# LordsMed Covid - 19 Antigen Rapid Test

| Catalog No. | Pack Size | Specimen Type |
|---|---|---|
| CVDLMR01 | 25 Test | Nasopharyngeal swab |
| CVDLMR02 | 50 Test | Nasopharyngeal swab |

**INTENDED USE**

LordsMed Covid 19 Ag Kit is an immuno-chromatographic assay kit for qualitative detection of SARS-nCoV-2 antigens present in the human nasopharynx , bronchial lavage, or throat swabs. This test is intended for initial screening as a professional aid to early diagnosis of SARS-nCoV-2 infection in patient with clinical symptoms suspected of SARS-nCoV- This kit is for professional use.

**TEST PRINCIPLE**

The LordsMed Covid 19 Ag Rapid Test consists of lysis buffer & test device. The swab specimen/aspirate is added into lysis buffer and mixed to lyse the viral cells to extract the nucleic acids (RNA) into buffer.

Antigen test device consists of a strip containing NCM, colloidal gold conjugate pad and sample release pad. NCM (Nitrocellulose membrane) is coated with control specific antibodies on control side (C) and SARS-CoV-2 specific monoclonal antibodies on Test side (T). Colloidal gold conjugate pad consists of control solution specific antibodies and SARS-CoV-2 specific monoclonal antibodies conjugated with colloidal gold nanoparticles. When sample (specimen & Lysis buffer mixture) is added on the sample port of test device, the sample migrates along with the colloidal gold nanoparticles. If sample contains detectable levels of Covid 19 Ag then it reacts with the conjugated monoclonal antibodies in colloidal gold particles to form antigen antibody complex. This complex then migrates on the membrane chromatographically and reacts with the coated SARS-CoV-2 monoclonal antibodies on the test line to form a test band (colored line on the test side). The unreacted complex and control specific gold particles then reacts with coated control line to form a colored band at control side. Control line shall be appeared, indicating that the proper volume of specimen has been added, right procedure and all reagents working properly.

**MATERIALS PROVIDED**

1. Test device
2. Lysis Buffer for Covid 19 Ag test
3. Sample extraction tubes for Covid 19 Ag test
4. Pack Insert
5. Nylon flocked Nasopharyngeal swab

**Materials required but not provided.**

1. Timing device

**PRECAUTIONS**

1. For in vitro diagnostic use only. Do not reuse the test device and kit components.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens and wash hands thoroughly afterwards.
4. Clean up spills thoroughly using an appropriate disinfectant.
5. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials (i.e., swab, extraction tube, test device) in a biohazard container as if they were infectious waste and dispose according to applicable local regulations.
6. Do not mix or interchange different specimens.
7. Do not store the test kit in direct sunlight.
8. To avoid contamination, do not touch the head of provided swab when opening the swab pouch.
9. The sterilized swabs should be used only for nasal specimen collection.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

**COLLECTION AND PREPARATION OF SAMPLE**

1. Do not use samples collected in viral transport media ( VTM).
2.To collect a nasopharyngeal swab specimen, take an extraction tube with 10 drops of extraction buffer. Label patient's ID using a marker. Carefully remove a sterile swab from its pack and insert the swab into the nostril of the patient , reaching the surface of the posterior nasopharynx while on the gentle rotation, push the swab ( about 7 cm for the adults or the measure of the distance between nostril and ear ) until resistance is met at the level of the turbinate and rotate the swab 3 to 4 times.
3. Remove the swab and immediately insert to the extraction buffer. Confirm the sample ID and handle according to the protocols. To collect a throat swab ( Oropharyngeal ) specimen, use a tongue depressor spatula and insert a sterile swab into the patient's throat, reaching the surface of the pharynx.
4. Rotate the swab a few times against the pharyngeal crypts and mucosa and follow .To process Broncho-alveolar samples from the lavage dipping the swab once to the well mixed fluid .
5. Specimen should be tested as soon as possible after collection. Specimen may be stored at room temperature for up to 1 hours or at 2-8 degree Celsius for upto 3 hours prior testing.

**PROCEDURE**

1. Open a test device from a foil pouch and place over a working table immediately before the test being performed. Label with sample ID.

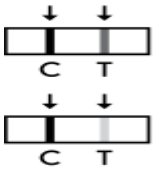
2. Add 10 drops ( Approx. 300 µl ) of lysis buffer provided in the kit in a sample extraction tube.
3. Collect the swab specimen and put in the sample extraction tube containing lysis buffer. Rotate and mix the swab specimen in lysis buffer.
4. Squeeze the sides of the tube to obtain as much liquid as possible. Dispose of swab properly.
5. Apply the cap on sample extraction tube. Use this dissolved specimen as a sample.
6. Keep device on flat surface and add 2 drops ( approx. 60µl) of sample (dissolved swab specimen in lysis buffer) by using a sample extraction tube in sample port of test device.
7. Start the timer.
8. Read results at 15 minutes. Do not read the results after 20 minutes.

**TEST INTERPRETATION (REFER TO FIGURE)**

1. Negative result: The presence of Purplish pink colour in control line (C) and absence of colour in test line (T) within the result window indicates a negative result.




2. Positive result: The presence of Purplish pink colour in test line (T) and in control line (C) within the result window, regardless of which line appears first, indicates a positive result.




Caution: The presence of any test line (T), no matter how faint, indicates a positive result.

3. Invalid result: A. If the control line (C) is not visible within the result window after performing the test, the result is considered invalid.
B. No line appears at 'C' region and line appears at 'T' region.




**LIMITATIONS**

1. Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.
2. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) will only indicate the presence of SARS-CoV-2 antigens in the specimen.
3. If the test result is negative or non-reactive and clinical symptoms persist, it is because the very early infection virus may not be detected, it is recommended to test again with a new kit or test with a molecular diagnostic device to rule out infection in these individuals.
4. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

**PERFORMANCE CHARACTERISTICS**

The results demonstrated 98.67% sensitivity and 98% specificity with an overall accuracy of 98.34%

**SENSITIVITY & SPECIFICITY**

| | Positive sample | Negative sample | Rate |
|---|---|---|---|
| Positive sample | 148 | 02 | 98.67% (Sensitivity) |
| Negative sample | 03 | 149 | 98% (Specificity) |
| Total | 151 | 151 | 98.34% (Total accuracy) |

**BIBLIOGRAPHY**

1. Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). National Health Commission & National Administration of Traditional Chinese Medicine.2020.
2. Diagnostic detection of Wuhan corona virus 2019 by real time RT-PCR.2020

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|---|---|---|---|
| REF | Catalog No | | Attention Caution |
| LOT | Batch No. | | Instruction for use |
| | Manufacturing Date | IVD | *In-vitro* Diagnostics |
| | Expiry Date | | Storage temperature |
| | Manufacturer | Σ | No. of Tests |



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