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# Coronavirus Ag Rapid Test Cassette (Swab)

**For Rapid Detection of SARS-CoV-2**

## INTENDED USE

The Coronavirus Ag Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first ten days of symptom onset. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. Negative results from patients with symptom onset beyond ten days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. The Coronavirus Ag Rapid Test Cassette (Swab) does not differentiate between SARS-CoV and SARS-CoV-2.

## 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.

This test is for detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

## PRINCIPLE OF THE TEST

The Coronavirus Ag Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive





monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in direct nasopharyngeal (NP) swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 nucleocapsid antigen is present in the sample, a complex forms between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the test line (T) suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

## MATERIALS PROVIDED

1.20 Test Cassettes
2.2 Extraction Buffer Vials
3.20 Sterile Swabs
4.20 Extraction Tubes and Tips
5.1 Workstation
6.1 Package Insert

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock, timer, or stopwatch

## WARNINGS AND PRECAUTIONS

1.For in vitro diagnostic use only.
2.The test device should remain in the sealed pouch until use.

3.Do not use kit past its expiration date.
4.Swabs, tubes, and test devices are for single use only.
5.Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
6.Do not interchange or mix components from different kit lots.
7.Testing should only be performed using the swabs provided within the kit.
8.To obtain accurate results, do not use visually bloody or overly viscous samples.
9.Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
10.Specimens must be processed as indicated in the SPECIMEN COLLECTION and SAMPLE PREPARATION PROCEDURE sections of this Product Insert. Failure to follow the instructions for use can result in inaccurate results.
11.Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Patient swabs, used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulatory requirements.
12.Inadequate or inappropriate specimen collection and storage can adversely affect results.
13.Humidity and temperature can adversely affect results.
14.Dispose of test device and materials as biohazardous waste in accordance with federal, state, and local requirements.

## STORAGE AND STABILITY

1.The kit can be stored at room temperature or refrigerated (2-30°C).
2.Do not freeze any of the test kit components.
3.Do not use test device and reagents after expiration date.





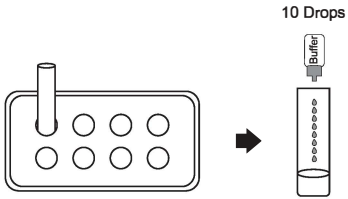
4.Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.
5.Close the kit box and secure its contents when not in use.

## SPECIMEN COLLECTION

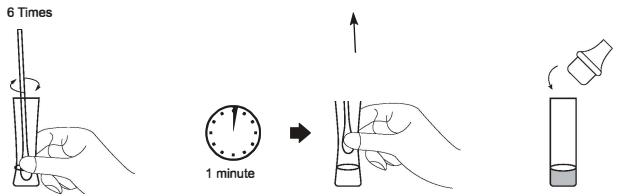
1.Using the sterile nasopharyngeal swab provided in the kit, carefully insert the swab in the patient's nostril.
2.Swab over the surface of the posterior nasopharynx and rotate the swab several times.
3.Withdraw the swab from the nasal cavity.

## SAMPLE PREPARATION PROCEDURE

1.Insert the test extraction tube into the workstation provided in the kit. Make sure that the tube is standing upright and reaches the bottom of the workstation.
2.Add 0.3 mL (approximately 10 drops) of the sample extraction buffer into the extraction tube.



3.Insert the swab into the extraction tube which contains 0.3 mL of the extraction buffer.
4.Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
5.Leave the swab in the extraction tube for 1 minute.
6.Squeeze the tube several times from the outside to immerse the swab. Remove the swab.




## SPECIMEN TRANSPORT AND STORAGE

**Do not return the nasopharyngeal swab to the original paper packaging.** Specimen should be tested immediately after collection. If immediate testing of specimen is not possible, insert the swab into an unused general-purpose plastic tube. Ensure the breakpoint swab is level with the tube opening. Bend the swab shaft at a 180 degrees angle to break it off at the breaking point. You may need to gently rotate the swab shaft to complete the breakage. Ensure the swab fits within the plastic tube and secure a tight seal. The specimen should be disposed and recollected for retesting if untested for longer than 1 hour.

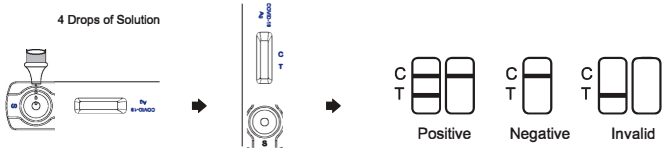
## TEST PROCEDURE

**Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.**





1.Just prior to testing remove the test device from the sealed pouch and lit it on a flat surface.
2.Push the nozzle which contains the filter onto the extraction tube. Ensure the nozzle has a tight fit.
3.Hold the extraction tube vertically and add 4 drops (approximately 100 µL) of test sample solution tube into the sample well.
4.Start the timer.
5.Read the results at 15 minutes. Do not interpret the result after 20 minutes.




## INTERPRETATION OF RESULTS

**1. POSITIVE:**
The presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.
**2. NEGATIVE:**
The presence of only control line (C) within the result window indicates a negative result.
**3. INVALID:**
If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.
**NOTE:**
1.The intensity of color in the test line region (T) may vary depending on the

concentration of analyses present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive. This is a qualitative test only and cannot determine the concentration of analytes in the specimen.

2.Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

## QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

## LIMITATIONS

1.The etiology of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test. The Coronavirus Ag Rapid Test Cassette (Swab) can detect both viable and non-viable SARS-CoV-2. The performance of the Coronavirus Ag Rapid Test Cassette (Swab) depends on antigen load and may not correlate with viral culture results performed on the same specimen.

2.Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.

3.If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of SARS-CoV-2 antigens in specimen, as they may be present below the minimum detection level of the test or if the sample was collected or transported improperly.

4.As with all diagnostic tests, a confirmed diagnosis should only be made by





a physician after all clinical and laboratory findings have been evaluated.

5.Positive test results do not rule out co-infections with other pathogens.

6.Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.

7.The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 10 of illness are more likely to be negative compared to a RT-PCR assay.

8.Negative results from patients with symptom onset beyond ten days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

9.Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

## PERFORMANCE CHARACTERISTICS

**1. Clinical Sensitivity, Specificity and Accuracy**

Clinical Performance of the Coronavirus Ag Rapid Test (Swab) was evaluated by being involved in 7 non-laboratory sites within the US, where patients were enrolled and tested. Testing was performed by 24 non laboratorian Health Care Workers that were not familiar with the testing procedure. A total of 317 fresh nasopharyngeal swab samples was collected and tested, which includes 61 positive samples and 256 negative samples. The Coronavirus Ag Rapid Test (Swab) results were compared to results of Emergency Use Authorized RT-PCR assays for SARS-CoV-2 from nasopharyngeal swab specimen. Overall study results are shown in Table 1.

**Table 1: The Coronavirus Ag Rapid Test vs PCR**

| Method | | PCR | | Total Results |
|---|---|---|---|---|
| | Results | Positive | Negative | |
| Coronavirus Ag Rapid Test Cassette (Swab) | Positive | 59 | 2 | 61 |
| | Negative | 2 | 254 | 256 |
| Total | | 61 | 256 | 317 |

Relative Sensitivity: 96.72% (95%CI*: 88.65%-99.60%) *Confidence Intervals
Relative Specificity: 99.22% (95%CI*: 97.21%-99.91%)
Accuracy: 98.74 (95%CI*: 96.80%-99.66%)

**2. Limit of Detection (LOD)**

LOD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive. Heat inactivated SARS-CoV-2 virus, with a stock concentration of $4.6\times10^5$ $TCID_{50}$ / mL, was spiked into negative specimen and serially diluted. Each dilution was ran in triplicate on the Coronavirus Ag test. The Limit of Detection of the Coronavirus Ag Rapid Test Cassette (Swab) is $1.15\times10^2$ $TCID_{50}$ / mL (Table 2).

**Table 2: Limit of Detection (LOD) Study Results**

| Concentration | No. Positive/Total | Positive Agreement |
|---|---|---|
| 1.15 x $10^2$ $TCID_{50}$ / mL | 180/180 | 100% |

**3. High Dose Hook Effect**

No high dose hook effect was observed when testing up to a concentration of 4.6 x $10^5$ $TCID_{50}$ / mL of heat inactivated SARS-CoV-2 virus.

**4. Cross Reactivity**

Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with the Coronavirus Ag Rapid Test Cassette (Swab).

| Pathogens | Concentration |
|---|---|
| Respiratory syncytial virus Type A | $5.5\times10^7$ PFU/mL |
| Respiratory syncytial virus Type B | $2.8\times10^5$ $TCID_{50}$/mL |
| Novel influenza A H1N1 virus (2019) | $1\times10^6$ PFU/mL |
| Seasonal influenza A H1N1 virus | $1\times10^5$ PFU/mL |
| Influenza A H3N2 virus | $1\times10^6$ PFU/mL |
| Influenza A H5N1 virus | $1\times10^6$ PFU/mL |
| Influenza B Yamagata | $1\times10^5$ PFU/mL |





| | |
|---|---|
| Influenza B Victoria | $1\times10^6$ PFU/mL |
| Rhinovirus | $1\times10^6$ PFU/mL |
| Adenovirus 3 | $5\times10^{7.5}$ $TCID_{50}$/mL |
| Adenovirus 7 | $2.8\times10^6$ $TCID_{50}$/mL |
| EV-A71 | $1\times10^5$ PFU/mL |
| Mycobacterium tuberculosis | $1\times10^3$ bacteria/mL |
| Mumps virus | $1\times10^5$ PFU/mL |
| Human coronavirus 229E | $1\times10^5$ PFU/mL |
| Human coronavirus OC43 | $1\times10^5$ PFU/mL |
| Human coronavirus NL63 | $1\times10^6$ PFU/mL |
| Human coronavirus HKU1 | $1\times10^6$ PFU/mL |
| Parainfluenza virus 1 | $7.3\times10^6$ PFU/mL |
| Parainfluenza virus 2 | $1\times10^6$ PFU/mL |
| Parainfluenza virus 3 | $5.8\times10^6$ PFU/mL |
| Parainfluenza virus 4 | $2.6\times10^6$ PFU/mL |
| Haemophilus influenzae | $5.2\times10^6$ CFU/mL |
| Streptococcus pyogenes | $3.6\times10^6$ CFU/mL |
| Streptococcus pneumoniae | $4.2\times10^6$ CFU/mL |
| Candida albicans | $1\times10^7$ CFU/mL |
| Bordetella pertussis | $1\times10^4$ bacteria/mL |
| Mycoplasma pneumoniae | $1.2\times10^6$ CFU/mL |
| Chlamydia pneumoniae | $2.3\times10^6$ IFU/mL |
| Legionella pneumophila | $1\times10^4$ bacteria/mL |

**5. Interfering Substance**

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the Coronavirus Ag Rapid Test Cassette (Swab) at the concentrations listed below and were found not to affect test performance.

| **Substance** | **Concentration** |
|---|---|
| Human blood (EDTA anticoagulated) | 20% (v/v) |
| Mucin | 5 mg/mL |

| | |
|---|---|
| Oseltamivir phosphate | 5 mg/mL |
| Ribavirin | 5 mg/mL |
| Levofloxacin | 5 mg/mL |
| Azithromycin | 5 mg/mL |
| Meropenem | 5 mg/mL |
| Tobramycin | 2 mg/mL |
| Phenylephrine | 20% (v/v) |
| Oxymetazoline | 20% (v/v) |
| 0.9% sodium chloride | 20% (v/v) |
| A natural soothing ALKALOL | 20% (v/v) |
| Beclomethasone | 20% (v/v) |
| Hexadecadrol | 20% (v/v) |
| Flunisolide | 20% (v/v) |
| Triamcinolone | 20% (v/v) |
| Budesonide | 20% (v/v) |
| Mometasone | 20% (v/v) |
| Fluticasone | 20% (v/v) |
| Fluticasone propionate | 20% (v/v) |

## INDEX OF SYMBOLS

| | | | | | |
|---|---|---|---|---|---|
| | Consult instructions for use | Σ | Tests per kit | EC REP | Authorized Representative |
| IVD | For *in vitro* diagnostic use only | | Use by | | Do not reuse |
| 2°C 30°C | Store between 2~30°C | LOT | Lot Number | REF | Catalog# |





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