areas with fewer public transit services and schedules. Racial and ethnic disparities in test site distribution have been found.3 Other factors that may affect both access to, and use of, testing services include: Delays in testing may also delay seeking care and treatment (when sick) as well as delays in self-isolation that could reduce the spread of the virus to others. CDC's COVID-19 Response Health Equity Strategy outlines a plan to reduce the disproportionate burden of COVID-19 among people in some racial and ethnic minority groups, people with disabilities, and other population groups (e.g., essential and frontline workers, people living in rural or frontier areas) who have experienced a disproportionate burden of COVID-19. One component to move towards greater health equity is ensuring availability of resources, including access to testing for populations who have experienced longstanding, systemic health and social inequities. All population groups, including racial and ethnic minority groups, should have equal access to affordable, quality, and timely SARS-CoV-2 testing—with fast turnaround time for results—for diagnosis and screening. Efforts should be made to address barriers that might overtly or inadvertently create inequalities in testing. In addition, completeness of race and ethnicity data is an important factor in understanding the impact the virus has on racial and ethnic minority populations. When possible, healthcare providers and public health professionals should ask and record race and ethnicity for anyone receiving a reportable test result and ensure these data are reported with the person's test results to facilitate understanding the impact of COVID-19 on racial and ethnic minority populations. Some strategies to achieve health equity in testing access and availability include: Positive test results using a viral test (NAAT, antigen or other tests) in individuals with signs or symptoms consistent with COVID-19 indicate that the person has COVID-19. A negative antigen test in individuals with signs or symptoms of COVID-19 should be repeated following FDA recommendations or confirmed by NAAT. For more information, see Antigen Test Algorithm. Additionally, consider other illnesses

with similar symptoms that may require testing. For many diseases, including flu, early diagnosis and prompt treatment are very important for preventing severe illness. Anyone who tests positive should isolate at home or, if in a healthcare setting, be placed on appropriate precautions. Some people should receive treatment. Most people with COVID-19 have mild illness and can recover at home. For more information, see CDC's COVID-19 isolation guidance. Viral testing is recommended for individuals who have been exposed to someone with COVID-19. People who have had an exposure to someone known or suspected of having COVID-19 should be tested at least 5 days after the exposure. If symptoms develop before 5 days, they should get tested immediately. People with a positive test result should follow CDC's COVID-19 isolation guidance. If someone has had exposure to someone with COVID-19 and is asymptomatic, but has had COVID-19 within the past 30 days*, testing to identify a new infection is generally not recommended. If someone has become newly symptomatic after having had COVID-19 within the past 30 days*, antigen tests should be used to identify a new infection. If they test negative, they should repeat the antigen test following FDA recommendations. If someone had exposure to another person with COVID-19, but the exposed individual has had COVID-19 within the past 31-90 days*, consider using antigen tests (rather than an NAAT, such as a PCR test) to identify a new infection. They should get tested at least 5 full days after their exposure. If they test negative with an antigen test, they should repeat the antigen test following FDA recommendations. *The clock starts from the day the person is tested (not the day they received their positive test result) or their original onset of symptoms, whichever came first. Some adults with severe illness or who are moderately or severely immunocompromised may produce replication-competent virus beyond 10 days that may warrant extending duration of isolation and precautions. A test-based strategy for ending isolation in these patients may be considered in consultation with infectious disease experts. For more information, including on retesting people previously infected

with SARS-CoV-2, visit Preventing Spread of Respiratory Viruses When You're Sick. Testing asymptomatic people without recent known or suspected exposure to SARS-CoV-2 for early identification, isolation, and disease prevention Screening testing allows early identification and isolation of people who are asymptomatic or pre-symptomatic and who might be unknowingly transmitting virus. Screening testing may be most valuable in specific settings where early identification is essential to reducing transmission and mitigating risk for severe disease among populations at high risk. When COVID-19 hospital admission levels are high, CDC recommends implementing screening testing in certain high-risk settings. When screening testing is used, it should be applied to participants regardless of vaccination status. Any type of viral test can be used for screening purposes; however, consider the characteristics (including accessibility, accuracy and efficiency) of different test types to determine which best suits screening testing needs. People without symptoms and without known exposure to COVID-19 do not need to take any special actions while awaiting screening test results. Settings that should be prioritized for screening testing include facilities and situations where transmission risk is high and the population served is at high risk of severe outcomes from COVID-19 or there is limited access to healthcare, including: Serial screening testing is less effective at reducing COVID-19's impacts in settings where disease rates are lower, risk of spread is lower, and risk of severe illness is lower. Because of this, CDC does not recommend serial screening testing in most lower risk settings. Public health surveillance testing may sample a certain percentage of a specific population to monitor for increasing or decreasing infection rate or to determine the population effect from community interventions. An example of public health surveillance testing is when a state public health department samples a random percentage of all people in a city on a rolling basis to assess local infection rates and trends. CDC is working with state, local, territorial, academic, and commercial partners to conduct surveillance testing to better understand COVID-19 in the United States. For

more on surveillance conducted by CDC: Updates as of May 27, 2022 As of January 21, 2022 As of October 22, 2021 As of August 2, 2021 As of July 1, 2021 As of June 14, 2021 As of September 18, 2020 As of August 24, 2020 As of July 17, 2020 As of July 2, 2020

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