KESTREL BIO SCIENCES COVID-19 IgM/IgG Test Kit

INTENDED USE

The Kestrel Bio Sciences COVID-19 IgM/IgG Rapid Test Kit is a lateral flow immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human whole blood, plasma, or serum. It is used as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

IgM and IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized.

If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. False positive results for COVID-19 IgM/IgG Rapid Test Kit may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Confirmation of positive results should be considered using different IgG or IgM assay.

PRINCIPLE

The Kestrel COVID-19 IgM/IgG Rapid Test Kit is a lateral flow immunochromatographic assay uses anti-human IgM antibody (test line M), anti-human IgG (test line G) and anti-chicken IgY (control line C) captured on a nitrocellulose membrane of strip. The conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens (SARS-CoV-2 Spike S1 antigen) and chicken IgY. When a specimen followed by running buffer is added to the sample well, any present IgM &/or IgG antibodies against COVID-19will bind to COVID-19 antigen conjugates making an antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the captured antibodies (anti-human IgM &/or anti-human IgG), the complex is trapped forming a colored band which confirms a positive test result. Absence of a colored band at the test region indicates a negative test result. A colored line will always appear at the control line region, indicating that the components of the test kit are complete and the performance of test kit is valid.

MATERIAL SUPPLY

25 sealed pouches each containing a test cassette and a desiccant.
1 Running buffer.
1 Package insert.

STORAGE AND STABILITY

The Kestrel COVID-19 Test Kit can be stored between 2-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNING AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after expiration date
3. The test should be performed between 15 to 30°C. If kit is stored refrigerated, ensure the pouch and buffer are brought to operating temperature before performing test.
4. This package insert must be read completely before performing the test. Failure to follow the instructions may result in inaccuracy.
5. Do not use the test kit if the pouch is damaged or broken.
6. The test kit is for single use only. Do not re-use under any circumstances.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
9. Testing must be performed within one hour of opening the test kit pouch.
10. The test kit has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

SPECIMEN COLLECTION

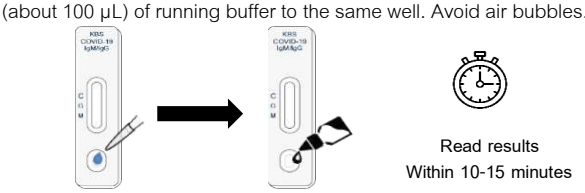
1. The Kestrel COVID-19 Test Kit can be performed using fingerstick and venous whole blood specimens, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C for up to several months.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well before testing. Specimens cannot be frozen and thawed more than 3 times.

TEST PROCEDURE

1. Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Testing must be performed within one hour of opening the test kit pouch.
3. Place the test device on a clean and flat surface.

For Serum or Plasma Specimens:

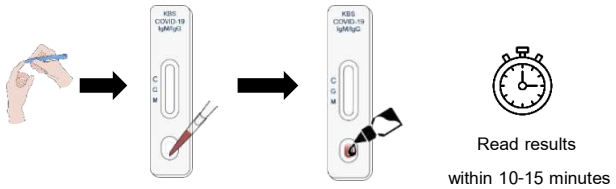
Pipette 5 µL of the serum/plasma specimen into the sample well. Then add 3 drops (about 100 µL) of running buffer to the same well. Avoid air bubbles.



5µL of serum/plasma 3 drops of running buffer

For Finger Stick & Venous Whole Blood Specimen:

Pipette 10 µL of the whole blood specimen into the sample well. Then add 3 drops (about 100 µL) of running buffer to the same well. Avoid air bubbles.



10 µL of whole blood 3 drops of running buffer

4. Wait for the colored line(s) to appear. After 2 minutes, if the red color has not moved across the test window, add 1 additional drop of the sample buffer to the buffer well.
5. The result should be read in 10-15 minutes. Positive results may be visible as soon as 2 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULT

Negative:

The colored line in the control line region (C) appears. No line appears in the test line regions M or G. The result is negative.

IgM Positive:

The colored line in the control line region (C) appears and a colored line appears in test line region M. The test result indicates the presence of IgM anti SARS-Cov-2 antibodies.

IgG Positive:

The colored line in the control line region (C) appears and a colored line appears in test line region G. The test result indicates the presence of IgG anti SARS-Cov-2 antibodies.

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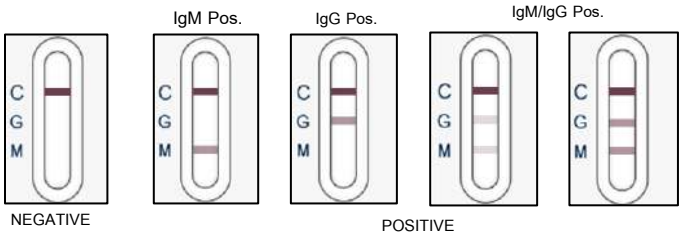
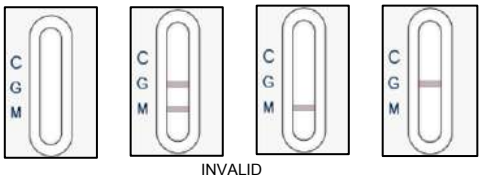
IgG and IgM Positive:

The colored line in the control line region (C) appears and a colored line appears in test line region M and G. The test result indicates the presence of IgM and IgG anti SARS-Cov-2 antibodies.



Invalid:

The colored line in the control line region (C) does not appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for the control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen and buffer volume and correct procedural technique.

LIMITATIONS

1. Use of Kestrel COVID-19 IgM/IgG Rapid Test Kit is limited to trained laboratory personnel. This is not for home use.
2. This product is only for testing of individual serum, plasma and whole blood. Other specimen types should not be used with this assay.
3. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particles that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult.
4. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
5. Reading test results earlier than 10 minutes after the addition of buffer may yield erroneous results. Do not interpret the result after 20 minutes.
6. This test detects the presence of SARS-CoV-2 IgM/IgG in the specimen and should not be used to diagnose or exclude SARS-CoV-2 infection.
7. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence in assessing the need for a second but different serology test to confirm an adaptive immune response.
8. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic conclusion is made.
9. A false negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or if the antibodies are not present during the stage of disease during which a sample is collected.
10. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
11. The COVID-19 IgM/IgG Rapid Test Kit is limited to the qualitative detection of antibodies specific for the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV2 antibody titer in the specimen.
12. Testing must be performed within one hour after opening the pouch.

PERFORMANCE CHARACTERISTIC

1. Sensitivity and Specificity

The clinical performance of the COVID-19 IgM/IgG Rapid Test Kit was evaluated by testing a total of 168 samples—18 positive serum samples (frozen) and 150 negative samples from 150 negative sample samples from finger stick whole blood, and 100 negative serum samples from frozen. Some negative samples from patient exhibit dengue IgG/IgM, HBS antibody and rheumatoid factor. Testing was performed at Ketrel Biosciences (Thailand) Co., Ltd. from July to October 2020. COVID-19 IgM/IgG Rapid Test Kit results for IgM and IgG detection were compared to the results of RT-PCR assays for SARS-CoV-2. Overall study results are shown in table below.

		True COVID status of IgM/IgG panel sera		
		SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
Kestrel COVID-19 IgM/IgG test Kit	Positive	17	1	18
	Negative	3	147	150
Total		20	148	168

Sensitivity of the COVID-19 IgM/IgG Rapid Test Kit: 94.4% (17/18)
Specificity of the COVID-19 IgM/IgG Rapid Test Kit: 98.0% (147/150)
Accuracy of the COVID-19 IgM/IgG Rapid Test Kit: 97.6% (164/168)

2. Cross Activity Assay

Cross-reactivity of the COVID-19 IgG/IgM Rapid Test Kit was evaluated using serum samples which contain antibodies to the pathogens listed below. A total of 51 specimens from 9 different categories were tested. No false positives were found with the following:

Sample Categories	Sample Number
Dengue IgM/IgG	20
Leptospirosis IgM/IgG	10
Mellioidosis IgG	5
HIV	5
Rhumatoide factor	1
HBV/HCV	10
HCV	5

REFERENCE

1. Li, Zhengtu et al. Development and clinical application of a rapid IgM-IgG combined antibody test for SARS-CoV-2 infection diagnosis. Journal of medical virology, 10.1002/jmv.25727. 27 Feb. 2020,
2. Hoffman, Tove et al. Evaluation of a COVID-19 IgM and IgG rapid test; an efficient tool for assessment of past exposure to SARS-CoV-2. Infection ecology & epidemiology vol. 10,1 1754538.14Apr.2020,
3. Long, Quan-Xin, et al. Antibody responses to SARS-CoV-2 in patients with COVID-19. Nature Medicine 29 Apr. 2020,

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