interchim®

COVID-19 Human IgM IgG Rapid Test
Instructions For Use

Abnova

Intended Use

This product is a lateral flow immunoassay for the rapid detection of human IgM and IgG antibodies in human whole blood and plasma in patients with suspected COVID-19 infection.

Background

In 2019, a novel coronavirus was identified as the cause of an outbreak of severe respiratory disease in China. On February 11, 2020, the disease was officially named "Coronavirus Disease 2019" (COVID-19). As the first line of defense against viral infection, human IgM antibody is generated when one becomes infected with the COVID-19 virus. The level of IgM will rise within 2 weeks and then drop; accordingly, a second antibody IgG, which is more protective than IgM antibody, develops within 4 weeks. Results from antibody testing should not be used as the sole basis to diagnose or exclude COVID-19 infection or to inform infection status.
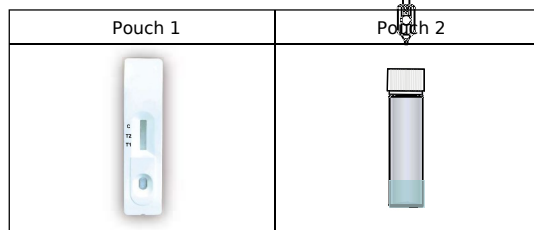
Principle

COVID-19 Human IgM IgG Rapid Test utilizes the technique of chromatography and qualitative immunoassay to detect the presence of IgM and IgG antibodies against COVID-19 virus in human whole blood and plasma. During testing, the blood sample firstly interacts with COVID-19 protein antigen labeled gold nanoparticles in the sample zone. By capillary action, the mixed sample flows across the membrane strip. Human IgM antibodies interact with the anti-human IgM antibodies coated in the IgM result zone showing a visible colored line. Similarly, a colored line in the IgG test zone demonstrates the presence of human IgG antibodies. Control line must appear every time to ensure the quality of the sample processing.
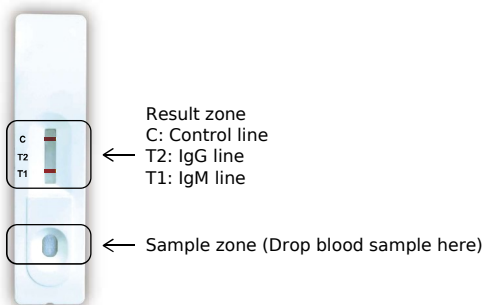
Content

COVID-19 Human IgM IgG Rapid Test contains Instructions for Use, COVID-19 Testing Strip (Pouch 1), and Sample Buffer (Pouch 2).

Pouch 1: COVID-19 Testing Strip
Pouch 2: Sample Buffer

Pouch 1	Pouch 2

The result zone and sample zone of Testing Strip are shown below:

Result zone
C: Control line
T2: IgG line
T1: IgM line

Sample zone (Drop blood sample here)

Reagent Ingredients

1. Testing Strip
   - Colloidal Gold-Labeled COVID-19 N Protein
   - Colloidal Gold-Labeled COVID-19 RBD Protein
   - Colloidal Gold-Labeled Control Antibody
   - Anti-Human IgM Antibody
   - Anti-Human IgG Antibody
   - Anti-Control Antibody

2. Sample Buffer

Expiration Date

Date of manufacture, expiration date and lot number are indicated on the packaging. Expiration date is 6 months after the date of manufacture.

Storage Environment

Store product at 15°C - 30°C and avoid direct exposure to sunlight. Do not open until ready to use. Do not freeze or store the product outside the temperature range described above. Do not use it after the expiration date.
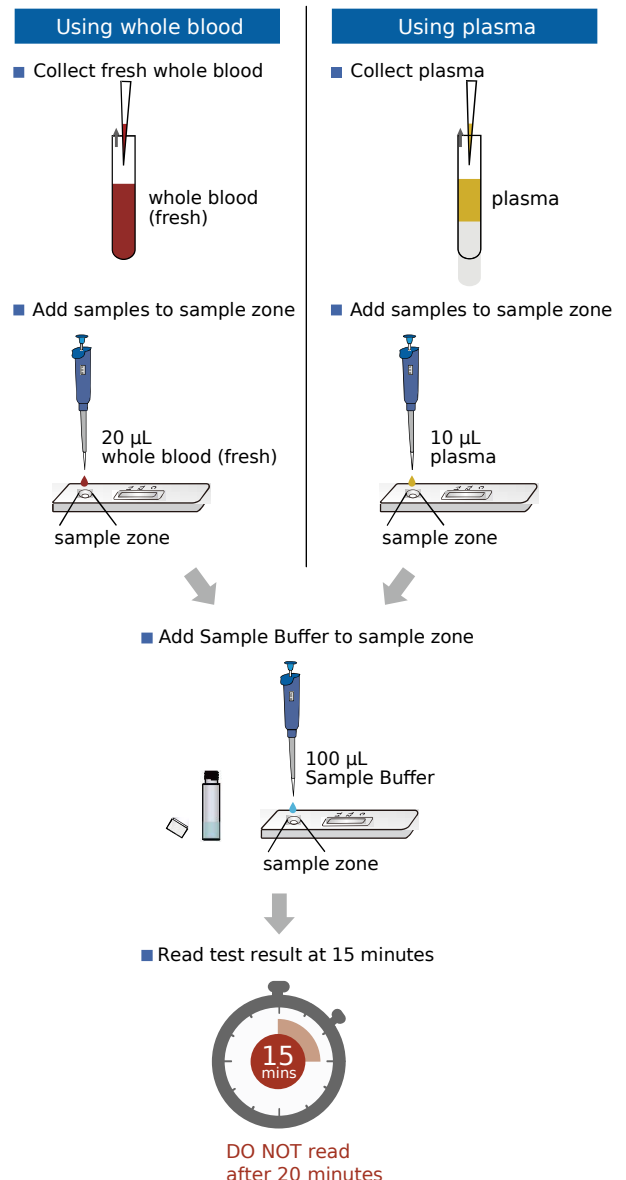
Instructions before Use

1. Operate this product at room temperature 15°C - 30°C.

2. Please read Test Limitations, Notification and Precautions carefully before using this product.

Sample Requirement

Whole blood sample should be used fresh. Plasma sample can be stored at 2°C - 8°C for no more than one week. Bring plasma back to room temperature (15°C - 30°C) 15 minutes before use.

Test Procedure

1. Take out Pouch 1 and Pouch 2, and adjust to room temperature (15°C - 30°C).

2. Unpack Pouch 1 and take out the Testing Strip. Place the Testing Strip on a balanced surface.

3. Take 20 μL whole blood or 10μL plasma with a pipette, and drop the sample into the sample zone of the Testing Strip (DO NOT drop the sample into the result zone).

4. Wait until the sample has fully penetrated the sample zone, unpack Pouch 2 and take 100 μL Sample Buffer with a pipette. Drop the Sample Buffer to the sample zone of the Testing Strip (DO NOT drop the Sample Buffer into the result zone).

5. Wait up to15 minutes for the colored line(s) to appear and then read the result at 15 minutes (DO NOT read after 20 minutes).
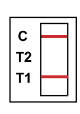
Using whole blood	Using plasma
■ Collect fresh whole blood	■ Collect plasma
whole blood (fresh)	plasma
■ Add samples to sample zone	■ Add samples to sample zone
20 μL whole blood (fresh) sample zone	10 μL plasma sample zone

■ Add Sample Buffer to sample zone

100 μL Sample Buffer

sample zone

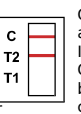■ Read test result at 15 minutes

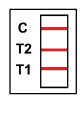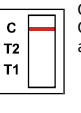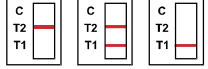15 mins

DO NOT read after 20 minutes

Test Limitations

1. This product can only be used to detect the IgG and IgM antibodies of the novel coronavirus in human venous whole blood and plasma. It cannot be used with other body fluids or secretions.

2. This product is only for qualitative testing and the specific content of each indicator must be measured using other quantitative methodologies.

3. Negative results may be caused by low concentrations of the novel coronavirus IgG/IgM antibody in the sample and therefore cannot completely rule out the possibility of infection.

4. The results of this test are for clinical reference only and should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods.

5. Test results can be affected by temperature and humidity.

Interpretation of Result

Result zone of the Testing Strip indicates human IgM line (T1 line), IgG line (T2 line) and control line (C line). C line must appear to ensure the quality of sample processing. Please refer to the diagram below for interpretation:

IgM Positive

Colored lines appear in C line and T1 line. Indicate high concentration of COVID-19 IgM in the whole blood or plasma. Please consult a physician for further follow-up.

IgG Positive

Colored lines appear in C line and T2 line. Indicate high concentration of COVID-19 IgG in the whole blood or plasma. Please consult a physician for further follow-up.

IgM and IgG Positive

Three colored lines appear in C line, T1 line and T2 line. Indicate high concentration of both COVID-19 IgM and IgG in the whole blood or plasma. Please consult a physician for further follow-up.

IgM and IgG Negative

One colored line appears in C line. T1 and T2 line are absent.

Invalid

All products are processed follow stringent manufacturing principles. If the C line fails to appear, the test is invalid even if T1 line or T2 line is colored.

Quality Control

Control line (C line in the above diagram) in the result zone on the Testing Strip serves as an indicator for product validity. Regardless if positive or negative samples, the C line must appear. It will also serve as internal control for sample processing.

Notification

Laboratories and healthcare providers must include this information in their patient test report:

1. This test is limited to testing in laboratories or by healthcare workers. It is considered as a high complexity test by default under CLIA requirements.

2. 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 should be considered to rule out infection in these individuals.

3. 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.

4. 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.

Precautions

1. This product is for professional use only.

2. Please check the expiration date before use. Do not use the product beyond expiration date.

3. Leave all components in their sealed pouches until use. Discard the product if not used immediately after unpacking pouches to avoid changes in product quality that may affect the test result.

4. Please follow the Instructions for Use and use it immediately after unpacking pouches. No interruption is allowed. Do not use methods not described in the Instructions for Use.

5. The product is for single-use only.

6. Clean possible contaminated areas with stringent cleaning procedure after use to avoid infection.

7. Before use COVID-19 Human IgM IgG Rapid Test, suitable procedure for sample collection should be used, otherwise it may cause unexpected test result or injury.

Performance Characteristics

Reactivity:

COVID-19 nucleocapsid humanized IgM and IgG antibodies validated against SARS-CoV, COVID-19, MERS-CoV, and HCoV-NL63 nucleocapsid proteins demonstrating SARS-CoV and COVID-19 specificity.

Nucleocapsid Protein	COVID-19 Nucleocapsid Humanized IgM Antibody	COVID-19 Nucleocapsid Humanized IgG Antibody
SARS-CoV NP	+	+
COVID-19 NP	+	+
MERS-CoV NP	-	-
HCoV-NL63 NP	-	-

COVID-19 humanized IgM and IgG antibodies were spiked in decreasing concentrations in EDTA normal venous whole blood samples demonstrating class-specific reactivity, repeatability, and limit of detection (LoD) sensitivity

	Spiked Concentration	Result (IgM/IgG)	Expected Result	Result Agreement
COVID-19 Humanized IgM Antibody Spiked	50 µg/mL	+/-	+/-	100% (3/3)
	30 µg/mL	+/-		100% (3/3)
	10 µg/mL (LoD)	+/-		95% (19/20)
COVID-19 Humanized IgG Antibody Spiked	1000 µg/mL	-/+	-/+	100% (3/3)
	400 µg/mL	-/+		100% (3/3)
	200 µg/mL (LoD)	-/+		95% (19/20)

Cross-Reactivity:

75 known negative EDTA venous whole blood samples were collected and tested for COVID-19 cross reactivity from a Taiwan population with minimal COVID-19 outbreak and a high prevalence of vaccination against and or infection with Influenza A, B, HBV, HCV, Haemophilus Influenza, alpha and beta 229E, NL63, OC43, HKU1 (non-COVID-19) Coronavirus.

Sample ID	Result (IgM/IgG)	Expected Result (IgM/IgG)	Result Agreement
N1	-/-	-/-	yes
N2	-/-	-/-	yes
N3	-/-	-/-	yes
N4	-/-	-/-	yes
N5	-/-	-/-	yes
N6	-/-	-/-	yes
N7	-/-	-/-	yes
N8	-/-	-/-	yes
N9	-/-	-/-	yes
N10	-/-	-/-	yes
N11	-/-	-/-	yes
N12	-/-	-/-	yes
N13	-/-	-/-	yes
N14	-/-	-/-	yes
N15	-/-	-/-	yes
N16	-/-	-/-	yes
N17	-/-	-/-	yes
N18	-/-	-/-	yes
N19	-/-	-/-	yes
N20	-/-	-/-	yes
N21	-/-	-/-	yes
N22	-/-	-/-	yes
N23	-/-	-/-	yes
N24	-/-	-/-	yes
N25	-/-	-/-	yes
N26	-/-	-/-	yes
N27	-/-	-/-	yes
N28	-/-	-/-	yes
N29	-/-	-/-	yes
N30	-/-	-/-	yes
N31	-/-	-/-	yes
N32	-/-	-/-	yes
N33	-/-	-/-	yes
N34	-/-	-/-	yes
N35	-/-	-/-	yes
N36	-/-	-/-	yes

Sample ID	Result (IgM/IgG)	Expected Result (IgM/IgG)	Result Agreement
N37	-/-	-/-	yes
N38	-/-	-/-	yes
N39	-/-	-/-	yes
N40	-/-	-/-	yes
N41	-/-	-/-	yes
N42	-/-	-/-	yes
N43	-/-	-/-	yes
N44	-/-	-/-	yes
N45	-/-	-/-	yes
N46	-/-	-/-	yes
N47	-/-	-/-	yes
N48	-/-	-/-	yes
N49	-/-	-/-	yes
N50	-/-	-/-	yes
N51	-/-	-/-	yes
N52	-/-	-/-	yes
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N56	-/-	-/-	yes
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N59	-/-	-/-	yes
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N65	-/-	-/-	yes
N66	-/-	-/-	yes
N67	-/-	-/-	yes
N68	-/-	-/-	yes
N69	-/-	-/-	yes
N70	-/-	-/-	yes
N71	-/-	-/-	yes
N72	-/-	-/-	yes
N73	-/-	-/-	yes
N74	-/-	-/-	yes
N75	-/-	-/-	yes

Class Specificity:

COVID-19 humanized IgM and IgG antibodies were spiked in increasing concentrations in EDTA normal venous plasma samples demonstrating class-specific reactivity and repeatability

	Spiked Concentration	Result (IgM/IgG)	Expected Result	Result Agreement
Normal Plasma Only	N/A	-/-	-/-	100% (2/2)
COVID-19 Humanized IgM Antibody Spiked in Normal Plasma	10 µg/mL	+/-	+/-	100% (2/2)
	50 µg/mL	+/-	+/-	100% (2/2)
	100 µg/mL	+/-	+/-	100% (2/2)

	Spiked Concentration	Result (IgM/IgG)	Expected Result	Result Agreement
Normal Plasma Only	N/A	-/-	-/-	100% (2/2)
COVID-19 Humanized IgG Antibody Spiked in Normal Plasma	200 µg/mL	-/+	-/+	100% (2/2)
	500 µg/mL	-/+	-/+	100% (2/2)
	1000 µg/mL	-/+	-/+	100% (2/2)

Precision:

Day, operator, humanized antibody concentration and kit lot# of COVID-19 Human IgM IgG Rapid Test reproducibility and repeatability study.

Time	Operator	Sample	Spiked IgM or IgG Concentration	Kit Lot	Result (IgM/IgG) Viewer 1	Result (IgM/IgG) Viewer 2	Expected Result (IgM/IgG)	Result Agreement Viewer 1	Result Agreement Viewer 2
Day 1	A	EDTA Venous Whole Blood	0	K5151	-/-	-/-	-/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgM Antibody Spiked in EDTA Venous Whole Blood	10 µg/mL	K5151	low+/-	low+/-	low+/-	100% (2/2)	100% (2/2)
			50 µg/mL	K5151	moderate+/-	moderate+/-	moderate+/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgG Antibody Spiked in EDTA Venous Whole Blood	500 µg/mL	K5151	-/ low+	-/ low+	-/ low+	100% (2/2)	100% (2/2)
			1000 µg/mL	K5151	-/ moderate+	-/ moderate+	-/ moderate+	100% (2/2)	100% (2/2)
Day 1	B	EDTA Venous Whole Blood	0	K5151	-/-	-/-	-/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgM Antibody Spiked in EDTA Venous Whole Blood	10 µg/mL	K5151	low+/-	low+/-	low+/-	100% (2/2)	100% (2/2)
			50 µg/mL	K5151	moderate+/-	moderate+/-	moderate+/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgG Antibody Spiked in EDTA Venous Whole Blood	500 µg/mL	K5151	-/ low+	-/ low+	-/ low+	100% (2/2)	100% (2/2)
			1000 µg/mL	K5151	-/ moderate+	-/ moderate+	-/ moderate+	100% (2/2)	100% (2/2)
Day 2	A	EDTA Venous Whole Blood	0	K5152	-/-	-/-	-/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgM Antibody Spiked in EDTA Venous Whole Blood	10 µg/mL	K5152	low+/-	low+/-	low+/-	100% (2/2)	100% (2/2)
			50 µg/mL	K5152	moderate+/-	moderate+/-	moderate+/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgG Antibody Spiked in EDTA Venous Whole Blood	500 µg/mL	K5152	-/ low+	-/ low+	-/ low+	100% (2/2)	100% (2/2)
			1000 µg/mL	K5152	-/ moderate+	-/ moderate+	-/ moderate+	100% (2/2)	100% (2/2)
Day 2	B	EDTA Venous Whole Blood	0	K5152	-/-	-/-	-/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgM Antibody Spiked in EDTA Venous Whole Blood	10 µg/mL	K5152	low+/-	low+/-	low+/-	100% (2/2)	100% (2/2)
			50 µg/mL	K5152	moderate+/-	moderate+/-	moderate+/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgG Antibody Spiked in EDTA Venous Whole Blood	500 µg/mL	K5152	-/ low+	-/ low+	-/ low+	100% (2/2)	100% (2/2)
			1000 µg/mL	K5152	-/ moderate+	-/ moderate+	-/ moderate+	100% (2/2)	100% (2/2)
Day 3	A	EDTA Venous Whole Blood	0	K5153	-/-	-/-	-/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgM Antibody Spiked in EDTA Venous Whole Blood	10 µg/mL	K5153	low+/-	low+/-	low+/-	100% (2/2)	100% (2/2)
			50 µg/mL	K5153	moderate+/-	moderate+/-	moderate+/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgG Antibody Spiked in EDTA Venous Whole Blood	500 µg/mL	K5153	-/ low+	-/ low+	-/ low+	100% (2/2)	100% (2/2)
			1000 µg/mL	K5153	-/ moderate+	-/ moderate+	-/ moderate+	100% (2/2)	100% (2/2)
Day 3	B	EDTA Venous Whole Blood	0	K5153	-/-	-/-	-/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgM Antibody Spiked in EDTA Venous Whole Blood	10 µg/mL	K5153	low+/-	low+/-	low+/-	100% (2/2)	100% (2/2)
			50 µg/mL	K5153	moderate+/-	moderate+/-	moderate+/-	100% (2/2)	100% (2/2)
		COVID-19 Humanized IgG Antibody Spiked in EDTA Venous Whole Blood	500 µg/mL	K5153	-/ low+	-/ low+	-/ low+	100% (2/2)	100% (2/2)
			1000 µg/mL	K5153	-/ moderate+	-/ moderate+	-/ moderate+	100% (2/2)	100% (2/2)

Clinical Agreement Study:

30 known COVID-19 positive and 75 known negative EDTA whole blood samples were collected, confirmed with EUA authorized RT-PCR, and tested for COVID-19 IgM and IgG reactivity following symptom onset with results read by two blinded, independent viewers.

COVID-19 Human IgM IgG Rapid Test	EUA Authorized RT-PCR Confirmed		
	Positive (+)	Negative (-)	Total
Positive (+)	27	0	27
Negative (-)	3	75	78
Total	30	75	105
Sensitivity	90%		
Specificity	100%		

Matrix Equivalency:

COVID-19 humanized IgM and IgG antibodies were spiked in increasing concentrations in EDTA venous whole blood versus venous plasma from 5 normal individuals with replicated results read by two blinded, independent viewers demonstrating matrix equivalency.

Sample ID: N73, N28, N31, N19, N58					
	Matrix	Spiked IgM or IgG Concentration	Result (IgM/IgG)	Expected Result (IgM/IgG)	Result Agreement
COVID-19 Humanized IgM Antibody Spiked in Normal Sample	EDTA Venous Whole Blood	0 µg/mL	-/-	-/-	100% (10/10)
	EDTA Venous Plasma		-/-		100% (10/10)
	EDTA Venous Whole Blood	10 µg/mL	low+/-	+/-	100% (10/10)
	EDTA Venous Plasma		low+/-		100% (10/10)
	EDTA Venous Whole Blood	50 µg/mL	moderate+/-		100% (10/10)
	EDTA Venous Plasma		moderate+/-		100% (10/10)
COVID-19 Humanized IgG Antibody Spiked in Normal Sample	EDTA Venous Whole Blood	0 µg/mL	-/-	-/-	100% (10/10)
	EDTA Venous Plasma		-/-		100% (10/10)
	EDTA Venous Whole Blood	500 µg/mL	-/ low+	-/+	100% (10/10)
	EDTA Venous Plasma		-/ low+		100% (10/10)
	EDTA Venous Whole Blood	1000 µg/mL	-/moderate+		100% (10/10)
	EDTA Venous Plasma		-/moderate+		100% (10/10)

Symbols

⊗	Do not reuse	⊗	Do not use if package is damaged	🌡	Temperature limit: 15°C - 30°C
📖	Consult instruction for use	🏭	Manufacturer	REF	Catalog number
LOT	Lot number	⧗	Use by date	〰	Date of manufacture
CE	CE Mark	Σ/20	20 tests	EC REP	Authorized Representative in the European Community

Adverse Events

Reporting Adverse Events, including problems with test performance or results, to Abnova by submitting the online Adverse Events Form. (http://www.abnova.com/support/AdverseEvents.asp)

CE IVD

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