Status™ COVID-19 Antigen Rapid Test for Home Use

Rapid Immunoassay for Direct Detection of SARS-CoV-2 Antigen

Healthcare provider instructions for use

For use with anterior nasal specimens

For in vitro Diagnostic Use

For Emergency Use Authorization (EUA) Only

Catalog No.	1 Test Kit	33301
	2 Test Kit	33302
	25 Test Kit	33325

Intended Use

The ***Status*™ COVID-19 Antigen Rapid Test for Home Use** is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult-collected anterior nasal (nares) swab samples from individuals aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The ***Status*™ COVID-19 Antigen Rapid Test for Home Use** does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with the ***Status*™ COVID-19 Antigen Rapid Test for Home Use** should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The ***Status*™ COVID-19 Antigen Rapid Test for Home Use** is intended for non-prescription self-use and/or, as applicable an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The ***Status*™ COVID-19 Antigen Rapid Test for Home Use** is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

Summary and Explanation of the Test

COVID-19 (short for 'Coronavirus Disease 2019') is a disease first recognized in 2019 that is caused by a type of novel coronavirus called SARS-CoV-2. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020. Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

The ***Status*™ COVID-19 Antigen Rapid Test for Home Use** is a lateral flow immuno-chromatographic assay that is designed to detect nucleocapsid antigen from the SARS-CoV-2 virus in anterior nares (AN) nasal swab samples from those who are suspected of COVID-19 within the first 5 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested at least three times over five days with at least 48 hours between tests. The ***Status*™ COVID-19 Antigen Rapid Test for Home Use** is validated for use with direct specimens without transport media. In the test procedure, anterior nares (AN) nasal swab specimen is collected and placed into the extraction reagent in the Extraction Well of the test device for one minute. During this time, the antigen is extracted from disrupted virus particles. The test device is then raised to stand up for a few seconds and laid back down onto a level surface. Through this simple action, the solution of extracted specimen flows onto the test strip and migrates through the pads and membrane of the test strip. The pads contain detector antibodies conjugated to gold dye and the membrane contains immobilized capture antibodies. If SARS-CoV-2 antigens are present in the specimen, they will react with anti-SARS-CoV-2 antibodies coupled to gold dye particles and migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized capture antibody line on the membrane, and generate a colored line in the specific test line position (CoV19). The rest of the sample and unbound/bound dye complexes continue to migrate to the Control line position (Ctrl), where immobilized antibodies to the anti-SARS-CoV-2 antibodies capture the dye complexes to form the Control line. Formation of the Control line serves as an internal control to demonstrate that test reagents are functional, antibody-dye conjugates in the dye pad have been hydrated and released, and sufficient sample solution has been applied to allow for migration through the Test (CoV19) and Control (Ctrl) lines. If the Control line (Ctrl) does not appear within the designated incubation time, the result is invalid, and the test should be repeated using a new test device and specimen.

***Status*™ COVID-19 Antigen Rapid Test for Home Use** has one Test line (CoV19) for SARS-CoV-2, and one Control line (Ctrl). If the Test line appears in the test result window, together with the Control line, the test result is positive for SARS-CoV-2.

Materials Provided

- ***Status*™ COVID-19 Antigen Rapid Test for Home Use** device; individually pouched
- Extraction reagent in capsule
- Sterile Swab in wrapper; for anterior nasal sample collection
- Instructions for Use (IFU)
- Quick Reference Guide (QRG)

NOTE: This test comes in a 1 test, 2 test, and 25 test quantity. The number of items supplied in the kit will vary depending on which kit was purchased.

Test Kit	Quantity Included in Kit Box			
	Test Device	Extraction Reagent Capsules	Sterile Swab in Wrapper	QRG
1 Test	1	1	1	1
2 Test	2	2	2	1
25 Test	25	25	25	1

Materials Required but not Provided

- Timer

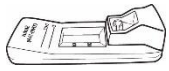
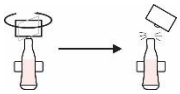
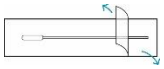
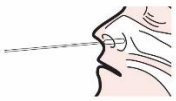
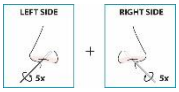
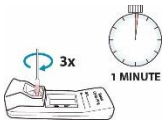
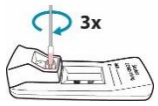
Quality Control

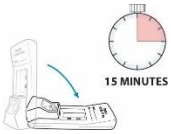
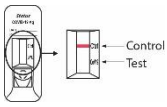
Each ***Status*™ COVID-19 Antigen Rapid Test for Home Use** has a built-in internal procedural control. The pink/purple line appearing at the "Ctrl" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred. A distinct pink/purple Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid, and a new test should be performed using a new sample and new test kit.

External run controls are not required to use the ***Status*™ COVID-19 Antigen Rapid Test for Home Use** in a home setting.

Test Procedure

- The test procedure must be followed to obtain accurate and reproducible results.
- Reagents, specimens, and devices must be at room temperature (18-30°C/64.4-86°F) for testing.
- Do not open the foil pouch until you are ready to test.
- Check expiration date printed on the test.
- Wash your hands with soap and water or use hand sanitizer and dry thoroughly.
- Place test device on a level surface.

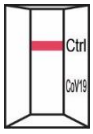
Prepare Test		Open the foil pouch and remove the test device and lay it on flat surface.
Open reagent capsule		Twist the tab at the top.
Add reagent		Hold the capsule directly over the Extraction Well and squeeze all of the reagent into the well. Discard the empty capsule in the trash. Warning: False negative results may occur, if all sample extraction reagent is not added to the well or spilled during the addition to the sample well. Do not touch the result window or the sample well of the test device.
		Do not add sample to the rectangular result window.
Open swab		Open the swab wrapper at the stick end. Be careful not to touch the swab tip.
Swab nostrils	 	Holding the stick end of the swab, gently insert the foam tip into the nostril no more than 1/2-3/4 in. Slowly rotate the swab in a circular motion 5 times by firmly pressing against the inside walls of the nostril. Do not just spin the swab. Gently remove the swab and repeat in the second nostril using the same swab. Warning! Inaccurate test results may occur if the nasal swab specimen is not properly collected. Note: A nasal swab sample can be self-collected by persons aged 14 and older. Children aged 2-13 should be tested by an adult. With children, you may need another person to steady the child's head while swabbing. Please wear a face mask when swabbing others.
Insert swab tip		Insert the swab tip into the Swab Stand in the Extraction Well where you previously added the reagent.
Rotate swab		Rotate the swab 3 times to mix the sample. Leave the swab in place. Set a timer for 1 minute. Warning! Results may be inaccurate if the swab is not rotated and left in place for 1 minute.
Rotate swab again		After 1 minute, rotate the swab 3 times again. Discard the swab in the trash.

Raise device to stand		Slowly raise the device to stand upright and let stand for 3 seconds. The solution will flow into the hole in the Test well. Failure to let the device stand upright for 3 seconds may result in an invalid result. Warning! If any reagent spills out of the test device, the test will be invalid, and you will need to perform another test.
Lay device down		Slowly lay the device back down on the flat surface and set a timer for 15 minutes. Do not move the device during this time.
Read test results at 15 minutes		Warning! Results may be inaccurate if read before 15 minutes or after 20 minutes. Look at the Result Window and locate the Ctrl and the CoV19 on the side of the window. A pink/purple color line should always appear at the C position. This is a control line and shows that the test is working properly.

Interpretation of Results

Do not read results before 15 minutes or after 20 minutes. Inaccurate test interpretation may occur.

Negative Result



If the Control (Ctrl) line is visible, but the Test (CoV19) line is not visible, the test is negative.

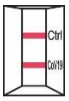
To increase the chance that the negative result for COVID-19 is accurate, you should:

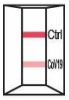
- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

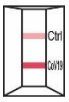
A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Positive Result







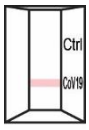
If the Control (Ctrl) line and the Test line (CoV19) line are visible, the test is positive. Any faint visible [color] test (CoV19) line with the control line (Ctrl) should be read as positive.

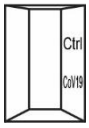
Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the ***Status***™ **COVID-19 Antigen Rapid Test for Home Use** should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID- 19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Invalid Result





If the control (Ctrl) line is not visible at 15 minutes, the test is invalid. Re-test with a new swab and new test device.

Serial Test Results Interpretation

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on first day of testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Warnings, Precautions and Safety Information

- Read the Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing. If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.**
- If you skip a step or perform a step incorrectly, discard the test device, start over with a new test and make sure to perform all steps correctly.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-coverings when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single-use. Do not reuse.
- Do not touch the swab tip.
- Inaccurate results may occur if used hand sanitizer cream lotion at more than 1.5 % v/v concentration)
- Leave the test device sealed in its pouch until just before use. Once opened, the test device should be used within 60 minutes.
- This test may give false negative results when tested in conditions of <15% humidity.
- Do not use the test after the expiration date shown on the external packaging.
- Ensure that there is sufficient lighting for testing and interpretation.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- The use of some hand sanitizer lotions may affect the results of the test. Please ensure your hands are dry before performing the test.
- Remove any piercings from the nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.

  Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit component. The Reagent Solution contains a harmful chemical (see table below). If contact with the body occurs, flush with a copious amount of water. **If irritation persists, seek medical advice. https://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name	GHS Code for each Ingredient	Concentration
Sodium Azide	H300, Harmful if swallowed H310, Skin irritation	0.09 %
Triton X-100	H302, Harmful if swallowed, H315, Causes skin irritation, H318, Causes serious eye damage, H410, Very toxic to aquatic life with long-lasting effects	0.2%

- For more information on EUAs please visit: "https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization"
- For the most up to date information on COVID-19, please visit:: "http://www.cdc.gov/COVID19"

Storage and Stability

- ***Status*™ COVID-19 Antigen Rapid Test for Home Use** should be stored between 2 to 30°C (36 to 86°F).
- Kit components are stable until the expiration date printed on the label.
- The Test Device must remain in the sealed foil pouch until use. Once the pouch has been opened, the test device should be used within 60 minutes.
- Test samples immediately after collection.

Limitations

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January 2023 – February 2023. The clinical performance has not been established for all

circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS- CoV-2 and their prevalence, which change over time.

- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19; however, additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- These test results are shown as lines of color. Because these lines can be very faint, users with conditions affecting their vision – such as far-sightedness, glaucoma, or color blindness – are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

Clinical Evaluation

A prospective study was completed at three (3) sites in the United States for clinical validation of the ***Status*™ COVID-19 Antigen Rapid Test for Home Use** for the detection of the SARS-CoV-2 in subject-collected anterior nasal (AN) swab samples. The study evaluated the investigational test's performance in symptomatic individuals (those suspected of COVID-19). A total of 273 evaluable symptomatic subjects were enrolled, and each were currently experiencing symptoms associated with COVID-19, within 5 days of symptom onset. Each enrolled subject either self-collected one sample from the anterior nares (AN) or had one sample collected from him/her by another individual. Each subject then had a mid-turbinate nasal swab sample collected from him/ her by one of the study personnel. Test results from the ***Status*™ COVID-19 Antigen Rapid Test for Home Use** were compared to highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assays to determine test performance. Test results from the ***Status*™ COVID-19 Antigen Rapid Test for Home Use** are compared to the results generated from the comparator in the table below. As shown, the positive percent agreement (PPA) is 88.0% and the negative percent agreement is 100% with the 95% confidence interval bounds of 76.2% to 94.4% for the PPA and 98.3% to 100% for the NPA, respectively.

Table 1. Status™ COVID-19 Antigen Rapid Test for Home Use Test results vs. Comparator results

		Comparator		
		Positives	Negatives	Total
***Status*™ COVID-19 Antigen Rapid Test for Home Use**	Positives	44	0	44
	Negatives	6	223	229
	Total	50	223	273
	Positive Percent Agreement (PPA) = (44/50) x 100% = 88.0% (95% CI = 76.2 to 94.4%)			
	Negative Percent Agreement (NPA) = (223/223) x 100% = 100% (95% CI = 98.3 to 100%)			

This table shows the distribution of samples tested across days post symptom onset.

Table 2. Clinical Performance in Subjects on Different Symptomatic Days

Days of COVID-19 Symptoms	Total Number of Specimens Tested	Status™ COVID-19 Antigen True Positives	Comparator (RT-PCR) Positives	PPA
Day 0	2	0	0	NA
Day 1	48	13	14	92.9%
Day 2	91	9	13	69.2%
Day 3	83	13	14	92.9%
Day 4	44	8	8	100%
Day 5	5	1	1	100%
Total	273	44	50	88.0%

Serial testing for SARS-CoV-2

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing. Performance of the antigen test with serial testing in individuals is described in Table below.

Table 3. Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the

course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97	35/89	44/78	34/57	47/51	44/47
	(9.3%)	(39.3%)	(56.4%)	(59.6%)	(92.2%)	(93.6%)
2	17/34	23/34	25/32	58/62	59/60	43/43
	(50.0%)	(67.6%)	(78.1%)	(93.5%)	(98.3%)	(100%)
4	16/21	15/20	13/15	55/58	53/54	39/40
	(76.2%)	(75.0%)	(86.7%)	(94.8%)	(98.1%)	(97.5%)
6	20/28	21/27	16/18	27/34	26/33	22/27
	(71.4%)	(77.8%)	(88.9%)	(79.4%)	(78.8%)	(81.5%)
8	13/23	13/22	4/11	12/17	12/17	7/11
	(56.5%)	(59.1%)	(36.4%)	(70.6%)	(70.6%)	(63.6%)
10	5/9	5/8		4/9	3/7	
	(55.6%)	(62.5%)		(44.4%)	(42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

Performance Characteristics

Analytical Sensitivity: Limit of Detection (LoD)

The Limit of Detection (LoD) of ***Status*™ COVID-19 Antigen Rapid Test for Home Use** was determined using serial dilutions of the gamma irradiated SARS-CoV-2 (USA-WA1/2020). 50 µL of the spiked sample preparation was pipetted onto the swab that was then processed per IFU. The LoD was confirmed as the lowest concentration of SARS-CoV-2 that was detected >95% of the time (i.e., concentration where 19 out of 20 test results were positive). The confirmed LoD for the ***Status*™ COVID-19 Antigen Rapid Test for Home Use** was 7.90×10^2 $TCID_{50}$/mL. Based upon the testing procedure for this study, the LoD of 7.90×10^2 $TCID_{50}$/mL equates to 39.5 $TCID_{50}$/swab.

NIH/RADx® Variant Testing

The performance of this test device in detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx team using clinical pooled samples from currently circulating Omicron strains and tested by RADx® to access performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the ***Status*™ COVID-19 Antigen Rapid Test for Home Use** detected 100% of live virus Omicron samples at a Ct-value of 27.3 (n=20), and 25 % of live virus Omicron samples at Ct-value of 28.7 (n=5). Testing was also compared to two additional EUA authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct- values greater than 30.1) were not detected by ***Status*™ COVID-19 Antigen Rapid Test for Home Use** in this study.

Table 4. Detection of serial dilutions of SARS-CoV-2 Omicron Live Pool with the ***Status*™ COVID-19 Antigen Rapid Test for Home Use**

Omicron Live Pool (LabCorp Samples)	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	*Status*™ COVID-19 Antigen Rapid Test for Home Use Percent Positive (n=20)
BA.5 Dilution 1	19.9	100	100	100 (20/20)
BA.5 Dilution 2	21	100	100	100 (20/20)
BA.5 Dilution 3	22.3	100	100	100 (20/20)
BA.5 Dilution 4	23.4	100	100	100 (20/20)
BA.5 Dilution 5	25	100	100	100 (20/20)
BA.5 Dilution 6	26.6	100	100	100 (20/20)
BA.5 Dilution 7	27.3	0	60	100 (20/20)
BA.5 Dilution 8	28.7	0	0	25 (5/20)
BA.5 Dilution 9	30.1	0	0	0
BA.5 Dilution 10	31	0	0	0
BA.5 Dilution 11	32.1	0	0	0

High-dose hook effect

The ***Status*™ COVID-19 Antigen Rapid Test for Home Use** was tested up to 7.90×10^5 $TCID_{50}$/mL of gamma irradiated SARS-CoV-2 (USA-WA1/2020) and no high-dose hook effect was observed.

Endogenous Interfering Substances

The interference study was performed for the potentially interfering substance that may be present un an upper respiratory tract specimen. The positive (3 x LoD SARS-CoV-2) and negative samples were teste with the addition of potentially interfering substances. The performance of ***Status*™ COVID-19 Antigen Rapid Test for Home Use** was not affected by any of the potentially interfering substances listed in the table below at the concentrations tested.

Potentially Interfering Substance	Concentration Tested
Human Whole Blood (EDTA tube)	4% v/v
Mucin (porcine stomach, type II)	0.5%
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Naso GEL (NeilMed)	5% v/v

Potentially Interfering Substance	Concentration Tested
Nasal Drops (Phenylephrine)	15% v/v
Nasal Spray (Oxymetazoline)	15% v/v
Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Homeopathic Nasal Wash (Alkalol)	10% v/v
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 µg/mL
Mupirocin	10 mg/mL
Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Fluticasone Propionate	5% v/v
Body & Hand Lotion	0.5% w/v
Body Lotion, with 1.2% Dimethicone	0.5% w/v
Hand Lotion	5% w/v
Hand Sanitizer with Aloe, 62% Ethyl Alcohol	5% w/v
Hand Sanitizer Cream Lotion	1.5% v/v
Hand Sanitizer, 80% Ethanol, Fast Drying	15% v/v
Hand Soap Liquid Gel	10% w/v

Analytical Specificity: Cross-reactivity and Microbial interference

Cross-reactivity and interference studies were performed for related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in a clinical specimen from the nasal cavity. Each organism and virus was tested in both the absence and presence of gamma irradiated SARS-CoV-2 at 3 X LoD. All targeting samples were prepared in pooled negative nasal wash. No cross reactivity or interference was observed at the concentration tested as shown in the table below.

Organism	Concentration Tested for Cross Reactivity/Microbial Interference
Human coronavirus 229E	1.43 x 10^5 $TCID_{50}$/mL
Human coronavirus OC43	8.50 x 10^4 $TCID_{50}$/mL
Human coronavirus NL63	5.85 x 10^4 $TCID_{50}$/mL
SARS-coronavirus	7.90 x 10^0 $TCID_{50}$/mL
MERS-coronavirus	1.00 × 10^6 $TCID_{50}$/mL
Adenovirus	1.43 x 10^5 $TCID_{50}$/mL
Human metapneumovirus 4 Type B2	1.43 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 1	1.43 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 2	1.43 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 3	1.43 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 4b	1.43 x 10^5 $TCID_{50}$/mL
Influenza A (H1N1)	1.43 x 10^5 $CEID_{50}$/mL
Influenza B	1.43 x 10^5 $CEID_{50}$/mL
Enterovirus 68	1.43 x 10^5 $TCID_{50}$/mL
Respiratory syncytial virus	1.00 x 10^5 PFU/mL
Rhinovirus	1.43 x 10^5 $TCID_{50}$/mL
Haemophilus influenzae	1.00 x 10^6 CFU/mL
Streptococcus pneumonia	1.00 x 10^6 CFU/mL
Streptococcus pyogenes	1.00 x 10^6 CFU/mL
Candida albicans	1.00 x 10^6 CFU/mL
Bordetella pertussis	5.00 x 10^3 CFU/mL
Mycoplasma pneumonia	1.00 x 10^6 CFU/mL
Chlamydia pneumoniae	1.00 x 10^6 IFU/mL
Legionella pneumophila	1.00 x 10^6 CFU/mL
Mycobacterium tuberculosis	1.00 x 10^6 CFU/mL
Pneumocystis carinii	1.00 x 10^6 Nuclei/mL
P. jiroveci-S. cerevisiae	1.00 x 10^6 CFU/mL
Staphylococcus aureus subsp. Aureus	1.00 x 10^6 CFU/mL
Staphylococcus epidermidis	1.00 x 10^6 CFU/mL
Pooled Negative Wash	N/A

Assistance

If you have any questions regarding the use of this product, please contact LifeSign's Technical Support via email: technical@lifesignmed.com, or via phone: 1-800-526-2125.

Test system problems may also be reported to the FDA using the MedWatch reporting system (phone: 1-800 FDA-1088; fax: 1-800 FDA-1078; or http://www.fda.gov/medwatch).

Index of Symbols

Manufacturer	Catalogue number
Contains sufficient for <n> tests	Use-by date
Temperature limit	Batch code
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