First Sign® SARS-CoV-2 Antigen Test

Only for Use with Anterior Nasal Swab Specimens

For in vitro Use Only

Rx Only

INTENDED USE

The First Sign® SARS-CoV-2 Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly collected from individuals suspected of COVID-19 by their healthcare provider within five days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The First Sign® SARS-CoV-2 Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in direct nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. Negative results should be treated as presumptive, and 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 a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

The First Sign® SARS-CoV-2 Antigen Test is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel or individuals trained in point of care settings.

SUMMARY

A novel coronavirus (2019-nCoV) was identified in December 2019, which has resulted in millions of confirmed human infections worldwide. Cases of severe illness and deaths have been reported. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2. The median incubation time is estimated to be approximately 5 days with symptoms estimated to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough, and shortness of breath. The First Sign® SARS-CoV-2 Antigen Test is a rapid lateral flow immunoassay for the qualitative detection of SARS-CoV-2 directly from specimen swabs eluted in an extraction buffer solution. The First Sign® SARS-CoV-2 Antigen Test kit contains all components required to carry out an assay for SARS-CoV-2.

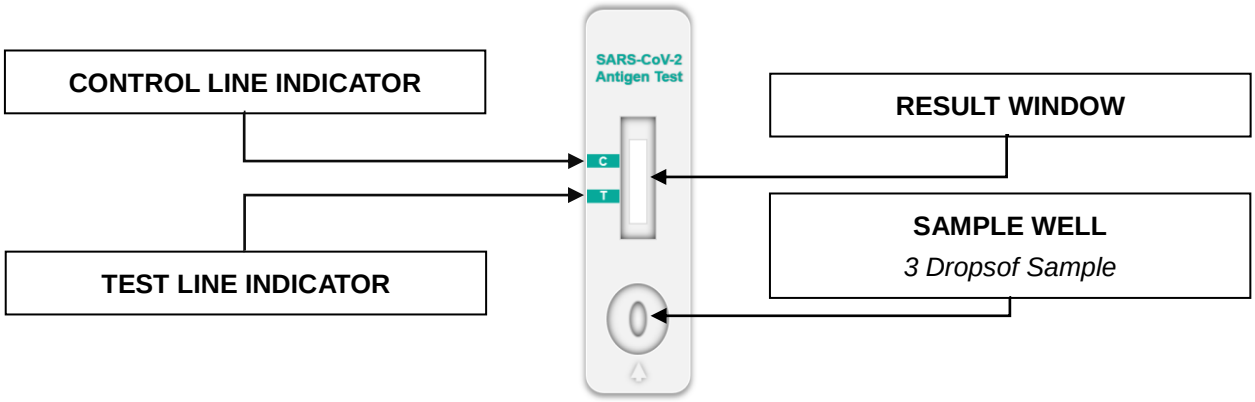
PRINCIPLES OF TEST

The First Sign® SARS-CoV-2 Antigen Test is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antigens in human nasal swab specimen. Anti-SARS-CoV-2 antibody is coated in the test line region (T). During testing, the specimen reacts with anti-SARS-CoV-2 antibody –coated particles in the reaction pad. The mixture then migrates upward on the membrane by capillary action and reacts with the anti-SARS-CoV-2 antibody in the test line region (T). If the specimen contains SARS-CoV-2 antigens, a colored line will appear in test line region (T) as a result of antigen capture. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region (T), indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region (C), indicating that the proper volume of sample has been added and membrane wicking has occurred.

PRECAUTIONS

1.For in vitro diagnostic use.
2. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
3. This test has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.
4. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories.
5. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
6. Proper sample collection, storage and transport are essential for correct results.
7. Leave the test cassette sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
8. Do not use kit past its expiration date.
9. Do not mix components from different kit lots.
10. Do not reuse the used test cassette.
11. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
12. Do not store specimens in viral transport media for specimen storage.
13. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
14. Solutions used to make the positive control swab are non-infectious. However, patient samples, controls, and test cassette should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
15. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
16. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the sample well. To ensure delivery of adequate volume, hold extraction buffer bottle vertically, ½ inch above the sample well, and add drops slowly.
17. False Negative results can occur if the sample swab is not mixed well with the extraction buffer.
18. Swabs in the kit are approved for use with the First Sign® SARS-CoV-2 Antigen Test. Do not use other swabs.
19. The extraction reagent packaged in this kit contains saline, detergents and preservatives that will inactivate cells and virus particles. Samples eluted in this solution are not suitable for culture.
20. Do not store the swab after specimen collection in the original paper packaging, immediately elute swab in extraction buffer bottle.

DEVICE DESIGN



TEST MATERIALS

MATERIALS PROVIDED

Item	Quantity	Description
First Sign® SARS-CoV-2 Antigen Test Cassette	20	Plastic cassette containing immunoassay test strip.
Extraction Buffer Bottle	20	Plastic single use dropper bottle containing 0.35ml extraction buffer with dual cap lid.
Patient Nasal Swab	20	Sterile swabs for use with First Sign® SARS-CoV-2 Antigen Test.
Positive Control Swab	1	Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab.
Negative Control Swab	See Patient Nasal Swab	Direct use of sterile Patient Nasal Swab as negative control.

MATERIALS REQUIRED BUT NOT PROVIDED

Clock, timer or stopwatch, and PPE such as lab coat, gloves, and gown.

STORAGE AND STABILITY

Store kit at 2-30°C. The First Sign® SARS-CoV-2 Antigen Test kit is stable until the expiration datemarked on the outer packaging and containers. Ensure all test components are at roomtemperature before use.Do not freeze.

SPECIMEN COLLECTION AND HANDLING

Do not return the nasal swab to the original paper packaging.

Direct nasal swab samples must be eluted in the Extraction Buffer Bottle immediately after collection. DO NOT return the nasal swab to the original paper packaging. Patient samples should be tested as soon as possible after collection. If immediate testing is not possible, a direct nasal swab sample eluted in the Extraction Buffer Bottle can stored for up to 48 hours at temperatures between 2°C - 30°C. If the transport of samples is required, transport the samples in a leak-proof container. Swirl eluted swab samples in Extraction Buffer Bottle gently to mix before testing. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.

PRE-TESTING PROCEDURE

STEP 1: Read all the instructions before starting.

STEP 2: Wash or sanitize your hands before specimen collection.

SPECIMEN COLLECTION PROCEDURE

Only the swab provided in the kit is to be used for nasal swab collection.To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visibledrainage, or the nostril that is mostcongested if drainage is not visible.

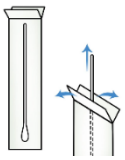
STEP 1: Remove the swab from the paper packaging. DO NOT touch the tip of the swab. Hold the swab with the score line above your hand.

STEP 2: Insert the tip of the swab in the vertical position into one nostril until there is gentle resistance. The entire tip of the swab (usually ½ to ¾ of an inch) should be placed inside the nose. Rub the swab tip in a circular motion against the side of the nostril. Continue rotating the swab in this manner for a minimum of 15 seconds and at least 5 full rotations

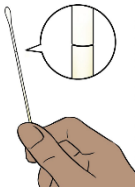
STEP 3: Repeat with the other nostril using the same swab. Once finished slowly remove the swab.

NASAL SWAB PROCEDURE

STEP 1	*STEP 2*	*STEP 3*	*STEP 4*

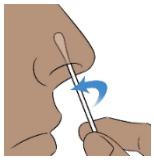


OPEN SWAB - DO NOT TOUCH TIP



NOTICE SCORE-LINE

INSERT SWAB TIP - 5 FULL ROTATIONS FOR 15 SECOND



REPEAT STEP 3 WITH SAME SWAB IN OTHER NOSTRIL.

CAUTION! *Simply twirling the swab against one part of the inside of the nose or leaving the swab in the nose for 10-15 seconds, is not proper technique and may result in an insufficient sample. This may lead to a false positive, a false negative, or an invalid result.*

SWAB EXTRACTION PROCEDURE

Check the expiration date on the Extraction Buffer Bottle prior to the addition of the specimen.

STEP 1: Unscrew and remove the large purple cap from the extraction buffer bottle.

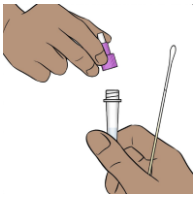
STEP 2: Lower the swab head into the bottle. Stir the swab head in the Extraction Buffer solution for 10 seconds.

STEP 3: Find swab **SCORE LINE**and align it with the top rim of the bottle.Squeeze the center of the bottle to hold the swab head in place. Slowly bend the swab in a downward motion until the swab shaft breaks at the **SCORE LINE** leaving the swab head in the bottle.

STEP 4: With the swab head in the Extraction bottle replace and screw the CAP back onto the bottle. Ensure the CAP is secured tightly.

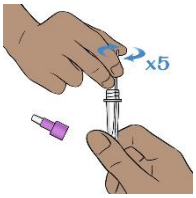
SWAB SAMPLE EXTRACTION

STEP 1



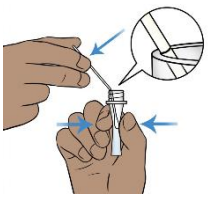
OPEN BOTTLE

STEP 2



STIR SWAB IN BUFFER FOR 10 SECONDS

STEP 3



SQUEEZE & BREAK SHAFT

STEP 4

REPLACE CAP

SPECIMEN TEST PROCEDURE

PATIENT SPECIMEN TESTING PROCEDURE

STEP 1: Carefully tear open the foil pouch containing the First Sign® SARS-CoV-2 Antigen Test device. Remove from pouch and lay the device flat on a clean, well-lit surface.

STEP 2: Shake up and down the Extraction Buffer bottle for 5 seconds. Remove the small white dropper cap from the top of the bottle.

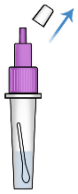
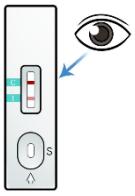
STEP 3: Hold the Extraction bottle vertically hovering 1/2 inch above the sample well. Slowly add 3 DROPS (approximately 100µL) to the sample well.

STEP 4: Set timer and wait 15 minutes.

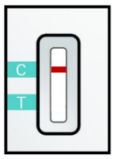
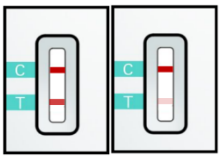
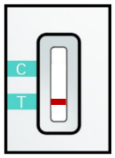
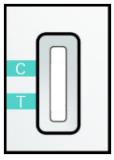
STEP 5: Read results in the RESULT WINDOW. Refer to RESULTS INTERPRETATION table for more information.

STEP 6: Follow all Federal, state, and local guidelines to dispose of used test.

PATIENT SAMPLE TESTING

STEP 1	***STEP 2***	***STEP 3***
		
OPEN TEST	**SHAKE FOR 5 SECONDSTHEN REMOVE DROPPER CAP**	**ADD 3 DROPS TO WELL**
STEP 4	***STEP 5***	***STEP 6***
		
READ RESULTS AT 15-30 MINUTES	**READ & RECORD RESULTS**	**DISPOSE OF TEST**

RESULT INTERPRETATION

	**NEGATIVE**	If the C line is present and the T line is NOT present the result is NEGATIVE for SARS-CoV-2 antigen.
	**POSITIVE**	If the C line is present and the T line is present the result is POSITIVE for SARS-CoV-2 antigen. ATTENTION: Do not compare T line to C line. Any intensity of T line is a line.
	**INVALID**	If the C line is NOT present and the T line is present the result is INVALID.
	**INVALID**	If the C line is NOT present and the T line is NOT present the result is INVALID.

QUALITY CONTROLS

INTERNAL QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

EXTERNAL QUALITY CONTROL

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. First Sign® SARS-CoV-2 Antigen Test kits contain one positive controls swab and sterile patient swabs that can be used as a negative control. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state, and federal regulations, accrediting groups, or your lab's standard Quality Control (QC) procedures. If the correct control results are not obtained, do not perform patient tests or reports patient results. Contact Technical Support during normal business hours before testing patient specimens. Only use external quality control swabs provided with the First Sign® SARS-CoV-2 Antigen Test.

POSITIVE QUALITY CONTROL PROCEDURE

STEP 1: Wash or sanitize your hands.

STEP 2: Remove the Positive Control Swab from the foil packaging. Do not touch the swab head.

STEP 3: Follow the Swab Extraction Procedure.

STEP 4: Follow the Specimen Test Procedure.

STEP 5: Confirm QC test result is POSITIVE.

NEGATIVE QUALITY CONTROL PROCEDURE

STEP 1: Wash or sanitize your hands.

STEP 2: Remove a sterile patient swab from the paper packaging. Do not touch the swab head.

STEP 3: Follow the Swab Extraction Procedure.

STEP 4: Follow the Specimen Test Procedure.

STEP 5: Confirm QC test result is NEGATIVE.

PERFORMANCE CHARACTERISTICS

PROSPECTIVE STUDY

The clinical performance characteristics of the First Sign® SARS-CoV-2 Antigen Test were evaluated in a multi-site prospective study in the U.S. in which patients were sequentially enrolled and tested. Testing was performed by operators with no laboratory experience and who are representative of the intended users of CLIA waived testing sites.

In this study, testing was conducted bythirteenintended users. To be enrolled in the study, patients had to be presenting at the participating study sites with suspected COVID-19 symptoms. Patients who presented within five days of symptom onset and met study protocol criteria were enrolled. A standard of care nasopharyngeal (NP) swab was first collected and eluted in VTM. Following the standard of care, an anterior nasal swab sample was self-collected by the patient under the observation of a study site health care professional using only the test kit components and Patient Quick Guide. At all sites, the standard of care NP swab eluted in VTM was tested with an EUA RT-PCR assay for the detection of SARS-CoV-2. Patient self-collected samples were tested with the First Sign® SARS-CoV-2 Antigen Test within 2 hours of sample collection by minimally trained operators who were blinded to the RT-PCR test results. External control testing was performed according to the IFU by each operator prior to testing patient samples. The performance of the First Sign® SARS-CoV-2 Antigen Test was determined by testing 146symptomatic patient samples and evaluating the level of agreement between operator reported antigen test results and results reported by an EUA RT-PCR comparator device.

PROSPECTIVE CLINICAL STUDY RESULTS

First Sign® SARS-CoV-2 Antigen Test	Comparator Results (RT-PCR)		
	Positive	Negative	Total
Positive	58	1	59
Negative	2	85	87
Total	60	86	146
Positive Percentage Agreement (PPA)	96.7% (88.5% - 99.6%)		
Negative Percentage Agreement (NPA)	98.8% (93.7% - 99.9%)		
RT-PCR Correlation	98.0% (94.1% - 99.6%)		

SYMPTOM ONSET TIMELINE & CT VALUE*

Symptom Onset Timeline	RT-PCR Comparator Positive Result Data				Study Device Performance
	RT-PCR Positive [Device Positive]			Mean Ct Value [Range]	PPA (CI 95%)
	Ct < 30	30 ≤ Ct < 35	Ct ≥ 35		
Day 1	6 [6]	2 [1]	0 [0]	25 [18-30]	87.5% (47.4%-99.7%)
Day 2	14 [14]	5 [5]	0 [0]	25 [19-34]	100% (71.5%-100%)
Day 3	11 [11]	1 [1]	2 [2]	26 [20-35]	100% (76.8%-100%)
Day 4	12 [12]	0 [0]	0 [0]	23 [20-29]	100% (73.5%-100%)
Day 5	5 [5]	0 [0]	2 [1]	29 [22-39]	85.7% (42.1%-99.6%)
Ct < 30 Total	48 [48]	---	---	23 [18-29]	100% (92.6%-100%)
30 ≤ Ct < 35 Total	---	8 [7]	---	32 [30-34]	87.5% (47.4%-99.7%)
Ct ≥ 35 Total	---	---	4 [3]	36 [35-39]	75.0% (19.4%-99.4%)
Combined Results	---	60 [58]	---	25 [18-39]	96.7%(88.5%99.6%)

**RT-PCR comparator reported Ct values have been rounded up to the nearest integer. Ct Values should be considered in the context of preanalytical factors such as variation in viral load distribution during sample collection.*

DEVICE LIMITATION

• This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Testperformance depends on the amount of virus (antigen) in the sample and may or may notcorrelate with viral culture results performed on the same sample.

• A negative test result may occur if the level of antigen in a sample is below the detection limitof the test.

• The performance of the First Sign® SARS-CoV-2 Antigen Test was evaluated using the proceduresprovided in this product insert only. Modifications to these procedures may alter theperformance of the test.

• False negative results may occur if a specimen is improperly collected, transported, orhandled.

• False results may occur if specimens are tested past 1 hour of collection. Specimens should betest as quickly as possible after specimen collection.
• False negative results may occur if inadequate extraction buffer is used (e.g., <3 drops).
• False negative results may occur if specimen swabs are not stirred well for 10 seconds.
• False negative results may occur if swabs are stored in their paper sheath after specimencollection.
• Positive test results do not rule out co-infections with other pathogens.
• Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
• Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
• Negative results, from patients with symptom onset beyond five days, should be treated aspresumptive and confirmation with a molecular assay, if necessary, for patient management,may be performed.
• If the differentiation of specific SARS viruses and strains is needed, additional testing, inconsultation with state or local public health departments, is required.

ANALYTICAL PERFORMANCE

LIMIT OF DETECTION (ANALYTICAL SENSITIVITY)

The LOD for the First Sign® SARS-CoV-2 Antigen Test was established using limiting dilutions of heat inactivated SARS-CoV-2 isolate USA-WA1/2020 (NR-52286). The study was designed to determine the LOD of the assay when using a direct nasal swab. The starting material was spiked into a volume of negative clinical matrix pool obtained from healthy donors and confirmed negative for SARS-CoV-2. At each viral dilution concentration, 50µL of contrived samples were added onto a sterile swab. The swab samples were tested in triplicate in the First Sign® SARS-CoV-2 Antigen Test using the test procedure in the study device IFU. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates to confirm the LOD.

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Starting Material Concentration	Estimated LOD	No. Positive/Total	% Positive
1.6 x 10^5 $TCID_{50}$/mL	1.0 x 10^3 $TCID_{50}$/mL	19/20	95%

CROSS REACTIVITY (ANALYTICAL SPECIFICITY) AND MICROBIAL INTERFERENCE

The Cross reactivity and potential interference First Sign® SARS-CoV-2 Antigen Test was evaluated by testing the commensal and pathogenic microorganisms listed below that may be present in the nasal cavity. Each potential cross-reactant was tested in triplicate in the absence or presence of heat inactivated SARS-CoV-2 virus. No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below.

Potential Cross-Reactant	Concentration Tested
Human coronavirus OC43	1.5 x $10^4$$TCID_{50}$/mL
Human coronavirus NL63	4.4 x $10^3$$TCID_{50}$/mL
Human coronavirus 229E	1.5 x $10^5$$TCID_{50}$/mL
Human rhinovirus 16	1.8 x 10^6TCID50/mL
Enterovirus	1.4 x $10^6$$TCID_{50}$/mL
Human respiratory syncytial virus	2.3 x 10^6 PFU/mL
Human metapneumovirus 16	1.2 x 10^5 $TCID_{50}$/mL
Human adenovirus 5	3.1 x $10^{5.5}$ $TCID_{50}$/mL
Human parainfluenza virus 1	1.2 x 10^5 $TCID_{50}$/mL
Human parainfluenza virus 2	3.7 x 10^5 $TCID_{50}$/mL
Human parainfluenza virus 3	1.0 x 10^7 $TCID_{50}$/mL
Human parainfluenza virus 4A	5.3 x 10^3 $TCID_{50}$/mL

Human parainfluenza virus 4B	1.6 x 10^4 $TCID_{50}$/mL
Influenza A virus (H1N1)	3.1 x $10^{5.5}$ $CEID_{50}$/mL
Influenza A virus (H3N2)	1.4 x 10^7 $CEID_{50}$/mL
Influenza B virus	1.0 x 10^5 $CEID_{50}$/mL
MERS-CoV	1.1 x 10^4 $TCID_{50}$/mL
Bordetella pertussis	3.0 x 10^7CFU/mL
Chlamydophila pneumoniae	5.7 x 10^6 IFU/mL
Haemophilus influenzae	5.3 x 10^6 CFU/mL
Legionella pneumophila	1.3 x 10^6 CFU/mL
Streptococcus pneumoniae	1.1 x 10^6 CFU/mL
Streptococcus pyogenes	3.0 x 10^7 CFU/mL
Mycoplasma pneumoniae	1.7 x 10^7 CCU/mL
Staphylococcus epidermidis	1.5 x 10^8 CFU/mL
Staphylococcus aureus	4.0 x 10^8 CFU/mL
Candida albicans	1.3 x 10^7 CFU/mL
Nasal cavity wash	N/A

To estimate the likelihood of cross-reactivity with SARS-CoV-2 in the presence of three microorganisms that were not available for wet testing due to inaccessibility of a Biosafety Level-3 laboratory or due to the unavailability of the microbial specimen through a vendor, an *in-silico* analysis using Basic Local Alignment Search Tool (BLAST) was utilized to assess the degree of protein sequence homology. The three microorganisms assessed using the *in-silico* method in this study include human coronavirus HKU1, Mycobacterium tuberculosis, and Pneumocystis jirovecii.

1) The likelihood of cross-reactivity with SARS-CoV-2 in the presence of coronavirus HKU1 cannot statistically be ruled out as the amino acid sequences of the nucleocapsid phosphoprotein of the two viruses are 36.7% (133/262) homologous across 86.4% (133/419) of the sequence.

2) The comparison between SARS-CoV-2 nucleocapsid phosphoprotein, M. tuberculosis, and P. jirovecii revealed no significant homology, and thus cross-reactivity can be ruled out.

ENDOGENOUS INTERFERING SUBSTANCES

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with The First Sign® SARS-CoV-2 Antigen Test. The substances were tested in singlicate on three different device lots at the concentrations listed below and were found not to affect test performance.

Interfering Substance	Interfering Substance Concentration
Whole blood	4.1%
Mucin	2.5 mg/mL
Cepacol	1.5 mg/mL
NasoGEL (NeilMed)	5.2%
Nose Drops	15.1%
Afrin	15.1%
NasalCrom Nasal Spray	15.1%
Zicam Cold Remedy	5.2%
Alkalol Nasal Wash	10.0%
Sore Throat Spray	15.1%
Flonase	5.2%
Tobramycin	4.0 µg/mL
Mupirocin	10.0 mg/mL

Tamiflu	5.1 mg/ml

HIGH-DOSE HOOK EFECT

The First Sign® SARS-CoV-2 Antigen Test was tested at a concentration of 6.25 x 10^5, 1.25 x 10^5, and 2.50 x 10^4 $TCID_{50}$/mL using heat-inactivated SARS-CoV-2 isolate Hong Kong/VM20001061/2020. No high-dose hook effect was observed.

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SYMBOLS

	Manufacturer	IVD	In vitro diagnostic medical devices
30°C 4°C	Temperature limit		Date of manufacture
LOT	Batch code		Validity period
	Warning		No reusing
	See instructions for use	EC REP	EU Authorized Representative

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