IVD CE

Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva)

REF:IOV87952.

Intended Use

Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigens in human saliva, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronvirus antigen. It will provide information for clinical doctors to prescribe correct medications.

Summary

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It 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. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.

Principle

The Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) 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.

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℃.
- Wear gloves when hanging 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 Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) at 2-30℃. Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

Materials

Materials Provided

1. Test Device
2. Saliva Swab
3. Extraction Tube with extraction buffer
4. Package Insert

Materials Required but not Provided

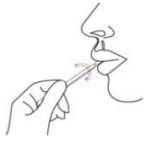
1. Timer

Specimen Collection and Precaution

The Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) is designed for the use of buffered human fresh saliva as the specimen. 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.

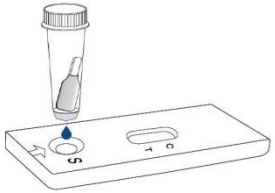
1. Remove the swab from the sealed pouch.
2. Cough deeply twice before collecting the samples.
3. Insert the sponge end of the collector into the mouth. Then swab back and forth along the gum line from one end to the other end of the upper and lower gum, both side of the cheek, and top of the tongue 3 to 5 times.
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. 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℃) 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.

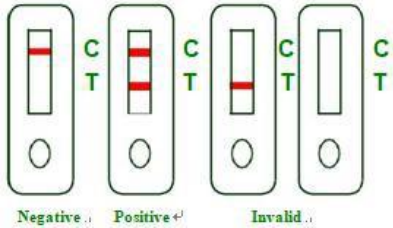
POSITIVE:

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.

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Limitations

• The Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) 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 Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) 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-1.
• 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 Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) and PCR. The results were summarized below:

Table: Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva) vs. PCR

		Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (Saliva)		Total Result
		+	-	
PCR	+	34	1	35
	-	0	200	200
Total Results		34	201	235

Relative sensitivity: 34/35= 97.1% (95%CI 85.47%~99.49%)
Relative specificity: 200/200 >99% (95%CI 98.12%~100%)
Overall agreement: (34+200)/(34+0+1+200)*100%=99.57% (95%CI 97.63%~99.92%)
CI: Confidence Interval

Cross Reaction

No cross reaction has been confirmed of The coronavirus (SARS-CoV-2) Test Device with the following pathogens:

①Bacteria

Acinetobacter baumannii,Bordetella pertussis,Branhamella catarrhalis, Candida albicans, Candida glabrata, Cardiobacterium hominis,Eikenella corrodens,Enterococcus faecalis, Enterococcus gallinarum.Escherichia coil, Group C streptococcus, Group G streptococcus, Haemophilus aphrophilus, Haemophilus influenzae, Haemophilus paraphrophilus, Klebsiella pneumoniae, Neisseria Gonorrhoeae Peptococcus asaccharolyticus, Peptostreptococcusanaerobius, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus agalactiae(group B), Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes(group A), Veillonella parvula

②Virus

Influenza A,Influenza B, Adenovirus Type 1～8, 11, 19, 37, Coxsackie virus Type A16, B1～5, Cytomegalovirus, Echovirus Type 3, 6, 9, 11, 14, 18, 30, Enterovirus Type 71, HSV-1,Mumps virus, Tyep I simple herpes virus Parainfluenza virus Type 1 ～ 3, Poliovirus Type 1 ～ 3, Respiratory syncytial virus, Rhinovirus Type 1A, 13, 14, Type I simple herpes virus.

③Mycoplasma etc.

No cross reaction with Chlamydia pneumoniae, Chlamydia psittaci, Chlamydia trachomatis, Mycoplasma pneumoniae.

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Symbols

	Consult instructions for use	30°C 2°C	Store between 2-30°C		Use by
IVD	For *in vitro* diagnostic use only		Do not reuse	LOT	Lot Number
	Manufacturer	Σ	Tests per kit	REF	Catalog No
EC REP	European union authorized representative		Keep dry		Don't use the product
	Biological risks	CE	The product meets the basic requirements of European in vitro, diagnostic medical		