Coronavirus

Technical White Paper

SureScreen Diagnostics

Introduction

The coronavirus is an infectious virus belonging to the family Coronaviridae, which affects mammals and birds. In humans, it typically causes the common cold, resulting in mild upper respiratory symptoms, like coughing, sneezing, mild fever and blocked sinuses. However, some strains of coronavirus can cause more severe illnesses, such as SARS and MERS. There is currently no cure or vaccine for coronavirus and in most cases the host immune system clears the virus in a week or two.

Currently, a new strain of the coronavirus (known as SARS-CoV-2) is spreading throughout the world, which causes an illness known as COVID-19 (coronavirus disease 2019). The symptoms of COVID-19 are generally mild, but in some cases can be more severe, such as high fever, breathing difficulties and a dry cough. So far, it has affected approximately 85,000 people and caused around 3000 deaths worldwide, with the vast majority of infections and deaths in China.

Current diagnosis of coronavirus

The current method of diagnosing COVID-19 is to measure body temperature and testing blood and sputum samples, as well as monitoring symptoms. However, symptoms can take 14 days or longer to develop, in which time the patient could have spread the virus to others. Additionally, analysing blood and sputum takes time, as samples have to be sent to laboratories for processing and analysis. Earlier diagnosis would mean infected individuals can be isolated sooner, preventing them spreading the virus to others.

SureScreen Diagnosis have developed a rapid lateral flow test to detect immune markers of coronavirus. This test uses a tiny capillary blood sample and takes as little as 10 minutes to get a result.

How does it work?

Lateral flow tests are common rapid tests used to diagnose a variety of illnesses, as well as other health parameters such as pregnancy. They are popular due to their simplicity and low cost. In general, lateral flow tests use monoclonal antibodies that are specific to the analyte of interest, which may be a protein or other molecule, to give a positive or negative result on a test strip.

Normally, the sample (blood, saliva etc.) is added to one end of the test strip, along with a buffer solution. The sample flows along the test strip via capillary action into a reservoir of antibodies that are specific to the analyte of interest. If the analyte is present in the sample, the antibodies will bind to it and continue to flow along the test strip. It will then reach a test line, which contains a second set of bound antibodies specific to the analyte. The analyte will bind to these (if present) and will be immobilised along the line. The remaining sample will continue to flow until it reaches a second line, known as the control line. The control line contains more bound antibodies, but these are specific to the flowing antibodies themselves, not the analyte. The remaining antibodies are captured on the control line. The flowing antibodies usually contain a coloured dye or gold nanoparticles, so the line can be seen with the naked eye when they bind.

If both test and control lines are seen, the sample is positive for the analyte. If only a control line is seen, the result is negative. If only the test line is seen, the test is void and should be repeated. Below is a diagram summarising the lateral flow test.
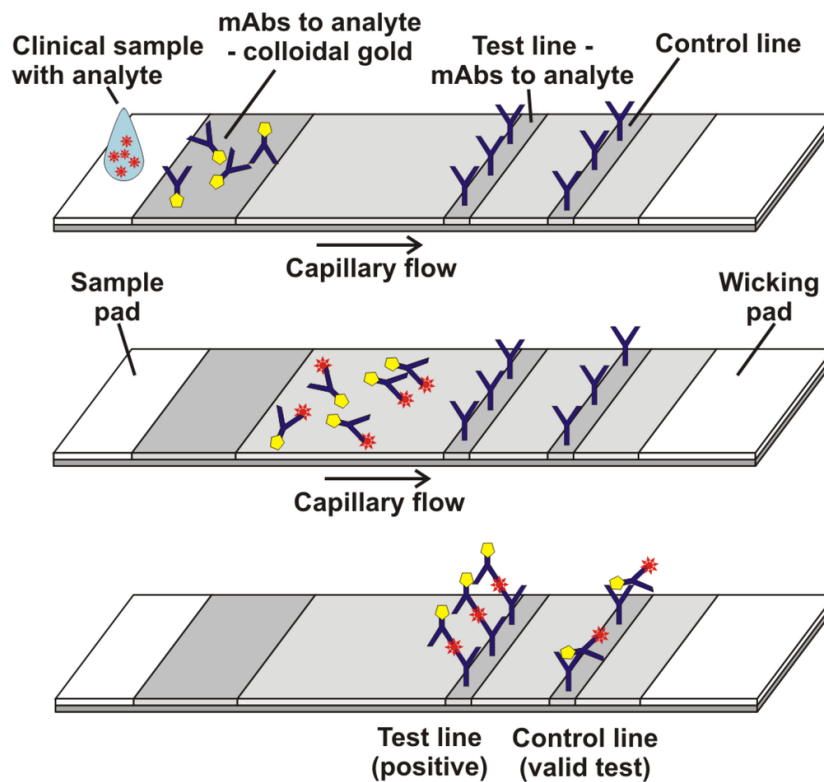
Fig. 1. Summary of lateral flow tests, taken from Lee et al. 'A Low-Cost, High-Performance System for Fluorescence Lateral Flow Assays' (2013).

Coronavirus lateral flow test

SureScreen's new coronavirus lateral flow test uses antibodies that are specific for immune glycoproteins that are produced by infected individuals in response to the new coronavirus. These glycoproteins are called Immunoglobulin M and G (IgM and IgG). Immunoglobulins are normally produced by the immune system in response to bacterial or viral infections and act to 'flag' the pathogen, so that other immune cells can detect and kill it. The IgG/IgM that the test detects are specific to the SARS-CoV-2 virus, so a positive result would indicate the patient has contracted COVID-19.

Since there are two analytes of interest (IgM and IgG), there are two test lines on the strip. Only one test line needs to be seen for a positive diagnosis (as well as the control line). Two test lines would also indicate a positive result.

The new test has the following specifications:

IgG
• Sensitivity = 97.4%
• Specificity = 99.3%
• Accuracy = 98.9%

IgM
• Sensitivity = 86.8%
• Specificity = 98.6%
• Accuracy = 96.1%

For more information on the test, including the directions for use, please contact us at sales@surescreen.com or +44 (0)1332 365318, or visit www.surescreen.com

SureScreen Diagnostics