COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/ Serum/ Plasma)

Package Insert

REF INGM-MC42 | English

A rapid test for the qualitative detection of antibodies (IgG and IgM) to SARS-CoV-2 in whole blood, serum, or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of SARS-COV-2 infections.

【SUMMARY】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of SARS-COV-2 antigen coated colored particles for the detection of IgG and IgM antibodies to SARS-COV-2 in human whole blood, serum, or plasma.

【PRINCIPLE】

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM, IgM antibodies to SARS-CoV-2, if present in the specimen, reacts with the anti-human IgM and the SARS-CoV-2 antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region.

Therefore, if the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to SARS-CoV-2, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to SARS-CoV-2, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always change from Blue to Red in the control line region, indicating that membrane wicking has occurred.

【REAGENTS】

The test cassette contains to specific antigen conjugated gold colloid particles and anti-human IgM, anti-human IgG coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma.
- Whole blood or plasma could be collected with tube containing Heparin or Citrate.
- To collect Fingerstick Whole Blood Specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test cassette by using a dropper, capillary or micropipette measuring 10ul. The dropper provided with the test dispenses approximately 10ul in one drop even if more blood is aspirated in the dropper or capillary.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- 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. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

【MATERIALS 】

Materials provided

Test cassettes | Droppers or capillaries | Buffer | Package insert

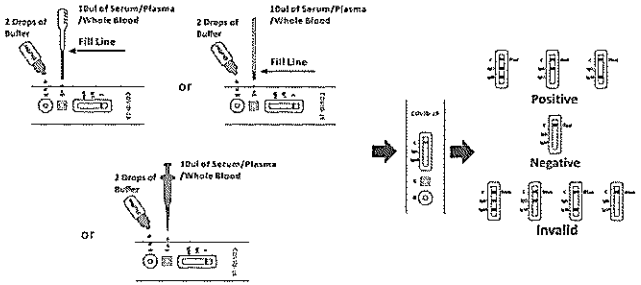
Materials required but not provided

Specimen collection containers | Centrifuge (for plasma only) | Micropipette | Timer | Lancets (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface.
   - For Serum or Plasma or Whole Blood Specimens:
     - To use a dropper/ capillary: Hold the dropper/ capillary vertically, draw the specimen up to the Fill Line (approximately 10µl), and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. Avoid trapping air bubbles in the specimen well.
     - To use a micropipette: Pipette and dispense 10µl of specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer.
3. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

IgG and IgM POSITIVE:* The colored line in the control line region (C) changes from Blue to Red, and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match.

IgG POSITIVE:* The colored line in the control line region (C) changes from Blue to Red, and a colored line appears in IgG test line region. The result is positive for SARS-COV-2 virus specific-IgG.

IgM POSITIVE:* The colored line in the control line region (C) changes from Blue to Red, and a colored line appears in IgM test line region. The result is positive for SARS-COV-2 virus specific-IgM antibodies.

*NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-COV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.

NEGATIVE: The colored line in the control line region (C) changes from **Blue to Red.** No line appears in IgG and IgM test line region(s).

INVALID: Control line (C) is still completely or partially blue, and fails to completely change from Blue to Red. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.
2. In the early onset of symptom, anti-SARS-COV-2 IgM concentrations may be below detectable levels.
3. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
4. Results from immunosuppressed patients should be interpreted with caution.
5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
6. 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.
7. 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.
8. 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.
9. Not for the screening of donated blood.
10. There may be false positive risk with the plasma in EDTA tube after a period storage.

【PERFORMANCE CHARACTERISTICS】

POSITIVE AGREEMENT:

Positive agreement was evaluated using specimens collected from symptomatic subjects. All subjects were confirmed positive for SARS-COV-2 by RT-PCR. The positive population consisted of the following subjects.

Living in Site A during the COVID-19 pandemic.

Living in Site B-1 during the COVID-19 pandemic.

Living in Site B-2 during the COVID-19 pandemic

Table1. IgM PPA (Per site and sites combined):

Site	Days post symptom onset	# PCR positive at any time	COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI
A & B-2 (Serum)	≤7	9	6	66.67%	(35.42% -87.94%)
	8-14	83	77	96.25%	(89.55% - 98.72%)
	≥15	158	150	94.94%	(90.33% - 97.41%)
B-1 (Plasma)	unknown	70	63	90.00%	(80.77% - 95.07%)
Sites combined	-	320	296	92.50%	(89.08% - 94.91%)

Table2. IgG PPA (Per site and sites combined):

Site	Days post symptom onset	# PCR positive at any time	COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI
A & B-2 (Serum)	≤7	9	6	66.67%	(35.42% - 87.94%)
	8-14	83	76	91.57%	(83.60% - 95.85%)
	≥15	158	152	96.20%	(91.96% - 98.25%)
B-1 (Plasma)	unknown	70	59	84.29%	(74.01% -90.99%)
Sites combined	-	320	293	91.56%	(88.00% - 94.14%)

CI means confidence interval.

NEGATIVE AGREEMENT

Negative agreement was evaluated using 210 samples collected from symptomatic subjects and all were confirmed negative for SARS-COV-2 by RT-PCR. The excluded cases consisted of the following subjects.

Living in Site A during the COVID-19 pandemic.

Living in Site B-1 during the COVID-19 pandemic.

Living in Site C during the COVID-19 pandemic

The overall NPA/specificity of the COVID-19 IgG/IgM Rapid Test Cassette is 98.10% (206/210); [95% CI; (95.12% - 99.26%)].

Table 3. IgM NPA (Per site and sites combined):

Site	# PCR negative	COVID-19 IgG/IgM Rapid Test Cassette		
		# negative results	NPA	95%CI
A (Serum)	150	146	97.33%	(93.34% - 98.96%)
B -1 (Plasma)	10	10	100.00%	(72.25% -100.00%)
C (Serum)	50	50	100.00%	(92.87% - 100.00%)
Sites combined	210	206	98.10%	(95.12% - 99.26%)

Table 4. IgG NPA (Per site and sites combined):

Site	# PCR Negative	COVID-19 IgG/IgM Rapid Test Cassette		
		# negative results	NPA	95%CI
A (Serum)	150	149	99.33%	(96.32% - 99.88%)
B -1 (Plasma)	10	10	100.00%	(72.25% -100.00%)
C (Serum)	50	50	100.00%	(92.87% - 100.00%)
Sites combined	210	209	99.52%	(97.38% - 99.99%)

CI means confidence interval.

SEROCONVERSION:

The sensitivity and specificity of the COVID-19 IgG/IgM Rapid Test Cassette was evaluated on samples from individuals residing in Site C for Diagnosis and Treatment of Infectious Disease. The sensitivity was evaluated on 104 samples from 30 hospitalized patients. All the studied cases are confirmed by RT-PCR. Of these objectives, seven subjects were both IgM and IgG positive at the first sample test, twenty subjects seroconverted during observation and three subjects never seroconverted. The sensitivity was 90% (27/30) for the subjects tested.

Table 5. IgM PPA (Site C)

Site	Days post symptom onset	# PCR positive at any time	COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI
C	≤7	32	10	31.25%	16.12%-50.01%
	8~14	27	14	51.85%	31.95%-71.33%
	≥15	45	43	95.56%	84.85%-99.46%

Table 6. IgG PPA (Site C)

Site	Days post symptom onset	# PCR positive at any time	COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI
C	≤7	32	5	15.63%	5.28%-32.79%
	8~14	27	12	44.44%	25.48%-64.67%
	≥15	45	41	91.11%	78.76%-97.52%

Table 7: Seroconversion

Case (Patient) ID No.	Sample ID No.	nCoV-2 RT-PCR Results	Days Between Symptoms Onset and Blood Collection	COVID-19 IgG/IgM Rapid Test Cassette		
				IgM(+)	IgG(+)	IgM(+) and /or IgG(+)
CJG-2000004116	CJG-2000004116-01	+	7	-	-	-
	CJG-2000004116-02	N/A	10	-	-	-
	CJG-2000004116-03	+	18	+	+	+
CSC-2000004214	CSC-2000004214-01	+	10	+	+	+
	CSC-2000004214-02	N/A	13	+	+	+
	CSC-2000004214-03	N/A	18	+	+	+
	CSC-2000004214-04	-	32	+	+	+
CZ-05148433	CZ-05148433-01	+	7	-	-	-
	CZ-05148433-02	-	8	+	+	+
	CZ-05148433-03	+	22	+	+	+
GJ-03013432	GJ-03013432-01	+	1	+	+	+
	GJ-03013432-02	+	2	+	+	+
	GJ-03013432-03	-	9	+	+	+
GXM-05143619	GXM-05143619-01	+	4	-	-	-
	GXM-05143619-02	N/A	6	+	+	+
	GXM-05143619-03	+	9	-	+	+
HHZ-05150218	HHZ-05150218-01	+	11	+	+	+
	HHZ-05150218-02	+	13	+	+	+
	HHZ-05150218-03	+	22	+	+	+
	HHZ-05150218-04	N/A	24	-	+	+
HSJ-03886796	HSJ-03886796-01	+	2	-	-	-
	HSJ-03886796-02	+	5	-	-	-
	HSJ-03886796-03	+	7	+	-	+
	HSJ-03886796-05	N/A	11	+	+	+
	HSJ-03886796-04	+	20	+	+	+
JXJ-2000004055	JXJ-2000004055-01	+	8	-	-	-
	JXJ-2000004055-04	-	14	+	-	+
	JXJ-2000004055-03	+	20	+	+	+
	JXJ-2000004055-02	N/A	24	+	+	+
LE-01613279	LE-01613279-01	-	7	-	-	-
	LE-01613279-02	+	14	-	-	-
	LE-01613279-03	-	33	+	+	+
LH-05079034	LH-05079034-01	+	6	-	-	-
	LH-05079034-02	+	7	+	+	+
	LH-05079034-03	+	20	+	+	+
LMX-05148953	LMX-05148953-06	N/A	7	-	-	-
	LMX-05148953-01	+	8	-	-	-
	LMX-05148953-02	+	10	-	-	-
	LMX-05148953-03	+	11	+	-	+
	LMX-05148953-07	N/A	13	+	+	+
	LMX-05148953-04	N/A	16	+	+	+
	LMX-05148953-05	N/A	24	+	+	+
	LMX-05148953-08	-	33	+	+	+
MRG-2000004008	MRG-2000004008-01	+	4	-	-	-
	MRG-2000004008-02	+	21	+	+	+
	MRG-2000004008-03	N/A	26	+	+	+
MXR-2000004129	MXR-2000004129-01	+	11	+	+	+
	MXR-2000004129-02	N/A	22	+	+	+
	MXR-2000004129-03	+	25	+	+	+
SBZ-2000004184	SBZ-2000004184-01	+	7	-	-	-
	SBZ-2000004184-02	N/A	8	-	-	-
	SBZ-2000004184-03	+	10	-	-	-
SGH-	SGH-2000004035-01	+	5	-	-	-
2000004035	SGH-2000004035-02	+	19	+	+	+
	SGH-2000004035-03	+	24	+	+	+
SWD-2000004137	SWD-2000004137-01	+	15	+	+	+
	SWD-2000004137-02	N/A	19	+	+	+
	SWD-2000004137-03	+	23	+	+	+
	SWD-2000004137-04	-	68	+	+	+
WCD-2000004024	WCD-2000004024-01	+	2	-	-	-
	WCD-2000004024-02	N/A	14	-	-	-
	WCD-2000004024-03	+	22	-	-	-
WCJ-05151120	WCJ-05151120-01	+	6	+	+	+
	WCJ-05151120-02	+	15	+	+	+
	WCJ-05151120-03	N/A	21	+	+	+
	WCJ-05151120-04	+	27	+	+	+
WH-2000004159	WH-2000004159-01	+	7	-	-	-
	WH-2000004159-02	+	10	-	-	-
	WH-2000004159-03	+	14	+	-	+
	WH-2000004159-04	-	29	+	+	+
WJQ-05149865	WJQ-05149865-01, WJQ-05149865-04	+	0	-	-	-
	WJQ-05149865-02	+	1	-	-	-
	WJQ-05149865-03	+	2	+	-	+
	WJQ-05149865-05	N/A	15	+	+	+
WMM-05148912	WMM-05148912-01	+	2	-	-	-
	WMM-05148912-02	+	18	+	+	+
	WMM-05148912-03	+	20	+	+	+
WYC-2000004016	WYC-2000004016-01	+	35	+	-	+
	WYC-2000004016-02	+	41	+	+	+
	WYC-2000004016-03	-	55	+	+	+
XYS-00987017	XYS-00987017-01	+	11	-	-	-
	XYS-00987017-02	+	21	+	+	+
	XYS-00987017-03	+	23	+	+	+
XZC-2000004086	XZC-2000004086-01	+	9	-	-	-
	XZC-2000004086-02	+	25	+	-	+
	XZC-2000004086-03	-	35	-	+	+
YYQ-05148957	YYQ-05148957-01	N/A	3	+	-	+
	YYQ-05148957-02	+	7	+	+	+
	YYQ-05148957-03	+	42	+	+	+
YYX-2000004130	YYX-2000004130-01	+	4	-	-	-
	YYX-2000004130-02	N/A	6	-	-	-
	YYX-2000004130-03	+	15	+	+	+
YZM-2000004131	YZM-2000004131-01	+	4	-	-	-
	YZM-2000004131-02	+	8	+	+	+
	YZM-2000004131-03	N/A	16	+	+	+
ZFS-2000004005	ZFS-2000004005-01	+	13	+	+	+
	ZFS-2000004005-02	+	16	+	+	+
	ZFS-2000004005-03	N/A	17	+	+	+
ZJH-00823994	ZJH-00823994-01	+	3	-	-	-
	ZJH-00823994-02	-	7	-	-	-
	ZJH-00823994-03	N/A	11	-	-	-
ZLQ-05150650	ZLQ-05150650-03	+	7	-	-	-
	ZLQ-05150650-01	+	19	+	-	+

Fingerstick Whole Blood Clinical Performance

The fingerstick whole blood clinical study was conducted in point-of-care (POC) sites. A total of thirty-two (32) subjects were studied who had negative PCR results within one week of test; all of these subjects also tested negative with the COVID-19 IgG/IgM Rapid Test Cassette. A total of 45 symptomatic subjects were studied who had positive PCR results; 41 of these subjects tested positive for IgG with the COVID-19 IgG/IgM Rapid Test Cassette, 40 of these subjects tested positive for IgM with the COVID-19 IgG/IgM Rapid Test Cassette.

Table 8: IgG PPA for COVID-19 IgG/IgM Rapid Test Cassette

Sample	Days post symptom onset	# PCR positive at any time	COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI*
Fingerstick Whole Blood	≤7	3	3	100.00%	(36.84%, 100.00%)
	8-14	8	6	75.00%	(34.91%, 96.81%)
	≥15	34	32	94.12%	(80.32%, 99.28%)
	Total	45	41	91.11%	(78.76%, 97.52%)

*CI means confidence interval.

Table 9: IgM PPA for COVID-19 IgG/IgM Rapid Test Cassette

Sample	Days post symptom onset	# PCR positive at any time	COVID-19 IgG/IgM Rapid Test Cassette		
			# positive results	PPA	95%CI*
Fingerstick Whole Blood	≤7	3	2	66.67%	(9.43%, 99.16%)
	8-14	8	8	100.00%	(68.77%, 100.00%)
	≥15	34	30	88.24%	(72.55%, 96.70%)
	Total	45	40	88.89%	(75.95%, 96.29%)

*CI means confidence interval

The overall NPA/specificity of COVID-19 IgG/IgM Rapid Test is 100% (32/32); [95%: (91.06% - 100%)] in fingerstick whole blood samples.

Table 10: IgG NPA for COVID-19 IgG/IgM Rapid Test Cassette

Sample	# PCR negative	COVID-19 IgG/IgM Rapid Test Cassette		
		# negative results	NPA	95%CI*
Fingerstick Whole Blood	32	32	100.00%	(91.06% - 100.00%)

*CI means confidence interval.

Table 11: IgM NPA for COVID-19 IgG/IgM Rapid Test Cassette

Site	# PCR negative	COVID-19 IgG/IgM Rapid Test Cassette		
		# negative results	NPA	95%CI*
Fingerstick Whole Blood	32	32	100.00%	(91.06% - 100.00%)

*CI means confidence interval.

Retrospective Study on Negative Serum Collected before November 2019. The 1010 serum samples were performed with the COVID-19 IgG/IgM Rapid Test Cassette.

Table 12: IgG NPA for COVID-19 IgG/IgM Rapid Test Cassette

Sample	# in total	COVID-19 IgG/IgM Rapid Test Cassette		
		# negative results	NPA	95%CI*
Serum collected before November 2019	1010	1010	100.0%	(99.70% - 100.00%)

Table 13: IgM NPA for COVID-19 IgG/IgM Rapid Test Cassette

Sample	# in total	COVID-19 IgG/IgM Rapid Test Cassette		
		# negative results	NPA	95%CI*
Serum collected before November 2019	1010	1009	99.90%	(99.45% - 100.00%)

Cross-reactivity

The COVID-19 IgG/IgM Rapid Test Cassette (whole blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV, anti-haemophilus influenza, ANA, H1N1, H3N2, H7N9, coronavirus HKU1, NL63, OC43, 229E and HAMA positive specimens. The results showed no cross-reactivity. Some cross reactivity was observed with samples positive for SARS-CoV antibody and Rheumatoid Factor. It is possible to cross-react with samples positive for MERS-CoV antibody.

Interfering Substances

The following potentially interfering substances were added to COVID-19 negative and spiked positive specimens.

Analytes	Concentration	Result			
		Negative Specimen		Spiked with Positive Specimen	
		IgG line	IgM line	IgG line	IgM line
Acetaminophen	20 mg/dL	Negative	Negative	Positive	Positive
Caffeine	20 mg/dL	Negative	Negative	Positive	Positive
Albumin	2 g/dL	Negative	Negative	Positive	Positive
Acetylsalicylic Acid	20 mg/dL	Negative	Negative	Positive	Positive
Gentisic Acid	20 mg/dL	Negative	Negative	Positive	Positive
Ethanol	1%	Negative	Negative	Positive	Positive
Ascorbic Acid	2g/dL	Negative	Negative	Positive	Positive
Creatine	200mg/dl	Negative	Negative	Positive	Positive
Bilirubin	1g/dL	Negative	Negative	Positive	Positive
Hemoglobin	1000mg/dl	Negative	Negative	Positive	Positive
Oxalic Acid	60mg/dL	Negative	Negative	Positive	Positive
Uric acid	20mg/ml	Negative	Negative	Positive	Positive

None of the substances at the concentration tested interfered in the assay.

【BIBLIOGRAPHY】

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

Index of Symbols

	Consult Instruction for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

Hangzhou Biotest Biotech Co., Ltd.
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