COVID-19 Antibody Home Test

INTENDED USE

The On/Go One COVID-19 Antibody Home Test is a qualitative, enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of the SARS-CoV-2 nucleocapsid protein in human serum or plasma. Test results are for the identification of IgG antibodies to SARS-CoV-2.

This product has been designed for the detection of SARS-CoV-2 IgG antibodies in human serum and plasma specimens. The test is intended for use by laboratory personnel. The test is not intended to be performed by non-laboratory personnel without appropriate training and supervision.

PRINCIPLE

The On/Go One COVID-19 Antibody Home Test is a qualitative sandwich ELISA for the detection of SARS-CoV-2 nucleocapsid protein. The test is performed in two steps: an incubation step and a separation step. The detection of IgG antibodies to SARS-CoV-2 is achieved using a test device that contains a membrane strip and a plastic cover. The test device is used with serum or plasma specimens and a reagent solution.

SPECIMEN COLLECTION AND PREPARATION

1. Follow the in-app self-paced, step-by-step instructions or paper instructions.
2. Punch through the perforated circle on the kit to form a tube hole.
3. Remove the foil from the top of the extraction buffer tube. Place the tube in the tube holder.
4. Immediately place the tube in boiling water for 30 seconds.
5. Rotate the swab 5 times before squeezing the tube.
6. Remove the swab while squeezing the tube to extract as much liquid as possible. Dispose the swab in the trash.
7. Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube. The test is valid if the negative control (C) line is visible and a visible color change occurs in the test line (T).
8. Set the timer for 15 minutes. Result should be read at 15 minutes. Do not read after 30 minutes. Dispose the test cassette in the trash.
9. Note: A false negative or false positive result may occur if the test result is read before or after 15 minutes or rotated 5 times.

INTERPRETATION OF RESULTS

The test results will be interpreted by visual reading following the in-app interpretation instructions or provided paper instructions.

NEGATIVE:

Only the control line (C) and test line (T) appears. This means that no SARS-CoV-2 antigen was detected. A negative result indicates that the individual may not have had COVID-19. You may continue to experience COVID-19 related symptoms (i.e., headache, fatigue, runny nose), which may persist beyond the window of detectability of the test.

The test can only be used to help identify COVID-19. It does not provide information on whether an individual’s immune system has produced antibodies to SARS-CoV-2. A negative test result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests than with antibody-based tests. False positive results are less common but may occur.

The test cassette should be used only for the detection of SARS-CoV-2 antibodies as specified in Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

POSITIVE:

Two distinct red lines appear. One red line in the control line region (C) and the other red line in the test line region (T). The test is positive. Test results that indicate that COVID-19 was present at some time in the past.

**Note:** A false positive result may occur if the test is used at temperatures below 36-37°C (96-99°F) or above 38°C (100°F).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Control line (C) fails to appear. Not enough specimen volume or incorrect operation are the likely reasons for an invalid test result. If a control line (C) is not visible, the test is invalid. Re-test with a new specimen.

VALID: All three lines appear. The test is valid. Test results are considered valid for 30 days from the date of the last test.

**Note:** The red shade in the test line region (T) may vary depending on the level of SARS-CoV-2 antigen present in the specimen. Therefore, any shade of red in the test line region (T) should be considered positive.
LIMITATIONS
1. The OnGo One COVID-19 Antigen Home Test is for in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in anterior nasal swab specimens only. The intensity of the test line does not necessarily correlate to the concentration of the virus in the specimen.
2. Specimens should be tested as quickly as possible after specimen collection.
3. A false-negative or false-positive result may occur if the test is performed incorrectly or if the test kit is not properly stored.
4. A false-negative result may occur if the level of antigen in a sample is below the detection limit of the test.
5. A false-negative result may occur if the sample was collected incorrectly or handled improperly.
6. A false-negative result may occur if the swab is not inserted at least 30 seconds or rotated five times.
7. A false negative or invalid result may occur if less than 4 drops of fluid are added to the Sample Well.
8. A false-negative or false-positive result may occur if the test plate reaches 15 minutes or after 30 minutes of development.
9. This test detects both viable (live) and non-viable, SARS-CoV-2, and SARS-CoV-2. Test performance depends on the amount of virus in the sample and may not reflect the results performed on the same sample.
10. The OnGo One COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.
11. Test results should be correlated with other clinical data available to the physician.
12. A positive or negative test result does not rule out COVID-19 and it may be necessary to obtain additional testing with a molecular assay for patient management.
13. All results are presumptive in asymptomatic individuals.
14. A negative result is not intended to rule out viral or bacterial infections.
15. If the differentiation of specific SARS viruses and strains is needed, additional testing is required, in consultation with state or local public health departments, if required. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March and May 2021. Clinical performance has not been established with all circulating variants, but is based on the evaluation of a limited number of clinical specimens collected between March and May 2021.
16. Cross-reactivity of the test is likely with related coronaviruses and with some viruses that are similar in structure or function.
17. Cross-reactivity with other viruses or antigens may occur as related coronaviruses and with some viruses that are similar in structure or function.
18. No high dose hook effect was observed when tested with up to a concentration of 1.0 x 10^6 TCID50/mL of heat-inactivated SARS-CoV-2 virus (USA-WA1/2020) with the OnGo One COVID-19 Antigen Home Test.

OnGo One COVID-19 Antigen Home Test was not affected by any of the potentially interfering substances listed in the table below at the concentrations tested.

BIBLIOGRAPHY

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, in silico analysis was used to assess the degree of protein sequence homology. The comparison between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 revealed a low homology of 38.3% across 82.8% of the SARS-CoV-2 nucleocapsid sequence. The result suggests that cross-reactivity with human coronavirus will be unlikely.

Comparison of the homology between the SARS-CoV-2 nucleocapsid protein and the structural protein of SARS-CoV revealed an even higher degree of cross-reactivity in the subunit. A high probability of cross-reactivity between the nucleocapsid proteins of SARS-CoV-2 and SARS-CoV. The OnGo One COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal or respiratory tracts, were evaluated. In addition to the materials that are found in the nasal cavity, substances that are commonly found on the hands were also tested. Each substance was tested in the absence or presence of SARS-CoV-2 virus (USA-WA1/2020) at a low concentration. The performance of