

For In Vitro Diagnostic Use

Intended Use

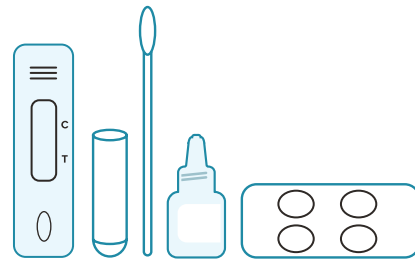
COVISTIX™ is a sensitive diagnostic test designed to detect COVID-19 virus antigens directly from a nasopharyngeal sample in 15 minutes. COVISTIX™ has been cleared for Emergency Use by healthcare professionals for the qualitative detection of SARS-CoV-2 in nasopharyngeal swab samples from patients.

For most patients, the average time to the onset of symptoms is from 5 to 6 days. Symptoms include:

- Cough
- Headache
- Shortness of breath or dyspnea
- Sore throat or new loss of taste or smell
- Fever
- Nausea
- Chills
- Vomiting or diarrhea

Materials Provided

- Test cassette
- Sample tube
- Sterile nasopharyngeal swab
- Lysis buffer (1 mL)
- Paper rack
- Quick reference guide



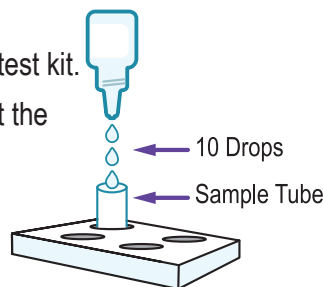
Instructions

1. Download the **COVISTIX™** App from the website (COVISTIX.COM) or your mobile phone.
2. Scan the QR code from the test kit and follow the steps for testing instructions.
3. Wash hands or apply hand sanitizer.



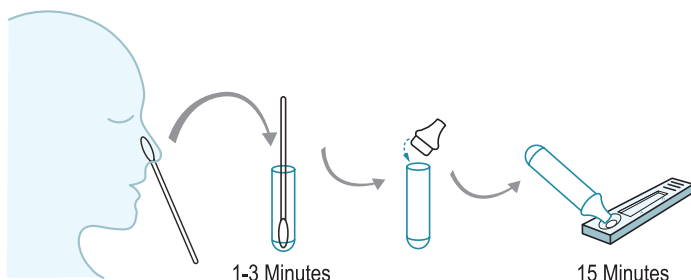
1 Setup

1. Lay out all of the items in the test kit.
2. Fold the paper rack and insert the sample tube.
3. Add 10 drops of lysis buffer to the sample tube



2 Specimen Collection

1. Remove the nasopharyngeal swab from its package. Do not touch the swab end with your hands.



2. Insert the entire absorbent tip of the swab into your nostril pharynx and push the swab until resistance is met at the level of the turbinate. Slowly rotate the swab at least 6 times against the nostril pharynx wall.
3. Using the same swab, repeat in the other nostril pharynx.
4. Transfer the swab to the sample tube containing the lysis buffer.
5. Leave the swab in the sample tube for 1-3 minutes.
6. Remove the swab from the sample tube by squeezing the outside of the sample tube with your fingers to remove as much liquid from the swab as possible and dispose properly.
7. Place the dropper in the sampling tube and put on the cap.

3

Test

1. Open the pouch, remove the test cassette, and place on a clean disinfected flat surface.
2. Set timer for 15 minutes.
3. Apply 4 drops from the sampling tube to the center of the sample well (labeled with an "S") on the cassette. Apply the drops slowly so that the liquid gets absorbed and doesn't overflow.
4. Start the timer.
5. Read results at 15-20 minutes. Do not read after 30 minutes.
6. Properly dispose of the used test cassette, sample tube, and nasal swab as medical waste.

4

Reading Results

This test contains a built-in control feature (C line) that develops after adding the specimen. The control line tells you that the test is valid. You must get a line at the C line. If no C line or only the T line appears, the test is considered invalid (you will need to retest with a new test kit). *Report results per instructions on the App.*

Invalid: If no C line or only the T line appears, the test is **invalid** (repeat).

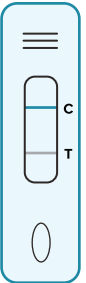


Negative:

If only the C line is visible, COVID-19 VIRUS antigen is **not detected**.

Positive:

If the C line and T line appear, COVID-19 VIRUS antigen **is detected**.



Product Information

- Description:** COVISTIX™ COVID-19 VIRUS Rapid Antigen Detection Test (Single Test) Kit, a rapid test for the detection of COVID-19 antigens in human nasal swab specimens
- Manufacturing:** In accordance with ISO 13485
- Components:**
- 1x Individually sealed foil bag containing a cassette and a desiccant
 - 1x Sample tube and cap
 - 1x Individually packaged sterile swab
 - 1x 1 mL lysis buffer bottle
 - 1x Paper rack (4-well)
 - 1x Quick Reference Guide
- Packaging:** 1 Test Kit Per Box (Dimensions 8.625" x 2.75" x 1.00")
- Storage:** Store unused test kit between 2° and 30°C. If stored at 2° to 8°C, test kit must be brought to room temperature before opening.
- Shelf Life:** 12 Months

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