

Refer to the Package Insert for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test.

All clinical specimens must be at room temperature before beginning the assay.

Performing the assay outside the time and temperature ranges provided may produce invalid results.

Assays not performed within the established time and temperature ranges must be repeated.

Expiration date: Check expiration on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

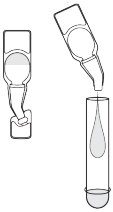
Test Procedure

1

Dispense all of the Reagent Solution into the Reagent Tube. Swirl the Reagent Tube to dissolve its contents.

NOTE:

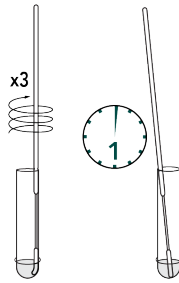
The Reagent Tube should remain in the tube holder for the entirety of the testing.



2

Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.

Leave the Swab in the Reagent Tube for one minute. Incorrect or invalid results may occur if the incubation time is too short or too long.



3

Express all liquid from the swab from the swab head by rolling the swab a minimum of 3 times as the swab is being removed.

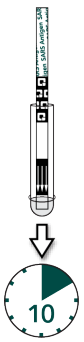
Discard the swab in accordance with your biohazard waste disposal protocol.



4

Place the Test Strip into the Reagent Tube with the arrows pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.

At 10 minutes, remove the Test Strip and read the result within 5 minutes according to the Interpretation of Results section on the other side of this card. Test strips should be read between 10 - 15 minutes.



Interpretation of Results

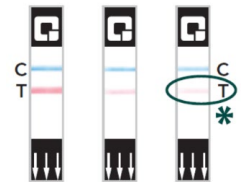
Positive Result

At 10 minutes, the appearance of **ANY shade of a pink-to-red Test Line AND** the appearance of a blue procedural Control Line indicates a positive result for the presence of SARS antigen. Results will remain stable for 5 minutes after the recommended read time. Do not read the result beyond the 5 minutes. False positive, False negative or invalid results may occur if the strip is read outside of the recommended time period.

***Look closely!** Even if you see a very faint, pink Test Line and a blue Control Line, you must report the result as POSITIVE.

A positive result does not rule out co-infections with other pathogens.

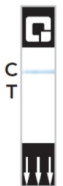
C = Control Line T = Test Line



Negative Result

At 10 minutes, the appearance of **ONLY the blue procedural Control Line** indicates SARS antigen was not detected. Results will remain stable for 5 minutes after the recommended time. False positive, false negative or invalid results may occur if the strip is read outside of the recommended time period.

A negative result does not exclude SARS-CoV-2 infection. Negative results should be treated as presumptive may need to be confirmed with a molecular assay.



Invalid Result

If at 10 minutes, the blue procedural Control Line does not appear, even if any shade of a pink-to-red Test Line appears, the result is invalid.

If at 10 minutes, the background colour does not clear and it interferes with the reading of the test, the result is also invalid.

If the result is invalid, a new test should be performed with a new patient sample and a new Test Strip.

