COVID-19 Antigen Rapid Test
(Nasopharyngeal Swab)

Instruction for use

Ref: SP-SW106U

A rapid test for the qualitative detection of Novel Coronavirus SARS-CoV-2 antigen in nasopharyngeal swab.

CE

For prescription use only
For professional in vitro diagnostic use only
For Emergency Use Authorization only

Store at 2°C – 30°C (36°F – 86°F)

CONTENT

1 INTENDED USE

The Spring Health COVID-19 Antigen Rapid Test is a rapid chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal swab (NP) specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first six 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 complexity, high complexity, or waived 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 Spring Health COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasopharyngeal 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. 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 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 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.

The Spring Health COVID-19 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care. The Spring Health COVID-19 Antigen Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

1.1. Abbreviations

SARS-CoV-2: novel coronavirus

COVID-19: novel coronavirus pneumonia

1.2. Summary

The new coronavirus belongs to the coronavirus of the genus β. It has an envelope and the particles are round or elliptical. They are often polymorphic and have a diameter of 60-140 nm. Its genetic characteristics are significantly different from SARS-CoV and MERS-CoV. Current research shows that the homology with bat SARS-like corona virus (bat-SL-CoVZC45) is more than 85%. When isolated and cultured in vitro, the new coronavirus can be found in human respiratory epithelial cells in about 96 hours, while it takes about 6 days to separate and culture in VeroE6 and Huh-7 cell lines.

The diagnosis is fast, accurate and requires low equipment and personnel, suitable for rapid investigation of suspected cases of novel coronavirus infection on a large scale. The rapid investigation of suspected cases can be used as a supplementary test for nucleic acid testing.

2 PRINCIPLE

The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in nasopharyngeal swab. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

3 REAGENTS

The test cassette contains antibodies against SARS-CoV-2 Nucleocapsid protein coated on the membrane.

4 CHEMICAL AND SAFETY

The extraction buffers included in the test kit contains NaCl, Casein Sodium, Tris and Proclin 300.

Ingredients	Hazards	Link to SDS
Tris	Causes skin irritation Causes serious eye irritation May cause respiratory irritation	Clickable Link (Tris Material Safety Data Sheet)
Proclin™ 300	Harmful if swallowed or if inhaled Causes severe skin burns and eye damage. May cause an allergic skin reaction.	Clickable Link (Proclin 300 Material Safety Data Sheet)

The extraction buffer solution in the extraction buffer tube contains Tris and Proclin™ 300, which are hazardous ingredients as shown in above table. If the extraction buffer solution contacts the skin or eye, immediately wash with plenty of running water. In case the irritation persists, please seek medical advice at: https://www.poison.org/contact-us or 1-800-222-1222

5 PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. For prescription use only.
3. Only for use under an Emergency Use Authorization In the USA.
4. Do not use the Spring Health COVID-19 Antigen Rapid Test after its expiration date, which is 12 months from the date the kit was manufactured.
5. This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity, high complexity 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.
6. This product has been authorized only for detecting the presence of the nucleocapsid protein from SARS-CoV-2, not from any other viruses or pathogens.
7. 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. § 360bbb3(b)(1), unless the declaration is terminated or the authorization is revoked sooner
8. Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
9. Follow the instructions for use carefully. Reliability of assay results cannot be guaranteed if there is any deviation from the instructions in this instruction for use.
10. The test should remain in the sealed pouch until ready to use.
11. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
12. All samples, even after the extraction procedure, and reagents containing biological materials used for the assay must be considered as potentially able to transmit infectious agents; accordingly samples, reagents and the waste must be handled with utmost care and disposed of in compliance with the laboratory guidelines and the statutory provisions in force in each country.
13. Avoid using samples with visible blood on the swab.
14. Wear protective clothing such as laboratory coats, disposable gloves and eye protection before start of testing.
15. The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
16. Allow the test cassette, specimen, supporting buffer to equilibrate to room temperature 15°C – 30°C (59°F – 86°F) prior to testing.
17. Do not store this kit in frozen condition.
18. Do not use the product if package is damaged.
19. Do not use the product after expiration date.
20. Do not re-use the product.
21. Use only the extraction solution provided with the kit.
22. Read and interpret the results at 10 minutes, do not interpret the results after 20 minutes.
23. Do not eat, drink or smoke in the area where the specimens or kits are handled.

6 STORAGE AND STABILITY

The test kit should be stored as packaged at room temperature or refrigerated 2°C – 30°C (36°F – 86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

7 SPECIMEN TRANSPORT AND STABILITY

For the best results, specimen should be tested immediately after collection. If collected specimen cannot be tested immediately, the swabs can be stored in a dry tube at room temperature for no longer than 1 hour and at 2-8°C for no longer than 24 hours.

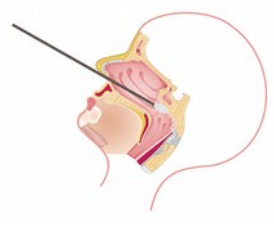
Test should be performed immediately after adding the swab into the extraction tube.

8 SPECIMEN COLLECTION AND PREPARATION

The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) can be performed using nasopharyngeal swab specimens. The quality of specimens obtained is of extreme importance. Detection of COVID-19 Antigen requires a vigorous and thorough collection technique that provides COVID-19 Antigen rather than just body fluids.

To collect Nasopharyngeal swab Specimen:

1. Tilt patient's head back 70 degrees.
2. Gently and slowly insert the swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.
3. Gently rub and roll the swab.
4. Leave swab in place for several seconds to absorb secretions.
5. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection.
6. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
7. Place swab, tip first, into the a dry tube or directly into the extraction buffer tube.



For more information, visit: https://www.cdc.gov/coronavirus/2019-ncov/downloads/lab/NP_Specimen_Collection_Infographic_FINAL_508.pdf

9 MATERIALS

9.1. Material Provided

Item number	Content	Quantity
1	Instruction for use	1
2	Quick User Guide	1
3	Individually Pouched Test Cassettes	25
4	Extraction Tubes with Buffers (NaCl + Casein Sodium + Tris + Proclin 300)	25
5	Sterile Nasopharyngeal swabs	25
6	Workstation	1
7	Positive Control swab	1
8	Negative Control swab	1

9.2. Materials required but not provided

Timer

Gloves

Addition control swabs (1 positive + 1 negative control swab) can be purchased separately.

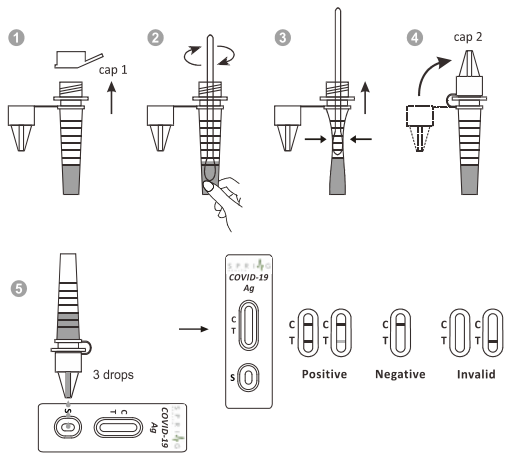
Spring Health Catalog Number: COV-SP-SW106-P (Positive Control)/ COV-SP106-N (Negative Control)

10 DIRECTIONS FOR USE

Allow the test cassette, specimen, extraction buffer to equilibrate to room temperature 15°C – 30°C (59°F – 86°F) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the extraction buffer in the workstation. Open the cap 1 (See illustration 1) and place the swab specimen in the extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. (See illustration 2). Leave the swab in the extraction buffer for 1 minute.
3. Remove the swab while squeezing the swab head against the inside of the extraction buffer as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol (See illustration 3).
4. Tighten cap 2 (See illustration 4), place the test cassette on a clean and level surface.
5. Add 3 drops (approx. 80µl) of the solution to the sample well (See illustration 5) and then start the timer. Read the result at 10 minutes. Do not interpret the result after 20 minutes.

   Note: Erroneous results can occur if the test results are read before or after 10-20 minutes.



11 INTERPRETATION OF THE RESULTS

11.1	**NEGATIVE** One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that COVID-19 antigen is not present in the specimen, or is present below the detectable level of the test.	
11.2	**POSITIVE:*** Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that COVID-19 was detected in the specimen. ***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of COVID-19 Antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.	
11.3	**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact the manufacturer or your supplier.	

12 QUALITY CONTROL

An internal procedural control is included in the test. A line appearing in the control line region (C) is an internal valid procedural control, and it confirms adequate membrane wicking. Positive and Negative Control standards are supplied with this kit; it is recommended that positive and negative controls be tested as a good laboratory practice with every new lot, shipment, or a new operator.

To perform a control test, remove the control swabs from the packaging and follow the instructions under “DIRECTION FOR USE” and interpret the result as per “INTERPRETATION OF RESULTS”. If the correct control results are not obtained, do not perform patient testing or report patient results. Contact the US Technical Support at 425-620-2090/ info@springhealthcare.org.

13 LIMITATIONS

1. This device is for professional in vitro diagnostic use only.
2. This device is only used for testing direct human nasopharyngeal swab specimens. Viral transport media (VTM) should not be used with this test.
3. Not for use in at-home testing settings.
4. Neither the quantitative value nor the rate of increase in SAR-CoV-2 virus concentration can be determined by this qualitative test.
5. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
6. The COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) will indicate the presence of SARS-CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirus strains.
7. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
8. A negative result should be treated as presumptive and confirmed by PCR. A negative result may be obtained if the concentration of the SARS-CoV-2 virus present in the sample is not adequate or is below the detectable level of the test.
9. A positive result for COVID-19 does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
10. If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
11. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after six days are more likely to be negative compared to RT-PCR.
12. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
13. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
14. Positive results may be due to present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1 and SARS-CoV.
15. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
16. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between 11/16/2020 and 12/30/2020. 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.

14 CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The Spring Health COVID-19 Antigen Rapid Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas. However, to assist clinical laboratories using the Spring Health COVID-19 Antigen Rapid Test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories* using your product must include, with test result reports, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories using your product must use your product as outlined in the "authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating tests.

D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Salofa Oy (via email: info@salofa.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F. All operators using your product must be appropriately trained in performing and interpreting the results of your product. Use appropriate personal protective equipment when handling this kit, and use your product in accordance with the labeling.

G. Salofa Oy and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by the FDA. Such records will be made available to the FDA for inspection upon request.

*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity, moderate complexity or waived complexity tests. This test is authorized for use at the Point of Care (POC) i.e. in patient care settings operating under CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation" as "authorized laboratories."

15 PERFORMANCE CHARACTERISTICS

15.1. Limit of Detection

The LOD for the Spring Health COVID-19 Antigen Rapid Test (Nasopharyngeal Swab) was established using serial dilutions of an inactivated viral sample (ZeptoMetrix, 0810587CFHI) in natural nasal clinical matrix. Contrived nasal swab samples were prepared by absorbing 50 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure. The LOD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive). The determined LOD is 1.25×10^3 $TCID_{50}$/mL.

15.2. Clinical Evidence

To evaluate the performance of the Spring Health COVID-19 Antigen Rapid Test at a POC setting, a prospective, non-interventional study was performed with 133 nasopharyngeal swab samples. The samples were sequentially collected from 133 symptomatic patients who presented symptoms of COVID-19 infection within 7 days of symptom onset, at one POC site in the United States, from November to December, 2020. All tests were performed by 5 non-laboratory healthcare providers (2 medical assistants, 1 registered nurse, 1 radiography technician, and 1 clinical trial coordinator) who were only provided with a Quick Reference Guide and the Instruction for Use on how to use the test and interpret the results. Two (2) nasopharyngeal swabs specimens (one for RT-PCR confirmation, and the another for antigen rapid test) were then collected randomly from each nostril. An US FDA EUA authorized RT-PCR was used as the reference method for the COVID-19 Antigen Rapid Test (Nasopharyngeal Swab). Specimens were considered positive if PCR indicated a positive result.

Subject Demographics

Age Group	No. of Subjects	Antigen Positive	Prevalence
≤ 5 years	0	N/A	N/A
6 – 21 years	8	3	37.50%
22 - 59 years	96	25	26.04%
≥ 60 years	29	8	27.69%
Total	133	36	27.07%

Specimen Positivity by days post symptom onset

Days post symptom onset	No. of Subjects	Antigen Positive	Prevalence
1	4	1	25.00%
2	59	15	25.42%
3	44	14	31.82%
4	9	2	22.22%
5	4	0	0.00%
6	11	4	36.36%
7	2	0	0.00%

Results

Method		RT-PCR		Total Results
	Results	Positive	Negative	
COVID-19 Antigen Rapid Test	Positive	35	1	36
	Negative	5	92	97
Total Results		40	93	133

Relative Sensitivity:	35/40 87.5% (95% CI: 68.6%-93.0%)
Relative Specificity:	92/93 98.9% (95% CI: 94.2%-99.9%)

15.3. Cross Reactivity

The following potentially cross-reactive microorganisms were tested with SARS-CoV-2 negative and spiked positive specimens at 3x LoD with inactivated SARS-CoV-2. All testing were performed with three different lots and tested in triplicate. The below listed organisms or viruses do not cross-react at the stated concentration.

Potential Cross-Reactant	Concentration	Results	
		Negative Specimen	Positive Specimen
Human Coxsackievirus	2.8×10^5 $TCID_{50}$/ml	Negative	Positive
Mumps virus	2.8×10^6 $TCID_{50}$/ml	Negative	Positive
Haemophilus para-influenzae	6×10^6 bacteria/ml	Negative	Positive
Staphylococcus aureus	6×10^6 bacteria/ml	Negative	Positive
Neisseria meningitides	10^5 organisms/ml	Negative	Positive
Streptococcus sp. Group A	10^8 organisms/ml	Negative	Positive
Streptococcus sp. Group B	6×10^6 bacteria/ml	Negative	Positive
Streptococcus sp. Group C	6×10^6 bacteria/ml	Negative	Positive
Influenza A Virus H3N2	$CEID_{50} \geqq 10^2$ per 0.2 ml	Negative	Positive
Mumps virus	2.8×10^6 $TCID_{50}$/ml	Negative	Positive
Adenovirus (e.g. C1 Ad. 71)-Type 7A	$7.05\ x10^4$ $TCID_{50}$/ml	Negative	Positive
Enterovirus (e.g. EV68)	$1.67\ x10^5$ $TCID_{50}$/ml	Negative	Positive
Human Metapneumovirus	$5.43\ x10^5$ $TCID_{50}$/ml	Negative	Positive
Influenza A H1N1 (New Cal/20/99)	$1.64\ x10^6$ $TCID_{50}$/ml	Negative	Positive
Influenza B (Florida/02/06)	$7.05\ x10^4$ $TCID_{50}$/ml	Negative	Positive
Parainfluenza virus 1	1.30×10^8 $TCID_{50}$/ml	Negative	Positive
Parainfluenza virus 2	1.64×10^6 $TCID_{50}$/ml	Negative	Positive
Parainfluenza virus 3	9.44×10^5 $TCID_{50}$/ml	Negative	Positive
Parainfluenza virus 4	$4.03\ x10^6$ $TCID_{50}$/ml	Negative	Positive
Respiratory syncytial virus-Type A	$5.43\ x10^5$ $TCID_{50}$/ml	Negative	Positive
Rhinovirus (Type 1A)	$1.78\ x10^5$ $TCID_{50}$/ml	Negative	Positive
Bordetella pertussis	$1.61\ x10^9$ CFU/ml	Negative	Positive
Candida albicans	$8.96\ x10^7$ CFU/ml	Negative	Positive
Haemophilus influenzae	$7.76\ x10^7$ CFU/ml	Negative	Positive
Legionella pneumophila	$2.69\ x10^9$ CFU/ml	Negative	Positive
Mycobacterium tuberculosis	$9.80\ x10^6$ CFU/ml	Negative	Positive
Mycoplasma pneumoniae	$4.51\ x10^7$ CCU/ml	Negative	Positive
Pneumocystis jirovecii (PJP)-S.cerevisiae Recombinant	$4.93\ x10^7$ CFU/ml	Negative	Positive
Pseudomonas aeruginosa	$1.21\ x10^9$ CFU/ml	Negative	Positive
Staphylococcus epidermis	$1.73\ x10^9$ CFU/ml	Negative	Positive
Streptococcus pneumoniae	$3.23\ x10^8$ CFU/ml	Negative	Positive
Streptococcus pyogenes	$2.34\ x10^8$ CFU/ml	Negative	Positive
Streptococcus salivarius	$1.17\ x10^8$ CFU/ml	Negative	Positive
Human coronavirus 229E	$2.09\ x10^5$ $TCID_{50}$/ml	Negative	Positive
Human coronavirus OC43	$1.50\ x10^5$ $TCID_{50}$/ml	Negative	Positive
Human coronavirus NL63	$8.50\ x10^4$ $TCID_{50}$/ml	Negative	Positive
MERS-coronavirus	$4.51\ x10^5$ $TCID_{50}$/ml	Negative	Positive
Chlamydophila pneumoniae	$1.75\ x10^7$ IFU/ml	Negative	Positive

*in silico analysis using Protein BLAST indicates that homology between SARS-CoV-2 nucleocapsid protein and hCoV-HKU1 nucleocapsid protein is at 37% across 87% of the sequences, therefore, cross-reactivity cannot be ruled out.

*in silico analysis using Protein BLAST indicates that homology between SARS-CoV-2 nucleocapsid protein and SARS-CoV nucleocapsid protein is at 91% across 100% of the sequences, therefore, cross-reactivity cannot be ruled out.

15.4. Interfering Substances

The following potentially interfering substances were added to SARS-CoV-2 negative and spiked positive specimens at 3x LoD. No substances showed any interference with the test.

Whole Blood (4%)	Mucin (0.5%)
NeilMed NasoGEL (5% v/v)	Zicam Cold Remedy Nasal Spray (5% v/v)
Flonase nasal spray (5% v/v)	CVS Nasal Drops (Phenylephrine) (15% v/v)
Afrin Original (Oxymetazoline) (15% v/v)	NasalCrom Nasal Spray (15% v/v)
Chloraseptic (15% v/v)	Alkalol Nasal Wash (10% v/v)
Tobramycin (4 µg/mL)	Mupirocin (10 mg/mL)
Oseltamivir Phosphate (5 mg/mL)	

15.5. High Dose Hook Effect

The potential high-dose hook effect on the performance of the COVID-19 Antigen Rapid Test was evaluated using positive inactivated virus culture. All testing were performed with three different lots and tested in triplicate. No hook effect was observed when tested at up to 1.0×10^5 $TCID_{50}$/ml.

15.6. Specimen Stability

The specimen stability of a nasopharyngeal swab specimen with the COVID-19 Antigen Rapid Test was evaluated with SARS-CoV-2 negative and spiked positive specimens at 2x LoD. The stability at room temperature was evaluated by placing the samples in a dry tube and stored at 30°C, for up to 180 minutes; the stability at refrigerated temperature was evaluated by storing the samples at ~4°C, for up to 36 hours. No false results were obtained during the study.

EXPLANATION OF THE SYMBOLS USED

IVD	For in vitro diagnostic use
REF	Catalogue number
LOT	Batch code
	Manufacturer
	Date of manufacture
	Use by
	Do not use if package is damaged
	Consult instruction for use
	Temperature limit at 2°C – 30°C.
	Contents sufficient for n tests
	Do not re-use
	Caution
	Keep dry
	Protect from direct sunlight
CE	CE Mark

17 REFERENCES

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18 DATE OF ISSUE

Spring Health COVID-19 Antigen Rapid Test insert.

Version 2, December 17st, 2021

19 GENERAL INFORMATION

Manufacturer:

Salofa Oy
Örninkatu 15, 24100 Salo, Finland
email: info@salofa.com
web: www.salofa.com

US Technical Support Contact:
TECH SUPPORT: 425-620-2090
info@springhealthcare.org

Distributed by:
Montfort Medical LLC
14205 SE 36th St
#100-288
Bellevue, WA US 98006