Abbexa COVID-19 IgG/IgM Rapid Test Kit

Version: 7.1.2 Revision Date: 14/04/2020

REF Catalog No: abx294171

RUO Research use only

INTENDED USE

The COVID-19 IgG/IgM Rapid Test Kit is a single-use device used for research use only. It is a lateral flow immunoassay which detects IgG and IgM antibodies in serum, plasma, and whole blood samples against SARS-CoV-2, the virus that causes COVID-19. The presence of such antibodies indicates if exposure to a coronavirus has taken place, and whether it is a newer or older exposure.

Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. A CLIA categorization of this device would be consistent with other serology lateral flow moderate complexity devices.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the abx294171 SARS-CoV-2 IgG/IgM Rapid Test Kit early after infection is unknown.

False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

At this time, it is unknown for how long IgM or IgG antibodies may persist following infection.

For in research use only.

BACKGROUND

The Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is an emergent virus responsible for the respiratory illness Coronavirus Disease 2019 (COVID-19). First documented in the city of Wuhan (China), it has spread to most countries across the globe.

The original source of SARS-CoV-2 is unknown. It has been reported to have high similarity to coronaviruses found in bats and pangolins, however, neither of these animals are thought to have been sold in the meat market that the earliest patients visited, suggesting an intermediate host.

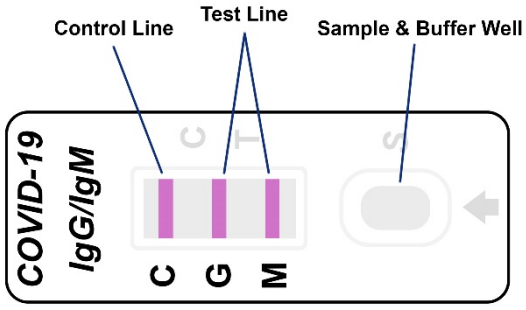
The virus is easily transmitted from person to person, primarily via droplets. Infected individuals can reduce transmission rates by wearing a face mask or covering the mouth when coughing/ sneezing, by sanitizing their hands regularly, and by self-isolating. People who have not yet been infected can wear a face mask and use eye protection to block droplets, not touch their face or food without sanitizing first, and avoid crowded areas.

The mortality rate for COVID-19 has been difficult to calculate due to the number of undiagnosed cases. Estimates range from 0.02% to 14%; most center at approximately 2-4%. The threat to the average healthy adult is low, however immunodeficiencies or respiratory illnesses can increase the mortality risk substantially. At time of writing, there is no specific treatment or vaccine approved for COVID-19.

TEST PRINCIPLE

The Abbexa COVID-19 IgG/IgM Rapid Test Kit is a lateral flow immunoassay which can detect antibodies against the SARS-CoV-2/COVID-19 virus. The sample pad inside the cassette contains gold nanoparticles coated with COVID-19 antigens and mouse IgG. Antibodies against human IgM and IgG are coated in their respective regions on a nitrocellulose membrane, creating the test lines, and Goat anti-Mouse IgG antibodies are coated on the control line. The control region on the upper end of the cassette confirms if the test has been successful.

The test comes with a cassette, buffer, pipette, and an optional disposable lancet. When a correct volume of test sample and buffer is dispensed into the sample well of the test cassette, the sample migrates by capillary action along the cassette. If there are any antibodies in the blood against SARS-CoV-2 virus, they will bind to the



SARS-CoV-2 conjugates. If IgG is present in the sample, the immunocomplex will then be captured by the anti-human IgG line, forming a purple-colored G Line, indicating a SARS-CoV-2 virus IgG positive test result. If IgM is present in the sample, the immunocomplex will be captured by the anti-human IgM line, forming a purple-colored M Line, indicating a SARS-CoV-2 virus IgM positive test result.

Information regarding the immune response to SARS-CoV-2 is limited and still evolving. At this time, it is unknown how long IgM or IgG antibodies may persist following infection.

The test contains an internal control (C Line) which exhibits a purple-colored band of goat anti-mouse IgG / mouse IgG-gold conjugate immunocomplex regardless of the color development on any of the test bands (G and M Lines). If no control band is observed, the test result is invalid and the sample must be retested.

REAGENTS AND MATERIALS

The kit can be bought in 25 test and 50 test sizes. The number of components for each size are as follows:

	Catalogue #	abx294171	
	Kit size (tests)	25	50
Components	Cassette (unit)	25	50
	Sample Buffer (ml)	5	5
	Transfer pipette (unit)	25	50
	Lancet* (unit)	25	50
	IFU (unit)	1	1

*Lancet is optional

Composition

Conjugate Pad	Gold nanoparticles coated with SARS-CoV-2 spike and nucleocapsid proteins, and mouse IgG.

G Line	Mouse monoclonal antibody to human IgG
M Line	Mouse monoclonal antibody to human IgM
C Line	Goat polyclonal antibody to mouse IgG
Sample Buffer	Tris(hydroxymethyl)aminomethane (Tris), polysorbate 20, ProClin 300.

Other Material Required But Not Provided

Paper towel (or similar clean absorbent material, soap, clean water.

STORAGE AND STABILITY

1. Store the buffer and cassette at 2-30°C (36-86°F). These components are stable for a minimum of 12 months.
3. If stored at 2-8˚C, ensure that the test device is brought to 15-25˚C before opening.
4. Do not freeze the kit or store the kit over 30˚C.

SAMPLE COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle using the appropriate standard biosafety procedures.

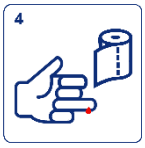
TEST PROCEDURE

Instructions for use with whole blood

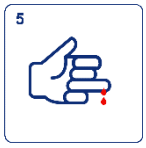
Place the cassette on a level surface at room temperature (15-25°C, 59-77°F).

Wash hands thoroughly with soap and water. Ensure fingertips are clean and dry.

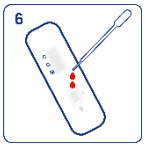
Puncture one of the patient's fingers using the lancet provided.



Use a clean paper towel or similar material to wipe off the first drop of blood.



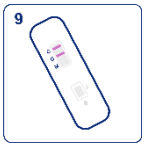
Gently massage the finger from knuckle to fingertip to allow a second drop of blood to form.



Add 2 drops of blood (using the pipette provided) into the cassette's well directly above the arrow.

Add 3 drops of buffer (using the dropper on the buffer bottle, 90-120 µl) into the well.

Wait 10 minutes.



Read the results (see interpretation of results section).

Instructions for use for serum and plasma

1. Briefly centrifuge sample to remove any precipitate.
2. Equilibrate sample and cassette to room temperature (15-25°C).
3. Add 20 µl of sample into the cassette's well.
4. Add 1 drop of buffer (30-40 µl) into the cassette's well.
5. Wait 10 minutes.
6. Read the results (see interpretation of results section).

QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C Line. The C Line develops after addition of the sample and sample diluent. If the C Line does not develop, the test is invalid. Review the procedure and repeat the test with a new device.

INTERPRETATION OF ASSAY RESULTS

1. Valid Assay

The readout should show 1 line in the C (control) region. Purple lines may appear next to the G (IgG) and M (IgM) regions depending on exposure to coronavirus. Faint lines are treated as a positive result.

1.1 C, G, and M regions are positive: patient recently infected or re-infected with coronavirus.

1.2 C and G regions positive, M region negative: patient previously infected with coronavirus.

1.3 C and M regions positive, G region negative: patient recently infected with coronavirus for the first time.

1.4 C region positive, G and M regions negative: patient not showing immune response to coronavirus.

1. Invalid Assay

C region negative, G and M regions either positive or negative: test did not function correctly.

Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test is necessary to rule out infection in these individuals.

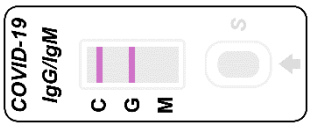
Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

False positive results may occur due to cross-reacting antibodies from previous infections, such as other coronaviruses, or from other causes.

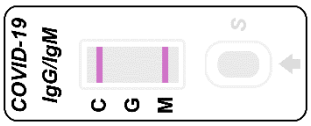
Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

#1
IgM/IgG Positive

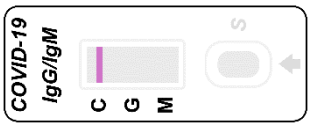
#2
IgG Positive



#3
IgM Positive



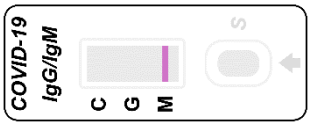
#4
Negative



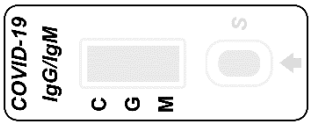
#5
Test Failure

#6
Test Failure

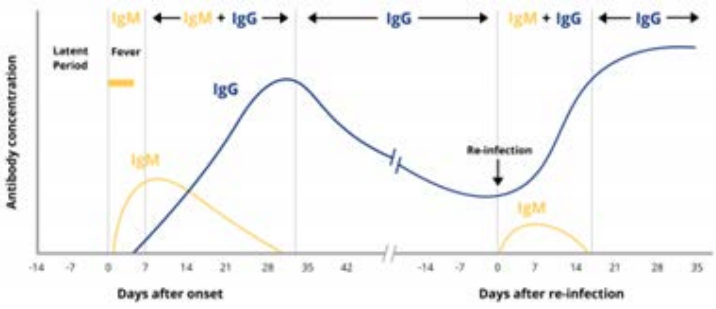
#7
Test Failure



#8
Test Failure



Relationship between antibody concentration and viral infection stage



During the first infection, IgM concentrations in the body rise quickly, then eventually decline as the concentration of IgG increases. In subsequent infections, IgM concentrations increase a small amount and IgG increases substantially.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance

1.1 Study of: Testing of RT-PCR positive clinical samples

Four hundred and twenty-one (421) positive serum samples collected from individuals who tested positive with a RT-PCR method for SARS-CoV-2 infection and were quarantined in a hospital were used in this study. These patients, at the time of sample collection, exhibited a range of clinical symptoms. These samples, along with one thousand, one hundred and sixty-four (1164) negative serum samples were coded and tested together with the abx294171 SARS-CoV-2 IgG/IgM Rapid Test Kit. Of the 421 positive samples, four hundred and fifteen (415) tested positive with IgG and/or IgM. Of the 1164 negative samples, one thousand, one hundred and forty (1140) tested negative.

Taken together, the abx294171 SARS-CoV-2 IgG/IgM Rapid Test had a sensitivity and specificity of 98.58% (95% CI: 97.44-99.71%) and 97.94% (95% CI: 97.12-98.76%), respectively.

		Hospital result		
		Positive	**Negative**	**Total**
Kit result	**Positive**	415	24	439
	Negative	6	1140	1146
	Total	421	1164	1585

Sensitivity = 415/421 (98.58%), 95% CI: 97.44% to 99.71%

Specificity = 1140/1164 (97.94%), 95% CI: 97.12% to 98.76%

1.2 Study of: Venous whole blood samples compared to serum samples.

One hundred and twenty-five (125) positive serum samples were compared to their venous blood equivalents. Another seventy-eight (78) negative serum samples were compared to their venous blood equivalent. These 203 samples were coded and tested with the abx294171 SARS-CoV-2 IgG/IgM Rapid Test kit. Of the 125 positive serum samples, all 125 tested positive with whole blood. Of the 78 negative serum samples, 75 tested negative with whole blood. Spearman's Rank Correlation Coefficient (ρ) was calculated to be 0.969.

2. Assay Cross Reactivity

Cross-reactivity of the COVID-19 IgG/IgM Rapid Test Kit was evaluated using serum or plasma samples which contain antibodies to the pathogens listed below. This test had no observable cross-reactivity with the following anti-pathogen antibodies:

Adenovirus
Chlamydia pneumoniae
Chickenpox virus
Coronavirus HKU1
Coronavirus OC43
Coronavirus NL63
Coronavirus 229E
Cytomegalovirus
Epstein-Barr virus (EBV)
Enterovirus 71
Hepatitis B virus (HBV)
Hepatitis C virus (HCV)
Human immunodeficiency virus (HIV)
Influenza A
Influenza B
Measles Virus
Mumps Virus
Mycoplasma pneumoniae
Respiratory syncytial virus
Treponema pallidum

3. Substance Interference

This test had no observable interference with the following substances at or below the listed concentrations.

Anti-mitochondrial antibodies	80U/ml
Anti-nuclear antibodies	1:240
Bilirubin	250 μMol/L
Hemoglobin	9 g/L

Mouse IgG	1000 µg/ml
Rheumatoid factor (anti-IgG autoantibodies)	80 IU/ml
Triglycerides	15 mMol/L

4. Therapeutic Interference

This test had no observable interference with the following therapeutic agents at or below the listed concentrations.

Azithromycin	100 mg/L
Ceftriaxone	400 mg/L
Histamine dihydrochloride	80 mg/L
Interferon alfa (IFN-α)	200 mg/L
Levofloxacin	200 mg/L
Lopinavir	40 mg/L
Meropenem	200 mg/L
Oseltamivir	30 mg/L
Peramivir	40 mg/L
Ribavirin (tribavirin)	40 mg/L
Ritonavir	40 mg/L
Tobramycin	100 mg/L
Umifenovir	40 mg/L
Zanamivir	40 mg/L

WARNINGS

1. This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
2. Keep out of reach of children.
3. Dispose of the kit after use or expiry. Dispose of used test in a biohazards bin.
4. Avoid exposure of test to high temperatures, humidity, and/or strong odors.
5. Do not eat any components of the test, including the buffer. If buffer is swallowed, take plenty of water and seek medical attention. Do not induce vomiting.
6. Do not use the components of any other type of test kit as a substitute for the components in this kit.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical samples. Wash hands thoroughly after performing the test.
8. Store kit at room temperature, or refrigerated (2-30°C). Do not freeze.
9. Do not remove outer packaging of components until ready to use.
10. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

LIMITATIONS OF THE PROCEDURE

1. The C region confirms that appropriate levels of capillary action (i.e. wicking) have taken place for the test to have worked.
2. The COVID-19 IgG/IgM Rapid Test Kit is intended for research use only. The kit is suitable only for the qualitative detection of human IgG and IgM antibodies in serum, plasma, or whole blood. Other sample types have not been tested.
3. There may be some cross-reactivity of this kit to other coronaviruses. A positive test is not proof that the causative agent is SARS-CoV-2 / COVID-19.
4. The test detects antibodies to COVID-19; it does not directly confirm if the patient is an active carrier of the virus. Conversely, active carriers of the virus may show a negative antibody result. Other tests (such as qPCR) may be required in combination for diagnosis, particularly for negative results. IgM antibodies can typically be detected approximately 7 days after infection.
5. A patient with a negative test result may obtain a positive result at a later date.
6. Results from patients with immune disorders (e.g. hyper-IgM syndrome, SCID, agammaglobulinemia) may need to be interpreted differently.
7. Lines may appear darker or fainter according to the relative antibody concentration in the sample.
8. If using a lancet and whole blood sample, it is recommended to use a non-index finger in the non-dominant hand.
9. This is a qualitative test; it is not suitable for quantitative or semi-quantitative determination of antibodies.
11. No hook effect was observed with clinically-relevant antibody concentrations.
12. Plasma and serum samples with hemolysis are not suitable for testing.
13. This test has not yet been validated by the FDA.
14. This test is not suitable for screening donated blood.

INQUIRIES AND GENERAL INFORMATION

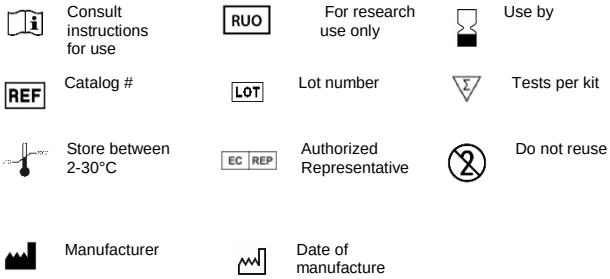
Please visit website www.abbexa.com

ORDERING

1. Contact Abbexa via email: orders@abbexa.com

TECHNICAL

1. Via email: info@abbexa.com



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