

QuikPac II™ Coronavirus (COVID-19) IgG & IgM Test

Catalog No. 29000

INSTRUCTIONS

INTRODUCTION AND INTENDED USE

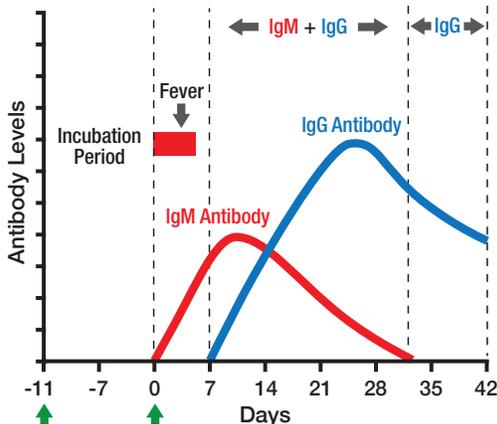
The QuikPac II™ 2019 COVID-19 IgG and IgM Test is a qualitative test for the detection of IgG and IgM antibodies to COVID-19 in human serum, plasma or whole blood. The test provides a differential detection of anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG antibodies and can be used for the presumptive distinction between a primary and secondary Coronavirus infection. This test is for in-vitro diagnostic use only. This test is for Prescription use only as set forth in Section IV.D of the FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019.

BACKGROUND

Coronavirus (CoV) belongs to the Coronaviridae family and is divided into three types: α , β and γ . Alpha and beta are only pathogenic to mammals and gamma mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route as well. So far there are seven types of human coronavirus (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and the novel coronavirus (2019). The novel coronavirus (2019) was discovered in 2019 in Wuhan, China with viral pneumonia cases and clinical manifestations were fever, fatigue, cough, and other symptoms which can rapidly develop into severe pneumonia, respiratory failure, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. and is life threatening.

Human coronaviruses primarily replicate in the respiratory tract and cause infections ranging from common colds to severe acute respiratory syndrome (SARS). Coronaviruses are single-stranded RNA viruses with outer envelopes that have distinct crown-like morphologies. Patients with SARS-CoV-2 infection often exhibit symptoms of viral pneumonia, including fever, cough, runny nose, shortness of breath, bilateral lung infiltration and respiratory failure in the most severe cases. Currently, there is no specific treatment or available vaccine that protects against SARS-CoV-2 infection. Spike (S) protein, nucleocapsid (N) protein, membrane (M) protein, and the envelope (E) protein are the four major structural proteins of SARS-CoV-2. Amongst them, the S-protein supports strong interaction with human cell receptors, indicating the greatest potential as an effective target for the development of neutralizing antibodies and antiviral drugs.

The general immune response to this virus includes the production of IgM antibodies by the 5th day of symptoms which remain in the circulatory system for 30-60 days. IgG antibodies appear by the 14th day of infection and may persist for life. A secondary infection also induces an IgM antibody response after 20 days of infection and IgG antibodies rise within 1-2 days after the onset of symptoms. Therefore, patients with secondary infections will have a positive



IgG result, usually along with a positive IgM result. Thus, the use of a reliable and sensitive rapid serological test that can simultaneously detect the presence of anti-coronavirus IgG and IgM antibodies is of great clinical utility.

The QuikPac II™ 2019 Coronavirus IgM and IgG Test provides an excellent methodology for specifically detecting anti-SARS-CoV-2 IgG and IgM antibodies. The presence of high titers of IgG antibodies does not interfere with the detection of IgM antibodies in the sample. By using a mixture of recombinant Nucleocapsid protein, the test is able to detect SARS-CoV-2 infection.

PRINCIPLE OF THE TEST

Serum, plasma or whole blood samples may be used with this test. When a specimen is added to the test, anti-CoV IgG and IgM in the specimen sample react with recombinant coronavirus nucleocapsid proteins of colloidal gold conjugates and form a complex of antibodies and colloidal gold conjugates. As this mixture moves along the length of the test strip by capillary action, the anti-coronavirus IgG or IgM complex is captured by the corresponding anti-human IgG and/or IgM immobilized in two lines across the test strip and generates a colored line. The appearance of a Pink color in a specific test region (IgG or IgM) should be considered as positive for that particular antibody type (IgG or IgM). A Red procedural control line should always develop on the test strip to indicate that the test has been performed properly.

MATERIALS PROVIDED

Each kit contains the following components in sufficient quantities to perform the number of tests indicated on the package label:

25 Test Kit

- 25 test packs individually foil pouch with a desiccant. Each strip contains two (2) test lines: one that captures human IgG antibodies and another that captures IgM antibodies. The strip also contains a third procedural control line.
- 1 Product Instruction Sheet
- 1 Dropper bottle of buffer reagent
- 25 x 15 microliter Capillary transfer tube (Optional Component)
- 25 Lancets (Optional Component)

MATERIALS REQUIRED BUT NOT PROVIDED:

- Sterile alcohol swab
- Timer capable of timing from 0 to 60 minutes

STORAGE AND STABILITY

Store the kit between 2°C and 30°C. Do not freeze. The test kit may be used until its expiration date, which can be found on the package label.

WARNINGS AND PRECAUTIONS

1. All specimens should be handled as being potentially infectious. The U.S. Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) recommend that all potentially infectious agents be handled at a Biosafety Level 2 facility.
2. Biological decontamination procedures should be followed for all equipment, containers, surfaces, etc. that come in contact with potentially infectious specimens. All disposables that come in contact with these samples should be disposed of as infectious waste.
3. For best results, strict adherence to these instructions is required. Be careful not to touch the tip of the buffer bottle to the sample tube when adding buffer to the tube. This will greatly minimize the likelihood of contaminating the buffer reagent.
4. The buffer contains a low concentration of sodium azide as a preservative (less than 0.1%). Sodium azide is toxic. Do not drink the buffer. High concentrations of sodium azide may also react with lead and copper in plumbing to form explosive compounds. If you dispose of this buffer down a drain, flush the drain with excess amounts of water to minimize the accumulation of potentially explosive metal-azide compounds.
5. Do not use the test strips or reagents beyond the stated expiration date marked on the package label.

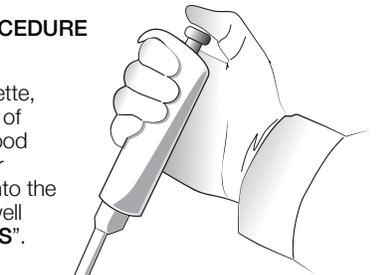
6. Store the test kits and reagents according to the temperature range stated on the package label.
7. All test strips, buffers and specimens must be at room temperature (15-30°C) before running the assay.
8. Do not re-use the test strips or buffer.

SPECIMEN COLLECTION AND HANDLING

1. Handle all specimens as capable of transmitting infectious diseases. Dispose of all materials that come in contact with the specimen as infectious waste.
2. Specimens should be collected aseptically by venipuncture or fingerstick according to the standardized methods such as those recommended by the National Committee for Clinical Laboratory Standards (NCCLS). The use of grossly lipemic or turbid samples should be avoided.
3. Whole blood samples should be used immediately, if possible. NCCLS provides recommendations for storing blood specimens (Approved Standard - Procedures for the Handling and Processing of Blood Specimens, H1SA, 1990).
4. If Serum or plasma specimens cannot be tested immediately, they should be refrigerated at 2 to 8°C. For storage periods greater than three (3) days, freeze the specimen at -20°C or below.

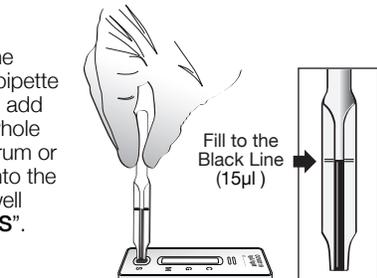
ASSAY PROCEDURE

1. Using a micropipette, add 15µl of whole blood /serum or plasma into the sample well marked "S".

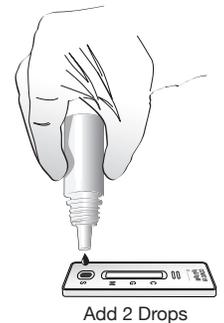


OR

- 1A. Using the capillary pipette provided, add 15µl of whole blood/serum or plasma into the sample well marked "S".



2. Put 2 drops of assay buffer reagent into the round shaped buffer reagent well.



3. Interpret the results within 15 minutes.

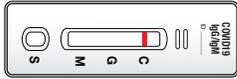


Do not read the results after 15 minutes.
Reading too late can give false results.

INTERPRETATION OF RESULTS

Negative

- (No antibody produced)
- One pink line "C" in result window.



Positive

- IgG positive (Secondary or post virus infection)
 - Two pink lines "C" and "G" in result window.
 - It is positive even if "G" line is weak.



- IgM positive (Primary Virus Infection)
 - Two pink lines "C" and "M" in result window
 - It is positive even if "M" line is weak.



- IgG and IgM positive (Late primary or early secondary virus infection)
 - Three pink lines "C", "G", and "M" in result window.



INVALID TEST RESULTS:

- No control ("C") line in result window.
- It is recommended that the specimen be re-tested.



EXPECTED VALUES

Primary virus infection is characterized by the presence of detectable IgM antibodies five (5) days after the onset of symptoms. Secondary virus is characterized by the elevation of specific IgG 1-2 days after the onset of infection and in the majority of cases this is generally accompanied by an elevation of IgM.

QUALITY CONTROL

- Internal Control: This test contains a built-in control feature. The "C" line develops after addition of the specimen and Test Buffer. If the "c" line does not develop, the test is invalid. Review the procedure and repeat the test with new test device
- Positive and Negative Control: Positive and negative controls should be tested to ensure the proper performance of the assay, particularly under the following circumstances:
 - A new operator uses the kit:
 - A new lot of test kit is used:
 - The temperature used during storage of the kit falls outside of 2°C-30°C;
 - The temperature of the test area falls outside of 15-30°C;
 - To verify a higher than expected frequency of positive or negative result;
 - A new test environment is used (e.g., nature light vs artificial light)

LIMITATIONS OF THE TEST

- This test detects the presence of antibodies to coronavirus in the specimen and should not be used as the sole criterion for the diagnosis of a coronavirus infection.
- This test is for in vitro diagnostic use only.
- In early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some patients may not produce detectable levels of antibody within the first 7-10 days of infection. If symptoms persist, a fresh sample should be drawn from the patient 3-4 days after the first testing date and the new specimen should be tested.
- As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and coronavirus infection suspicion still exists, additional follow-up testing using other clinical methods is recommended.
- If the test results are negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result does not preclude the possibility of an early infection of coronavirus.

- For Rx use only.
- This test has not been reviewed by the FDA. For use in clinical laboratories by health care professionals following FDA guidance "Policy for Diagnostic Tests for Coronavirus Disease-2019 (COVID-19) during the Public Health Emergency".
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic assay should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- Not for the screening of donated blood.

PERFORMANCE CHARACTERISTICS

Accuracy:

The test was validated using 602 clinically positive or negative patients' samples that were confirmed using PCR. The data is shown in the following table:

QuikPac II™ COVID-19 IgG/IgM Rapid Test					
	IgG+/IgM+	IgG-/IgM+	IgG+/IgM-	IgG-/IgM-	Sub Total
PCR Test (+)	57	1	10	8	76
PCR Test (-)	0	4	8	514	526
Sub Total	57	5	18	522	

Positive Percent Agreement = 68/76 = 89.4%
Negative Percent Agreement = 514/526 = 97.7%

As seen from the tests, QuikPac II™ COVID-19 IgG/IgM Test is a readily deployable test with sufficient sensitivity and specificity to detect COVID-19 during the current outbreak.

ANALYTICAL SPECIFICITY

Assay Cross Reactivity:

Cross reactivity of the QuikPac II™ COVID 19 IgG/IgM Rapid test was evaluated using serum or plasma samples which contain antibodies to the pathogens listed below. No false positive or false negative were found with the following table:

QuikPac II™ COVID-19 IgG/IgM Rapid Test Result			
	Serum	IgG	IgM
Other Disease State	Influenza A (+)	Negative	Negative
	Influenza B (+)	Negative	Negative
	Adenovirus (+)	Negative	Negative
	HBsAg (+)	Negative	Negative
	Syphilis (+)	Negative	Negative
	H.Pylori (+)	Negative	Negative
	HIV I (+)	Negative	Negative
	HIV II (+)	Negative	Negative
	HCV (+)	Negative	Negative
	TB (+)	Negative	Negative

Potentially Endogenous Interference Substances:

QuikPac II™ COVID-19 IgG/IgM rapid test was evaluated for interference. Low titer SARS-Cov-2 antibody positive serum samples with human IgG, Low titer SARS-CoV-2 antibody with human IgM and SARS-CoV-2 antibody negative serum samples were spiked with one of the following substances to specific concentrations on the table and tested 5 replicates. No false positive or false negative results were found with the following substances:

Potential Interference Substance	Concentrations
Acetaminophen	20mg/dl
Acetylsalicylic acid	20mg/dl
Human serum Albumin	2000mg/dl
Hemoglobin	1000mg/dl
Ascorbic acid	2000mg/dl
Gentisic Acid	20mg/dl
Caffeine	20mg/dl
Creatine	200mg/dl
Oxalic acid	60mg/dl
Uric acid	10mg/dl
Bilirubin	1000mg/dL
Ethanol	0.1%
HAMA (Human anti-mouse antibody)	2000ng/ml
RF (Rheumatoid Factor)	1000IU/ml

Of the compounds tested, none were found to cause significant interference using the test concentrations indicated in the table above.

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INDEX FOR SYMBOL



Syntron Bioresearch Inc.
2774 Loker Ave. West
Carlsbad, CA 92010 USA

 Catalog Number	 Batch Number
 In-Vitro Diagnostics Only	 Do Not Re-use
 Consult Operating Instruction	 EU Representative
 Temperature Limitation	 Use By
 EMERGO EUROPE Mole nstraat 15 2513 BH The Hague • Netherlands Tel 31. 70. 345. 8570 Fax: 31 70 346	