DELTA CHEMIE BIOTECHNOLOGY

COMPANY WITH CERTIFIED QUALITY MANAGEMENT SYSTEM
ISO 9001 - ISO 13485

OneCheck

COVID-19 Ag Saliva

CROMATOGRAPHIC IMMUNOASSAY RAPID TEST

REF **TR189** **IVD** Σ **10 pcs**

INTENDED USE

The COVID-19 Ag Rapid Test is a lateral flow chromatographic immuno-assay for the qualitative detection of Sars-CoV-2 Antigen in oral fluid specimen as an aid in the rapid diagnosis in individuals with symptoms of SARS-CoV-2 infection.
Antigen is generally detectable in upper respiratory specimens during the acute phase of infection, but the titer may be too low to detect in the early stages or in asymptomatic individuals.
In case of positive result it is recommended to confirm it with an alternative method. Clinical correlation with patient history and other diagnostic information is necessary to determine infection status.
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.
This test is for professional and in vitro diagnostic use only and it is intended for use by trained clinical laboratory personnel.

SUMMARY

COVID-19 is an acute respiratory infectious disease caused by the novel coronavirus SARS-CoV-2. The incubation period of the disease is 1 to 14 days, mostly 3-7 days.
Currently, the patients infected by the novel coronavirus, symptomatic and asymptomatic, are the main source of infection. An infected person can be contagious even during the incubation period.
The main manifestations include fever, fatigue and dry cough, breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.
The Antigen is present before the formation of antibodies and its detection is the most suitable test for an early diagnosis of the infection.

PRINCIPLE

The COVID-19 Ag Saliva Rapid Test is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Antigens in oral fluid specimen. During testing, the specimen reacts with SARS-CoV-2 antibody-coated particles in the test. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region. If the specimen contains SARS-CoV-2 Antigens, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

MATERIALS PROVIDED

- 10 test cassettes
- 10 collection tubes with mouthpiece and dropper caps
- 10 vials with extraction buffer
- 10 droppers
- 10 biosafety bugs
- 1 workstation
- 1 user manual

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- Do not use test if pouch is damaged.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch at room temperature (4-30°C). Do not freeze.
- The test is stable through the expiration date if it remain in the sealed pouch until use and properly stored.

SPECIMEN COLLECTION AND PREPARATION

SPECIMEN COLLECTION

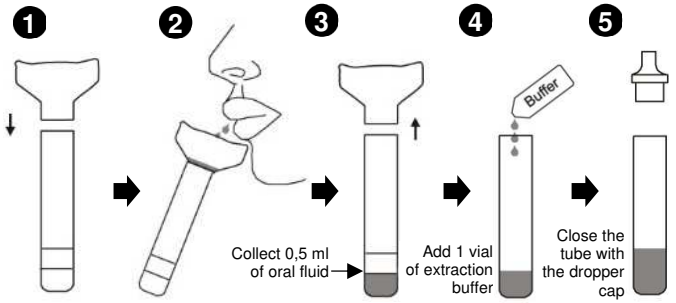
Before sample collection, ensure that the patient has not ingested or introduced food, drink, gum or tobacco into the mouth for at least 10 minutes.

1. Instruct the patients to deeply cough 3-5 times to release sputum from deep throat to the mouth.
2. Insert the mouthpiece on the collection tube provided in the kit;
3. Collect 500 µl of oral fluid in the tube (up to the first mark of the tube);

Note: Remove any excess sample using the dropper supplied with the kit

SPECIMEN PREPARATION

1. Remove the mouthpiece from the collection tube;
2. Add 500 µl of extraction buffer (an entire vial) to the collected sample (up to the second mark of the tube);
3. Close the tube with the dropper cap;
4. Gently shake the mixture for 10 seconds;

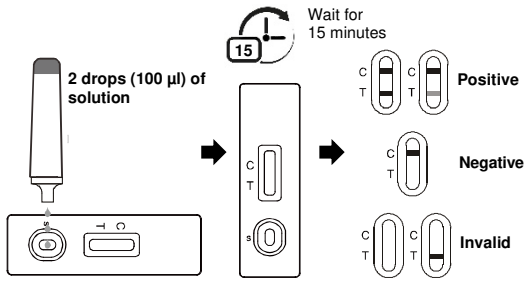


SPECIMEN STORAGE

Specimens should be tested as soon as possible after collection.
The specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8°C.

PROCEDURE

1. Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
2. Remove the test cassette from the foil pouch and place it on a clean and level surface.
3. Transfer **2 drops of solution** (100 µl) to the specimen well avoiding the formation of air bubbles.
4. Wait **15 minutes** and read the result.
5. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

One colored line appears in the control line region if the test was performed correctly.
NEGATIVE: Only one colored line appears in the control line region "C" and **no line appears in the test region "T".** Antigen in the sample is not present or is below the detection limits of the test.
POSITIVE: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Test region (T). Positive result indicates detection of SARS-CoV-2 antigens in the sample.
Note: The intensity of the color of the test line (T) will vary based on the amount of COVID-19 antigen present in the sample. So any shade of color should be considered positive.

INVALID: If no line appears in the control line region the test should be considered invalid and must be repeated. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The COVID-19 Ag Saliva Rapid Test is for professional and in vitro diagnostic use only.
- The COVID-19 Ag Saliva Rapid Test is a screening test for the acute phase of the disease. Samples collected before or after this step may contain antigenic titers below the minimum detection limit of the test and give negative results.
- Collect the correct amount of sample. A higher or lower amount can lead to incorrect results.
- The accuracy of the test depends on the quality of the sample. False negatives may result from improper sample collection or storage.
- Use only the tubes and the solution included in the kit, do not use or add VTM (viral transport medium);
- This test should be used for detection of SARS-CoV-2 Antigens in oral fluid specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
- If the test result is negative and clinical symptoms persist, it is recommended to re-sample the patient and test again or test with a molecular diagnostic device to rule out infection in these individuals.
- The test will show negative results if the titer of the antigens in the sample is lower than the minimum detection limit of the test.
- In some cases, a positive result may be due to infection with strains of coronaviruses other than SARS-CoV-2.
- **If the result is positive, the test must be confirmed with an alternative method (RT-PCR). Comply with the provisions of the authorities.**
- The COVID-19 Ag Saliva Rapid Test will only indicate the presence of SARS-CoV-2 Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

PERFORMANCE

SENSITIVITY, SPECIFICITY E ACCURACY

The COVID-19 Ag Saliva Rapid Test has been compared with the reference RT-PCR. Results showed high sensitivity and specificity.

Method		RT-PCR		Total Results
Test Rapido COVID-19 Ag Saliva	Results	Positive	Negative	
	Positive	91	2	93
	Negative	10	303	313
Total Results		101	305	406

Relative Sensitivity: 90,1%
Relative Specificity: 99,3%
Accuracy: 97,0%

SPECIFICITY

The COVID-19 Ag Saliva Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations:

Description	Concentration
Adenovirus type 3	3.16 x 10^4 TCID50/ml
Adenovirus type 7	1.58 x 10^5 TCID50/ml
Human coronavirus OC43	1 x 10^6 LD50/ml
Human coronavirus 229E	5 x 10^5 LD50/ml
Human coronavirus NL63	1 x 10^6 LD50/ml
Human coronavirus HKU1	1 x 10^6 LD50/ml
Influenza A H1N1	3.16 x 10^5 TCID50/ml
Influenza A H3N2	1 x 10^5 TCID50/ml
Influenza B	3.16 x 10^6 TCID50/ml
Measles	1.58 x 10^4 TCID50/ml
Mumps	1.58 x 10^4 TCID50/ml
Parainfluenza virus 2	1.58 x 10^7 TCID50/ml
Parainfluenza virus 3	1.58 x 10^8 TCID50/ml
Respiratory syncytial virus	8.89 x 10^4 TCID50/ml

PRECISION

Within-run and Between-run precision has been determined by using three specimens of COVID-19 standard control. Three different lots of COVID-19 Ag Saliva Rapid Test have been tested using negative SARS-COV-2 Antigen weak and SARS-COV-2 Antigen Strong. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

CROSS-REACTIVITY

The following organisms were tested at 1.0x10^8 org/ml and all found to be negative when tested with the COVID-19 Ag Saliva Rapid Test:

Arcanobacterium
Candida albicans
Corynebacterium
Escherichia coli
Moraxella catarrhalis
Neisseria lactamica
Nesseria subllava
Pseudomonas aeruginosa
Staphylococcus aureus subspaureus
Staphylococcus epidermidis
Streptococcus pneumoniae
Streptococcus pygenes
Streptococcus salivarius
Streptococcus sp group F

INTERFERING SUBSTANCES

The following substances were tested with COVID-19 AG Saliva Rapid Test and no interference was observed:

Dexamethasone	0.8mg/ml	*Tobryamycin*	2.43mg/ml
Mucin	50µg/ml	*Tea*	33.3mg/ml
Flunisolide	6.8ng/ml	*Milk*	11.2%
Mupirocin	12mg/ml	*Orange juice*	100%
Oxymetazoline	0.6mg/ml	*Mouthwash*	2%
Phenylephrine	12mg/ml	*Caffeine*	1mg/ml
Rebetol	4.5µg/ml	*Coca Cola*	/
Relenza	282ng/ml	*Toothpaste*	/
Tamiflu	1.1µg/ml		

BIBLIOGRAPHY

1. Westgard J.O., Barry P.L., Hunt M.R., Groth T., *A multi-rule Shewhart for quality control in clinical chemistry*, Clinical Chemistry 1981;27:493-501

CE

Comply with EC Directive 98/79/CE

INDEX OF SYMBOLS

4°C–30°C	Store between 4-30°C		Use by (YYYY-MM)
LOT	Lot Number	IVD	For in vitro diagnostics use only
	Manufacturer	REF	Catalog Number
Σ n	Tests per kit		Consult Instruction for Use
2	Do not reuse	CE	CE Mark

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