IMMUVIEW®

COVID-19 Antigen Home Test

Healthcare Provider Instructions for Use

For Emergency Use Authorization (EUA) Only.

For use with nasal swab specimens.

***In vitro* diagnostic use.**

TABLE OF CONTENTS

INTENDED USE

The ImmuView® COVID-19 Antigen Home 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 7 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 ImmuView® COVID-19 Antigen Home 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 ImmuView® COVID-19 Antigen Home 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 ImmuView® COVID-19 Antigen Home 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 ImmuView® COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C line. If the C line does not develop after sample application, the result is invalid. Review the entire procedure and repeat the test with a new device.

EXPLANATION OF TEST

SARS-CoV-2 belongs to the broad family of coronaviruses which are capable of causing illnesses ranging from the common cold to more severe diseases[1]. SARS-CoV-2 infections cause COVID-19 disease resulting in a wide range of clinical symptoms, ranging from asymptomatic to fever, tiredness, and dry cough, and possibly leading to severe sickness and even death. Most patients recover without special treatment. According to recent data, approximately 15-20% of infected individuals become seriously ill and develop difficulty breathing[2]. The elderly and those with underlying medical problems, such as high blood pressure, heart problems or diabetes are more likely to develop serious illness[2].

Human-to-human transmission of the virus has been confirmed and occurs primarily via respiratory droplets from coughs and sneezes within a range of about six feet (1.8 m)[3]. Viral RNA has also been found in stool samples from patients. It is possible that the virus can be infectious even during the incubation period, but this has not yet been proven[4].

The gold standard laboratory method for detecting COVID-19 is PCR. However, this method requires sophisticated equipment and highly trained laboratory technicians. The ImmuView® COVID-19 Antigen Home Test is an easy-to-use assay that can be performed by lay populations in diverse settings.

The ImmuView® COVID-19 Antigen Home Test detects the presence of antigens from the SARS-CoV-2 virus within the first seven days of the onset of symptoms. Test results can be interpreted after 15 minutes. Results should not be interpreted after 30 minutes.

TEST PRINCIPLE

The ImmuView® COVID-19 Antigen Home Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a colored conjugate pad containing anti-SARS-CoV-2 antibodies conjugated with colloidal gold (antibody conjugates) and 2) a nitrocellulose membrane strip containing a test line (Ag line) and a control line (C line). The test line is pre-coated with anti-SARS-CoV-2 antibodies and the C line is pre-coated with control antibodies.

The specimen is collected with a nasal swab and the SARS-CoV-2 antigen is extracted from the swab with an extraction buffer. When applied to the sample well, the extracted specimen migrates across the test strip by capillary action. SARS-CoV-2 antigen, if present in the extract, binds to the antibody conjugates, and the immunocomplex is then captured on the membrane by the pre-coated anti-SARS-CoV-2 antibody, forming a colored Ag line that indicates a COVID-19 positive test result.

The test contains an internal control (C line), which should exhibit a colored line regardless of color development on the Ag line. If the C line does not develop, the test result is invalid and the specimen must be retested with a new device.

MATERIALS PROVIDED

Contents of 2 Test Kit:	x2 "Buffer and Nozzle" pouches	x2 Cassette Pouches	x2 Swabs	x1 Instructions for Use
Contents of 5 Test Kit:	x5 "Buffer and Nozzle" pouches	x5 Cassette Pouches	x5 Swabs	x1 Instructions for Use
Contents of 20 Test Kit:	x20 "Buffer and Nozzle" pouches	x20 Cassette Pouches	x20 Swabs	x4 Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Watch or timer
- Tissues
- Soap and water or hand sanitizer
- Mirror (optional)

TEST PROCEDURE

- If testing another person, always wear gloves. If you are testing more than one person, always clean

the test space and wash your hands and change gloves between each test.

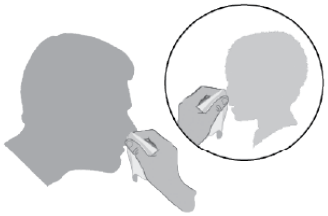
- Do not use the kit if the items are damaged, missing or expired. Use buffer and cassette within 30 minutes of opening pouches. For 2, 5 and 20 test kits, do not discard the kit box until all tests are used.
- Children aged 14 to 17 may self-test with adult supervision. Do not touch your cheeks, teeth, gums or any other surfaces with the fabric tip of the swab, or it might contaminate your sample. DO NOT touch the fabric tip of the swab with your hands.

BEFORE OPENING THE TEST

Step 1

You will need (not included in the kit)

- **Watch or timer**
- Tissues
- Soap and water or hand sanitizer
- Mirror (optional)



Step 2

Clean and dry a **flat, well-lit surface**, such as a table or counter top.

Step 3

Blow your nose and discard the tissues.

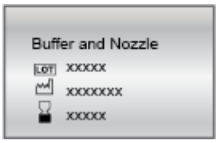
Step 4

Wash your hands and **DRY** them thoroughly.

PREPARE FOR TESTING

Step 5

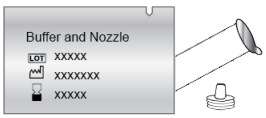
Remove all items needed for 1 test. Check that the seal is still intact in all items.



Check the expiration dating of the kit. For current information on the expiration dating of the product please visit: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests#list

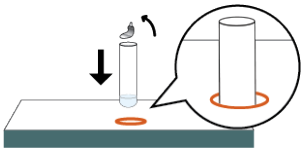
Step 6

Open the pouch labeled "Buffer and Nozzle':



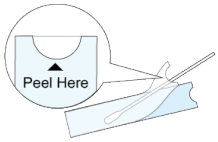
Step 7

Push in the perforated circle on the kit box and place the buffer tube. Slowly peel off the buffer tube seal. Place the open tube in the **rack.**



Step 8

Open the swab packaging and hold the swab by its handle. **DO NOT** touch the fabric tip of the swab.



COLLECT SAMPLE

Step 9

- Carefully insert fabric tip of the swab 1/2 to 3/4 of an inch into first nostril. With children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch, and you may need to have a second person to hold the child's head while swabbing.
- **DO NOT** insert the swab any deeper if you feel strong resistance or pain. If self-testing, use a mirror to help.
- Slowly rub swab in a complete circle around the inside of the nostril at least 5 times.
- Using the **SAME SWAB**, repeat process in the second nostril.
- **Children 2-14 years old should be tested by an adult (wear a face cover when swabbing others)**

PROCESS THE SWAB SAMPLE

Step 10

Remove the buffer tube from the rack. Insert the fabric tip of the swab into the tube.

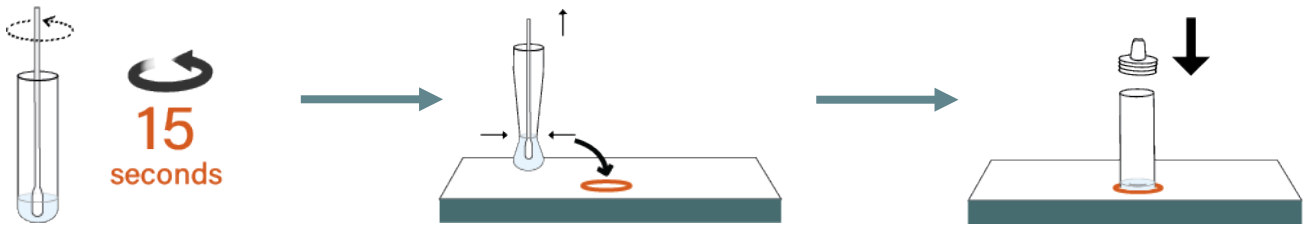
Swirl the swab in the liquid for 15 seconds.

Step 11

Remove the swab from the tube while squeezing tube into the swab tip, to press out excess liquid. Place the tube back on the tube rack.

Step 12

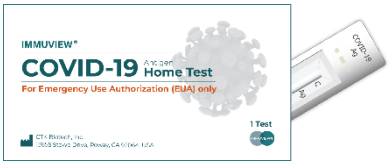
Insert the nozzle into the tube while holding the tube with your other hand. It should fit snug like a cork.



TEST THE SAMPLE

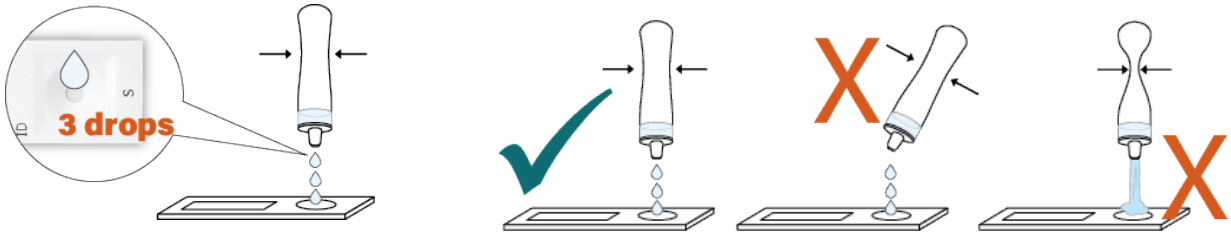
Step 13

Open the pouch labeled "COVID-19 Antigen Home Test" and remove the test cassette. Do not use after the test cassette has been opened for more than 30 minutes. Lay the cassette on clean, flat, well-lit surface.



Step 14

Invert the buffer tube over the cassette and gently squeeze to **slowly** add 3 drops of the liquid into the sample well (S), avoiding forming bubbles. **Immediately start timing 15 minutes and wait. DO NOT** move the cassette during the test.



Add the liquid drop by drop in a vertical manner.

READ THE RESULT

Step 15

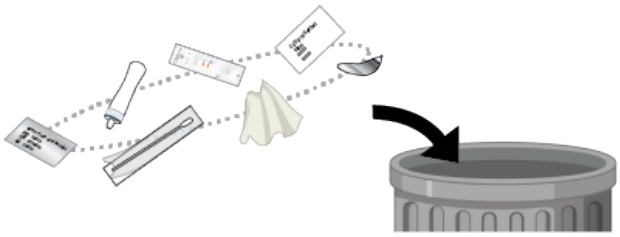
Read result after 15 minutes. You must read the result after 15 minutes, but not past 30 minutes.

For result interpretation, please see the "INTERPRETATION Of ASSAY RESULTS" section below.

SAFELY DISPOSE OF USED TEST

Step 16

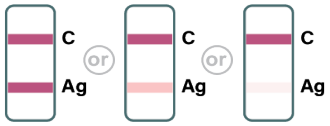
When testing is completed, dispose of used items (except Instructions for Use) in a trash can (not recycling) or according to your local guidelines. Thoroughly wash or sanitize your hands and any surfaces and items used during testing.



INTERPRETATION OF ASSAY RESULTS

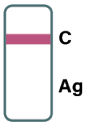
POSITIVE

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



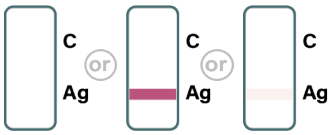
NEGATIVE

If the Control (C) line is visible, but the antigen (Ag) line is not visible, the test is negative.



INVALID

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



For additional information on result interpretation, please see the section below.

COVID-19 Positive (+)

If the Control (C) line and the antigen (Ag) line are visible, the test is positive. Any faint (red) antigen (Ag) line with the control line (C) 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 ImmuView® COVID-19 Antigen Home Test 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 COVID19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)

If the Control (C) line is visible, but the antigen (Ag) 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 the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does 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.

Invalid

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

Result Interpretation for Serial Testing

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

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.

STORAGE AND STABILITY

1. In a dry place, at 35°F-86°F (2°C-30°C).
2. Keep away from direct sunlight and do not store it in a freezer.
3. If you stored the kit in an area colder than 59°F (10°C), leave it at room temperature for 30 minutes before starting the test.

WARNINGS AND PRECAUTIONS

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. 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.**
4. **If you have had symptoms for longer than 7 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 age 14 years and older. Children age 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 card should be used within 30 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 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	Harms (GHS Code) for each ingredient at stock for reference only:	Concentration
Tergitol 15 S-9	H302, H332, H315, H318, H401	0.4%
ProClin 300	H302, H312, H314, H317, H332, H411	0.1%
Sodium Azide	H300, H400, H410	0.095%

15. For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
16. For the most up to date information on COVID-19, please visit: https://www.cdc.gov/coronavirus/2019-ncov/index.html.
17. For detailed instructions, please visit: https://immuviewathome.com

PERFORMANCE CHARACTERISTICS

1. Clinical Performance

1.1 Clinical Performance in Nasal Swab Specimens

The clinical performance of the ImmuView® COVID-19 Antigen Home Test was evaluated at 6 clinical sites in nasal swab specimens collected from symptomatic subjects suspected of COVID-19. Two nasal swabs were collected from each subject, one for testing by the ImmuView® COVID-19 Antigen Home Test and one for testing by commercially available real-time Polymerase Chain Reaction (RT-PCR) assay EUA authorized for the detection of SARS-CoV-2, used as the reference method for this study. The combined performance of the ImmuView® COVID-19 Antigen Home Test in these studies is shown in the table below:

Performance of ImmuView® COVID-19 Antigen Home Test in symptomatic subjects

ImmuView® COVID-19 Antigen Home Test	RT-PCR Method		
	Positive	Negative	Total
Positive	43	2	45
Negative	5	164	169
Total	48	166	214
Positive Percent Agreement (PPA)	89.6% (95%CI: 77.8%-95.5%)		
Negative Percent Agreement (NPA)	98.8% (95%CI: 95.8%-99.7%)		

1.2 Serial Testing Study Conducted by the National Institutes of Health (NIH)

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 1.2.1

Table 1.2.1: 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.

2. Analytical Performance

2.1 Analytical Sensitivity (Limit of Detection, LoD)

The LoD of the ImmuView® COVID-19 Antigen Home Test was determined by evaluating a serial dilution of inactivated SARS-CoV-2 (USA-WA1/2020, ZeptoMetrix, 0810587UV). Multiple negative nasal swab specimens were eluted in buffer and combined to create clinical negative matrix pools to be used as the diluent. Inactivated SARS-CoV-2 virus lysate was diluted in this matrix to generate virus dilutions for testing. Each nasal swab was spiked with 50 µL of each virus dilution, extracted with ImmuView® COVID-19 Antigen Home Test extraction buffer and tested following the product IFU. The assay LoD was determined as the lowest concentration that was detected $\geqslant$ 95% of the time.

The LoD of the ImmuView® COVID-19 Antigen Home Test in nasal swab matrix was determined to be 421.3 $TCID_{50}$/mL. The LoD per swab, based upon 50µl pipetted onto the swabs, is 21.1 $TCID_{50}$/Swab.

2.2 Analytical Specificity (Cross-Reactivity and Microbial Interference)

The analytical specificity of the ImmuView® COVID-19 Antigen Home Test was evaluated by testing commensal and pathogenic microorganisms that may be present in the nasal cavity. Each of the organisms was tested in triplicate in the absence or presence of 2-3X LoD inactivated SARS-CoV-2 virus (USA-WA1/2020, ZeptoMetrix, 0810587UV). No cross-reactivity (except SARS-coronavirus) or microbial interference was seen with the following microorganisms when tested at the concentration presented in the table below:

Potential Cross-Reactant	Concentration	Cross-Reactivity (YES/NO)	Microbial Interference (YES/NO)
SARS-coronavirus NP antigen	25 µg/mL[1]	Yes (3/3 POSITIVE)	NO (3/3 POSITIVE)
MERS-coronavirus	1.17×10^4 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Human coronavirus HKU1 NP antigen	66 µg/mL[2]	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Human coronavirus 229E	1.26×10^5 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Human coronavirus OC43	1.70×10^4 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Human coronavirus NL63	1.17×10^4 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Adenovirus	7×10^5 NIU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Human Metapneumovirus (hMPV)	3.80×10^5 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Parainfluenza virus 1	1.01×10^5 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Parainfluenza virus 2	1.6×10^5 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Parainfluenza virus 3	1.6×10^5 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Parainfluenza virus 4	1.15×10^5 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Influenza A	1.0×10^5 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Influenza B	7.3×10^5 $CEID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Enterovirus	2.8×10^5 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Respiratory syncytial virus	3.55×10^4 $TCID_{50}$/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Rhinovirus	2.2×10^5 PFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Haemophilus influenzae	5.2×10^5 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Streptococcus pneumoniae	1.47×10^6 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Streptococcus pyogenes	3.6×10^6 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Candida albicans	4.5×10^6 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Pooled human nasal wash – *representative of normal respiratory microbial flora*	N/A	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Bordetella pertussis	1.95×10^6 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Mycoplasma pneumoniae	3.0×10^6 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Chlamydophila pneumoniae	1.4×10^6 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Legionella pneumophila	3.68×10^6 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Staphylococcus aureus	1.38×10^6 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Staphylococcus epidermidis	9.27×10^6 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Mycobacterium tuberculosis	$>1 \times 10^4$ CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)
Pneumocystis jirovecii (PJP)	3.45×10^6 CFU/mL	NO (3/3 NEGATIVE)	NO (3/3 POSITIVE)

[1] *In silico* analysis of SARS-coronavirus NP antigen showed a high similarity with SARS-CoV-2 NP antigen. The data on the table above shows cross-reactivity with SARS-coronavirus NP antigen.

[2] *In silico* analysis of HKU1 NP antigen showed some similarities with SARS-CoV-2 NP antigen. We cannot rule out cross-reactivity, but we concluded that there is low probability of cross-reactivity, supported by the data on the table above.

3. Endogenous Interfering Substances

The following potentially interfering substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity were evaluated with the ImmuView® COVID-19 Antigen Home Test at the concentrations listed in the following table and were found not to affect test performance for detection of both positive and negative specimens:

Substance	Concentration	Interference in Positive Samples (YES/NO)	Interference in Negative Samples (YES/NO)
Whole Blood	4%	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Mucin	0.5%	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Chloraseptic (Menthol / Benzocaine)	15% v/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Naso GEL (NeilMed) (Saline)	5% v/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
CVS Nasal Drops (Phenylephrine)	15% v/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Afrin (Oxymetazoline)	15% v/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
CVS Nasal Spray (Cromolyn)	15% v/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Zicam	5% v/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Homeopathic (Alkalol)	1:10 Dilution	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Sore Throat Phenol Spray	15% v/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Tobramycin	4 µg/mL	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Mupirocin	10 mg/mL	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Fluticasone Propionate	5% v/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Biotin	100 µg/mL	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Body & Hand Lotion (Aveeno)	0.5% w/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Body Lotion (1.2% dimethicone) (Aveeno)	0.5% w/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Hand Sanitizer with Aloe (70% ethyl alcohol (CVS)	5% v/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Hand Sanitizer Cream Lotion (Vaseline)	10% w/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Hand Sanitizer, fast drying (80% ethanol) (NatureWell)	15% w/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)
Hand Soap Liquid Gel (Softsoap)	10% w/v	NO (3/3 POSITIVE)	NO (3/3 NEGATIVE)

4. Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 9.14×10^5 $TCID_{50}$/mL of inactivated SARS-CoV-2 Virus (USA-WA 1/2020, ZeptoMetrix, 0810587UV) with the ImmuView® COVID-19 Antigen Home Test.

5. Flex Studies

A robust use of ImmuView® COVID-19 Antigen Home Test was demonstrated by eight (8) flex studies as follows:

1. Device orientation
2. Cassette moving during analysis
3. Swab elution variability
4. Sample volume variability
5. Result reading time variability
6. Extraction buffer volume variability
7. Lighting
8. Temperature and humidity

LIMITATIONS OF TEST

1. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March, 2022 and August, 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 SARS-CoV-2 and their prevalence, which change over time.
2. The performance of the ImmuView® COVID-19 Antigen Home Test was evaluated using the procedures provided in Instruction for Use (IFU) only. Modifications to these procedures may alter the performance of the test.
3. 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.
4. All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
5. Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
6. 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.
7. 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.
8. This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
9. Incorrect test results may occur if a specimen is incorrectly collected or handled.
10. 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.
11. This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.

REFERENCES

1. Naming the coronavirus disease (COVID-19) and the virus that causes it. (n.d.). Retrieved from https://www.who.int/emergencies/diseases/novelcoronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it.
2. "Frequently Asked Questions - General Assembly of the United Nations." United Nations, www.un.org/pga/75/coronavirus/faqs/.
3. World Health Organization. (2020). Advice on the use of masks in the community, during home care, and in health care settings in the context of COVID-19: interim guidance, 19 March 2020 (No. WHO/2019-nCoV/IPC_Masks/2020.2). World Health Organization.
4. Healthcare Professionals: Frequently Asked Questions and Answers. (2020, March 22). Retrieved from https://www.cdc.gov/coronavirus/2019ncov/hcp/faq.html.

TECHNICAL SUPPORT

For assistance regarding the ImmuView® COVID-19 Antigen Home Test, please call Technical Support at (833) 919-0617 (Available Hours: Mon. to Fri.: 9 a.m. – 5 p.m. PST) or email at support@immuview.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

CTK Biotech, Inc. | support@immuview.com

Call center 1-833-919-0617 | https://immuviewathome.com

INTERNATIONAL SYMBOL USAGE

Consult instructions for use	For *in vitro* diagnostic use only	Tests per kit
Catalog #	Lot Number	Use by
Store between 35-86°F	Do not reuse	
Manufacturer	Date of manufacture	

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