MEDIVEN®
MEDICAL INNOVATION VENTURES

PRODETECT™ ProDetect® COVID-19 Antigen Rapid Test (Oral Fluid)

IVD *In vitro* Diagnostic Use Only

CE

REF PR-CVDCAgO1
PR-CVDCAgO20

Σ 1 or 20

Please read the Instruction Sheet Carefully Before Performing the Test.

INTENDED USE

ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) is a rapid lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in human oral fluid specimens. The test serves as an aid in the diagnosis of coronavirus infection disease (COVID-19) for individuals suspected of SARS-CoV-2 infection. ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) is used in conjunction with clinical presentation and the results of other laboratory tests. ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) is intended for professional use only.

SUMMARY AND EXPLANATION OF THE TEST

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) was identified as the causative agent for the outbreak of pneumonia cases in early January 2020. It is associated with common symptoms include fever, cough, fatigue, shortness of breath or breathing difficulties, and loss of smell and taste. While most people have mild symptoms, some people develop acute respiratory distress syndrome (ARDS). It starts with mild symptoms for about a week and then progresses to rapid deterioration and ARDS requiring advanced life support.

ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) detects SARS-CoV-2 nucleocapsid protein antigens. During the acute phase of infection, an antigen is commonly detectable in the upper respiratory specimens.

PRINCIPLE OF THE TEST

ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human oral fluid specimen. During the testing, the specimen reacts with SARS-CoV-2 nucleocapsid protein antibody-coated particles in the test line region of the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with SARS-CoV-2 nucleocapsid protein antibody in test line region. A colored line will appear in test line region if specimen contains SARS-CoV-2 antigens. 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 procedure control, a colored line will appear at the Control Region (C), indicating that the test has been performed properly.

REAGENTS AND MATERIALS SUPPLIED

Catalog Number	Item
PR-CVDCAgO1/ PR-CVDCAgO20	Each box consists of the following components: 1. 1 or 20 individually sealed pouches, each containing: • One test device • One desiccant pouch 2. 1 or 20 collection devices, each consisting of: • One funnel • One collection tube • One dropper 3. 1 or 20 biosafety bags 4. 1 or 20 single use buffers. 5. 1 procedure card 6. 1 leaflet with instruction for use

MATERIALS NEEDED BUT NOT SUPPLIED

1. Gloves
2. Clock or Timer
3. Timer
4. Appropriate biohazard waste containers and disinfectants.

WARNINGS AND PRECAUTIONS

1. This kit is *for in vitro* diagnostic and professional use only.
2. This instruction for use must be read completely before performing the test. Failure to follow directions in the instruction for use may yield inaccurate test results.
3. Wear protective gloves such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or when performing assay procedures.
4. Wash hands thoroughly after performing the test.
5. Do not eat, drink or smoke in the area where the specimens or kits are handled.
6. Clean up spills thoroughly with appropriate disinfectants.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
8. Avoid splashing or aerosol formation while collecting the sample.
9. Discard after first use. The test kit cannot be used more than once.
10. Do not use the test kit beyond the expiry date.
11. Do not use the test kit if the pouch is punctured or not well sealed.
12. Do not mix and interchange different specimens.
13. Keep out of reach of children.
14. Do not read after 20 minutes.
15. Do not swallow.
16. Dispose of all specimens and used devices in a proper bio-hazard container.

STORAGE

1. The test cassette is stable until the indicated expiry date when stored in the sealed pouch at 2-30°C and protected from direct sunlight, moisture and heat.
2. DO NOT FREEZE.
3. The test cassette must remain in the sealed pouch until use.

SAMPLE COLLECTION AND PREPARATION

Specimen Collection and Extraction

Oral fluid specimen should be collected using the collection device provided with the kit. Do not use other collection devices. Oral fluid collected at any time of the day may be used. Specimens should be tested immediately after collection if possible. If the oral fluid is not processed immediately, it is stable up to 8 hours at room temperature and 24 hours at 2-8°C.

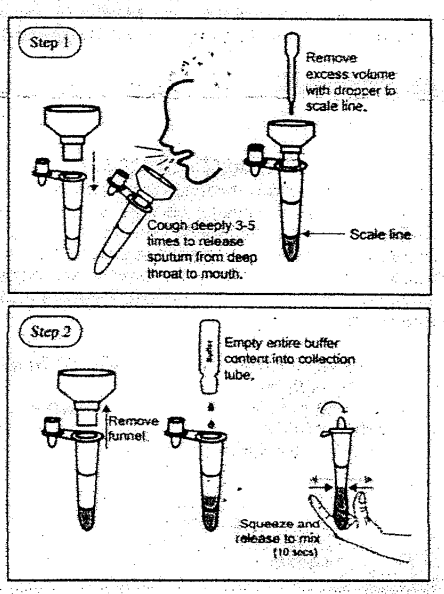
Prior to collection of oral fluid, patients must not place anything in their mouth including food, drink, gum or tobacco products for at least 10 minutes before collection.

Step 1:

- Attach the funnel to the collection tube prior to sample collection.
- Instruct the patient to deeply cough 3-5 times to release sputum from deep throat to mouth and into the collection device.
  Note: It is recommended to collect the first sputum after deep coughing in the morning.
- Repeat the steps above for sample collection until the oral fluid reaches the scale line indicated on the collection tube.
- Remove excess oral fluid volume from the collection device using the dropper.

Step 2:

- Remove the funnel from collection tube.
- Empty the entire content of the disposable buffer into the collection tube.
- Place the cap securely on the collection tube. Gently squeeze the collection tube for 10 seconds to mix the sample with the buffer thoroughly.
  Note: The storage of the specimen after extraction is stable for 2 hrs at room temperature or 24 hours at 2-8°C.



TEST PROCEDURE

Bring the device, buffer, and sample to room temperature (15-30°C) prior to testing. Best results will be obtained if the test is performed immediately after opening the foil pouch.

1. Remove test device from the foil pouch (use within 1 hr) and place it on a flat and clean surface.
2. Transfer extracted sample to the test device.
3. Wait for the colored line(s) to appear, Read the results at 15 minutes.
4. Do not read results after 20 minutes.

INTERPRETATION OF RESULTS

Positive (+)

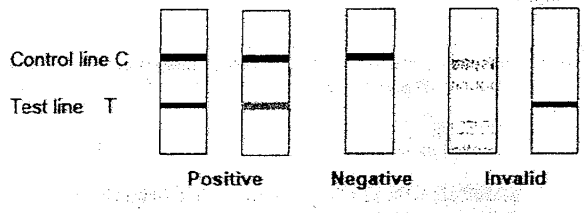
Two colored lines appear at test line (T) and control line (C). It indicates a positive result for the SARS-CoV-2 antigens in the specimen.
Note: Color intensity of the line appearing in the test (T) region may vary depending on the SARS-CoV-2 antigen level in the specimen. Therefore, any shade of color in the test (T) region is to be considered as a positive result.

Negative (-)

The colored line appears at the control line (C) only. It indicates that the concentration of the SARS-CoV-2 antigen is zero or below the detection limit of the test.

Invalid

Control line fails to appear. 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.



LIMITATIONS OF THE TEST

1. The test procedure must be carefully followed when testing the presence of SARS-CoV-2 nucleocapsid protein antigens in human oral fluid specimen from suspected individuals. Failure to follow the instructions may cause incorrect results.
2. The performance of ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) was validated using the procedures provided in this instruction for use. Modification to these procedures may cause inaccurate performance.
3. Extracted specimens for PCR tests or Viral Transport Media (VTM) specimen must not be used for the test.
4. ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) is for *in vitro* diagnostic use only. It is used for the detection of SARS-CoV-2 nucleocapsid protein antigens in human oral fluid specimens as an aid in the diagnosis of patients suspected of SARS-CoV-2 infection in conjunction with clinical symptoms and the results of other laboratory tests. This qualitative test does not provide quantitative value and cannot determine the rate of increase in the concentration of SARS-Cov-2 nucleocapsid protein antigens.
5. This 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 infection. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
6. If the test result is negative or non-reactive but clinical symptoms persist, it is recommended to re-sample the patient after a few days and test again or test with a molecular diagnostic device to rule out infection in the patient.
7. Negative results may be obtained if the titre of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test. However, they do not rule out SARS-CoV-2 infection, particularly in patients who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these patients.
8. Infection with non-SARS-CoV-2 coronavirus strains or other interference factors may show in positive results with ProDetect COVID-19 Ag Rapid Test (Oral Fluid).

QUALITY CONTROL

Although there is an internal procedural control line in the test device of the control region, the use of external controls is strongly recommended as Good Laboratory Testing Practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted. Positive/negative controls are not included in this kit.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity:

ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) was compared with a leading commercial PCR kit. The results showed that the ProDetect COVID-19 has high sensitivity and specificity.

ProDetect COVID-19 Antigen Rapid Test Oral Fluid	Method	PCR		Total
	Results	Positive	Negative	Results
	Positive	56	1	57
	Negative	4	99	103
Total Result		60	100	160
Relative Sensitivity		93.3% (95%CI: 83.8% to 98.2%)		
Relative Specificity		99.0%(95%CI: 94.6% to 100.0%)		
Accuracy		96.9%(95%CI: 92.9% to 99.0%)		

CI: Confidence Intervals

Specificity with other viral strains

ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) has been tested with other viral strains. The results showed no discernible line at the test-line regions at the following concentrations:

Virus Type	Concentration ($TCID_{50}$/ml)
Adenovirus type 3	3.16×10^4
Adenovirus type 7	1.58×10^5
Human coronavirus OC43	1.00×10^6
Human coronavirus 229E	5.00×10^5
Human coronavirus HKU1	1.00×10^6
Human coronavirus NL63	1.00×10^6
Influenza A H1N1	3.16×10^5
Influenza A H3N2	1.00×10^5
Influenza B	3.16×10^6
Measles	1.58×10^4
Mumps	1.58×10^4
Parainfluenza virus 2	1.58×10^7
Parainfluenza virus 3	1.58×10^8
Respiratory syncytial virus	8.89×10^4

TCID50 = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

Precision (Intra-assay & Inter-assay)

Precision was determined by using three specimens of COVID-19 standard control. Three different lots of ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) have been tested using negative, weak SARS-CoV-2 Antigen and strong SARS-CoV-2 Antigen. 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 the concentration of 1.0×10^8 org/ml using the test kit. All were found to be negative.

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus sub aureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pygenes*
Neisseria lactamica	*Streptococcus salivarius*
Neisseria subflava	*Streptococcus sp. Group F*

Interfering Substances

The following substances were tested with ProDetect COVID-19 Antigen Rapid Test (Oral Fluid) and no interference was observed:

Caffeine	1mg/ml
Dexamethasone	0.8mg/ml
Flunisolide	6.8ng/ml
Milk	11.2%
Mouthwash	2.0%
Mucin	50µg/ml
Mupirocin	12mg/ml
Orange Juice	100.0%
Oxymetazoline	0.6mg/ml
Phenylephrine	12.0 g/ml
Rebetol	4.5µg/ml
Relenza	282ng/ml
Tamiflu	1.1µg/ml
Tea	33.3mg/ml
Tobryamycin	2.43mg/ml

REFERENCES

1. Huang, C. et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet 395, 497–506 (2020).
2. David, L.H, Shindo, N. Covid-19: what is next for public health? 2020. The Lancet, 1-3.
3. *Emerging respiratory viruses, including COVID-19: methods for detection, prevention, response and control.* (2020). World Health Organization. https://openwho.org/courses/introduction-to-ncov

INDEX OF SYMBOLS USED

Consult instructions for use	Do not re-use
REF Catalog number	No. of tests
LOT Batch code	Temperature limitation
Date of manufacture	Use by
Manufacturer	EC REP European Representative

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