



Vincere Cancer Center
COVID-19 Antigen and Antibody Testing
Patient Consent Form

Patient: _____

Patient DOB: _____

COVID-19 Antigen Testing:

The COVID-19 antigen test (Quidel Sofia SARS Antigen Fluorescent Immunoassay) that you will receive today tests for an active infection from SARS-CoV-2, the virus that causes COVID-19. This test works by looking for specific proteins on the coronavirus' surface. This antigen test (Quidel Sofia SARS Antigen Fluorescent Immunoassay) has received Emergency Use Authorization by the United States Food and Drug Administration (FDA) as a diagnostic test for COVID-19.

Risks Associated with the Test:

- Possible pain or discomfort during the nasal swab
- Possible incorrect test result (see below for more information)

Accuracy of the Test:

The antigen test that you will receive today (Quidel Sofia SARS Antigen Fluorescent Immunoassay) is quite accurate. Of those who have the infection, 93.8% will test positive on this test. That means, there is a 6.2% chance of a false negative. Of those who do not have the virus, almost 100% will test negative on this test. The chance of a false positive is extremely unlikely.

Coronavirus Antibody Test:

The coronavirus antibody test that you will receive today (IgM / IgG Rapid Test) tests for exposure to SARS-CoV-2. It works by looking for IgM (immunoglobulin M) and IgG (immunoglobulin G) towards the coronavirus. IgM antibodies are generated initially by the body as a result of an infection (when symptoms appear) and dissipates within a few weeks. IgG antibodies are generated approximately a week or two after an infection starts and lasts for extended periods of time. The presence of IgM antibodies is suggestive of a recent infection, while IgG antibodies suggest a prior infection.

This test kit has been approved by the FDA for research and surveillance purposes. It is CE-certified in Europe. It is currently pending FDA clearance for diagnostic testing. It has been permitted for use by healthcare facilities for emergency situations.

Risks Associated with the Test:

- Possible pain or discomfort during the fingerstick blood collection
- Slight risk of bleeding, bruising, or infection at the fingerstick site
- Possible incorrect test result (see below for more information)

Accuracy of the Test:

This coronavirus antibody test that you will receive today is quite accurate. Of those who have contracted the coronavirus in the past, >90% will test positive on this test. There is a <10% chance of a false negative – which means, you have had the coronavirus but test negative. Of those who have not contracted the coronavirus in the past, >95% will test negative on this test. There is a <5% chance of a false positive – which means, you have not had the coronavirus but test positive.

NOTE: The results of both the antigen and antibody test indicates your current status only. If in the future, you have symptoms, and think you may have an active infection, you should contact your doctor to be tested again.

Consent:

Do you give permission for Vincere Cancer Center to perform the:

Coronavirus **antigen** test (Quidel Sofia SARS Antigen Fluorescent Immunoassay)? ☐ Yes ☐ No
Coronavirus **antibody** test (COVID-19 IgM / IgG Rapid Test)? ☐ Yes ☐ No

By signing below, I acknowledge that I understand that these tests are new and that the results of my tests may not be fully accurate – I am aware that there is the possibility of errors in these tests. I understand the importance of continuing to take all necessary safety precautions. I acknowledge these uncertainties and wish to receive the coronavirus antigen (Quidel Sofia SARS Antigen Fluorescent Immunoassay) and/or antibody test (COVID-19 IgM / IgG Rapid Test).

Patient Signature: _____

Patient Name (Printed): _____

Date: _____ **Phone:** _____

The individual listed above received the coronavirus antigen test (Quidel Sofia SARS Antigen Fluorescent Immunoassay) and/or coronavirus IgM / IgG antibody testing (COVID-19 Rapid IgM / IgG Test) at Vincere Cancer Center on the above-mentioned date. The process of the tests was explained to the individual and all questions were answered. Test(s) were performed, and there were no complications.

Results of the coronavirus antigen test: ☐ SARS-CoV-2 positive ☐ SARS-CoV-2 negative

Results of the coronavirus IgM / IgG antibody test: ☐ IgM positive ☐ IgM negative

☐ IgG positive ☐ IgG negative

Test Read By: _____ **Signed By:** _____