Speedy Swab Rapid COVID-19 Antigen Self-Test

Healthcare Provider Instructions for Use

For in vitro diagnostic use
For use with anterior nasal swab specimens
For use under an Emergency Use Authorization (EUA) Only

Intended Use

The **Speedy Swab Rapid COVID-19 Antigen Self-Test** is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

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 6 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 **Speedy Swab Rapid COVID-19 Antigen Self-Test** 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 definite cause of disease. Individuals who test positive with the **Speedy Swab Rapid COVID-19 Antigen Self-Test** 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 **Speedy Swab Rapid COVID-19 Antigen Self-Test** is intended for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years of age or older in a non-laboratory setting. The **Speedy Swab Rapid COVID-19 Antigen Self-Test** is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved."

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. Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection to severe respiratory illness and even death. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

The Speedy Swab Rapid COVID-19 Antigen Self-Test is a rapid, qualitative immunochromatographic assay for the determination of the presence of SARS-CoV-2 antigens in anterior nasal swab specimens. The test strip in each device contains mouse monoclonal capture antibodies to the nucleocapsid protein (NP) of SARS-CoV-2 and goat anti Chicken IgY control antibody immobilized in the test and control regions on the nitrocellulose membrane, respectively. The conjugate pad is coated with colloidal gold conjugated SARS-CoV-2 antibody and colloidal gold conjugated chicken IgY. Once the extracted specimen is added in the sample well of the test card, it migrates chromatographically on the membrane by capillary action. The formation of the specific antibody-antigen conjugate complex Au-chicken IgY- Goat anti Chicken IgY is visualized by the presence of a colored band in the control region, which validates the test results. If SARS-CoV-2 nucleocapsid antigen is present in a specimen, the specific antibody antigen colored conjugate complex (Au-SARS-CoV-2-Ab)-(SARS-CoV-2-Ag)-(SARS-CoV-2-Ab) is formed and a distinct color band in the test region is observed. Absence of this colored band in the test region indicates a negative result (when the control band is present).

Materials Provided

The components supplied with the different test configurations are as follows:

Component Name	Description	Kit Configurations Number of Test Units/Box			
		1	**2**	**4**	**25**
Test Card	Cartridge containing the test strip in a sealed foil pouch with desiccant	1	2	4	25
Buffer Solution	Vial with reagent used to extract the sample	1 x 300 µL	2 x 300 µL	4 x 300 µL	25 x 300 µL
Sterile Swab	Individually packaged disposable sterile swab used to collect nasal specimen	1	2	4	25
Test Tube	Empty specimen extraction tube used to pour sample extraction solution, add specimen collected with swab and extract specimen	1	2	4	25
Dropper Top	Cap to close tube and allow for specimen transfer to test card	1	2	4	25
Tube Holder	Marked hole in the front of the kit box where the test tube is pressed in place	1	2	4	25
IFU	Instructions for Use	1	1	1	1

Materials Required but not Provided

- A timer: required to determine the time to read the test results after addition of the extracted specimen to the test card.
- Personal protective equipment: mask (if swabbing others) and gloves.

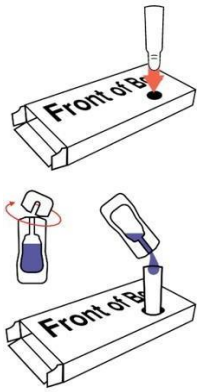
Quality Control

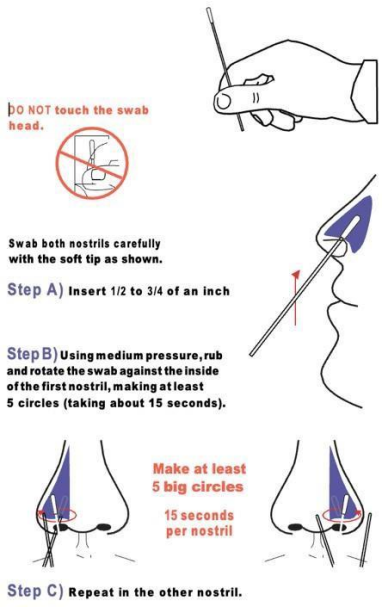
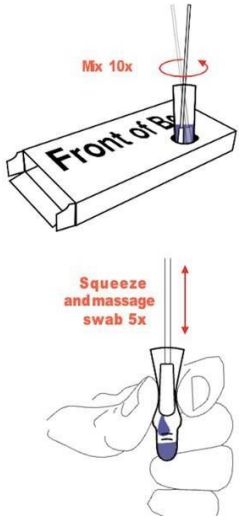
Each Speedy Swab Rapid COVID-19 Antigen Self-Test has a built-in internal procedural control. The reddish/pink line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred. A distinct reddish/pink Control line should always 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 swab and new test kit.

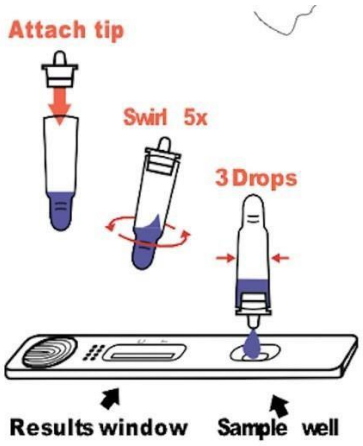
External run controls are not required to use the Speedy Swab Rapid COVID-19 Antigen Self-Test in a home setting.

Test Procedures

Steps outlining the test are as follows:

Speedy Swab Rapid COVID-19 Antigen Self-Test Steps		
Prepare the Materials		**NOTE:** Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples. It is recommended that gloves are used during testing. A face mask should be worn if swabbing others. Avoid exposure of your skin, eyes, nose or mouth to the solution in the tube. Ensure all test components are at room temperature before use Press the test tube into the marked hole on the front of the box. Twist the top off the buffer solution and pour all of it into the test tube. If any liquid spills and does not enter into the tube, discard test kit, and re-start test using a new test kit.

Speedy Swab Rapid COVID-19 Antigen Self-Test Steps		
Collect the Sample		Open swab package from its stick end and remove the swab from this end. **DO NOT** touch the swab head or lay the swab on any surface. Swab both nostrils carefully using the sterile swab provided in kit. Insert the swab ½ to ¾ of an inch. **DO NOT** insert the swab any farther if you feel any resistance. Using medium pressure, rub and rotate the swab against the inside of the nostrils, making at least 5 circles in each nostril (taking about 15 seconds per nostril). For test accuracy, make sure to collect sample from both nostrils. **NOTE**: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than 1/2 of an inch. For very young children, you may need another person to steady the child's head while swabbing.
Insert swab into extraction buffer, mix, extract and remove swab		Completely immerse the swab tip in the solution and mix well by rotating at least 10 times with one hand while holding the box with the other. Be sure to mix thoroughly. While holding the swab stable in the liquid, take the test tube out of the box. Raise the swab tip out of the buffer, holding it in place within the side walls of the tube, and squeeze the tube **5 times** to remove as much of the liquid from the swab as possible. Discard the swab.

Speedy Swab Rapid COVID-19 Antigen Self-Test Steps		
Cap buffer and apply sample on card		Push the dropper tip securely into the tube, swirl 5 times and gently squeeze 3 drops into the sample well on the test card. **DO NOT** add sample to the rectangular results window. **DO NOT** touch the result window or the sample well of the test device. Squeeze only 3 drops. Do not squeeze all the solution out of the tube. Sample volume other than the recommended amount may interfere with test performance, potentially yielding an inaccurate result.
Wait Time & Read Result		Set the timer and read the test result at 15 minutes. **DO NOT** disturb the card during this time. Inaccurate results can occur if the card is disturbed/moved or test results are read before 15 minutes. Do not interpret test results after 30 minutes. **NOTE:** False positive or false negative results could occur if results are read before 15 minutes or after 30 minutes.

1.3 Interpretation of Results

Test results are read and interpreted visually. Read results at 15 minutes with good lighting. WARNING: Do not read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.

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.

1. Positive result:

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red test (T) line with the control line (C) should be read as positive.

You do not need to perform repeat testing if you have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and 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).

2. **Negative result:**

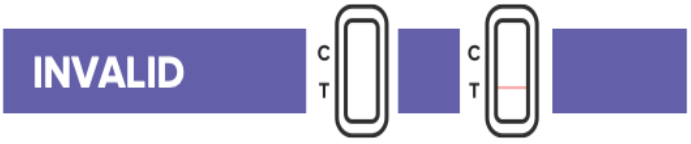
If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

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 your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

2. **Invalid result**:



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

Storage and Stability

- Speedy Swab Rapid COVID-19 Antigen Self-Test should be stored between 2 to30^{0}C (35.6 to 86^{0}F).
- Ensure all test components are at room temperature before use.
- Kit components in the Speedy Swab Rapid COVID-19 Antigen Self-Test 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. Use beyond one hour may not produce accurate results.
- Test samples immediately after collection. Swabs should be placed into buffer within 60 minutes of collection. Inoculated buffer should be added to the device within 30 minutes of swab addition and mixing.

Warnings, Precautions, and Safety Information

1 Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

2 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.

3 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.

4 If you have had symptoms longer than 6 days, you should consider testing at least three times over five days with at least 48 hours between tests.

5 An anterior nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.

6 Do not use on anyone under 2 years of age.

7 Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.

8 Do not use if any of the test kit contents or packaging is damaged.

9 Test components are single-use. Do not re-use.

10 Do not use kit past its expiration date.

11 Do not touch the swab tip.

12 Once opened, the test strip should be used within 60 minutes.

13 Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.

14 Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your [e.g., skin, eyes, nose, or mouth]. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your [e.g., skin, eyes, nose, or mouth], flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name	GHS Code for each Ingredient	Concentrations
Proclin 300	H317, allergic skin reaction	0.1%
Trimethylsilyl acetamide	H316, mild skin irritation	0.03%

Hazardous Ingredients (%)	Hazard Category (mixture)	GHS Hazard Class for mixture	Labeling of Harm(s)	Recommended PPE
Proclin 300 (0.1%)	Category 1	Skin sensitization	May cause an allergic skin reaction (H317)	Gloves
BIS (trimethysilyl acetamide) (0.03%) Proclin 300 (0.1%)	Category 3	Skin irritation	Causes mild skin irritation (H316)	NA

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: www.cdc.gov/COVID19.

Limitations

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January and June 2022. 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 SARSCoV-2 and their prevalence, which change over time.
- 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.
- 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 the individual likely has COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- 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.

1.4 Clinical Performance: Prospective Serial Testing Study at National Institutes of Health

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 SARSCoV-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 RTPCR, 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 the table below.

Table: 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 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (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.

Analytical Sensitivity: Limit of Detection (LoD).

The Limit of Detection (LoD) of the Speedy Swab Rapid COVID-19 Antigen Self-Test was determined using serial dilutions of gamma irradiated SARS-CoV-2 (isolate USA-WA1/2020). Contrived samples were prepared by spiking the inactivated virus into pooled human nasal swab matrix obtained from healthy volunteers confirmed negative by RT-PCR. 50-µL of the spiked sample preparation was pipetted onto a swab and subsequently transferred to a pre-filled vial containing 300 µL of sample Buffer Solution and tested as per the IFU. The preliminary LoD initially determined by testing a dilution series of 3 replicates per concentration was confirmed by testing 20 replicates. The confirmed LoD for the Speedy Swab Rapid COVID-19 Antigen Self-Test was 2.8 x 10^2 $TCID_{50}$/mL which equates to 14 $TCID_{50}$/swab.

NIH/RADx Variant Testing

The performance of this device in the detection
n 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 the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. The clinical specimens used to prepare this dilution series were not identical to the previous specimen pools prepared and tested by RADx to assess 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 Speedy Swab Rapid COVID-19 Antigen Self-Test detected 100% of live virus Omicron samples at a Ct-value of 24.8 (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 25.8) were not detected by the Speedy Swab Rapid COVID-19 Antigen Self-Test in this study.

Omicron Pool 2 – Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	Speedy Swab Rapid COVID-19 Antigen Self-Test Percent Positive (n=5)
Dilution 1	19.8	100	100	100
Dilution 2	20.8	100	100	100
Dilution 3	21.5	100	100	100
Dilution 4	22.7	100	100	100
Dilution 5	23.6	100	0	100
Dilution 6	24.0	60	0	100
Dilution 7	24.8	0	0	100

Dilution 8	25.8	0	0	0
Dilution 9	27.4	0	0	0
Dilution 10	28.1	0	0	0
Dilution 11	29.1	0	0	0

High-dose hook effect

The Speedy Swab Rapid COVID-19 Antigen Self-Test was tested up to 2.8 x $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 Speedy Swab Rapid COVID-19 Antigen Self-Test was evaluated for performance in the presence of potentially interfering substances that may be present in an upper respiratory tract specimen. The positive (3x LoD SARS-CoV-2) and negative samples were tested with the addition of potentially interfering substances. The performance of the Speedy Swab Rapid COVID-19 Antigen Self-Test 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
Nasal Drops (Phenylephrine)	15% v/v
Nasal Spray (Oxymetazoline)	15% v/v
Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Homeopathic (Alkalol)	10% v/v
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 µg/mL

Potentially Interfering Substance	Concentration Tested
Mupirocin	10 mg/mL
Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Fluticasone Propionate	5% v/v
Body & Hand lotion (Cerave)	0.5%w/v
Body Lotion with 1.2% dimethicone	0.5%w/v
Hand Lotion (Eucerin)	5% w/v
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v
Hand Sanitizer cream lotion (Vaseline)	15% v/v
Hand Sanitizer, 80% ethanol, fast drying	15% v/v
Hand Soap liquid gel (soft soap)	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 the clinical specimen of the nasal cavity. Each organism (13 bacteria and 16 viruses) was tested in triplicate in both the absence and presence of gamma irradiated SARS-CoV-2 (SARS-CoV-2 isolate USA-WA1/2020) at 3x LoD (1xLoD = 2.8 x 10^2 $TCID_{50}$/mL). All testing samples were prepared in pooled negative nasal matrix (PNM). No cross reactivity or interference was observed at the concentrations tested as shown in the table below, except for SARS-coronavirus which exhibited cross-reactivity when tested at 1.58 x 10^2 $TCID_{50}$/mL or higher due to high homology between SARS-CoV and SARS-CoV-2 nucleocapsid protein.

ID	Organism/Description	Source/Strain/ID No./Catalog number	Concentration Tested for Cross Reactivity and for Interference	Units for Cross Reactivity and for Interference
229E	Human coronavirus 229E	229E	2.86E+05	$TCID_{50}$/mL
OC43	Human coronavirus OC43	OC43	1.70E+05	$TCID_{50}$/mL
NL63	Human coronavirus NL63	NL63	1.70E+05	$TCID_{50}$/mL
MERS	MERS-coronavirus	EMC/2012	2.00E+06	$TCID_{50}$/mL
AV1	Adenovirus	Adenoid 71	2.86E+05	$TCID_{50}$/mL
hMPV	Human metapneumovirus 4 Type B2	Peru 1-2002	2.86E+05	$TCID_{50}$/mL
P1	Parainfluenza virus 1	1	2.86E+05	$TCID_{50}$/mL
P2	Parainfluenza virus 2	2	2.86E+05	$TCID_{50}$/mL
P3	Parainfluenza virus 3	3	2.86E+05	$TCID_{50}$/mL
P4	Parainfluenza virus 4b	4b	2.86E+05	$TCID_{50}$/mL
FluA	Influenza A	H1N1	2.86E+05	$TCID_{50}$/mL
FluB	Influenza B	B	2.86E+05	$TCID_{50}$/mL
EV68	Enterovirus 68	Fermon	2.86E+05	$TCID_{50}$/mL
RSV	Respiratory syncytial virus	Long	2.00E+05	$TCID_{50}$/mL
RV	Rhinovirus	7	2.86E+05	$TCID_{50}$/mL
HI	*Haemophilus influenzae*	TD4	2.00E+06	cfu/mL
SPN	*Streptococcus pneumonia*	Z022	2.00E+06	cfu/mL

SPY	*Streptococcus pyogenes*	Bruno	2.00E+06	cfu/mL
CA	*Candida albicans*	CBS 562	2.00E+06	cfu/mL
BP	*Bordetella pertussis*	5375 [3865]	≥1.00E+04	cfu/mL
MP	*Mycoplasma pneumonia*	FH	2.00E+06	cfu/mL
CP	*Chlamydia pneumoniae*	AR-39	2.00E+06	IFU/mL
LP	*Legionella pneumophila*	Philadelphia	2.00E+06	cfu/mL
ID	**Organism/Description**	**Source/Strain/ID No./Catalog number**	**Concentration Tested for Cross Reactivity and for Interference**	**Units for Cross Reactivity and for Interference**
MT	*Mycobacterium tuberculosis*	H37Ra-1	2.00E+06	cfu/mL
PC	*Pneumocystis carinii*	M167-6	2.00E+06	cfu/mL
PJ	*P. jiroveci-S. cerevisiae*	W303-Pji	2.00E+06	nuclei/mL
SA	*Staphylococcus aureus* subsp. *aureus*	NCTC 8532 [IAM 12544, R.Hugh 2605]	2.00E+06	cfu/mL
SE	*Staphylococcus epidermidis*	FDA Strain PCI 1200	2.00E+06	cfu/mL

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *in silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology. HKU1 nucleocapsid phosphoproteins were analyzed and results are below.

The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 nucleocapsid phosphoproteins is relatively low, at 38.2 % across 29 complete sequences analyzed, but cross-reactivity cannot be ruled out.

Flex Study

The robust use of the Speedy Swab Rapid COVID-19 Antigen Self-Test was demonstrated by nine (9) flex studies as follows:

1) Non-level positioning of Test Device in both, the face up and face down orientations
2) Producing delays at various points in the procedure
3) Producing disturbances while developing the test results
4) Varying lighting intensity while reading the results
5) Varying the result reading time
6) Varying the swab rotation number and sample extraction conditions

7) Varying the volume of sample added to the device.
8) Running the test at high and low temperature and humidity 9) Open kit stability

Clinical Evaluation

A prospective clinical study was completed for clinical validation of the Speedy Swab Rapid COVID-19 Antigen Self-Test for the detection of the SARS-CoV-2 in subject-collected and tested anterior nasal (AN) swab samples. Subjects were enrolled for home testing in regions of high COVID-19 incidence through a digital protocol (the MyDataHelps app) and at six geographically diverse clinical sites within the United States. The clinical study evaluated the investigational test's performance in symptomatic individuals suspected of COVID-19 infection against the results generated by highly sensitive molecular EUA SARSCoV-2 comparators. The study enrolled 494 subjects two (2) years of age or older presenting with fever or two or more symptoms associated with COVID-19, within seven (7) days of symptom onset that were currently experiencing symptoms. Each enrolled subject either self-collected their sample from the anterior nares (swabbing both nostrils) or had their sample collected from him/her by another individual (who swabbed both nostrils) and performed the self-test according to the test Quick Reference Instructions (QRI, or layperson instructions for use). At the six physical sites, subjects then had samples collected from them by one of the study personnel. Within the digital study, the subjects then collected a sample using an EUA SARS-CoV-2 home collection kit, which was then shipped to a reference laboratory for testing with the EUA comparator assay(s).

The study included a total of 67 evaluable positive samples and 343 evaluable negative samples (defined as positive or negative according to comparator assay(s)). Analysis of the CT values of the comparator RT-PCR assay(s) confirmed that 24 (35.8%) of study subjects that were positive according to comparator assay(s) had low viral loads (high Ct values). This may be associated with the Omicron variant since the low positive percentage in this study is higher than that observed in prior clinical studies for previously authorized COVID-19 rapid antigen tests. Antigen test performance decreases as the percentage of low positives increases since the molecular comparator method is more sensitive than the candidate antigen test. Therefore, to be consistent with previous studies, the analysis for the primary performance calculation was conducted to reflect study populations with low positives ranging from 10 to 20% (controlled analysis). Multiple Percent Positive Agreements (PPAs) were calculated for the positive samples cohort when different proportions of low positive samples were included and are shown in the table below. At 10% low positives, the PPA was 83.3% and the NPA was 100% with 95% confidence interval bounds of 70.4%- 91.3% for PPA and 98.9%-100% for NPA respectively. This was the basis of the authorization. At 20% low positives, the PPA was 77.8% with 95% confidence interval bounds of 65.1%- 86.8%.

Controlled Analysis of Speedy Swab Rapid COVID-19 Antigen Self-Test low positive results vs molecular comparator results					
	10% Low Positive	**12.5% Low Positive**	**15% Low Positive**	**17.5% Low Positive**	**20% Low Positive**
High positive samples	43	43	43	43	43
Low positive samples	5	7	8	10	11

Controlled Analysis of Speedy Swab Rapid COVID-19 Antigen Self-Test low positive results vs molecular comparator results					
	10% Low Positive	**12.5% Low Positive**	**15% Low Positive**	**17.5% Low Positive**	**20% Low Positive**
Total Comparator Positive for PPA calculation	48	50	51	53	54
Total Test Positives for PPA Calculation	40	41	41	42	42
PPA	**83.3%**	**82.0%**	**80.4%**	**79.3%**	**77.8%**
95% CI (XX% - XX%)	70.4%-91.3%	69.2%-90.2%	67.5%-89.0%	66.5%-88.0%	65.1%-86.8%
NPA	**100% (343/343)**				
95% CI (XX%-XX%)	98.9%-100%				

When all study participants are included, the PPA is 67.2% and the NPA is 100% with the 95% confidence interval bounds of 55.3% to 77.2% for the PPA and 98.9% to 100% for the NPA, respectively.

Clinical Performance in Subjects on Different Symptomatic Days				
Days Post Symptom Onset	**Number of Specimens Tested**	**Watmind Positives**	**Composite Comparator Positives**	**PPA *(95% CI)***
0 day (onset day)	21	1	3	33.3% (6.2%-79.2%)
1 day	61	9	12	75.0% (46.8%-91.1%)
2 days	102	12	23	52.2% (16.7%-70.8%)
3 days	100	15	16	93.8% (71.7%-98.9%)
4 days	58	3	6	50.0% (18.8%-81.2%)
5 days	39	4	6	66.7% (30.0%-90.3%)
6 days	23	1	1	100% (20.7%-100%)
Total	410	45	67	67.2% (55.3%-77.2%)

Positivity Rate by Age			
Age group	**Number of Specimens**	**Number of Positives by Comparator**	**% Positivity Rate**
2 to 13 years	62	8	12.9%
14 to 24 years	67	11	16.4%
25 to 64 Years	253	45	17.8%
65 Years and older	28	3	10.7%
Total	410	67	16.3%

Technical Support

For questions, or to report a problem, please call Technical Support at +1 866-928-6463

(Available Hours: Mon. to Fri. 8 am to 8 pm EST) or technicalsupport@watmindusa.com

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).

Ordering and Contact Information

DNA BIOPHARM LLC
Tel: (833) 362-9336
Email: sales@dnabiopharm.net

International Symbol Usage

The following symbols may be included on the labeling and packaging of the product:

	Manufacturer		Date of manufacture
	Contains sufficient for <n> tests		Catalogue number
	*In vitro* diagnostic medical device		Use-by date
	Consult instructions for use		Batch code
	Temperature limit		Do not reuse

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