Made in USA

VIVERA PHARMACEUTICALS

COVx-RT

SARS-CoV-2 IgM/IgG Rapid Test Kit

Catalog No.: COVXRT-10

INSTRUCTIONS FOR USE

- Do not use for the screening of donated blood.
- This test has not been reviewed by the FDA.
- Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
- Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection.
- 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.

1. INTENDED USE

COVx-RT is a lateral flow immunoassay intended for qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human serum and whole blood (venipuncture and/or fingerstick) samples. The COVx-RT rapid test kit should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to facilities certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform high complexity tests.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

2. SUMMARY

COVID-19 is the infectious disease caused by the most recently discovered SARS-CoV-2 coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. Coronaviruses are zoonotic. Detailed investigations found that SARS-CoV was transmitted from civet cats to humans and MERS-CoV from camels to humans.

SARS-CoV-2 is an enveloped β-coronavirus with a positive-sense, single-stranded RNA genome similar to the SARS-CoV and MERS-CoV viruses. The viral genome encodes four structural proteins: surface or Spike (S1 and S2), Membrane (M), Envelope (E), and Nucleocapsid (N) proteins. The surface or Spike 1 protein is responsible for binding to the target cell receptor, known as the Angiotensin Converting Enzyme-2 (ACE-2) receptor. Patients produce antibodies against the S1 antigen after infection. Detection of antibodies against SARS-CoV-2, the virus responsible for COVID-19 infection is important for screening purposes.

3. MATERIALS PROVIDED

- Foil Pouch with Test Cassette
- Single Use Pipette
- Buffer Solution
- Single Use Safety Lancet
- Biohazardous Waste Bag
- Instructions for Use

4. MATERIALS REQUIRED BUT NOT SUPPLIED

- Stopwatch or clock and/or watch capable of displaying minutes
- Topical antiseptic to sterilize the specimen collection site
- Sterile gauze
- Gloves

5. WARNINGS AND PRECAUTIONS

1. Not for screening of donated blood.
2. Follow your clinical and/or laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens, including the items supplied in this test kit.
3. Read all directions before use.
4. Follow all directions carefully. Do not end the test halfway. If the test is half finished, it should not be resumed.
5. Do not reuse the test cassette. Each test cassette is meant for a single use, on a single patient, only.
6. Do not substitute the buffer solution. Only use the buffer solution provided with the test cassette.
7. Do not use test cassette after the stated expiration date.
8. Do not eat, drink, or smoke while handling specimens and performing the test.
9. Blood specimens must be transported in accordance with applicable law.

NOTE: The test may be infectious after use. Follow your clinical and/or laboratory safety guidelines for disposal of patient specimens and all items exposed to patient specimens, including the items supplied with this test.

6. PRINCIPLE OF THE PROCEDURE

1. Blood, plasma, or serum is applied to the sample well. The chromatographic membrane strip is pre-coated with a monoclonal antibody against IgG at test line IgG and against IgM at test line IgM.
2. The patient's specimen contains antibodies that will migrate by capillary action along the chromatographic membrane.
3. Gold-labeled Spike (S1) and Nucleocapsid (N) viral proteins are pre-coated just distal to the sample well labeled A.
4. Patient's SARS-CoV-2 antibodies will bind the gold-coated viral antigen and the antigen antibody complex migrates toward the capture lines.
5. If IgG specific antibody is present, a discrete band is observed at the test line labeled IgG.
6. If IgM specific antibody is present, a discrete band is observed at the test line labeled IgM.
7. If neither IgG or IgM specific antibodies are present, then no discrete bands would be observed at either test line.

7. STORAGE

It is essential to store the test kit at temperatures between 4 and 30 degrees Celsius. The kit should be kept out of direct sunlight.

8. SPECIMEN COLLECTION AND PREPARATION AND TEST PROCEDURE

COVx-RT may be performed with specimens of whole blood from the fingertip, whole blood directly from a venipuncture site, or serum. Do not freeze specimens. Do not use the test with severely hemolytic, severely lipemic, or jaundiced specimens.

The test cassette is contained in a protective foil package. Do not remove the test cassette until you are ready to begin the test procedure.

Whole Blood:

1. Remove the test cassette from the foil bag and place on a clean, dry, level surface.
2. Collect **two** drops **(10 µL)** of blood with a calibrated pipettor or with the included single-use pipette.
3. Add two drops of blood to the sample well **(A)**.
4. Add **three** drops of chase buffer solution to the buffer well **(B)**. After each drop, pause before adding the next drop to allow the buffer to be absorbed.
5. Read the test at **15 minutes**. Do not read the results after 30 minutes.
6. Place all test components and other materials used for the test (topical antiseptic, gauze, etc.) in the biohazardous waste bag provided and dispose of them in accordance with protocol for disposing biohazardous materials.

Serum:

Do not use frozen and thawed serum. Sediments and suspended solids in serum samples may interfere with the test result and should be removed by centrifugation. Ensure that the samples are not contaminated/cloudy prior to use.

1. Remove the test cassette from the foil bag and place on a clean, dry, level surface.
2. Collect two drops **(10 µL)** of serum with a calibrated pipettor or with the included single-use pipette.
3. Add two drops of serum to the sample well **(A)**.
4. Add **three** drops of chase buffer solution to the buffer well **(B)**. After each drop pause before adding the next drop to allow the buffer to be absorbed.
5. Read the test at **15 minutes**. Do not read the results after 30 minutes.
6. Place all test components and other materials used for the test (topical antiseptic, gauze, etc.) in the biohazardous waste bag provided and dispose of them in accordance with protocol for disposing biohazardous materials.

IgG positive | IgM positive | IgG and IgM positive | IgG weak positive | IgM weak positive | IgG and IgM weak positive | Negative

Positive Results: The control line **(C)** is visible and either of the test lines **(IgG)** or **(IgM)** or both reveal a visible signal. If a visible signal is observed, this indicates antibodies to SARS-CoV-2 are present.

Negative Results: If the control line **(C)** has a discrete band and the test lines (IgG) and (IgM) reveal no discernible visible bands the test is negative for antibodies to SARS-CoV-2.

Invalid: If a color band does not appear at the control line **(C)**, the test results are invalid. The sample may have been added to the wrong well or the test cassette may have deteriorated. The specimen should be re-tested using a new cassette.

Invalid

NOTE:

1. DISREGARD TEST AND RETEST IF EXCESSIVE BLOOD STAINING OBSCURES THE TEST RESULTS.
2. EXCESSIVE LOADING OF THE SAMPLE WELL MAY LEAD TO FALSE NEGATIVE RESULTS.

10. QUALITY CONTROL

The kit contains a pre-coated antibody against the Spike protein S1 antigen as an internal quality control line. The identification of a pink or rose color at the control line (C) should be observed. Good laboratory practice requires use of an outside control to ensure proper kit performance. All quality control samples should be tested according to the quality control requirements established by your laboratory.

11. INTERPRETATION OF POSITIVE RESULTS

Detection of IgM antibodies with specificity for the S1 protein may identify individuals recently exposed to the SARS-CoV-2 virus. These individuals may currently be asymptomatic or have mild, moderate or severe symptoms of COVID-19 infection.

Detection of IgM and IgG antibodies with specificity for the S1 protein may identify individuals recently exposed to the SARS-CoV-2 virus, possibly as early as 10 to 21 days after exposure. These individuals may currently be asymptomatic or have mild, moderate or severe symptoms of COVID-19 infection.

Detection of IgG antibodies with specificity for the S1 protein may identify individuals recently exposed to the SARS-CoV-2 virus, possibly 14 days to 3 months previously. They may be currently asymptomatic.

12. TEST CHARACTERISTICS AND PERFORMANCE

Serology tests should not be used for the diagnosis of acute SARS-CoV-2 infection. The diagnosis of acute infection relies on a positive molecular test result.

In clinical evaluation, a compilation of studies showed that this test had a Sensitivity of 91.4% in correlation to PCR positive patients 11-28 days from the first day of COVID-19 symptoms, a Specificity of 96% in correlation to commercially available negative Serum samples and a total Accuracy of 94.1% in correlation to patients that were 11-28 days from the first day of COVID-19 symptoms.

Cross-Reactivity

Cross-reactivity of COVx-RT was evaluated using serum samples which contain antibodies to the pathogens listed below. No false positivity or false negativity was found with the following:

		Test Results	
Specimen*	**Number**	**IgG Line**	**IgM Line**
HIV	20	-	-
HBV	11	-	-
Zika	50	-	-
Chiku	9	-	-
Dengue	8	-	-
Syphilis	11	-	-
RSV	7	-	-
HSV-1	6	-	-
HSV-2	6	-	-
CMV	7	-	-
RUBELLA	6	-	-
Toxoplasma	6	-	-
Tuberculosis	5	-	-
P. Chlamydia	6	-	-
P. Mycoplasma	7	-	-
Influenza A	6	-	-
Influenza B	6	-	-
Normal serum	50	-	-

**Positions were validated by ELISA or PCR*

Specificity

To evaluate for possible interference, a variety of common biological and chemical analytes were sparked into the Negative and Positive weak and strong specimens. The results with three lots of COVx-RT indicates there are no interferences found.

Specific Study

No interference was observed with the potential interfering substances list below:

Bilirubin	20 mg/DL
Human hemoglobin	20 g/DL
Human albumin	20 g/DL
Rheumatoid Factor	3000 IU/ml
Gelatin	20 mg/DL
Lectin	20 mg/DL

Clinical Agreement

			Comparator		
			POS	NEG	Subtotal
SARS-CoV-2	POS	IgG - / IgM +	7	4	11
		IgG - / IgM +	26	2	28
		IgG - / IgM +	31	0	31
	NEG	IgG - / IgM +	4	96	100
Total			68	102	170

Positive Correlation to SARS-CoV-2: Sensitivity: 64/70 = 91.4%
Negative Correlation to SARS-CoV-2: Specificity: 96/100 = 96.0%

13. LIMITATIONS

As with all diagnostic assays, the results obtained with this test kit yield data that must only be used as an adjunct to other information available to the healthcare professional.

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. Testing with a molecular diagnostic should be performed to evaluate for active infection in symptomatic individuals.

It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.

The result is for use as a clinical reference only. Treatment of patients should be based on a combination of symptoms, clinical signs, medical history, other laboratory tests and therapeutic responses.

The test includes products of animal origin. The manufacturer possesses certificates on the origin and/or health status of the animals involved but cannot completely guarantee the absence of transmissible pathogenic components.

Icteric, lipemic, hemolyzed, heat-treated, and contaminated whole blood specimens may give false results. In those instances, the test should be repeated using serum and a new test cassette.
Due to differences in methodology or antibody specificities, assays from different manufacturers may produce different values even when using the same specimen. Measurements from different manufacturers are not directly comparable for clinical interpretation.

MANUFACTURER/ DISTRIBUTOR
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To report adverse events, complaints or other product issues, please email: adversereports@viverapharma.com

Report adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**.

BIBLIOGRAPHY

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4. Sona announces key partner for Coronavirus Rapid Screening Test [press release]. February 13, 2020 Sona Nanotech. https://www.newsfilecorp.com/release/52396/Sona-announces-key-partner-forCoronavirus-Rapid-Screening-Test. Accessed February 28, 2020.

SYMBOLS

IVD	*In Vitro* Diagnostic Use		See Instructions for Use		Expiry Date
Σ	Tests per Kit		Manufacturing Date		Keep Dry
LOT	Batch Number		Manufacturing		Keep away from Sunlight
2°C 30°C	Store between 2-30°C		Do not reuse	REF	Catalog #

*Illustrations provided are not for diagnostic purposes.