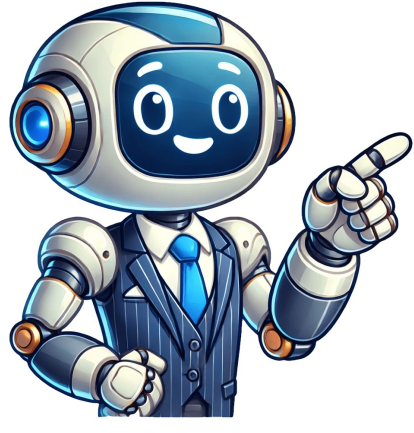


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Telford SR, Wormser GP. Bartonella transmission by ticks not established.Emerg Infect Dis. 2010 Mar;16(3) 379-84. This overview describes current information on the types of tests used to detect SARS-CoV-2 infection and their intended uses. This information 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. Viral tests, including nucleic acid amplification tests (NAATs) and PCR tests, as well as antigen tests, are used as diagnostic tests to detect current infection with SARS-CoV-2, determine the need for prevention measures, and inform a person's medical care. Nucleic acid amplification tests (NAATs) are highly sensitive and highly specific tests that detect one or more viral ribonucleic acid (RNA) genes. PCR tests are the most common type of NAAT used for COVID-19 testing. Viral RNA may stay in a person's body for up to 90 days after they test positive. Therefore, NAATs should not be used to test someone who has tested positive in the last 90 days. Most NAATs need to be performed in a laboratory, although some are performed at the point-of-care. Most NAATs produce qualitative (positive/negative) results.Antigen tests are immunoassays that detect the presence of specific viral proteins, called antigens. A positive test indicates current infection. Antigen tests generally have high specificity, similar to NAATs, but are less sensitive than most NAATs. Because antigen tests have lower sensitivity, FDA recommends that negative antigen tests be repeated up to three times, with each test 48 hours apart to confirm a negative result. Most antigen tests are less expensive than NAATs and can provide results in minutes. Antigen tests are available for at-home testing (self-testing), at the point of care, or in a laboratory.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.Other diagnostic tests may be used to detect SARS-CoV-2 from non-traditional respiratory specimens, such as breath. These tests' results may be presumptive and require confirmation by NAAT. Please refer to each test's Instructions for Use (IFU) for specific interpretation.Positive viral test results indicate current infection and the person with COVID-19 should take steps to prevent spreading COVID-19 to others. Negative viral test results mean the test did not detect the virus, but this doesn't rule out that the person 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).1 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 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. Testing individuals with signs or symptoms consistent with COVID-19 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. Additionally, consider other illnesses with similar symptoms that may require testing. For many diseases, including flu, early diagnosis and prompt treatment can be important for preventing severe illness. Anyone who tests positive should take steps to prevent spreading COVID-19 to others 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. Vaccination does not affect the results of someone's SARS-CoV-2 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. * 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 guidanceon 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 found2. Other factors that may affect both access to, and use of, testing services include:Lack of health insuranceConcern about the costs or co-paysOccupational factors such as not being able to take time off work and lack of paid leaveLack of accessible options for people with disabilities, andDistrust of the government and healthcare systems3,4,5,6Delays in testing may also delay seeking care and treatment (when sick) as well as delays in prevention measures that could reduce the spread of the virus to others. One component to move toward 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 testingwith fast turnaround time for results. 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 persons 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: Use a social vulnerability index to assist in selecting testing sites.Increase the availability of free testing sites in communities. Employers, community-based, and faith-based organizations can be important partners to increase the number of free, community-based testing sites. This expansion ensures that wait times both for testing and reporting of results are decreased.Increase accessible and culturally appropriate public messaging about the importance of testing and communicate these messages in multiple accessible formats, languages, and venues, particularly in communities at higher risk and disproportionately impacted by the virus. Morris SB, Schwartz NG, Patel P, et al. Case Series of Multisystem Inflammatory Syndrome in Adults Associated with SARS-CoV-2 Infection United Kingdom and United States, March–August 2020. MMWR Morb Mortal Wkly Rep. 2020;69(40):1450-1456. Published 2020 Oct 9. doi:10.15585/mmwr.mm6940e1Dalva-Baird NP, Alobuia WM, Bendavid E, Bhattacharya J. Racial and ethnic inequities in the early distribution of U.S. COVID-19 testing sites and mortality. Eur J Clin Invest. 2021;51(11):e13669. doi:10.1111/eci.13669Economic Policy Institute. Black Workers Face Two of the Most Lethal Preexisting Conditions for CoronavirusRacism and Economic Inequality [online]. 2020 [cited 2020 Jun 28].Berchick, Edward R., Jessica C. Barnett, and Rachel D. Upton Current Population Reports, P60-267(RV), Health Insurance Coverage in the United States: 2018, Government Printing Office, Washington, DC, 2019.Institute of Medicine (US) Committee on the Consequences of Uninsurance. Care Without Coverage: Too Little, Too Late. Washington (DC): National Academies Press (US); 2002.Institute of Medicine (US) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Smedley BD, Süth AY, Nelson AR, eds. Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Washington (DC): National Academies Press (US); 2003. Fit tests confirm that a respirator forms a tight seal to your face before you use it in the workplace.A qualitative fit test relies on your senses to determine if there is a gap in the seal of your respirator.A quantitative fit test uses an instrument to numerically measure the effectiveness of your respirator.Facial hair can impact the fit of your respirator. A fit test is a test protocol conducted to verify that a respirator is both comfortable and provides the user with the expected protection. Before using a tight-fitting respirator in the workplace, The Occupational Safety and Health Administration (OSHA) requires users to pass a fit test to confirm proper fit and a tight seal against the user's face. Loose-fitting respirators, such as powered air-purifying respirators with loose-fitting hoods, do not form a tight seal with the face and, therefore, do not require fit testing. Tight-fitting respirators include: Fit testing is important to ensure the expected level of protection is provided by minimizing the total amount of contaminants that leak into the facepiece through the face seal. Respirators are available in multiple size configurations and are not standardized across models. Fit testing is needed to determine if a particular size and model of respirator provides you with an acceptable fit. You must be fit tested for each respirator model you will wear for your designated work tasks. For answers to common questions about fit testing see our fit testing fact sheet. NIOSH provides information about fit testing in healthcare settings in our Hospital Respiratory Protection Program Toolkit. A summary of fit test requirements appears in Figure 11 on page 31. Hospital Respiratory Protection Program Toolkit There are two types of fit tests that you can complete to determine whether a respirator fits: a qualitative fit test or a quantitative fit test. A qualitative fit test relies on your senses to determine if there is a gap in the seal of your respirator. The test is a pass/fail test that determines whether you can detect a test agent, such as through taste, smell, or an involuntary cough. The OSHA-accepted fit test protocols provide complete instructions for conducting qualitative fit tests with the accepted test agents. NIOSH does not endorse or recommend the use of the irritant smoke fit test. Instances may arise in which there is a shortage in supply of fit testing solutions. NIOSH and OSHA created a document with information on preparing solutions for qualitative fit testing. A quantitative fit test uses a fit testing instrument(s) to provide quantitative, or numerical, measurements of the amount of face seal leakage present when you wear a respirator. During a quantitative fit test, you perform a series of simple exercises that help ensure that the respirator seals well to your face even when you are speaking or moving. Respirator user reading the "rainbow passage" script aloud as part of a quantitative fit test. Quantitative fit testing requires a hole punched in the respirator to perform the test. Therefore, the fit tester must dispose of the respirator after the test. OSHA requires an annual fit test to confirm the fit of any respirator that forms a tight seal to your face before you use it in the workplace. Because each brand, model, and size of respirators will fit slightly different, you should also be fit tested every time you wear a new model, manufacturer type/brand, or size. Additionally, if your weight changes or facial/dental alterations occur, a fit test should be done again to ensure your respirator remains effective. NIOSH conducted a study on respirator fit over time and the results confirm the necessity of the current OSHA respirator fit testing requirement, both annually and when physical changes have occurred. View LargerDownload Infographic that provides facts on the need for annual fit testing. Download English, Spanish There are companies and organizations that provide training on performing a fit test. The ANSI/ALHA/ASSE Z88.10-2010 Respirator Fit Testing Methods standard consists of recommendations for qualifications of individuals who conduct respirator fit testing. For additional guidance, contact OSHA as they are the agency that regulates fit testing. CDC recommends testing people who are at increased risk for TB infection.People with symptoms of TB disease or positive TB blood test or TB skin results should be evaluated for TB disease.TB testing activities should be accompanied by a plan for medical evaluation and treatment. Targeted testing for tuberculosis (TB) is a strategy to diagnose and treat latent TB infection among persons who are at risk for developing TB disease. Treating latent TB infection supports U.S. TB elimination goals through preventing TB disease, stopping the spread of TB to others. TB is not as common in the United States as it was many years ago and health care providers may not always consider the possibility of TB disease when evaluating patients who have symptoms. As a result, the diagnosis of TB disease may be delayed or even overlooked, and the patient may remain ill and possibly infectious for a prolonged period. It is important for health care providers to "Think TB," especially for patients with risk factors. For Everyone: Testing for Tuberculosis CDC and the U.S. Preventive Services Task Force (USPSTF) recommend testing people who are at increased risk for TB infection. Testing for TB infection is a routine and integral part of health care for patients with increased risk for TB. People who are at low risk generally should not be tested because the predictive value of a positive result is lower. Testing people at low risk increases the number of false positive test results and can divert resources away from preventing TB among those most likely to develop it. False positive results cause people to undergo unnecessary evaluation and treatment. TB testing activities should generally be targeted towards groups or people at risk. Certain individuals may be required to have testing for employment or school attendance independent of risk. CDC discourages a testing approach that is independent of a risk assessment. Frequency of testing depends on a person's risk factors. This could range from one-time only testing among persons at low risk for future TB exposure to annual testing among those at continued risk of exposure. TB testing activities should be done only when there is a plan for follow-up care to evaluate and treat all individuals diagnosed with latent TB infection or TB disease. Contact your state or local TB program for more information. People who are at higher risk of exposure to TB bacteriaPeople who are at higher risk of TB disease developing once infected with TB bacteriaContacts of people known or presumed to have infectious TB diseasePeople who were born in or who frequently travel to countries where TB disease is commonPeople who currently live or used to live in large group settings where TB is more common, such as homeless shelters, correctional facilities, or nursing homesEmployees of high-risk congregate settingsHealth care workers who serve patients with TB diseasePopulations defined locally as having an increased incidence of latent TB infection or TB disease, possibly including medically underserved populations, low-income populations, or persons with alcohol use or substance use disordersInfants, children, and adolescents exposed to adults who are at increased risk for latent TB infection or TB diseasePeople with HIVChildren younger than 5 years of agePeople recently infected with TB bacteria (within the last 2 years)People with a history of untreated or inadequately treated TB diseasePeople who are receiving immunosuppressive therapy such as tumor necrosis factor-alpha (TNF) antagonists, systemic corticosteroids equivalent to/greater than 15 mg of prednisone per day, or immunosuppressive drug therapy following organ transplantationPeople with silicosis; chronic renal failure; leukemia; or cancer of the head, neck, or lungPeople with diabetes mellitusPeople who have had a gastrectomy or jejunoileal bypassPeople with low body weight {

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