BIO LAB DIAGNOSTICS
ISO 9001:2016
ISO 13485: 2015

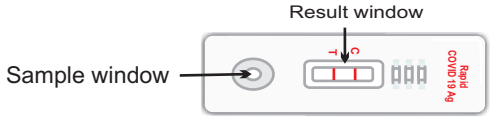
RAPID COVID-19 Ag

INTENDED USE

RAPID COVID-19Ag Kit is an immuno-chromatographic assay kit for qualitative detection of SARS-nCoV-2 antigens present in human nasopharynx, bronchial lavage or throat swabs. This test is intended for initial screening as a professional aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms suspected of SARS-CoV-2 infection.

PRINCIPLE

RAPID COVID-19Ag Test has two pre-coated invisible lines within the result window, "T" Test line, "C" Control line on the nitrocellulose membrane.



As a solid phase reagents "T" (test) zone is coated with Mouse monoclonal anti-SARS-CoV-2 antibodies specific to nCoV 2 NP (core) antigen and monoclonal Goat anti-Chicken IgY antibody is coated on the "C" (control) zone. As a detection reagent colloidal gold conjugated with anti-SARS-CoV-2 antibodies specific to nCoV-2-NP antigen and Chicken IgY.

During the test, a sample containing SARS-nCoV-2 virus antigen that interact with Conjugate of colloidal gold with monoclonal anti-SARS-CoV-2 antibodies forming an antigen-antibody color complex and migrates on the membrane by chromatographic capillary action until the test line, where it will be captured by the mouse monoclonal anti-SARS-CoV-2 antibodies forming a sandwich of colloidal gold mouse monoclonal anti-SARS-CoV-2 antibodies and the SARS-nCoV-2 virus antigen. A colored test line would be visible in the result window if SARS-nCoV-2 virus antigens are present in the specimen. The intensity of colored test line will vary depending upon the amount of SARS-nCoV-2 virus antigen present in the specimen. No color appears on test line in the absence of SARS CoV-2 virus antigens available to react in the specimen . The control line is used as a procedural control, therefore, it should always appear if the test procedure, as well as, the reagents were performed properly.

PRECAUTIONS

1. Handle all specimens as if they contain infectious agents. Dispose off all specimens and materials used to perform the test as bio-hazard waste. Clean up spills thoroughly using an appropriate disinfectant. Observe established precautions against microbiological hazard throughout testing procedures. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
2. This test device is for single use only and do not use the test kit if the pouch found damaged or the seal is broken.
3. Do not use the buffer of a different lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment (PPE), such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.

KIT COMPONENTS (Quantity as per pack size of the kit)

1. Each Sealed Pouch contains one Test Device and a moisture absorbents.
2. Extraction Tube and Dropper Cap Nozzle *
3. Extraction Buffer
4. Sample collection swab *
5. Instruction for use.

* Cat. No. 9136 Can be purchased separately

MATERIALS REQUIRED, BUT NOT PROVIDED

1. Marker pen
2. Test Tube stand
3. Timer
4. PPE

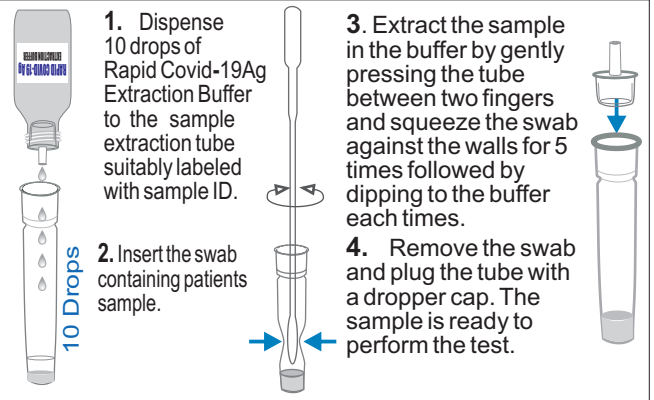
STORAGE AND STABILITY

1. Store the kit at room temperature, 2~30°C / 36-86°F, out of direct sunlight. Do not freeze the kit.
2. Kit materials are stable until the expiration date printed on the labels.

COLLECTION AND PREPARATION OF SAMPLE

1. Do Not Use Samples Collected In Viral Transport Media (VTM) .
   Use specimen collection device and extraction buffer specified for Biolab's Rapid Covid19 Ag tests as part of the kit or may be purchased separately (Cat. No. 9136).
2. To collect a nasopharyngeal swab specimen, carefully remove the sterile swab from the swab tube and insert the swab into the nostril of the patient, reaching the surface of the posterior nasopharynx while on gentle rotation, push the swab (about 7 cm for adults or the measure of the distance between nostril and ear) until resistance is met at the level of the turbinate and rotate the swab 3 to 4 times.
3. Remove the swab and store swab in the tube tightly. Mark sample ID and handle according to the protocols.
4. To collect a throat swab (Oropharyngeal) specimen, use a tongue depressor spatula and insert a sterile swab into the patients throat, reaching the surface of the pharynx.
5. Rotate the swab a few times against the pharyngeal crypts and mucosa and follow as above in step 3.
6. To process Broncho-alveolar samples from the lavage dipping the swab once to the well mixed fluid and follow as above in step 3.
7. Specimen should be tested as soon as possible after collection.
8. Specimens may be stored at room temperature for up to 1 hours or at 2-8°C/ 36-46°F for up to 4 hours prior to testing.

SAMPLE PROCESSING

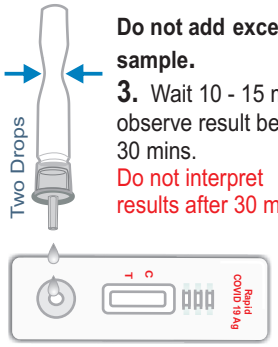


PTO

PROCEDURE

1. Open a test device from a foil pouch and place over a working table immediately before the test being performed. Label with sample ID.

2. Add 2 (two) drops (60µL) of sample from the nozzle of sample proc-essing tube to the sample window of device.



Do not add excess sample.

3. Wait 10 - 15 mins observe result before 30 mins.

Do not interpret results after 30 mins.

INTERPRETATION OF THE RESULT

NEGATIVE RESULT

A negative result indicates no line in "T" zone and a burgundy colored band appe-ared in "C" zone of result window to show that the test is working properly.

POSITIVE RESULT

A positive result indicates burgundy colored band appeared in "T" zone and "C" zone of the result window. The presence of any faint line within 30 minutes, regardless of the intensity, on "T" zone the result is considered positive.

A positive result should be evaluated in conjunction with the clinical history and other data available. Confirmation the result with more specific antigen tests (PCR test/Virus isolation) to establish SARS-CoV-2 infection.

INVALID RESULT

An invalid result indicates the absence of a burgundy colored band in "C" zone of result window and the test must be repeated with a new test device.

ANALYTICAL PERFORMANCE

Limit of Detection (LoD): An in-house study used "SARS-CoV-2 (2019-nCOV) Antigen isolated from Wuhan (Wuhan, China strain). The titer of virus antigen was confirmed by EIA and spiked into different specimens (Nasopharyngeal, Oropharyngeal, Sputum and mouth gargle swab specimen from various non Covid19 patients.

The LoD is 0.5 ng/mL. There was no prozone effect detected till 50 ug/mL.

25ng/mL Stock	SARS-CoV-2 (2019-nCOV) Antigen							
Antigen Dilution	1 /2	1 /4	1 /8	1/16	1/32	1/64	1/128	0
Ag Con ng/mL	12.5	6.25	3.125	1.563	0.78	0.39	0.2	0
Batch A (Signal)	4+	3+	2+	2+	+	±	-	-
Batch B (Signal)	4+	3+	2+	2+	+	±	±	-
Batch C (Signal)	4+	3+	2+	2+	+	+	-	-

SPECIFICITY

An in-house study used **RAPID COVID19 Ag** evaluated against clinical samples of volunteers having no history of Covid-19 and their results are shown as under.

		Positive	Negative	Total
RAPID COVID19 Ag	Positive	0	0	0
	Negative	0	157	157
	Total	0	157	157
Specificity 100%				

PERFORMANCE CHARACTERISTICS

3 Batches of **RAPID COVID19 Ag** ware evaluated against clinical samples confirmed by PCR and their results are shown as under.

		PCR		
		Positive	Negative	Total
RAPID COVID19 Ag	Positive	90(TP)	5 (FP)	
	Negative	15(FN)	100(TN)	
	Total	105	105	210

Sensitivity : TP/(TP + FN) = 90/ (90+15) = **85.71 %**

Specificity : TN/(TN+FP) = 100/(100+5) = **95.23 %**

Positive Predictive Value: TP/(TP +FP) = 90/(90+5) = **94.73%**

Negative Predictive Value: TP/(TN +FN) = 100/(100+15) = **86.95%**

LIMITATIONS OF THE TEST

1. False positive result may be seen while comparing Viral RNA based PCR results of patients recovering from Covid 19 infection as Rapid Covid-19 Ag test is a SARS-CoV-2 (2019-nCOV) antigen detection technology, whereas, the presence of antigen may be found for more number of days than the Virus RNA. Therefore the acceptance of result should be considered with the limitations.
2. Samples collected in VTM contribute to (a) excessive dilution of samples as well as (b) background color from the medium, leading to false results.
3. This test is quantitative for SARS-CoV-2 antigen concentration.
4. The test should be used for the detection of SARS-CoV-2 antigen in human nasopharyngeal, Oropharyngeal, or Broncho-alveolar lavage specimens swabs only.
5. The test performance is highly depend of accuracy in proper sample collection, extraction, storage, test procedure, precautions and interpretation of results.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance.
7. A false negative result may occur if the concentration of antigen in specimen is below the detection limit (LoD) of the test or if the specimen was collected or transported improperly, therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or by molecular assays.
8. Samples with unexpected results may be repeated with 48 hours intervals or additional testing using other laboratory methods is recommended.
9. A positive test results do not rule out co-infections with other pathogens.
10. Negative test results are not intended to rule in other corona virus infection except the SARS-CoV-2.
11. Patients with varied immune response tend to shed virus for longer periods of time than usual adults, which may result in differences in sensitivity.
12. Although the test demonstrates superior accuracy in detecting COVID-19 virus antigen, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated. There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.

INDEX OF SYMBOLS

	Consult Instructions	2°C 30°C	Store Between		Use by
IVD	For *invitro* diagnostic use	2	Do not reuse	Batch	Batch Number
	Manufacturer	Σ	Tests per kit	REF	Catalog No.

BIBLIOGRAPHY

1. Clinical management of severe acute respiratory infection when novel corona virus(nCoV) infection is suspected. Interim guidance. WHO.2020
2. Diagnostic detection of Wuhan corona virus 2019 by real-time RT-PCR.2020
3. Diagnosis and treatment of pneumonia caused by new corona virus (trial version 4) National Health Commission. 2020

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Manufactured in India by

BIO LAB DIAGNOSTICS
ISO 9001:2016
ISO 13485: 2015

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