Speedy Swab Rapid COVID-19 Antigen Self-Test

Healthcare Provider Instructions for Use

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

1. Intended Use

The **Speedy Swab Rapid COVID-19 Antigen Self-Test** is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. The test is authorized for non-prescription home use with self-collected anterior nasal (nares) swabs from individuals aged 14 years and older when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab specimens from individuals aged 2 years and older when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The test is authorized for individuals aged 2 years and older with symptoms of COVID-19 within the first 6 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19. The **Speedy Swab Rapid COVID-19 Antigen Self-Test** does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen 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 patient 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 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.

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. 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-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. 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, for an adult lay user testing another aged 2 years or older. The **Speedy Swab Rapid COVID-19 Antigen Self-Test** is only for use under the Food and Drug Administration's Emergency Use Authorization.

2. 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).

2.3 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

2.4 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.

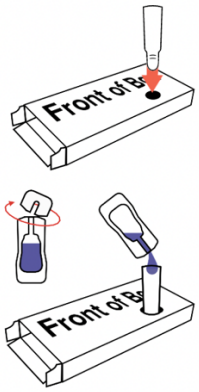
2.5 Quality Control

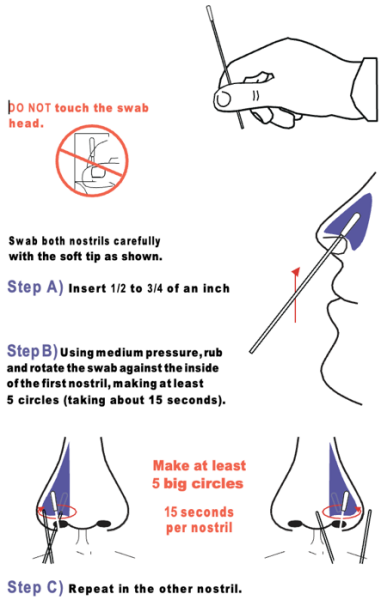
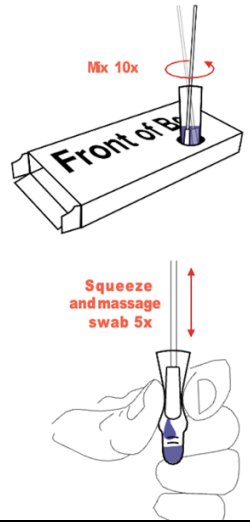
Each Speedy Swab Rapid COVID-19 Antigen Self-Test has a built-in internal procedural control. The reddish/pink line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred. A distinct reddish/pink Control line should always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

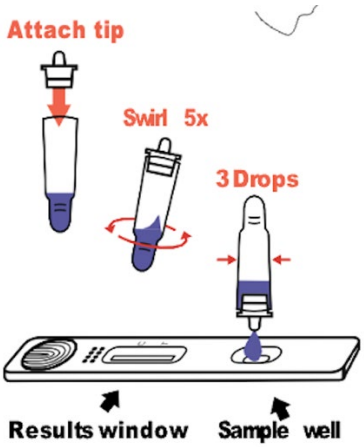
External run controls are not required to use the Speedy Swab Rapid COVID-19 Antigen Self-Test in a home setting.

2.6 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, you may not need to insert the swab as far into the nostril. 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.

2.7 Interpretation of Results

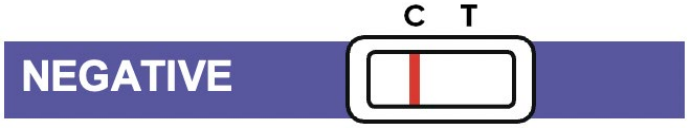
Test results are read and interpreted visually. Read results at 15 minutes with good lighting. WARNING: Do not read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.

Positive result: Two reddish/pink lines appear in the test window, one on the test line position (T) and the other on the control line position (C).

A Positive test result is interpreted as protein antigen from the virus that causes COVID-19 was detected in the specimen. The individual is positive for COVID-19. Test results should be considered in association with the patient's history and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations).

Note: The Test line (reddish/pink line) may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen present in the sample. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result. Any faint visible reddish/pink Test line should be interpreted as positive when the control line (C) line is also present.

2. **Negative result**: Only one reddish/pink line on the control line (C) position appears with no line on the test line position (T).



A negative test means that antigen from the virus that causes COVID-19 is not detected in the sample.

Negative results do not rule out SARS-CoV-2 infection. All individuals that test negative should be tested again with at least 24 hours and no more than 48 hours between tests. All negative results are considered presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed.

3. **Invalid result**: If a line does not appear on the control line position (C) in 30 minutes, even if a Test line (T) is visible, the test result is invalid. Re-test with a new Speedy Swab Rapid COVID-19 Antigen Self-Test.

2.8 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.

2.9 Warnings and Precautions

1. For in-vitro diagnostic use.
2. This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA).
3. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
4. 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 the 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.
5. Read the Instructions for Use carefully before performing a test. Failure to follow directions may produce inaccurate test results.
6. Use only the components of this test kit.
7. Do not use this test kit beyond the expiration date printed on the outside of the box.
8. When collecting a sample, use only the nasal swab provided in the kit.
9. All kit components are intended for single-use. Do not re-use.
10. Do not use if any of the test kit contents or packaging is damaged.
11. Do not open the kit contents until ready for use. Use within 60 minutes of opening pouch.
12. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
13. Speedy Swab Rapid COVID-19 Antigen Self-Test should be performed at ambient temperature (i.e., 15-30°C).
14. The use of personal protection equipment such as gloves is recommended.
15. Wear a face mask when collecting a specimen from another individual.
16. Inadequate or inappropriate sample collection may yield false negative test results.
17. False negative results may occur if the specimen is not mixed well in the tube.
18. Adding fewer or greater than 3 drops of the sample buffer solution to the test card may lead to false results.
19. Do not touch the swab tip when handling the swab sample.
20. Ensure Test Card remains flat and it is not disturbed throughout the duration of the test. Improper handling and setup may yield inaccurate results.

21. This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
22. 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.
23. Do not ingest any kit components.
24. Keep testing kit and components out of the reach of children and pets before and after use.
25. Avoid exposure of your skin, eyes, nose or mouth to the solution in the tube.
26. Do not mix components from different kit lots.
27. Dispose of used specimens and test components in accordance with Federal, State, and Local requirements.
28. In the event of a spillage, ensure it is cleaned thoroughly using a suitable disinfectant.
29. Test devices that contain patient samples should be handled as though they could transmit disease. Follow universal precautions when handling samples, this kit, and its contents. Wear appropriate personal protection equipment (PPE) and gloves when running the test and handling a patient's test device. Change gloves between tests.
30. Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
31. The chemicals in the reagent solution may be hazardous to the skin and eye. Please see the table below for safety recommendations for skin and eye irritation. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

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

2.10 Limitations

- Do not use on anyone under 2 years old.
- Children aged 2-13 years should be tested by an adult.
- Testing should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Because it is not possible to know the viral load in a patient's sample prior to testing, serial testing should be performed for all subjects (i.e., both symptomatic and asymptomatic) to increase the likelihood of detecting COVID-19.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after 7 days are more likely to be negative compared to RT-PCR.
- 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.
- The performance of the Speedy Swab Rapid COVID-19 Antigen Self-Test was evaluated using the procedures provided in Instruction for Use (IFU) only. Modifications to these procedures may alter the performance of the test.
- Positive test results do not exclude co-infection with other pathogens.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Negative results do not rule out COVID-19, should be treated as presumptive and may need to be confirmed with an FDA-authorized molecular assay.
- The performance of this test in individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection or for serial screening, when tested twice over two to three days with at least 24 but not more than 48 hours between tests has not yet been determined.
- This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January, to June, 2022. The clinical performance has not been established in 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.

2.11 Performance Characteristics

2.11.1 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.

The performance of this device in the 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 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

2.11.1 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.

2.11.3 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

2.11.4 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 = 2.8×10^2 $TCID_{50}$/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 1.58×10^2 $TCID_{50}$/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.

2.11.5 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

2.12 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 SARS-CoV-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 percent 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%

2.13 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).

2.14 Ordering and Contact Information

Watmind USA
Tel: (800) 778-8119
Email: Sales@WatmindUSA.com

2.15 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

Document Version 001/July 2022