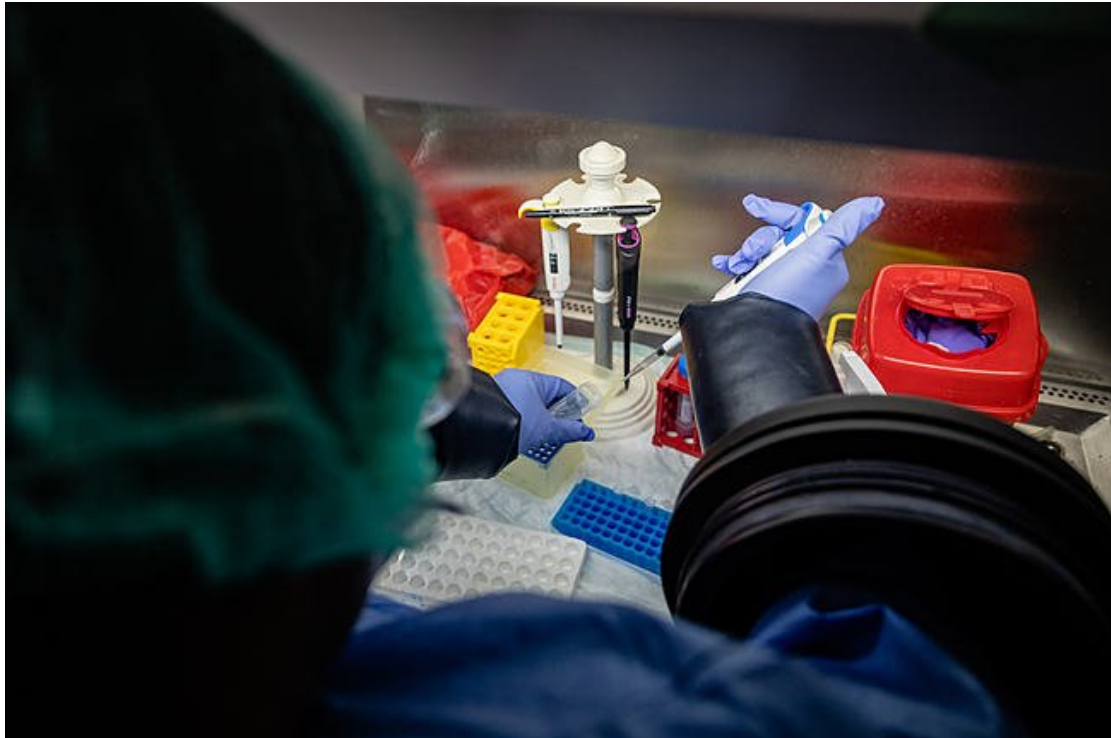### Step 1.8 How can we test for infection?

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In this article Rosanna Peeling, Professor of Diagnostics Research and Director of the International Diagnostics Centre (IDC) at the London School of Hygiene and Tropical Medicine and Ben Gannon, Senior Microbiologist from the UK-Public Health Rapid Support Team, give an overview of diagnostic testing for COVID-19. They cover the different methods used to diagnose COVID-19, the importance of validation of tests and some of the challenges faced in testing methods worldwide. As you read it, consider the advantages and disadvantages of the different types of test.

What is a diagnostic test?

A diagnostic test for an infectious disease can be used to demonstrate the presence or absence of infection, or to detect evidence of a previous infection.

Demonstration of the presence of the bacteria or virus causing the infection is important for effective patient management and for guiding treatment of infection and informing any public health measures required.

How are diagnostic tests used in an outbreak?

In an outbreak situation such as COVID-19, a triad of diagnostic tests are needed, to detect either the virus (SARS-CoV-2) or the antibodies made in response to the virus.

These are:

1. A highly sensitive (chance of test detecting those **with** the disease) and specific (chance of test detecting those **without** the disease) molecular test. For molecular testing, viral genetic material is usually detected for a few days after the onset of symptoms, but in the case of COVID-19, can also be detected 1-2 days before. These tests take 1-4 hours to perform in a laboratory. Protocols for molecular detection of SARS-CoV-2 are available from the WHO website. Automated molecular tests that can be performed by non-laboratory staff at the point-of-care (POC) are commercially available. They only require a few minutes of hands-on time and results are available in 5-45 minutes.

2. An antigen test that can be used to detect viral proteins. These tests are immunoassays that can be performed in a laboratory or as simple rapid tests that can be performed by non-laboratory personnel with results being available in 10-15 minutes. They are less sensitive than molecular tests but usually allows a longer window for viral detection. A few antigen detection tests have been developed for COVID-19 but their performance has not been evaluated.

3. A serology test that can be used to detect antibodies that patients develop in response to infection. Antibodies are markers of exposure. These tests can be used to assess the true extent of an outbreak, and inform prevention and control strategies. Serological tests are available as high throughput immunoassays performed in a laboratory in 2-4 hours or as rapid tests for use in community settings with results available in 15-20 minutes.

For COVID-19, the degree and length of antibody production is unclear. We also do not know the extent to which people who have been infected with SARS-CoV-2 are protected from re-infection, either through production of antibodies or through other (cellular) mechanisms which could also contribute to immunity.

What has been done to build diagnostic capacity for COVID-19?

Laboratory infrastructure is limited in many countries. To increase this, in the context of COVID-19, the WHO and the Africa CDC, together with partners from organisations such as the Foundation for Innovative New Diagnostics (FIND), the African Society for Laboratory Medicine (ASLM) and Universities including the Charité in Berlin, the London School for Hygiene & Tropical Medicine and Robert Koch Institute, have supported training for molecular testing in over 46 countries within the 55 member states of the African Union.

What are the major challenges we face?

The role of diagnostics in COVID-19 has been highlighted by the World Health Organization (WHO) and Director General Dr Tedros' mantra to "test, test, test". In many contexts there is a very active public debate on testing. The scale of the testing planned or being implemented in many countries is substantial, and in almost all countries there is greater demand than supply. Increased capacity requires new or repurposed laboratories, and technological innovation, such as automated robotic analysers. It also requires skilled staff – as well as an effective logistical operation to get specimens as well as reagents, consumables and personal protective equipment, to laboratories or testing centres.

Serological tests are in high demand, to determine the extent of the outbreak and to investigate immunity, particularly in contexts where there are country-wide restrictions in place to reduce transmission. However, there are major gaps in our knowledge of immunity against COVID-19 (as described in the WHO brief on immunity and immunity passports here). In addition, evaluation of many serological tests shows sub-optimal performance. WHO currently recommends that immunodiagnostic tests should be used for research purposes only and not for patient management.

See Also

Country & Technical Guidance - Coronavirus disease (COVID-19)

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications

COVID-19: guidance for sampling and for diagnostic laboratories

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories

FIND, ASLM, LSHTM - online course on COVID-19: Diagnostics and testing

https://www.futurelearn.com/courses/covid-19-diagnostics-and-testing

SARS-CoV-2 diagnostic pipeline

https://www.finddx.org/covid-19/pipeline/