



COVID-19 Ag Rapid Saliva Test Device

Cat#: CO-03

For professional *in vitro* diagnostic use only.

Intended Use

COVID-19 Ag Rapid Saliva Test Device is a rapid chromatographic immunoassay for the qualitative detection of N antigen from SARS-CoV-2 present in human saliva within the first 7 days of symptom onset. This test is for professional used only, as an aid to early diagnosis of SARS-CoV-2 infection in patient. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.

Summary

Coronavirus can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. The 2019 new coronavirus, or “SARS-CoV-2 (COVID-19)” named by the World Health Organization can cause pneumonia epidemic. The detection results of this kit are for clinical reference only.

Principle

The COVID-19 Ag Rapid Saliva Test Device uses double antibody sandwich immunoassay. The NC membrane pre-immobilized with monoclonal antibodies against SARS-CoV-2 antigen and anti-mouse polyclonal antibodies, and the colloidal-gold conjugated with monoclonal antibodies specific to SARS-CoV-2 antigen. If SARS-CoV-2 antigen present in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the antigen will be caught by the specific anti- SARS-CoV-2 monoclonal coated on the T region. Results appear in 10 to 20 minutes in the form of a red line that develops on the strip. Whether the sample contains the SARS-CoV-2 antigen or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

Kit Content

- 1) Test device (individually packed in a foil pouch).
- 2) Extraction buffer vial.
- 3) Saliva swab.
- 4) Instruction for use.

Materials required but not provided

Timer

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 handling 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.

Storage and Stability

Store the COVID-19 Ag Rapid Saliva Test Device at 2-30 °C. Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

Specimen Collection and Precaution

The COVID-19 Ag Rapid Saliva Test Device is designed for the use of buffered human saliva as the specimen. The specimen can keep stability at room temperature (25°C) for 8 hours, in 4°C for 7 days and in -20°C for 6 months. Collecting specimen must follow standard clinical procedure.

Do not place anything into the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection of saliva specimen.

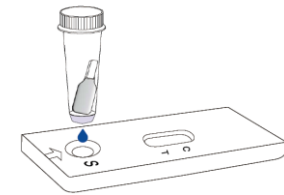
- 1) Remove the swab from the sealed pouch.
- 2) Cough deeply twice before collecting the samples.
- 3) Insert the sponge end of the collector into the mouth. Then swab back and forth along the gum line from one end to the other end of the upper and lower gum for about 3 to 5 times. Then slowly scrape the cheek inside the mouth for 3 to 5 times and slowly scrape the tongue surface for 3 to 5 times. Then put the collection pad on the tongue for 1 minutes.
- 4) Open the lid of the collection tube. Remove the saturated collector pad out of the mouth and place it into the tube which contains 1 ml sample extraction buffer, and then fully stirred along the wall of the tube, squeeze the pad on the tube wall to make as much liquid as possible from the pad. Break off the collector, leaving the sponge end of the collector in the chamber.
- 5) Tighten the lid of the collection tube and mixing liquid of the chamber well before using (Shaking up and down for about 20 times).



Test Procedure

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30 °C) prior to testing.

- 1) Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
- 2) Put the test device on a clean and level surface.
- 3) Shake the swab specimen in the extraction vial to well mix.
- 4) To run test, twist open the bottom screw cap of the extraction vial to expose dropper tip. Transfer 3 drops (~90µl) of the specimen to the sample well of the test device and make sure a colored liquid appearing in the detection window in 30 seconds. Replace cap cover on the extraction vial.
- 5) Start timer. Read the result at 10~20 minutes. Do not interpret the result after 20 minutes.



Interpretation of 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.

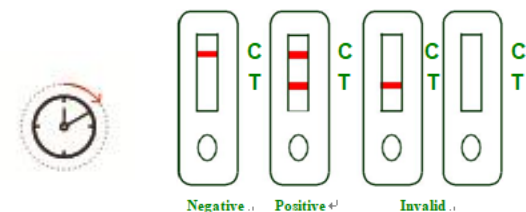
POSITIVE:

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.



Do not interpret the result after 20 minutes.

Limitations



- The COVID-19 Ag Rapid Saliva Test Device 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 COVID-19 Ag Rapid Saliva Test Device 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 may be 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.

Performance Characteristics

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by COVID -19 Ag Rapid Saliva Test Device and PCR. The results were summarized below:

Table 1: COVID Ag Rapid Saliva Test Device vs. PCR

		COVID Ag Rapid Saliva Test Device		Total Result
		+	-	
PCR	+	129	6	135
	-	0	200	200
Total Results		129	206	335

Relative sensitivity: $129/135 = 95.6\%$ (95%CI 93.79%~98.66%)

Relative specificity: $200/200 >99\%$ (95%CI 97.12%~100%)

Overall agreement: $(129+200)/(129+0+6+200) \times 100\% = 98.21\%$

(95%CI 96.55%~99.36%)

CI: Confidence Interval

Cross Reaction:

The COVID -19 Ag Rapid Saliva Test Device was evaluated with a total of 47 other viruses and bacteria. The results show that the

COVID-19 Ag Rapid Saliva Test Device has no cross-reactivity with other viruses or microorganisms include MERS-coronavirus, Adenovirus, Influenza A, Influenza B, Respiratory syncytial virus, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumonia, Streptococcus Pyrogens, Mycoplasma Pneumoniae, Coronavirus(229E, OC43, NL63, HKU1), Human etapneumovirus (hMPV) 3 Type B1, Human Metapneumovirus (hMPV) 16 Type A1, Parainfluenza virus and RhinoVIRUS A16 etc.

Microbial Interference:

Microbial interference study was performed to evaluate microbial interference effect, using samples spiked at $3 \times \text{LoD}$ SARS-CoV-2 concentration and a high interferent level.

The results show that microorganism include Streptococcus hemolyticus, Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Candida albicans, and Aspergillus niger has no microbial interference on the negative and positive test results at the concentration of 1×10^5 cfu/ml, and these substances do not cross-react with COVID-19 Ag Rapid Saliva Test Device.

Endogenous Interference:

The COVID -19 Ag Rapid Saliva Test Device was evaluated with a total of 13 endogenous interference substances include whole blood(4%), mucin(0.5%), benzocaine(1.5 mg/mL), NeilMed(5% v/v) , CVS nasal drops (phenylephrine) (15% v/v), oxymetazoline(15% v/v), CVS nasal spray (cromolyn)(15% v/v), zicam (5% v/v), sore throat phenol spray(15% v/v) , tobramycin(4 µg/mL), mupirocin (10 mg/mL), fluticasone propionate(5% v/v) and tamiflu(5 mg/mL).

The results show that above mentioned endogenous interference substances has no inference effect on the negative and positive test results, and these substances do not cross-react with COVID-19 Ag Rapid Saliva Test Device.

Food/beverage Interference:

Food/beverage interference study was performed to evaluate the potential interference of food/beverage in saliva samples on the COVID-19 Ag Rapid Saliva Test Device.

These interference substances include mouth wash, orange juice, alcohol, MSG, salt, tooth paste, gum, cough syrup, sugar, tea, food color(red, blue, green), cranberry juice, carbonated cola, baking soda, and cigarette.

The results show that 1% substance has no inference effect on the negative and positive test results, and these substances have no interference on COVID-19 Ag Rapid Saliva Test Device.

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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

V3.0