# Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (saliva) Package Insert

**A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS IN HUMAN SALIVA.**

**For professional In Vitro Diagnostic Use Only.**

## INTENDED USE

The Novel 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

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

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to Novel coroinavirus.

The test strip is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus; the reaction membrane contains the secondary antibodies for Novel coroinavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

When the test device was inserted into saliva sample,conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coroinavirus is present in the sample, a complex formed between the anti- Novel coroinavirus conjugate and the virus will be caught by the specific anti- Novel coroinavirus monoclonal coated on the T region.

Whether the sample contains the virus 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.

## REAGENTS

The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus; the reaction membrane contains the secondary antibodies for Novel coroinavirus,and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

## PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform test at room temperature 15 to 30°C.
- 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 bloody samples.

## STORAGE AND STABILITY

Store The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) at room temperature or refrigerated (2-30°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

## SPECIMEN COLLECTION AND PREPARATION

**1. Specimen collection:**

The oral fluid specimen should be collected using the saliva collector provided with the kit.Follow the detailed Directions for Use below.No other collection cup should be used with this assay. Oral fluid collected at any time of the day may be used.

**2. Specimen preparation:**

Take out a sample extraction tube, insert the sponge of sample collector with the saliva sample into the tube and Squeeze the wall of the extraction tube against the sponge by hand, so that the saliva in the sponge of the saliva collector flows into the extraction tube, twist close the whole cap of sample collector.

## MATERIALS

**Materials provided**

- Test device
- Saliva collector
- Extraction buffer
- Package Insert
- Nozzle
- Extraction tube

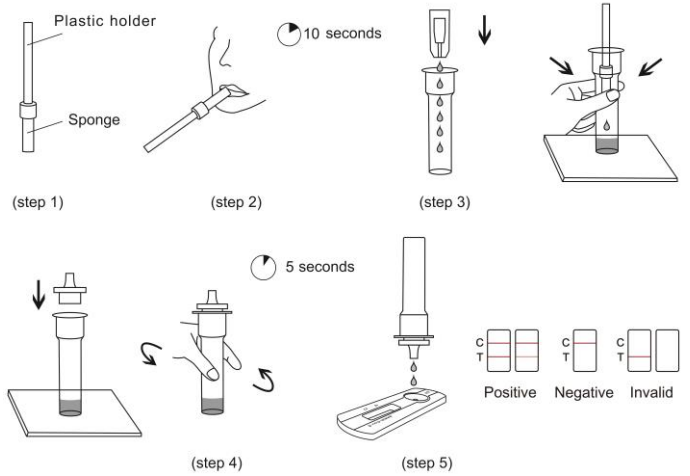
**Materials required but not provided**

- Timer

## DIRECTIONS FOR USE

**Allow the test device, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.Do not place anything in the mouth including food,drink,gum, tobacco,water and mouthwash products for at least 10 minutes prior to collection of oral fluid specimen.**

1. Open the package with the saliva collector, then remove the saliva collector from the sealed plastic bag.
2. Insert the sponge of saliva collector into the mouth, actively swab the inside of the mouth and tongue to collect oral fluid for approximately 10 seconds until the sponge becomes soft and fully saturated,The sponge will be free from hard spots when fully saturated.
3. Take out an extration tube and a bottle of extraction buffer, remove the extraction buffer bottle cap, add all the buffer into the extraction tube. Remove the collector from the mouth and put the saturated oral fluid collector into the extraction tube.
4. Squeeze the wall of the extraction tube against the sponge by hand, so that the saliva in the sponge of the saliva collector flows into the extraction tube, twist close the whole cap of sample collector.
5. Take out the saliva collector and discard it, take out a nozzle and close into the extraction tube, gently shake the extraction tube vertically for about 5 seconds to allow saliva mix well with extraction buffer.
6. 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. Put the test device on a clean and flat surface.
7. Transfer 3 drops of sample into the sample well of test device vertically, start the timer.
8. Read the result at 10~20 minutes. Don't interpret the result after 20 minutes.




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**POSITIVE:** Two red lines appear. One red line appears in the control region(C), and one red line in the test region(T). The shade of color may vary，but it should be considered positive whenever there is even a faint line.

**NEGATIVE:** Only one red line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no Novel coroinavirus particles in the sample or the number of viral particles is below the detectable range.

**INVALID:** No red line appears in the control region(C). The test is invalid even if there is a line 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## LIMITATIONS

- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) is an acute-phase screening test for qualitative detection. Sample collected may contain antigen concentration below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.
- The Novel 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 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-2.
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children List.
- The concentration of virus in saliva is greatly affected by factors such as meals, diet, smoking, breath fresheners, etc. Therefore, please strictly follow this manual before collecting samples

A negative result may occur if the concentration of antigen 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 PCR.

## PERFORMANCE CHARACTERISTICS

**Clinical Evaluation**

Clinical evaluation was performed to compare the results obtained by Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) and PCR. The results were summarized below:

Table: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) vs. PCR

| Method | | 2019-nCoV Nucleic Acid Test Kit (RT-PCR) | | Total Results |
|---|---|---|---|---|
| The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) | Results | Positive | Negative | |
| | Positive | 62 | 0 | 62 |
| | Negative | 4 | 156 | 160 |
| Total Results | | 66 | 156 | 222 |

Clinical sensitivity = 62/66= 93.94 % (95%CI*84.99% to 98.06%)

Clinical specificity =156/156＞99.9% (95%CI* 98.98% to 100%)

Accuracy: (62+156)/ (62+0+4+156) *100%=98.20% (95%CI* 95.29% to 99.46%)

*Confidence Interval

**Limit of Detection (LoD)**

| 2019-nCoV Strain Tested | Realy Tech product | | | | |
|---|---|---|---|---|---|
| Stock 2019-nCoV Concentration | 1 X $10^5$ $TCID_{50}$/mL | | | | |
| Dilution | 1/100 | 1/200 | 1/400 | 1/800 | 1/1600 |
| Concentration in Dilution tested ($TCID_{50}$/ml) | 1X$10^3$ | 5X$10^2$ | 2.5X $10^2$ | 1.25X$10^2$ | 62.5 |
| Call rates of 20 replicates near cut-off | 100(20/20) | 100(20/20) | 100(20/20) | 95(19/20) | 10(2/20) |
| Limit of detection (LoD) per Virus Strain | 1.25 X $10^2$ $TCID_{50}$/mL | | | | |

**Cross Reaction**

The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

| Virus/Bacteria/Parasite | Strain | Concentration |
|---|---|---|
| MERS-coronavirus | N/A | 72 μg/mL |
| Adenovirus | Type 1 | 1.5 x $10^6$$TCID_{50}$/mL |
| | Type 3 | 7.5 x $10^6$$TCID_{50}$/mL |
| | Type 5 | 4.5 x $10^6$$TCID_{50}$/mL |
| | Type 7 | 1.0 x $10^6$$TCID_{50}$/mL |
| | Type 8 | 1.0 x $10^6$$TCID_{50}$/mL |
| | Type 11 | 2.5 x $10^6$$TCID_{50}$/mL |
| | Type 18 | 2.5 x $10^6$$TCID_{50}$/mL |
| | Type 23 | 6.0 x $10^6$$TCID_{50}$/mL |
| | Type 55 | 1.5 x $10^6$$TCID_{50}$/mL |
| Influenza A | H1N1 Denver | 3.0 x $10^8$$TCID_{50}$/mL |
| | H1N1 WS/33 | 2.0 x $10^8$$TCID_{50}$/mL |
| | H1N1 A/Mal/302/54 | 1.5 x $10^8$$TCID_{50}$/mL |
| | H1N1 New Caledonia | 7.6 x $10^8$$TCID_{50}$/mL |
| | H3N2 A/Hong Kong/8/68 | 4.6 x $10^8$$TCID_{50}$/mL |
| Influenza B | Nevada/03/2011 | 1.5 x $10^8$$TCID_{50}$/mL |
| | B/Lee/40 | 8.5 x $10^8$$TCID_{50}$/mL |
| | B/Taiwan/2/62 | 4.0 x $10^8$$TCID_{50}$/mL |
| Respiratory syncytial virus | N/A | 2.5 x $10^6$$TCID_{50}$/mL |
| Legionella pneumophila | Bloomington-2 | 1 x $10^5$ PFU/mL |
| | Los Angeles-1 | 1 x $10^5$ PFU/mL |
| | 82A3105 | 1 x $10^5$ PFU/mL |
| Rhinovirus A16 | N/A | 1.5 x $10^6$$TCID_{50}$/mL |
| Mycobacterium tuberculosis | K | 1 x $10^5$PFU/mL |
| | Erdman | 1 x $10^5$PFU/mL |
| | HN878 | 1 x $10^5$PFU/mL |
| | CDC1551 | 1 x $10^5$PFU/mL |
| | H37Rv | 1 x $10^5$PFU/mL |
| Streptococcus pneumonia | 4752-98 [Maryland (D1)6B-17] | 1 x $10^5$PFU/mL |
| | 178 [Poland 23F-16] | 1 x $10^5$PFU/mL |
| | 262 [CIP 104340] | 1 x $10^5$PFU/mL |
| | Slovakia 14-10 [29055] | 1 x $10^5$PFU/mL |
| Streptococcus pyrogens | Typing strain T1 [NCIB 11841, SF 130] | 1 x $10^5$PFU/ml |
| Mycoplasma pneumoniae | Mutant 22 | 1 x $10^5$PFU/ml |
| | FHstrainofEatonAgent [NCTC10119] | 1 x $10^5$PFU/ml |
| | 36M129-B7 | 1 x $10^5$PFU/ml |

| | | |
|---|---|---|
| Coronavirus | 229E | 1.5 x$10^6$$TCID_{50}$/ml |
| | OC43 | 1.5 x$10^6$$TCID_{50}$/ml |
| | NL63 | 1.5 x $10^6$$TCID_{50}$/ml |
| | HKU1 | 1.5 x $10^6$$TCID_{50}$/ml |
| Human etapneumovirus (hMPV) 3 Type B1 | Peru2-2002 | 1.5 x $10^6$$TCID_{50}$/ml |
| Human Metapneumovirus (hMPV) 16 Type A1 | IA10-2003 | 1.5 x $10^6$$TCID_{50}$/ml |
| Parainfluenza virus | Type 1 | 1.5 x 106$TCID_{50}$/ml |
| | Type 2 | 1.5 x 106$TCID_{50}$/ml |
| | Type 3 | 1.5 x 106$TCID_{50}$/ml |
| | Type 4A | 1.5 x 106$TCID_{50}$/ml |

**Interfering Substances Reaction**

When tested using the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (saliva), there was no interference between the device reagents and the Potential interference substances listed in below table that would create false positive or negative results for SARS-Cov-2 antigen.

| Substance | Concentration | Substance | Concentration |
|---|---|---|---|
| Mucin | 100μg/mL | Acetylsalicylic acid | 3.0 mM |
| Whole Blood | 5% (v/v) | Ibuprofen | 2.5 mM |
| Biotin | 100μg/mL | Mupirocin | 10 mg/mL |
| Neo-Synephrine (Phenylephrine) | 5%(v/v) | Tobramycin | 10μg/mL |
| Afrin Nasal Spray (Oxymetazoline) | 5%(v/v) | Erythromycin | 50uM |
| Saline Nasal Spray | 5%(v/v) | Ciprofloxacin | 50uM |
| Homeopathic | 5%(v/v) | Ceftriaxone | 110mg/mL |
| Sodium Cromoglycate | 10 mg/mL | Meropenem | 3.7μg/mL |
| Olopatadine Hydrochloride | 10 mg/mL | Tobramycin | 100μg/mL |
| Zanamivir | 5 mg/mL | Histamine Hydrochloride | 100μg/mL |
| Oseltamivir | 10 mg/mL | Peramivir | 1mmol/mL |
| Artemether-lumefantrine | 50uM | Flunisolide | 100μg/mL |
| Doxycycline hyclate | 50uM | Budesonide | 0.64nmol/ L |
| Quinine | 150uM | Fluticasone | 0.3ng/mL |
| Lamivudine | 1 mg/mL | Lopinavir | 6μg/mL |
| Ribavirin | 1 mg/mL | Ritonavir | 8.2mg/mL |
| Daclatasvir | 1 mg/mL | Abidor | 417.8ng/mL |
| Acetaminophen | 150uM | Pooled human nasal wash | N/A |

## SYMBOLS

| 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 for use |
| LOT | Batch code | CE | Meet the requirements of EC Directive 98/79/EC |

**HANGZHOU REALY TECH CO., LTD.**
4th Floor, #12 Building, Eastern Medicine Town,
Xiasha Economic &Technology Development,
310018 Hangzhou, Zhejiang, P. R. China
**Website: www.realytech.com**

EC REP **Luxus Lebenswelt GmbH**
Kochstr.1,47877, Willich, Germany

Number:1101431601
Version:1.0
Effective Date:2020-12-15