COVID-19 Saliva Antigen At-Home Test

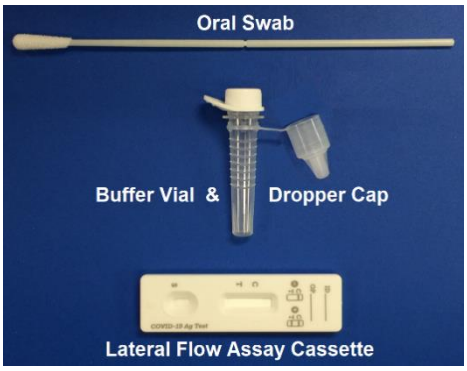
For Investigational Use Only. **The performance characteristics of this product have not been established (current data is in FDA review for EUA).**

Detects Delta, Lambda & Omicron variants!

REAL-TIME ANALYZERS

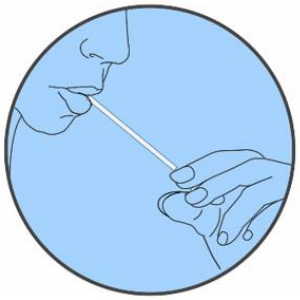
Providing Chemical & Biological Information When & Where You Need It

TEST KIT COMPONENTS IN POUCH:

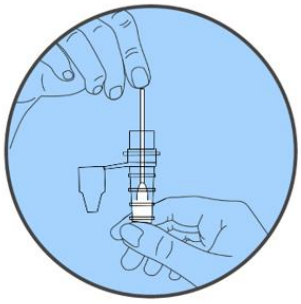


TEST INSTRUCTIONS (use a timer):

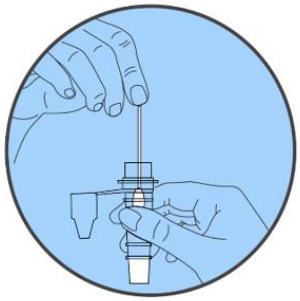
Store at 40-80ºF (5-27ºC). ⚠Do not eat, smoke or drink (except water) 15 minutes before use.



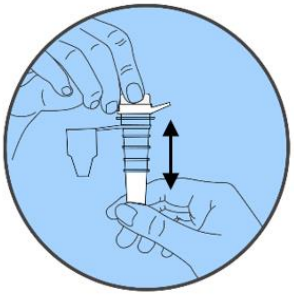
Place Swab on Tongue & **Suck** for **30 seconds** to gather Saliva on Swab.



Remove Buffer Vial Cap, Insert Swab into Buffer & **Stir** for **30 seconds**.

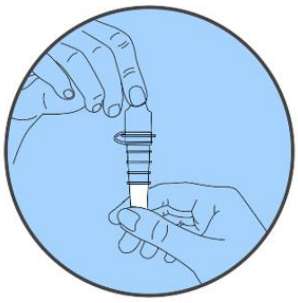


Pinch Neck of Vial **to Squeeze Solution out** of Swab while pulling it out.



Add Cap to Vial, **Shake** up & down **5 times**.

Set aside for **5 minutes.**



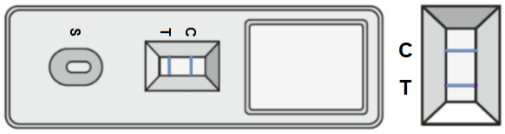
Replace Cap with Dropper Cap.

Add 3 Drops of Solution **to Cassette.**

Wait 15-20 minutes for **1** or **2** Lines to appear.

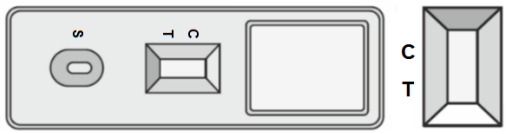
TEST RESULTS:

⚠ Interpret Results within 30 minutes. Test is invalid after 30 minutes of adding sample.



Blue-gray lines, EVEN IF FAINT, appearing at the T (Test) Line and the C (Control) Lines indicate a **POSITIVE TEST** and **COVID-19 was likely detected**. **You should self-isolate and follow-up with your healthcare provider.**

A single blue-gray line at the C (Control) Line indicates a **NEGATIVE TEST** and **COVID-19 was likely NOT detected**.



No lines at either the T (Test) or C (Control) lines indicate an **INVALID TEST**.

⚠Warnings: Wear appropriate latex gloves & mask if testing others. Keep away from children. Reseal kit components in pouch & dispose of as Biohazard Waste.

Visit www.RTA.biz and Order Kits at sales@RTA.biz or 860-635-9800

REAL-TIME ANALYZERS
Providing Chemical & Biological Information When & Where You Need It

Certificate of Free Sale
United States of America

Covid-19 Saliva Antigen At-Home Test

This Test kit is APPROVED FOR SALE by the American World Trade Chamber of Commerce and is *IN REVIEW* with the USA FDA for Emergency Use Authorization. It *IS* available for investigational use.

Intended Use

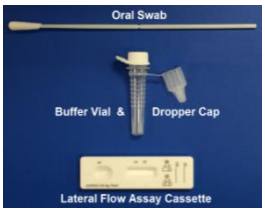
The *COVID-19 Saliva Antigen At-Home Test* can be used to test patients suspected of SARS-CoV-2 within the first 5 days of infection in combination with other clinical presentations, such as fever, cough, congestion, runny nose, loss of smell, fatigue, shortness of breath, and difficulty breathing. Negative results do NOT rule out infection. Positive results do NOT always mean infection. All tests should be confirmed by a standard molecular test, such as Polymerase Chain Reaction (PCR).

Test Principle

The *COVID-19 Saliva Antigen At-Home Test* is a lateral flow immunoassay test that is used to detect the presence of the SARS-CoV-2 virus in saliva. The test employs an antibody that specifically binds to the spike glycoprotein protein found on the surface of the SARS-CoV-2 virus and the nucleocapsid inside the virus, which is generally present in saliva during the acute phase of infection. During the test, 3 drops of buffer treated saliva are added to the lateral flow immunoassay test cassette. The sample flows across the cassette strip driven by capillary action. If the sample contains the SARS-CoV-2 viral antigen, two visible blue-gray lines will form. If the sample does not contain the antigen, a single blue-gray line will form. In all cases, a blue-gray line must form, otherwise the assay is not working.

Kit Contents

The *COVID-19 Saliva Antigen At-Home Test* kit comes in a sealed aluminum pouch. Each pouch contains 3 items: 1) a sterilized Swab to collect the saliva, 2) a Buffer Vial containing a solution to inactivate the virus with a dropper cap to transfer 3 drops of the saliva sample to 3) the Lateral Flow Assay Cassette. The Swab is contained in a paper pouch, while the Cassette is contained in a foil pouch.



Safety

Follow all government and workplace safety precautions when performing this test and when disposing of the kit. The kit components can be resealed in the kit pouch for added safe disposal. Therefore, the used kit, along with healthcare provider safety masks and gloves, should be treated as biohazard waste.

Storage and Expiration

The kit should be stored between 5 and 27 ºC (40 and 80 ºF). Tests should be performed at room temperature, 15 to 30 ºC (60 to 85 ºF), for acceptable results. Kits can be used up to 6-months after the date of manufacture. The Expiration Date is supplied on the kits.

Product Performance

1) **Limit of Detection (LoD) (Analytical Sensitivity):** 20 of 20 samples of heat inactivated Isolate USA-WA1/2020 were successfully detected at **$1.6x10^3$ $TCID_{50}$ per mL** (Table 1). The study used SARS-Related Coronavirus 2, Isolate USA-WA1/2020, heat Inactivated (BEI Resources, NR-52286, Lot: 70037779). **Saliva specimens**, confirmed by PCR to be Covid-19 negative, were used to prepare test samples (Lee Biosolutions, Maryland Heights, MO). Test samples consisted of the viral isolate spiked into the **saliva specimens** from $1.6x10^4$ to $2x10^2$ $TCID_{50}$ per mL.

Table 1. *COVID-19 Saliva Antigen At-Home Test* Limit of Detection Data.

(SARS-CoV-2), isolate USA-WA1/2020, 1.6×10^5 $TCID_{50}$ per mL					
Dilution	1/10	1/100	1/200	1/400	1/800
Conc.	1.6×10^4	**1.6×10^3**	8×10^2	4×10^2	2×10^2
5 replicates	100% (5/5)	**100% (5/5)**	60% (3/5)	0% (0/5)	NA
20 replicates	100% (20/20)	**100% (20/20)**	50% (10/20)	0% (0/20)	NA

2) **Cross-reactivity (Analytical Specificity):** 19 of 19 **related pathogens** tested negative using the *COVID-19 Saliva Antigen At-Home Test* (Table 2). Cross-reactivity studies were performed to demonstrate that the test does not react with related pathogens, high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in a clinical specimen. The organisms in the table below were measured **in pooled saliva samples**.

Table 2. *COVID-19 Saliva Antigen At-Home Test* Cross-Reactivity Data.

Virus/Bacteria	Source	Concentration	Result
Adenovirus	BEI, cell preparation	2.5×10^7 $TCID_{50}$/ml	Negative
Respiratory syncytial virus	ATCC	4×10^5 $TCID_{50}$/ml	Negative
Haemophilus influenzae	Hardy Diagnostics	3×10^6 $TCID_{50}$/ml	Negative
Human Metapneumovirus	BEI, Inactive cell lysate	5×10^5 $TCID_{50}$/ml	Negative
Enterovirus	BEI, cell preparation	2.4×10^5 $TCID_{50}$/ml	Negative
Rhinovirus	BEI, Inactive cell lysate	2×10^6 $TCID_{50}$/ml	Negative
Influenza A	BEI, Inactive cell lysate	6×10^5 $CEID_{50}$/ml	Negative
Influenza B	BEI, Inactive cell lysate	5.3×10^4 $CEID_{50}$/ml	Negative
Human coronavirus 229E	ZeptoMetrix	1×10^5 $TCID_{50}$/ml	Negative
Human coronavirus OC43	ZeptoMetrix	1×10^5 $TCID_{50}$/ml	Negative
Human coronavirus NL63	ZeptoMetrix	1×10^5 $TCID_{50}$/ml	Negative
MERS	BEI, Inactive cell lysate	8.9×10^5 $TCID_{50}$/ml	Negative
Streptococcus pneumoniae	ATCC	5×10^6 cells/ml	Negative
Streptococcus pyogenes	ATCC	8×10^5 cells/ml	Negative
Mycoplasma pneumoniae	ATCC	3.2×10^6 cells/ml	Negative
Chlamydia pneumoniae	ATCC	7.5×10^7 cells/ml	Negative
Legionella pneumophila	ATCC	5×10^5 cells/ml	Negative
Mycobacterium tuberculosis	Univ. Rhode Island	6.3×10^6 cells/ml	Negative
Candida albicans	ATCC	4×10^6 cells/ml	Negative

Manufactured by Real-Time Analyzers, Inc. at:
362 Industrial Park Rd (#8), Middletown, CT 06457
Please contact us for any concerns, inquires, or suggestions:
Sales@RTA.biz 860-635-9800 www.RTA.biz

3) **Microbial and Endogenous Substances Interferent Studies:** Contrived specimens of SARS-CoV-2 with the following interferents were prepared **in pooled saliva samples** (Lee BioSolutions) and tested for the interference with 3 replicates. In all contrived specimens SARS-CoV-2 was detected, i.e. the specimens tested positive, using the *COVID-19 Saliva Antigen At-Home Test*, indicating NO interference (Table 3).

Table 3. *COVID-19 Saliva Antigen At-Home Test* Interferent Data.

Interferent	Concentration	SARS-CoV-2 Concentration	Result n = 3
Influenza A		$1.6x10^3$ $TCID_{50}$ per mL	Positive
Streptococcus pneumoniae	5×10^6 cells/ml	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Streptococcus mutans	1×10^7 cells/ml	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Whole Blood	4%	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Human Blood, EDTA	5% v/v	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Mucin	0.5%	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Acetaminophen	1 mg/ml	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Aspirin	1mg/ml	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Caffeine	5mg/ml	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Amoxicillin	5 mg/ml	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Benzocaine	1.5 mg/mL	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Listerine	50%	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Colgate Toothpaste	1%	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Orajel	1%	$1.6x10^3$ $TCID_{50}$ per mL	Positive
NasoGel (NeilMed)	5% v/v	$1.6x10^3$ $TCID_{50}$ per mL	Positive
CVS Nasal Drops (Phenylephrine)	15% v/v	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Afrin (Oxymetazoline)	15% v/v	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Homeopathic (Alkalol)	1:10 dilution	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Sore Throat Phenol Spray	15% v/v	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Tobramycin	0.3% v/v	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Mupirocin	10 mg/mL	$1.6x10^3$ $TCID_{50}$ per mL	Positive
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	$1.6x10^3$ $TCID_{50}$ per mL	Positive

4) **Clinical Evaluation:** 50 of 50 (100%) volunteers that had PCR tests performed by government labs, self-administered the *COVID-19 Saliva Antigen At-Home Test* the same day and correctly tested Negative. 29 of 38 (76.32%) Positive saliva samples with Ct values, obtained from Boca Biolistics and Lee Biosolutions, correctly tested Positive. All 38 samples were tested 3 times by RTA lab personnel. 29 of 29 (100%) Positive samples with Ct values from 13 to 29 correctly tested Positive using the RTA kit. All 9 samples that incorrectly tested negative had Ct values from 30-33 (Table 4).

Table 4. *COVID-19 Saliva Antigen At-Home Test* Sensitivity, Specificity, Predicted Positive, and Predicted Negative percents are provided for Ct 13-33 values and Ct 13-29 values.

LFA Statistics	Sensitivity	Specificity	Predicted Positive	Predicted Negative
Total True Positive = a, Total False Positive = b, Total False Negative = c, Total True Negative = d				
	a/(a+c)	d/(d+b)	a/(a+b)	d/(d+c)
Ct =13-33	29/(29+9)	50/(50+0)	29/(29+0)	50/(50+9)
a=29, b=0, c=9, d=50	**76.32%**	**100.00%**	**100.00%**	**84.75%**
Ct =13-29	29/(29+0)	50/(50+0)	29/(29+0)	50/(50+0)
a=29, b=0, c=0, d=50	**100.00%**	**100.00%**	**100.00%**	**100.00%**

Test Limitations

1) This product can only be used to detect the SARS-CoV-2 virus in human saliva. It cannot be used for testing other body fluids or secretions.
2) This product is only for qualitative testing and will not indicate the concentration (level) of infection.
3) Optimized specimen type and time of peak SARS-CoV-2 virus levels has not been finalized, and therefore multiple specimen collection (type and time) is often necessary.
4) Predictive positive and negative infection is based on virus levels.
5) Negative results may be caused by low levels of the SARS-CoV-2 virus in the sample and therefore cannot completely rule out the possibility of infection.
6) Positive results may be caused by other coronavirus strains, and therefore cannot completely rule out the possibility of non-infection.
7) Detection using the kit cannot exclude infection by other bacteria or pathogen induced diseases.
8) The results of this test should not be the only basis for diagnosis.
9) Results should be used in combination with clinical observations, medical history, and other testing methods.
10) Follow-up testing with a molecular diagnostic test like PCR should be performed to rule out infection or confirm infection.
11) Epidemiological or clinical features of SARS-CoV-2 induced infection have not been fully studied and therefore the performance of the kit might be affected.
12) Monitoring treatment of a SARS-CoV-2 infection using the kit has not been evaluated.
13) Do not use an expired kit.
14) Improper specimen collection, transportation and processing may lead false negative results.
15) Improper storage or handling of this test kit, either below 5 ºC or above 30 ºC, or exposure to water or high humidity can cause incorrect results.
16) This is a single use test, and should be discarded as biomedical waste according to regulations.

Warnings and Precautions

1) This test is currently being reviewed by the US Food & Drug Administration.
2) Healthcare providers should be well trained in handling samples and performing this test.
3) Healthcare providers performing this test should use Personal Protective Equipment (PPE) according to regulations. We strongly advise wearing latex lab gloves, a lab gown, and N95 masks, and washing hands frequently with disinfectant (or soap and water if not available).
4) All used kits, gloves and masks should be disposed in a biomedical hazard waste container.

Patents

1) US 7,393,691 SERS Method and Apparatus for Rapid Extraction and Analysis of Drugs in Saliva
2) US 9,134,247 Method and Apparatus for Two-Step Surface-Enhanced Raman Spectroscopy
3) Patent Pending: Method and Apparatus for Effecting the Rapid Detection of the SARS-Cov-2 Virus.

Manufacturer	Manufacture Date	Caution	Temperature Limitations	Consult Instructions for Use	Catalog Number	In-Vitro Diagnostic Medical Device	Use by	Batch Code
					REF	IVD		LOT