

## COVID-19 Antigen Rapid Test Pen (Saliva)

### 1. INTENDED USE

The COVID-19 Antigen Rapid Test Pen is an in vitro immunoassay. The assay is for the direct and qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from saliva samples. This test is intended for professional use only.

### 2. SUMMARY AND EXPLANATION

The novel coronaviruses belong to the  $\beta$  genus. COVID-19 is an acute respiratory infectious disease to which people are generally susceptible. Currently, the patients infected by the novel coronavirus are the primary source of infection; however, asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days; most commonly seen is 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.

### 3. PRINCIPLE

The COVID-19 Antigen Rapid Test Pen detects SARS-CoV-2 viral antigens through visual interpretation of color development. Anti-SARS-CoV-2 antibodies are immobilized on the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to colored particles are immobilized on the conjugated pad. A sample is added to the extraction buffer, which is optimized to release the SARS-CoV-2 antigens from the specimen.

During testing, target antigens, if present in the saliva samples, will be released into the extraction buffer individually packed in the kit. Consequently, the extracted antigens will bind to anti-SARS-CoV-2 antibodies conjugated to colored particles. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by the anti-SARS-CoV-2 antibodies at the test region. Excess colored particles are captured in the internal control zone.

The presence of a colored band in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane

wicking is working.

### 4. MATERIALS

#### Materials Provided

- Individually packed Saliva Collector with Test Strip
- Individually packed Extraction Buffer
- Package insert

#### Materials Required but Not Provided

- Clock, timer, or stopwatch

### 5. PRECAUTIONS

- For in vitro Diagnostic Use Only.
- Read the Package Insert prior to use. Directions should be read and followed carefully.
- Do not use kits or components beyond the expiration date.
- The device contains material of animal origin and should be handled as a potential biohazard. Do not use if the pouch is damaged or open.
- Test devices are packaged in foil pouches that prevent moisture during storage. Inspect each foil pouch before opening. Do not use devices with holes in the foil or where the pouch has not been completely sealed. An erroneous result may occur if test reagents or components are improperly stored.
- Do not use the Extraction Buffer if it is discolored or turbid. Discoloration or turbidity may be a sign of microbial contamination.
- All patient specimens should be handled and discarded as if they are biologically hazardous. All specimens must be mixed thoroughly before testing to ensure a representative sample before testing.
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Avoid skin contact with the buffer.
- If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to the state or local health

department for testing.

- Viral isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens are NOT recommended, except in a BSL3 laboratory using BSL3 work practices.

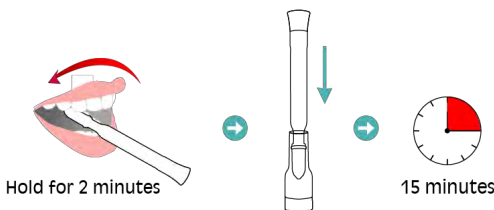
**6. STORAGE AND STABILITY**

- Store the COVID-19 Antigen Rapid Test Pen at 2~30°C when not in use.
- **DO NOT FREEZE.**
- Kit contents are stable until the expiration dates marked on their outer packaging and containers.

**7. TEST PROCEDURE**

Bring devices to room temperature (15~30°C) before use.

1. Remove the test device from its packing. Label the device with the patient’s identification. For the best results, the assay should be performed within two hours.
2. 1) Take the test device out of the tube with extraction buffer. 2) Remove the protector.
3. Place the saliva test pen collector in the mouth at the root of the tongue (close to the throat), hold for 2 minutes...
4. Place the test device vertically into the Extraction Buffer.
5. Read the results at 15 minutes.



**8. RESULT INTERPRETATION**

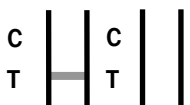
**POSITIVE: Two colored bands appear on the membrane.** One band appears in the control region (C), and another band appears in the test region (T).



**NEGATIVE: Only one colored band appears in the control region (C).** No apparent colored band appears in the test region (T).



**INVALID: Control band fails to appear.** Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.



**NOTE:**

1. The color intensity in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is only a qualitative test and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure, or expired tests are the most likely reasons for control band failure.

**9. QUALITY CONTROL**

**Internal Procedural Controls:**

The COVID-19 Antigen Rapid Test Pen has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the colored band located at the “C” region is present before reading the result.

**10. LIMITATIONS OF THE TEST**

1. The COVID-19 Antigen Rapid Test Pen is for professional in vitro diagnostic use and should only be used for the qualitative detection of the SARS-CoV-2 antigen. The intensity of color in a positive band should not be evaluated as “quantitative or semi-quantitative.”
2. Both viable and nonviable SARS-CoV-2 viruses are detectable with the COVID-19 Antigen Rapid Test Pen.
3. 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.
4. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect the test performance and/or invalidate the test result.
5. Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.
6. Negative results do not preclude SARS-CoV-2 infection and should be confirmed via molecular assay.

**11. PERFORMANCE CHARACTERISTICS**

**Analytical Sensitivity (Limit of Detection):**

The limit of detection was determined with a quantified SARS-CoV-2 virus and has been evaluated at 4x10<sup>1.4</sup>TCID<sub>50</sub>/mL.

The limit of detection was also determined with recombinant

SARS-CoV-2 nucleoprotein and has been evaluated at 0.1 ng/mL.

### Clinical Evaluation:

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

**Table: COVID-19 Rapid Test vs. RT-PCR**

		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen Rapid Test (Saliva)	Positive	18	2	20
	Negative	2	64	66
Total		20	66	86

Relative Sensitivity: 90.0 % (69.9% ~ 97.2%)\*

Relative Specificity: 97.0 % (89.6% ~ 99.2%)\*

Overall Agreement: 95.3 % (88.6% ~ 98.2%)\*

\*95% Confidence Interval

### Cross-Reactivity:

Cross-reactivity with the following organisms has been studied. Samples positive for the following organisms were negative when tested with the COVID-19 Antigen Rapid Test Pen (Saliva).

HCoV-HKU1	Influenza A (H5N1)	Coxsackie virus A16
HCoV-OC43	Influenza A (H7N9)	Norovirus
HCoV-NL63	Influenza A (H7N7)	Mump virus
HCoV-229E	Influenza B Victoria lineage	<i>Legionella pneumophila</i>
Measles virus	Influenza B Yamagata lineage	<i>Mycoplasma pneumoniae</i>
<i>Streptococcus pneumoniae</i>	Respiratory syncytial virus	<i>Chlamydia pneumoniae</i>
Epstein-Barr virus	Adenovirus	<i>Streptococcus pyogenes</i>
<i>Bordetella parapertussis</i>	Parainfluenza 1/2/3 virus	<i>Streptococcus agalactiae</i>
Influenza A (H1N1) pdm09	Human metapneumovirus	Group C <i>Streptococcus</i>
Influenza A (H3N2)	Rhinovirus	<i>Staphylococcus aureus</i>

### Interfering Substances:

The following substances, naturally present in respiratory specimens or artificially introduced into the respiratory tract, were evaluated at the concentrations listed below. None of them were found to affect the test performance of the COVID-19 Antigen Rapid Test Pen.










Substance	Concentration	Substance	Concentration
3 OTC nasal sprays	10%	Guaiacol glyceryl ether	20 mg/ml
3 OTC mouthwashes	10%	Mucin	1%
3 OTC throat drops	10%	Mupirocin	250 µg/ml
4-acetamidophenol	10 mg/ml	Oxymetazoline	10 mg/ml
Acetylsalicylic acid	20 mg/ml	Phenylephrine	10 mg/ml
Albuterol	20 mg/ml	Phenylpropanolamine	20 mg/ml
Chlorpheniramine	5 mg/ml	Relenza* (zanamivir)	20 mg/ml
Dexamethasone	5 mg/ml	Rimantadine	500 ng/ml
Dextromethorphan	10 mg/ml	Tamiflu* (oseltamivir)	100 mg/ml

Diphenhydramine	5 mg/ml	Tobramycin	40 mg/ml
Doxylamine succinate	1 mg/ml	Triamcinolone	14 mg/ml
Flunisolide	3 mg/ml		

## 12. LITERATURE REFERENCES

- Forni, D., Cagliani, R., Clerici, M. & Sironi, M. (2017). *Molecular evolution of human coronavirus genomes*. Trends Microbiol. 25, 35–48.
- Ithete, N. L. et al. (2013). *Close relative of human Middle East respiratory syndrome coronavirus in bat, South Africa*. Emerg. Infect. Dis. 19, 1697–1699.

## 13. GLOSSARY OF SYMBOLS

	Catalog number		Temperature limitation
	Consult instructions for use		Batch code
	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse		

Manufactured by:

**Assure Tech. (Hangzhou) Co., Ltd.**

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