Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva)

REF: IOV87953

For professional *in vitro* diagnostic use only.

Expected Usage

The INVBIO Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) is a polymer immunochromatographic technology and double antibody sandwich principle that is intended for the qualitative detection of the N protein antigen from SARS-CoV-2 in human saliva specimens directly. Testing is limited to laboratories and medical institutions.

Results are for the identification of SARS-CoV-2 N protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The INVBIO COVID-19 Antigen Rapid Test Kit is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic procedures, and proper infection control procedures and individuals similarly trained in point of care settings.

Summary and Explanation

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.

Inspection Principle

The polymer immunochromatographic technology and double antibody sandwich principle were used to detect the novel coronavirus antigen in human saliva specimens with the principle of capture method.

During the test, a specimen solution is added to the sample well of the kit. The specimen is first mixed with the colored polymer-labeled novel coronavirus monoclonal antibody 1 on the release pad, and then chromatographed on a nitrocellulose membrane. If the specimen contains novel coronavirus antigens, these antigens will first bind to colored polymer-labeled novel coronavirus monoclonal antibody 1, so that when the mixture is chromatographed on a nitrocellulose membrane, it will be immobilized with the novel coronavirus monoclonal antibody 2. The detection line (T line) was captured to form a colored polymer-labeled novel coronavirus monoclonal antibody1-antigen- novel coronavirus monoclonal antibody 2 immune complex. Therefore, a red line appeared on the T line, which was a positive result. If no novel coronavirus antigen is present in the specimens of the subject, a red line will not be formed on the test line (T line), which is a negative result. The quality control line (C line) on the test cassette is coated with goat anti-mouse antibody. Under normal circumstances,a red line should appear on the quality control line(C line) during the test to prove that the test cassette is working properly.

Main Ingredients

1.Material Provided:

(1) 20 Test Cassettes; (2) 20 Saliva Collectors;
(3) 20 Collection Tubes; (4) 20 Specimen Extraction Buffers ;
(5) 20 Droppers; (6) 1 Work Station; (7) 1 Instructions Manual.

2.Material required but not provided: Timer.

Storage Conditions and Stability

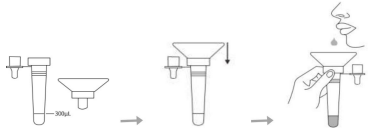
Store the Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) at 2-30°C. Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

Specimen Requirements

1.The applicable specimen type for this test kit is saliva specimen.

2.DO NOT place anything in the mouth including food, drink, gum or tobacco products for at least 30 minutes prior to collection.

3.Saliva specimen collection method: Use the collection tube and saliva collector to collect saliva. Insert the saliva collector into the collection tube, then put the saliva collector close to lips and let the saliva flow into the collection tube. The volume of saliva needs to be at the scale mark (approx.300 μ L). If the volume of saliva is too much, use a dropper to remove the excess saliva until the final solution at the scale mark(approx. 300 μ L).



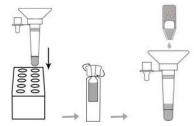
4.Freshly collected specimens should be tested as soon as possible, but no later than one hour after specimen collection.

Testing Method

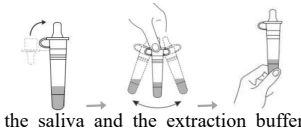
Note: Allow the test cassettes, specimen extraction buffers and specimens to equilibrate to room temperature prior to testing.

1.Please read the instruction manual carefully before testing.

2.Place the collection tube with saliva collector which has saliva in the work station. Unscrew the lid of an extraction buffer. Add all of the extraction buffer into the collection tube.

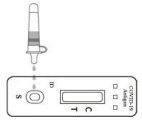


3.Discard the saliva collector; Cover the collection tube with the dropper tip onto the collection tube. Shake the collection tube more than 3 times vigorously to mix the saliva and the extraction buffer, then squeeze the mixed solution 10 times to allow the saliva to be thoroughly mixed.



4.Remove the test cassette from the sealed pouch.

5.Specimen adding: Reverse the collection tube, holding the tube upright, transfer 3 drops (approximately 100 μL) slowly to the specimen well (S) of the test cassette, then start the timer.



6. Timing observation: judge the result 10 minutes after specimen.adding, do not observe the result 20 minutes later.

Interpretation of Test Results

NEGATIVE:

Only one red band appears in the control region (C), and no band in the test region (T). The negative result indicates that there are no Novel coronavirus antigen in the sample or the number of viral particles is below the detectable range.

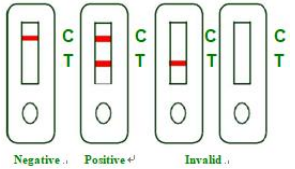
POSITIVE:

Two red bands appear. One red band appears in the control region (C), and one red band in the test region (T).

The shade of color may vary， but it should be considered positive whenever there is even a faint band.

INVALID:

No red band appears in the control region (C). The test is invalid even if there is a band on test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device.



Limitations of Detection Method

• The Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) is an initial screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.

• The Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens maybe present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.

• A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.

• Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.

• Positive test results do not rule out co-infections with other pathogens.

• Negative test results are not intended to rule in other coronavirus infection except the SARS-CoV-2.

• Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children list.

• A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit 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 a molecular assay or ELISA.

Warning and Precautions

• For in vitro diagnostic use only.
• Do not re-use the test device.

• Do not use after the expiration date.
• Do not use the test kit if the pouch is damaged or the seal is broken.
• Perform test at room temperature 15 to 30°C.
•Wear gloves when hanging the samples, avoid touching the reagent membrane and sample window.
• All samples and used accessories should be treated as infectious and discarded according to local regulations.
• Avoid using blood samples.

Clinical Performance

The clinical performance of the INVBIO COVID-19 Antigen Rapid Test Kit was established with a study using 379 previously collected saliva specimens.

		INVBIO Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva)		**Total Result**
		+	-	
PCR	+	148	0	148
	-	5	226	231
Total Results		153	226	379

The sensitivity of INVBIO COVID-19 Antigen Rapid Test Kit is 96.73% (95% CI= 92.54% ~ 98.93%), the specificity is 100.00% (95% CI= 98.38% ~ 100.00%), and the total coincidence rate is 98.68% (95% CI= 96.95% ~ 99.57%).

Analytical Performance

1.Limit of Detection

Take the inactivated novel coronavirus (concentration 3.6×105 TCID50/mL) and use the extract of the negative specimen as the clinical matrix diluent of the virus for serial dilution, and use three batches of kits to test the above specimens. Each batch of the kit was detected 5 tests in parallel. When the virus solution with a concentration of 3.6 ×105 TCID50/mL is diluted 7.2×103 times (50 TCID50/mL) by the negative clinical matrix diluent, theINVBIO COVID-19 Antigen Rapid Test Kit can detect a positive result. Then use the extract of the negative specimen as the clinical matrix diluent of the virus to perform several gradient dilutions of the novel coronavirus inactivated at adilution factor of 7.2×103 times (50 TCID50/mL), and test three batches of kits for each concentration. Repeat the test 20 times, with the lowest concentration with 95% positive detection rate as the Limit of Detection. According to the test, the Limit of Detection for this product is 50 TCID50/mL.

Cross-Reactivity

Cross reactivity and potential interference of INVBIO COVID-19 Antigen Rapid Test Kit was evaluated by testing various microorganisms and viruses that could cross-react with INVBIO COVID-19 Antigen Rapid Test Kit. Each of the microorganisms and viruses were tested in triplicate. The following microorganisms

Hook Effect

No high dose hook effect was observed up to 3.6 x 10^5 $TCID_{50}$/mL from SARS-CoV-2 with the INVBIO Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva).

Microorganism	Concentration	Cross-Reactivity (Yes/No)
Influenza A (H1N1, H3N2)	1.0 x 10^5 $TCID_{50}$/mL	No
Avian influenza (H5N1, H7N9)	1.7 x 10^5 $TCID_{50}$/mL	No
Influenza B (Victoria, Yamagata)	2.5 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus	1.0 x 10^5 $TCID_{50}$/mL	No
Respiratory Syncytial Virus	3.8 x 10^5 $TCID_{50}$/mL	No
Rhinovirus	1.4 x 10^5 $TCID_{50}$/mL	No
Adenovirus	1.1 x 10^5 $TCID_{50}$/mL	No
Measles virus	1.0 x 10^6 $TCID_{50}$/mL	No
Human coronavirus (OC43, 229E, NL63)	1.0 x 10^5 $TCID_{50}$/mL	No
MERS coronavirus	1.2 x 10^5 $TCID_{50}$/mL	No
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No
Chlamydia pneumaniae	1.0 x 10^6 CFU/mL	No
Legionella pneumophila	1.1 x 10^6 CFU/mL	No

Symbols

Symbol	Meaning
	Consult instruction for use
	In-Vitro Diagnostic Medical Device
	Manufacturer
	Batch code
	Caution, consult accompanying documents
	Keep away from sunlight
	Do not reuse
	Temperature Limitation
	Use by date
	Production Date
	Contains sufficient for <n>test
	Authorized representative in the European Community
	Meet the requirements of EC Directive 98/79/EC

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