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

Catalog No. 29000

INSTRUCTIONS

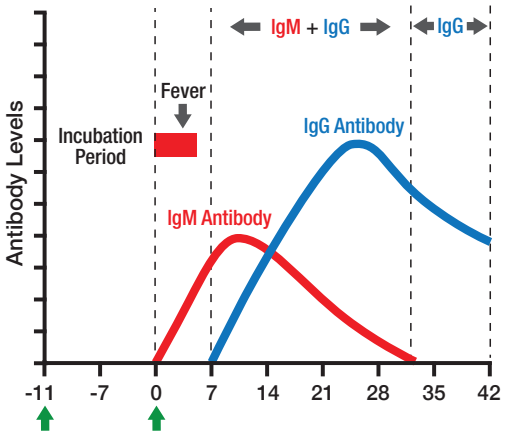
INTRODUCTION AND INTENDED USE

The QuikPac II™ 2019 Coronavirus IgM and IgG Test is a qualitative test for the detection of IgM and IgG antibodies to COVID-19 in human serum, plasma or whole blood. The test provides a differential detection of anti-COVID-19 IgM and anti-COVID-19-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.

Coronavirus (CoV) belongs to the Cronoaviridae 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 severed pneumonia, respiratory failure, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. and is life threatening.

Human corona viruses primarily replicate with the respiratory tract and cause infections ranging from common colds to severe acute respiratory syndrome (SARS). Coronavirus 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. Spike (S) protein, nucleocapsid (N) protein, membrane (M) protein, and the envelope (E) protein are four major structural proteins of SARS-CoV-2. Amongst, S-protein supports strong interaction with human cell receptors, indicating the great 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 5th day of symptoms which remain in the circulatory system for 30-60 days. IgG antibodies appear by the 14th day of infection and 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 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-n Corona virus 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 COVID-19 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-corona virus IgG and IgM in the specimen sample react with recombinant corona virus nucleocapsid proteins of colloidal gold conjugates and forms a complex of antibodies and colloidal gold conjugates. As this mixture along the length of the teat strip by capillary action, the anti-corona virus IgG or IgM complex is captured by the relevant anti-human IgG and or IgM immobilized in two lines across the test strip and generate a colored line. The appearance of 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 desiccated. 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
- 1 Dropper bottle of buffer
- 25-15 microliter Capillary transfer tube (Optional Component).

MATERIALS REQUIRED BUT NOT PROVIDED:

- Sterile alcohol swab
- Lancer
- 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 (CDC) and the National Institutes of Health (NIH) recommend that all potentially infectious agents be handled at a Biosafety Level 2.
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 this 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.

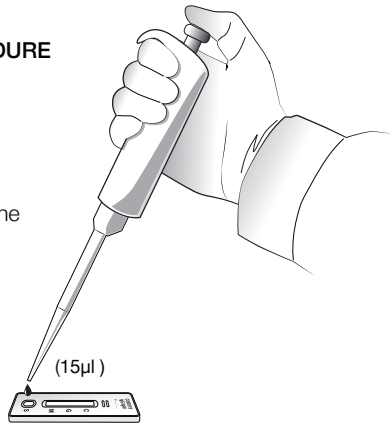
SPECIMEN COLLECTION AND HANDLING

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.

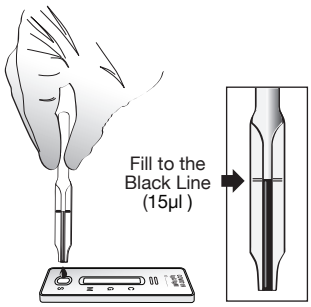
ASSAY PROCEDURE

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

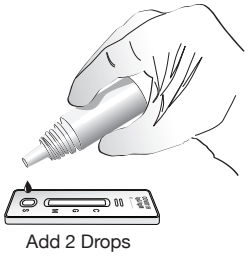
Or



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 diluents into the round shaped assay diluents well.



3. Interpret the results in **15 minutes**.

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

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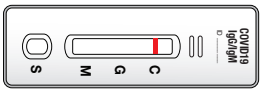
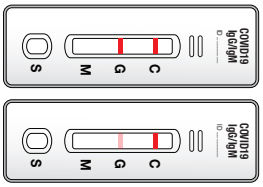
INTERPRETATION OF RESULTS

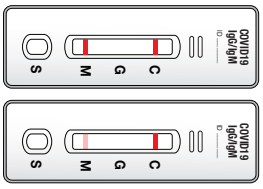
Negative
(No antibody produced)
- One pink line “C” in result window.



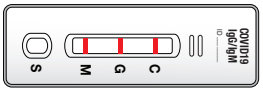
Positive
1. IgG positive (Secondary or post virus infection)
   - Two pink lines “C” and “G” in result window.
   - It is positive even if “G” line is weak.



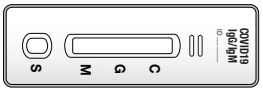
2. IgM positive (Primary Virus Infection)
   - Two pink lines “C” and “M” in result window
   - It is positive even if “M” line is weak.



3. 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 5 days after the onset of infection. Secondary virus is characterized by the elevation of specific IgG 1-2 days after the consent of infection and in the majority of cases this is generally accompanied by an elevation of IgM

LIMITATIONS OF THE TEST

1. 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.
2. This test is for in vitro diagnostic use only.
3. In early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some patents may not produce detectable levels of antibody within the first seven to ten 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 retested.
4. 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.
5. If the test results are negative and clinical symptom persist, additional follow-up testing using other clinical methods are recommended. A negative result does not preclude the possibility of any early infection of Coronavirus.

PERFORMANCE CHARACTERISTICS

Accuracy:
The test was validated using 602 clinically positive and negative patients' samples that were confirmed using PCR. The data show as following table:

	QuikPac II™ COVID-19	
	Disease(+)	Disease (-)
PCR Test (+)	68	8
PCR Test (-)	12	514
Sensitivity	89.4%	
Specificity	97.7 %	

The overall test sensitivity of QuikPac II™ COVID-19 IgG/IgM is 89.4 % and specificity is 97.7 %
As seen from the tests, QuikPac II™ COVID-19 IgM/IgG Rapid Test is a readily deployable test with sufficient sensitivity and specificity to detect COVID-19 IgM/IgG during the current outbreak.

No cross reactive with other disease state as following table:

Serum	QuikPac II™ COVID-19 Test Result	
	IgG	IgM
HIV (+)	Negative	Negative
HBV (+)	Negative	Negative
HCV (+)	Negative	Negative
HAV (+)	Negative	Negative
HP (+)	Negative	Negative
TP (+)	Negative	Negative
TB (+)	Negative	Negative

REFERENCES

1. Li, etc., Early Transmission Dynamics in Wuhan, China of Novel Coronavirus–Infected Pneumonia,DOI: 10.1056/NEJMoa2001316.
2. Li Taisheng, Peking Union Medical College Hospital’s Proposal for Diagnosis and Treatment of “Novel Coronavirus Infected Pneumonia” (V2.0), Union Medical Journal, 2020.1.27.
3. Wei Qiuhua, Disinfection measures for pneumonia epidemic sources of novel coronavirus infection in 2019, Chinese Journal of Disinfection, 2020 (37) 1,59-62.
4. Chao, E.L.; Henshaw, J.L., Occupational Safety and Health Administration: Model Plans and Programs for the OSHA Bloodborne Pathogens and Hazard Communications Standards. OSHA 3186-06R, 2003.
5. Callow, K.A., H.F.Parry, M. Sergeant, and D.A. Tyrrell. 1990. The time course of the immune response to experimental coronavirus infection of man. Epidemiol. Infect. 105:435-446.
6. Hamre, D., and J.J. Procknow. 1966. A new virus isolated from the human respiratory tract. Proc. Soc. Exp. Biol. Med. 121: 190-193.
7. Hruskova, J.,F. Heinz, E. Svandova, and S. Pennigerova. 1990. Antibodies to human coronaviruses 229E and OC43 in the population of C.R. Acta Virol. 34:346-352.
8. Kahn, J.S. 2006. The widening scope of coronaviruses. Curr. Opin. Pediatr. 18:42-47.
9. Lehmann, C., H. Wolf, J. Xu, Q. Zhao, Y. Shao, M.Motz, and P. Lindner. 2008. A line immunoassay utilizing recombinant nucleocapsid proteins for detection of antibodies to human coronaviruses. Diagn. Microbiol. Infect.Dis.61:40-48.
10. Mourez, T. , A. Vabret, Y. Han, J. Dina, L. Legrand, S. Corbet, and F. Freymuth. 2007. Baculovirus expression of HCoV-OC43 nucleocapsid protein and development of a Western blot assay for detection of human antibodies against HCoV-OC43. J. Virol. Methods 139:175-180.
11. Patrick, D. M., M. Petric, D.M. Skowronski, R. Guasparini, T.F. Booth, M. Krajden, P. McGeer, N. Bastien, L. Gustafson, J. Dubord, D. Macdonald, S.T. David, L. F Srour, R. Parker, A. Andonov, J. Issac-Renton, N. Loewen, G. McNabb, A. McNabb, S.H. Goh, S. Henwick, C. Astell, J.P. Guo, M. Drebort, R. Tellier, F. Plummer, and R. C. Brunham. 2006. An outbreak of human coronavirus OC43 infection and serological cross-reactivity with SARS coronavires. Can. J Infect. Dis. Med Microbiol. 17:330-336.
12. Peiris, J. S. , S. T. Lai, L. L. Poon, Y. Guan, L. Y. Yam, W. Lim, J. Nicholls, W.K. Yee, W. W. Yan, M.T. Cheung, V.C. Cheng, K.H. Chan, D. N. Tsang, R. W. Yung, T.K. Ng, K. Y. Yuen and SARS study group. 2003. Coronavirus as a possible cause of severe acute respiratory syndrome. Lancet 361:1319-1325.
13. Pyrc, K., B. Berkhout, and L. van der Hoek. 2007. The novel human coronaviuses NL63 and HKU1. Virol. 81:3051-3057.
14. Schmidt, O. W., I. D. Allan, M. K. Cooney, H. M. Foy, and J. P. Fox. 1986. Rises in titers of antibody to human coronaviruses OC43 and 229E in Seattle families during 1975-1979. Am. J. Epidemiol. 123:862-868.
15. Shao, X., X. Guo, F. Esper, C. Weibel, and J. S. Kahn. 2007. Seroepidemiology of group I human coronaviruses in children. J. Clin. Virol. 40:207-213.
16. Tyrrell, D. A. J., and M.L. Bynoe. 1965, Cultivation of novel tpye of common-cold virus in organ cultures. Br. Med. J. 1:1467-1470.
17. Van Der Hoek, L. 2007. Human coronaviruses: what do they cause? Antivir. Ther. 12:651-658.
18. Van Der Hoek, L., K. Pyrc, M. F. Jebbink, W. Vermeulen-Oost, R. J. Berkhout, K. C. Wolthers, P.M. Wertheim-van Dillen, J. Kaandorp, J. Spaargaren, and B. Berkhout. 2004. Indentification of a new human coronavirus. Nat. Med. 10:368-373.
19. Woo, P. C., S. K. Lau, C.M. Chu, K. H. Chan, H. W. Tsoi, Y. Huang, B. H. Wong, R. W. Poon, J. J. Cai, W. K. Luk, L. L. Poons, S. S. Wong, Y. Guan, J.S. Peiris, and K. Y. Yuen. 2005. Characterization and complete genome sequence of a novel coronavirus, coronavirus HKU1, from patients with pneumonia, J. Virol. 79:884-895.

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