# COVID-19 Ag Saliva Easy Test Device (Immunochromatography)

English

## [INTENDED USE]

The Test Device is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from 2019-nCoV in saliva specimens directly collected from individuals who are suspected of COVID-19.

Results are for the identification of 2019-nCoV nucleocapsid protein antigen. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive, and do not rule out 2019-nCoV infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. 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, and confirmed with a molecular assay.

## [SUMMARY AND EXPLANATION]

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 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.

## [PRINCIPLE OF THE TEST]

This Card uses double-antibody sandwich to legally detect the antigen of novel coronavirus (2019-nCoV) in saliva samples. During detection, the gold labeled anti-2019-nCoV monoclonal antibody in the labeling pad binds to the 2019-nCoV antigen in the sample to form a complex, and the reaction complex moves forward along the nitrocellulose membrane under the action of chromatography, it is captured by the anti-2019-nCoV monoclonal antibody pre-coated by the detection zone (T) on the nitrocellulose membrane, and finally a red color reaction line is formed in the T zone. If the sample does not contain 2019-nCoV antigen, a red color reaction line cannot be formed in the T zone. Regardless of whether the sample to be tested contains 2019-nCoV antigen, a red reaction line will always form in the quality control area (C).

## [MATERIALS AND COMPONENTS]

***Materials provided with the test kits**

| Specifications / Ingredients | HRK-8601 | HRK-8605 | HRK-8620 |
|---|---|---|---|
| Test Device | 1 | 5 | 20 |
| Instructions for use | 1 | 1 | 1 |

***Materials required but not provided**

Timer



## [STORAGE AND STABILITY]

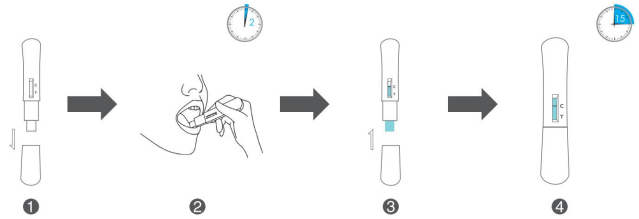
1.Store the test device as packaged between 2-30°C.
2.The test device is stable until the expiration date printed on the outer packing, the product will be expired after 24 months.
3.Do not use beyond the expiration date.
4.Do not freeze any contents of the test
The test device must remain in the sealed pouch until use.

## [TEST PROCEDURE]

Before test, please read the instructions carefully.

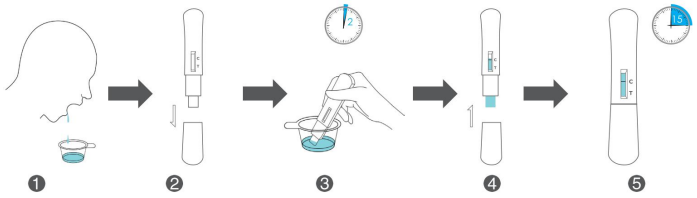
### *Method A:*

1. Open the aluminum foil bag, take out the test device, un-plug the cap.
2. Place the absorbent tip beneath tongue for 2 minutes.
3. Keep the test device upright and let the saliva fluids to move upward until reaching over Line C, then plug the cap back.
4. Wait for 15 minutes and read the results.



### *Method B:*

1. Collect enough fresh saliva in a single use disposable cup.
2. Open the aluminum foil bag, take out the test device, un-plug the cap.
3. Place the absorbent tip into the saliva specimens, let the absorbent tip to immerse in and absorb saliva fully.
4. Keep the test device upright and let the saliva fluids to move upward until reaching over Line C, then plug the cap back.
5. Wait for 15 minutes and read the results.



**NOTE:**

*When sampling, gently hold it in mouth and let saliva naturally adsorb on the absorbent tip.*
**Do not eat, drink, or smoke prior to the test for at least 30 Minutes.*
**Any saliva specimen is appropriate for testing but the saliva specimen collected in the morning, before mouth rinsed, eating or drinking, is recommended.*

## [INTERPRETATION OF TEST RESULTS]

This product can only perform qualitative analysis on the detection object.

**Positive Result**:

If both C and T lines are visible within 10 minutes, the test result is positive and valid.

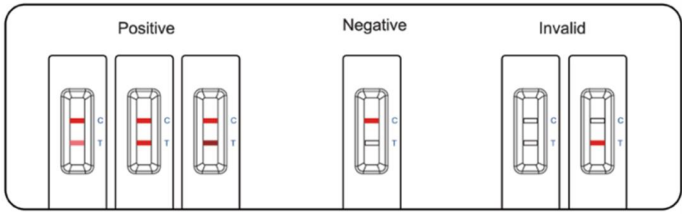


**Negative Result**:

If test area (T line) has no color and the control area displays a colored line, the result is negative and valid

**Invalid Result**:

The test result is invalid if a colored line does not form in the control region. The sample must be re-tested, using a new test device.




## [LIMITATIONS]

1. The result of the test should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made alongwith RT-PCR results, clinical symptoms, epidemiological information, and further clinical data.
2. The Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
3. The test must be equilibrated to room temperature (18°C~26°C) before used, otherwise the results may be incorrect.
4. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
5. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
6. React less than 10 minutes may lead a false negative result; React more than 10 minutes may lead a false positive result.
7. Positive test results do not rule out co-infections with other pathogens.
8. Negative test results are not intended to rule in other viral or bacterial infections.
9. Negative results should be treated as presumptive and confirmed with a molecular assay.
10. Clinical performance was evaluated with fresh samples.
11. Users should test specimens as quickly as possible after specimen collection.

## [PERFORMANCE CHARACTERISTIC]

### 1.Clinical Verification

The performance of Test was established with 244 sample collected from symptomatic patients, who with symptoms onset within 7 days.

| COVID-19 Ag Saliva Easy Test Device (Immunochromatography) | Comparative RT-PCR Test Reslt | | |
|---|---|---|---|
| | Positive (+) | Negative (-) | Total |
| Detected Positive | 123 | 0 | 123 |
| Detected Negative | 11 | 110 | 121 |
| Total | 134 | 110 | 244 |
| Sensitivity | 91.79%, 95% CI (85.45, 95.63) | | |
| Specificity | 100.00%, 95% CI (95.79, 99.92) | | |
| Accuracy | 95.49%, 95% CI (91.85, 97.61) | | |

Positive results broken down by days since symptom onset:

| Days since symptom onset | RT-PCR Positive(+) | COVID-19 Ag Saliva Easy Test Device(Immunochromatography) | PPA |
|---|---|---|---|
| 1 | 13 | 13 | 100% |
| 2 | 32 | 32 | 100% |
| 3 | 52 | 51 | 98.08% |
| 4 | 69 | 67 | 97. 10% |
| 5 | 86 | 83 | 96.51% |
| 6 | 102 | 97 | 96.00% |
| 7 | 115 | 108 | 93.91% |

Positive results broken down by CT value:

| COVID-19 Ag Saliva Easy Test Device(Immunochromatography) | Comparative RT-PCR Method (Positive by Ct Value) | |
|---|---|---|
| | Positive (Ct<=25) | Positive(Ct>25) |
| Detected Positive | 69 | 39 |
| Total | 70 | 45 |
| Positive agreement | 98.57% | 86.67% |

## 2.Limit of Detection

The experimental results show that for the virus culture concentration above 100 $TCID_{50}$/mL, the positive rate of detection is greater than or equal to 95%. For the virus culture concentration of 50 $TCID_{50}$/mL and below, the positive rate of detection is lower than 95%. So, the limit of detection of the Test is 100 $TCID_{50}$/mL.

## 3.Cross-reactivity

Cross-reactivity of the test device was evaluated. The results showed no cross reactivity with the following specimen.

| No. | Specimen type | Conc. |
|---|---|---|
| 1 | HCoV-HKU1 | $10^5$ $TCID_{50}$/mL |
| 2 | Staphylococcus aureus | $10^6$ CFU / mL |
| 3 | Streptococcus pyogenes | $10^6$ CFU / mL |
| 4 | Measles virus | $10^5$ $TCID_{50}$/mL |
| 5 | Paramyxovirus parotitis | $10^5$ $TCID_{50}$/mL |
| 6 | Adenovirus 3 | $10^5$ $TCID_{50}$/mL |
| 7 | Mycoplasma pneumoniae | $10^6$ CFU / mL |
| 8 | Parainfluenza virus 2 | $10^5$ $TCID_{50}$/mL |
| 9 | Human Metapneumovirus (hMPV) | $10^5$ $TCID_{50}$/mL |
| 10 | Human coronavirus OC43 | $10^5$ $TCID_{50}$/mL |
| 11 | Human coronavirus 229E | $10^5$ $TCID_{50}$/mL |
| 12 | Human coronavirus NL63 | $10^4$ $TCID_{50}$/mL |
| 13 | MERS-Coronavirus EMC/2012 | $10^4$ $TCID_{50}$/mL |
| 14 | Bordetella parapertussia | $10^6$ CFU / mL |
| 15 | Influenza B (Victoria strain) | $10^5$ $TCID_{50}$/mL |
| 16 | Influenza B (Y strain) | $10^5$ $TCID_{50}$/mL |
| 17 | Influenza A (H1N1 2009) | $10^5$ $TCID_{50}$/mL |
| 18 | Influenza A (H3N2) | $10^5$ $TCID_{50}$/mL |
| 19 | Avian influenza virus (H7N9) | $10^5$ $TCID_{50}$/mL |
| 20 | Avian influenza virus (H5N1) | $10^5$ $TCID_{50}$/mL |
| 21 | Epstein-Barr virus | $10^5$ $TCID_{50}$/mL |
| 22 | Enterovirus CA16 | $10^5$ $TCID_{50}$/mL |
| 23 | Rhinovirus | $10^5$ $TCID_{50}$/mL |
| 24 | Respiratory syncytial virus | $10^5$ $TCID_{50}$/mL |
| 25 | Streptococcus pneumoniae | $10^6$ CFU / mL |
| 26 | Candida albicans | $10^6$ CFU / mL |
| 27 | Chlamydia pneumoniae | $10^6$ CFU / mL |
| 28 | Bordetella pertussis | $10^6$ CFU / mL |
| 29 | Pneumocystis jirovecii | $10^6$ CFU / mL |
| 30 | Mycobacterium tuberculosis | $10^6$ CFU / mL |
| 31 | Legionella pneumophila | $10^6$ CFU / mL |

The test results do not be interfered with the substance at the following concentration

| No. | Interference substances | Conc. |
|---|---|---|
| 1 | Whole Blood | 4% |
| 2 | Ibuprofen | 1mg / mL |
| 3 | Tetracycline | 3μg / mL |
| 4 | Chloramphenicol | 3μg / mL |
| 5 | Erythromycin | 3μg / mL |
| 6 | Tobramycin | 5% |
| 7 | Throat spray（Menthol） | 15% |
| 8 | Mupirocin | 10mg/mL |
| 9 | Throat lozenge（Menthol） | 1.5mg/mL |
| 10 | Tamiflu (Oseltamivir) | 5mg/mL |
| 11 | Naphthoxoline hydrochloride nasal drops | 15% |
| 12 | Mucin | 0.50% |
| 13 | Fisherman's Friend | 1.5mg/mL |
| 14 | Compound Benzocain Gel | 1.5mg/mL |
| 15 | Cromoglycate | 15% |
| 16 | Sinex (Phenylephrine Hydrochloride) | 15% |
| 17 | Afrin (Oxymetazoline) | 15% |
| 18 | Fluticasone propionate spray | 15% |

## 5.Precision

1. Test 10 replicates of negative and positive by using the reference materials of enterprises. The negative agreement and the positive agreement were 100%.
2. Test three different lots kits including positive and negative reference materials of enterprises. The negative results and the positive results were 100%.

## 6.Hook Effect

The Test Device was tested up to $1.6\times10^5$ $TCID_{50}$/mL of heat-inactivated 2019-nCoV strain and no high-dose effect was observed.

## [PRECAUTIONS ]

1.For in vitro diagnostic use.
2.Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used test contents.
3. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples.
4. Do not reuse the used test device or saliva swab.
5. Should never open the foil pouch of the Test Device exposing it to the ambient environment until the Test Device is ready for immediate use.
6.Discard and do not use any damaged or dropped Test Card or material.
7.Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
8.Sample collection and handling procedures require specific training and guidance.
9.To obtain accurate results, do not use visually bloody or overly viscous samples.
10.To obtain accurate results, an opened and exposed Test Device should not be used.
11.Testing should be performed in an area with adequate ventilation.
12.Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this test.
13.Wash hands thoroughly after handling.

## [PRECAUTIONS ]

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|
| IVD | In vitro diagnostic medical device | | Storage temperature limit |
| | Manufacturer | EC REP | Authorized representative in the European Community |
| | Date of Manufacture | | Use by date |
| | Do not reuse | | Consult instruction foe use |
| LOT | Batch code | CE | Meet the requirements of EC Directive 98/79/EC |

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