inveox®

Covid-19 IgM/IgG Rapid Test

Description	The Covid-19 IgM/IgG Rapid Test is intended for qualitative detection of antibodies indicative of SARS-CoV-2 infection and is to be used as an aid for diagnosis of SARS-CoV-2 infection.
Intended use	For patients suspected of COVID-19 infection, the Covid-19 IgM/IgG Rapid Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in serum, plasma (EDTA, citrate) or venipuncture whole blood specimens. Results from this test alone should not be used as the sole basis for diagnosis. The Covid-19 IgM/IgG Rapid Test is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests.
Storage and stability	**1.** Store the detector buffer at 2-30 ˚C (35.6-86 °F). The buffer is stable up to 12 months. **2.** Store the Covid-19 IgM/IgG Rapid Test at 2-30 ˚C (35.6-86 °F); its shelf life is up to 12 months. **3.** If stored at 2-8 ˚C (35.6-46.4 °F), ensure that the test device is brought to 15-30 ˚C (59-86 °F) before opening. **4.** Do not freeze the kit or store the kit over 30 ˚C (86 °F).
Instructions for collection of specimen	Consider any materials of human origin as infectious and handle using standard biosafety procedures.

Plasma	**1.** Collect blood specimen into a lavender or blue top collection tube (containing EDTA or citrate, respectively, in a Vacutainer®) by venipuncture. **2.** Separate the plasma by centrifugation. **3.** Carefully withdraw the plasma into a new pre-labeled tube.
Serum	**1.** Collect blood specimen into a red top collection tube (containing no anticoagulants in a Vacutainer®) by venipuncture. **2.** Allow the blood to clot. **3.** Separate the serum by centrifugation. **4.** Carefully withdraw the serum into a new pre-labeled tube.
Whole Blood	**1.** Drops of whole blood can be obtained by venipuncture. Do not use hemolyzed blood for testing. The Covid-19 IgM/IgG Rapid Test has not been tested with fingerstick specimens. Use with fingerstick blood is not recommended. **2.** Whole blood specimens should be stored at 2-8 ˚C (35.6-46.4 °F) if not tested immediately. The specimens must be tested within 24 hours of collection.

Results

IgG positive

IgM positive

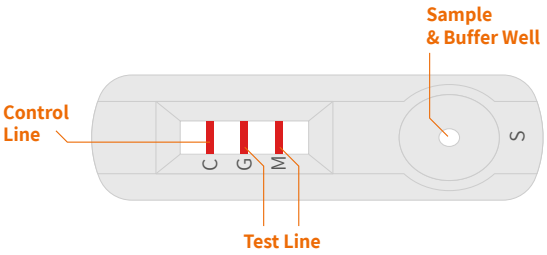
IgG and IgM positive

IgG weak positive

IgM weak positive

IgG and IgM weak Positive

Negative



If the C Line does not develop, the assay is invalid regardless of color development of the G or M Lines as indicated below. Repeat the assay with a new device.

Warnings

1. Test results should be read between 15 and 20 minutes after a specimen is applied to the sample well. Results read after 20 minutes may give erroneous results
2. Bring all reagents to room temperature (15-30°C/59-86 °F) before use.
3. Do not use expired devices.
4. Do not use the components of any other type of test kit as a substitute for the components in this kit.
5. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
6. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
7. Dispose of all specimens and materials used to perform the test as biohazardous waste.
8. Handle the negative and positive controls in the same manner as patient specimens for operator protection.
9. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

Background

Coronaviruses (CoV) are a large family of viruses which cause illness ranging from the common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS-CoV). Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Several known coronaviruses are circulating in animals that have not yet infected humans. 2019 Novel Coronavirus (SARS-CoV-2) is a new strain of coronavirus which was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Patients with SARS-CoV-2 report a mild to severe respiratory illness with symptoms of: fever, cough, shortness of breath.

To place an order, please get in touch via email: sampling@inveox.com

Due to high demand and the need to integrate and optimize various supply chains,
the delivered product may vary in appearance and packaging from item in this description.

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