CONSULT® McKESSON

Rapid COVID-19 Antigen Test

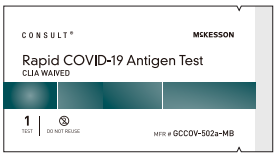
HEALTHCARE PROVIDER QUICK REFERENCE GUIDE

IVD **R_x ONLY** **CLIA Categorization: Waived**

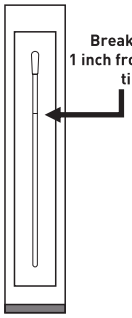
IMPORTANT

- These are not the full Instructions for Use. Refer to "Instructions for Use" for additional information. Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- The test is intended for use with nasal (anterior nares) swab specimens from individuals: suspected of having COVID-19 by their healthcare provider within the first six (6) days of symptom onset.
- Negative results are presumptive and should be confirmed with a molecular test, if necessary.
- Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals.
- All test materials must be at room temperature 59°F-86°F (15°C-30°C) before use. Do not open the Test Cassette until you are ready to perform the test.
- Wear appropriate personal protective equipment when performing this test.
- Check expiration date of each test device before use. Do not use any test past the expiration date. Refer to test device pouch or outer box labeling for expiration date.
- External Controls are required to demonstrate that the reagents and assay procedure perform properly. Refer to the Consult COVID-19 Antigen Control Kit for additional information.

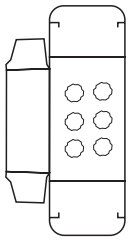
MATERIALS



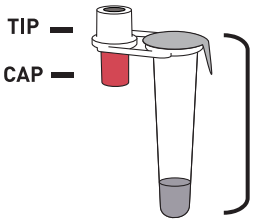
TEST CASSETTE POUCH



SWAB



TUBE HOLDER (unfolded)



TUBE (with liquid)



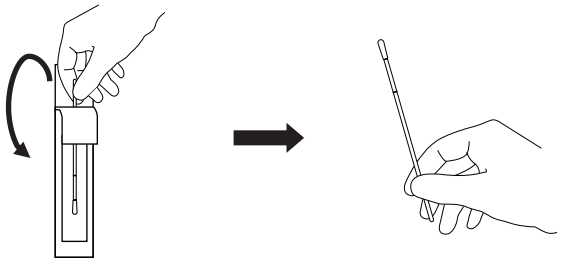
TIMER (not included)

SPECIMEN COLLECTION

See reverse side of page for TEST PROCEDURE

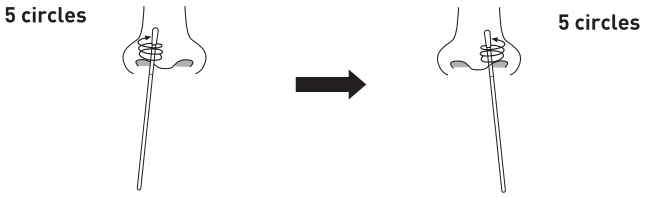
1 OPEN SWAB

Open the swab pouch by peeling the cover back. Hold the **plastic stick end** of the swab and remove from pouch. Do not touch the swab tip.



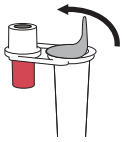
2 SWAB BOTH NOSTRILS

To collect the anterior nasal swab sample, tilt the patient's head back 70 degrees and insert the swab tip into one nostril of the patient, at about **1/2 to 3/4 inches deep**. For children and young children, swab should not be inserted more than 1/2 inch. Rotate the swab along the inside walls of nostril in a complete circle at least 5 times. Remove swab from the nostril and use the same swab to **repeat in another nostril.**



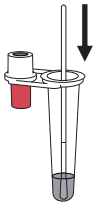
3 OPEN TUBE

While maintaining tube upright, remove seal from tube. Avoid spilling liquid.



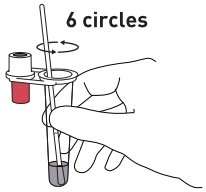
4 PLACE SWAB IN TUBE

Insert swab tip in tube opening.



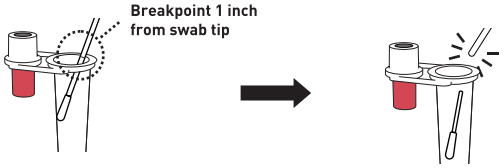
5 MIX WITH SWAB

Grab swab shaft and mix well by rolling swab in a circular motion **at least 6 times. Press the swab tip against the bottom and sides of tube while rolling swab.**



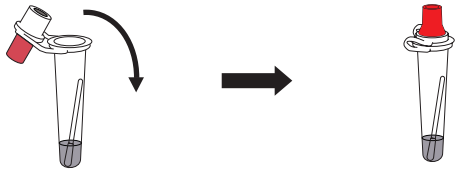
6 BREAK SWAB SHAFT

While holding the tube in your hand, place the swab's tip near the top of the tube. Gently bend the swab until it snaps at the breakpoint.



7 CLOSE TUBE

Hold tube upright. Close the flip cap of the tube tightly to ensure there is a secure fit so it does not leak. **Do not remove red cap or swab tip from tube.**

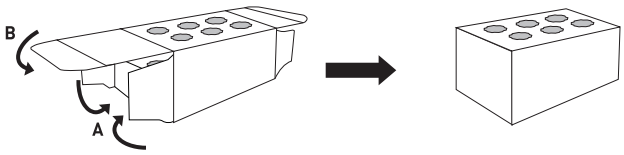


TEST PROCEDURE

See reverse side of page for **SPECIMEN COLLECTION**

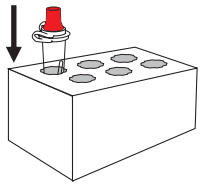
1 FOLD TUBE HOLDER

Fold tube holder by folding vertical flaps towards center **(A)**. Hold vertical flaps in place and fold horizontal flap down and inward **(B).**



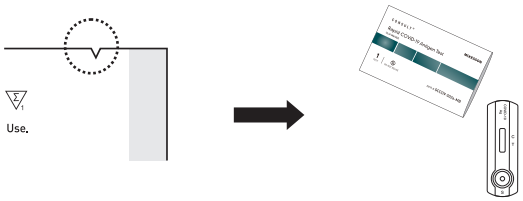
2 PLACE TUBE IN TUBE HOLDER

Allow the swab to sit in buffer tube for **at least 1 minute, but no longer than 30 minutes immediately after specimen collection.**



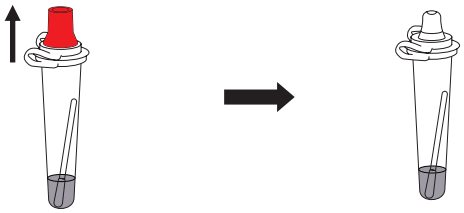
3 OPEN TEST DEVICE

Open the test cassette pouch by tearing the area circled below. Place the test device on a flat surface.



4 REMOVE CAP

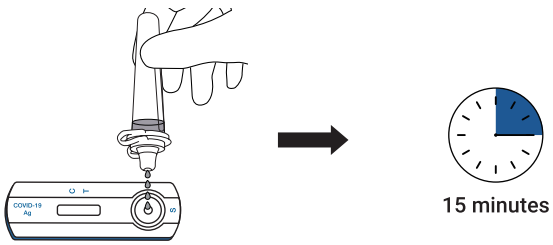
Gently remove red cap from tip. Ensure tip remains secure within tube opening.



5 ADD 4 DROPS OF SAMPLE

Invert the tube and gently squeeze, from the middle of the tube, to add **4 drops** of solution into the sample well, labeled as "S" on the test device.

Start timer for 15 minutes.



6 READ TEST RESULT

After 15 minutes find result window, labeled as "C" and "T" on the test cassette.

Do not read result after 20 minutes.

Below are results examples for positive, negative and invalid results.

External positive and negative control swabs are supplied separately as "COVID-19 Antigen Control Kit". These controls provide additional quality control material to assess that the test kit reagents perform as expected. Process the controls in the same manner as a clinical sample swab, and conduct the assay as described in "Test Procedure" section.

Used test materials should be discarded as biohazard waste according to Federal, State and local regulatory requirements.

7 RESULTS INTERPRETATION

POSITIVE

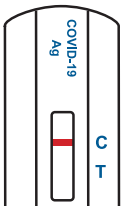
If the Control (C) line and the Test (T) line are visible, the test is positive. Any visible faint red or pink Test (T) line with a visible Control (C) line should be read as positive. Repeat testing is not needed for individuals with a positive result.



NEGATIVE

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. A negative test result indicates that the virus that causes COVID-19 was not detected in the sample.

NOTE: Negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours or followed up with a molecular test.



INVALID

If a Control (C) line is not visible, the test is not valid. Invalid tests should be repeated with a new test.



TECHNICAL SUPPORT

General Questions? Call 1-800-777-4908
Technical Support? Call toll-free 1-866-982-3818 (Monday-Friday 8:30 a.m. to 5:00 p.m. CT)

INDEX OF SYMBOLS

IVD	For *in vitro* diagnostic use only
R_x ONLY	Prescription use only

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