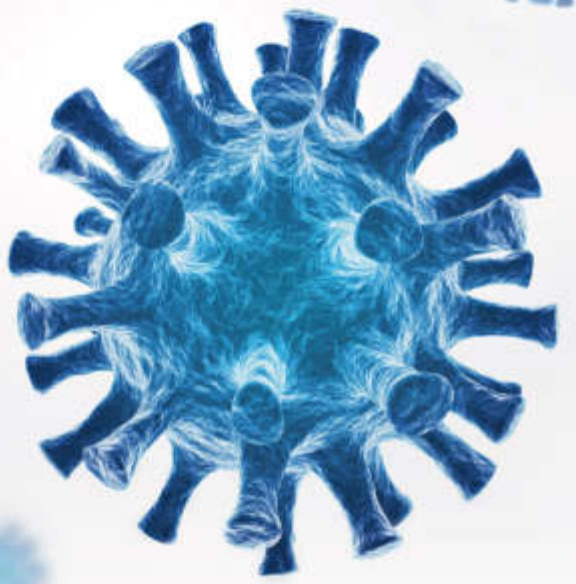
Flowflex™

SARS-CoV-2

Antigen Rapid Test
(Nasal/Saliva)

NUOVA GOOD LUCK

A rapid, highly reliable and affordable kit, providing an aid in early diagnosis of individuals who are suspected of COVID-19 by their healthcare provider and who are asymptomatic.



The Global Leader of Rapid Test with **26** Years Experience.

- Fast
- Accurate
- Easy to Use
- Reliable
- CE Marked

ACON®

Flow*flex* SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)

The Flow*flex* SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab and saliva specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test can also test specimens from asymptomatic individuals.

- **Specimen: Nasal swab and Saliva specimens**
- **Test Time: Results at 15 min.**
- **Shelf life: 24 months**
- **Storage temperature: 2-30˚C**

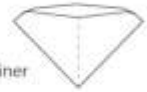
Test Procedure

Test Preparation

A. Open your test kit:

B. You should have:


Swab


Saliva Collection Container


Test cassette


Extraction Buffer Tube


Insert

Specimen Collection

Nasal Swabs


MEDICAL PROFESSIONAL COLLECTION

or


SELF COLLECTION


1 Using gentle rotation, push the swab up to 2.5 cm (1 inch) from the edge of the nostril.

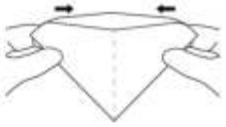

2 Rotate the swab 5 times against the mucosa inside the nostril.


3 Using the same swab, repeat this process in the other nostril.


4 Withdraw the swab from the nasal cavity. The sample is now ready for preparation.

Saliva

or



Note: False negative results may occur if the swab is not fully saturated with saliva.

Sample Preparation

Running the Test

Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flow*flex* SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)	L031-12525√	Cassette	Nasal swabs and Saliva	1 Test/Kit 20 Kits/Box
	L031-12535√	Cassette	Nasal swabs and Saliva	5 Tests/Kit

√ CE Marked

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1351353601

SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) Package Insert

REF L031-12525 REF L031-12535	English

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab and saliva specimens.
For professional in vitro diagnostic use only.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab and saliva specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test can also test specimens from asymptomatic individuals. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.
Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples 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.
Negative results, from patients with symptom beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. 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 SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings. SARS-CoV-2 Antigen Rapid Test is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab and saliva specimens.
When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the anti-SARS-CoV-2 antibody-coated particles, which have been pre-coated on the test strip. The mixture then migrates upward on the membrane by capillary action. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibody bound on the membrane. Test results are interpreted visually at 15-30 minutes based on the presence or absence of visually colored lines.
To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test cassette contains anti-SARS-CoV-2 antibodies.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink, or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against biological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves, mask and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations. The used test should be considered potentially infectious and be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- The test line for a high viral load sample may become visible within 15 minutes, or as soon as the sample passes the test line region.
- The test line for a low viral load sample may become visible within 30 minutes.

STORAGE AND STABILITY

- The kit can be stored at temperatures between 2 - 30 °C.
- The test is stable until the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Do not use after the expiration date.

MATERIALS

Materials Provided

- Test Cassettes
- Disposable Swabs*
- Package Insert
- Extraction Buffer Tubes
- Saliva Collection Container(s)

* *The Disposable Swabs are produced by another manufacturer.*

Materials Required But Not Provided

- Personal Protective Equipment
- Timer

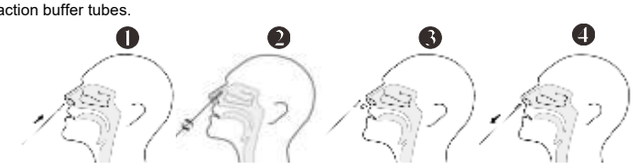
SPECIMEN COLLECTION AND PREPARATION

- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).
- An anterior nasal swab sample can be collected by a medical professional or by an individual performing a self-swab.
- Specimen collection, on children under 12 years of age, should be performed by a medical professional. Children aged 12 to 17 should be under adult supervision if they perform the anterior nasal swab by themselves. Adults aged 18 and over can perform the anterior nasal swab by themselves. Please follow your local guidelines for specimen collection by children.

MEDICAL PROFESSIONAL COLLECTION

SELF COLLECTION

- **How to collect an anterior nasal swab sample:**
  1. Carefully insert one of the Disposable Nasal Swabs, provided with your kit, into one nostril. Using gentle rotation, push the swab less than 2.5 cm (1 inch) from the edge of the nostril.
  2. Rotate the swab 5 times against the mucosa inside the nostril to ensure sufficient specimen collection
  3. Using the same swab, repeat the process in the other nostril to ensure that an adequate amount of sample is collected from both nasal cavities.
  4. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer tubes.



- **To collect a saliva sample:**

  Do NOT eat, drink, smoke, chew gum or brush your teeth 30 minutes prior to collecting a saliva sample.
  1. Before collecting a saliva sample, gently massage the cheeks for 15-30 seconds. Rest the tongue against the lower jaw and the roots of the teeth, and let saliva collect in that area.
  2. Insert a disposable swab into the mouth for at least 30 seconds until the tip of the swab is saturated with saliva.

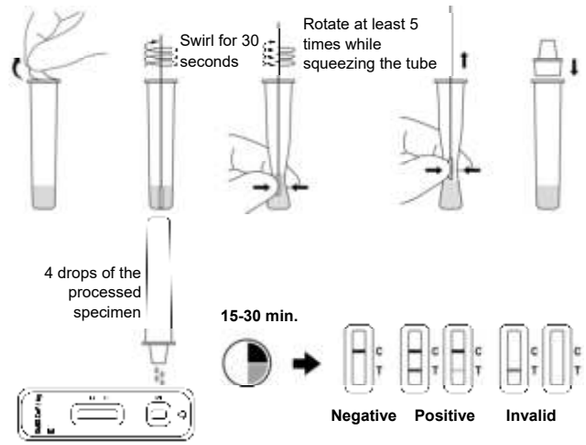
  Alternatively, saliva can be collected by carefully spitting into the saliva collection container. When using the saliva collection container, to collect saliva, plunge the absorbent tip of the disposable swab into the saliva collection container until the swab tip is fully saturated with saliva.

Note: *False negative results may occur if the swab is not fully saturated with saliva.*

DIRECTIONS FOR USE

Allow the test and extraction buffer to reach room temperature (15-30 °C) prior to testing.

1. Use an extraction buffer tube for each specimen to be tested and label each tube appropriately.
2. Remove the aluminum foil from the top of extraction buffer tube.
3. Insert the swab into the tube and swirl it for 30 seconds. Then rotate the swab at least 5 times while squeezing the sides of the tube. Take care to avoid splashing contents out of the tube.
4. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
5. Attach the dropper tip firmly onto the extraction buffer tube containing the sample. Mix thoroughly by swirling or flicking the bottom of the tube.
6. Remove the test cassette from the foil pouch and use it as soon as possible.
7. Place the test cassette on a flat and clean surface.
8. Add the processed specimen to the sample well of the test cassette.
   a. Invert the extraction buffer tube with the dropper tip pointing downwards and hold it vertically.
   b. Gently squeeze the tube, dispensing 4 drops of the processed specimen into the sample well.
9. Wait for the colored line(s) to appear. The result should be read at 15-30 minutes. **Do not read the result after 30 minutes.**



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE: Only one colored control line appears in the control region (C). No apparent colored line appears in the test line region (T). This means that no SARS-CoV-2 antigen was detected.
POSITIVE:* Two distinct colored lines appear. One line in the control line region (C) and the other line in the test line region (T). This means that the presence of SARS-CoV-2 antigen was detected.
***NOTE:** The intensity of the color in the test line (T) may vary depending on the level of the SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control swabs are not supplied with this kit; however, it is recommended that positive and negative controls should be tested as a good laboratory practice to ensure that the test cassette and that the test procedure performed correctly.

LIMITATIONS

1. The SARS-CoV-2 Antigen Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in nasal swab and saliva specimens. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.
   Please note that the viral load in saliva sample is relatively low, hence using nasal sample is recommended. Saliva sample can be used if nasal sampling is not possible.
2. Specimens should be tested as quickly as possible after specimen collection and at most within the hour following collection.
3. Use of viral transport media may result in decreased test sensitivity.
4. A false-negative test may result if the level of antigen in a sample is below the detection limit of the test or if the sample was collected incorrectly.

5. Test results should be correlated with other clinical data available to the physician.
6. A positive test result does not rule out co-infections with other pathogens.
7. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
8. A negative test result is not intended to rule out other viral or bacterial infections.
9. A negative result, from a patient with symptom onset beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management.
(If the differentiation of specific SARS viruses and strains is needed, additional testing is required.)

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

Nasal swabs specimens

The performance of SARS-CoV-2 Antigen Rapid Test was established with 605 nasal swabs collected from individual symptomatic patients who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test	**Results**	Negative	Positive	
	Negative	433	5	438
	Positive	2	165	167
Total Results		435	170	605

Relative Sensitivity: 97.1% (93.1%-98.9%)* Relative Specificity: 99.5% (98.2%-99.9%)*
Accuracy: 98.8% (97.6%-99.5%)* *95% Confidence Intervals

Stratification of the positive samples post onset of symptoms between 0-3 days has a positive percent agreement (PPA) of 98.8% (n=81) and 4-7 days has a PPA of 96.8% (n=62).
Positive samples with Ct value ⩽33 has a higher positive percent agreement (PPA) of 98.7% (n=153) .

Saliva specimens

The performance of SARS-CoV-2 Antigen Rapid Test was established with 341 saliva specimens collected from individual symptomatic patients who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test	**Results**	Negative	Positive	
	Negative	235	9	244
	Positive	1	96	97
Total Results		236	105	341

Relative Sensitivity: 91.4% (84.3%-95.6%)* Relative Specificity: 99.6% (97.4% - 99.9%)*
Accuracy: 97.1% (94.6% - 98.5%)* *95% Confidence Intervals

Limit of Detection (LOD)

The LOD of SARS-CoV-2 Antigen Rapid Test was established using limiting dilutions of an inactivated viral sample. The viral sample was spiked with negative human nasal and saliva sample pool into a seral of concentrations. Each level was tested for 30 replicates. The results show that the LOD is $1.6*10^2$ $TCID_{50}$/mL.

Cross-Reactivity (Analytical Specificity) and Microbial Interference

Cross-reactivity was evaluated by testing a panel of related pathogens and microorganisms that are likely to be present in the nasal cavity. Each organism and virus were tested in the absence or presence of heat-inactivated SARS-CoV-2 virus at low positive level.
No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in the table below. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Potential Cross-Reactant		Test Concentration	Cross-Reactivity (in the absence of SARS-CoV-2 virus)	Interference (in the presence of SARS-CoV-2 virus)
Virus	Adenovirus	1.14×10^6 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Enterovirus	9.50×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Human coronavirus 229E	1.04×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Human coronavirus OC43	2.63×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Human Metapneumovirus	1.25×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	MERS-coronavirus	7.90×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Influenza A	1.04×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Influenza B	1.04×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 1	1.25×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 2	3.78×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Parainfluenza virus 4	2.88×10^6 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Respiratory syncytial virus	3.15×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Rhinovirus	3.15×10^5 $TCID_{50}$/mL	No 3/3 negative	No 3/3 positive
	Human coronavirus-HKU1	1×10^5 copies/mL	No 3/3 negative	No 3/3 positive
Bacteria	Bordetella pertussis	2.83×10^9 CFU/mL	No 3/3 negative	No 3/3 positive
	Chlamydia trachomatis	3.13×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Haemophilus influenza	1.36×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Legionella pneumophila	4.08×10^9 CFU/mL	No 3/3 negative	No 3/3 positive
	Mycobacterium tuberculosis	1.72×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Mycoplasma pneumoniae	7.90×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Staphylococcus aureus	1.38×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Staphylococcus epidermidis	2.32×10^9 CFU/mL	No 3/3 negative	No 3/3 positive
	Streptococcus pneumoniae	1.04×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Streptococcus pyogenes	4.10×10^6 CFU/mL	No 3/3 negative	No 3/3 positive
	Pneumocystis jirovecii-S. cerevisiae	8.63×10^7 CFU/mL	No 3/3 negative	No 3/3 positive
	Pseudomonas aeruginosa	1.87×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
	Chlamydia pneumoniae	1×10^6 IFU/ml	No 3/3 negative	No 3/3 positive
Yeast	Candida albicans	1.57×10^8 CFU/mL	No 3/3 negative	No 3/3 positive
Pooled human nasal wash			No 3/3 negative	No 3/3 positive

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. Each substance was tested in the absence or presence of SARS-CoV-2 virus at low positive level. The final concentration of the substances tested are listed below and were found not to affect test performance.

Interfering Substance	Active Ingredient	Concentration	Results (in the absence of SARS-CoV-2 virus)	Results (in the presence of SARS-CoV-2 virus)
Endogenous	Biotin	2.4 mg/mL	3/3 negative	3/3 positive
	Mucin	0.5% w/v	3/3 negative	3/3 positive
	Whole Blood	4% v/v	3/3 negative	3/3 positive
Afrin Original Nasal Spray	Oxymetazoline	15% v/v	3/3 negative	3/3 positive
ALKALOL Allergy Relief Nasal Spray	Homeopathic	1:10 Dilution	3/3 negative	3/3 positive
Chloraseptic Max Sore Throat Lozenges	Menthol, Benzocaine	1.5 mg/mL	3/3 negative	3/3 positive
CVS Health Fluticasone Propionate Nasal Spray	Fluticasone propionate	5% v/v	3/3 negative	3/3 positive
Equate Fast-Acting Nasal Spray	Phenylephrine	15% v/v	3/3 negative	3/3 positive
Equate Sore Throat Phenol Oral Anesthetic Spray	Phenol	15% v/v	3/3 negative	3/3 positive
Original Extra Strong Menthol Cough Lozenges	Menthol	1.5 mg/mL	3/3 negative	3/3 positive
NasalCrom Nasal Spray	Cromolyn	15% v/v	3/3 negative	3/3 positive
NeilMed NasoGel for Dry Noses	Sodium Hyaluronate	5% v/v	3/3 negative	3/3 positive
Throat Lozenge	Dyclonine Hydrochloride	1.5mg/mL	3/3 negative	3/3 positive
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5% v/v	3/3 negative	3/3 positive
Antibiotic	Mupirocin	10 mg/mL	3/3 negative	3/3 positive
Tamiflu	Oseltamivir Phosphate	5 mg/mL	3/3 negative	3/3 positive
Antibiotic	Tobramycin	4 µg/mL	3/3 negative	3/3 positive
Mometasone Furoate Nasal Spray	Mometasone Furoate	5%v/v	3/3 negative	3/3 positive
Physiological Seawater Nasal Cleaner	NaCl	15%v/v	3/3 negative	3/3 positive

PRECISION

Intra-Assay

Within-run precision was determined using 60 replicates of specimens: negative specimen and SARS-CoV-2 antigen positive specimen. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision was determined using 60 independent assays on the same specimens: negative specimen and SARS-CoV-2 antigen positive specimen. Three different lots of the SARS-CoV-2 Antigen Rapid Test were tested using these specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502
2. Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Volume 81: 85-164

Index of Symbols

	Manufacturer	Σ	Contains sufficient for <*n*> tests		Temperature limit
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
	Consult instructions for use	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community				Date of manufacture

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30175 Hannover, Germany

Distribuito da: **Nevia Biotech S.r.l**
Via Piedipastini,14
83048 Montella (AV)
ITALY

Numero: 1151321701
Data di rilascio: 2021-XX-XX

Test Antigenico Rapido per SARS-CoV-2 (nasale/salivare)

Foglietto Illustrativo

REF L031-12525 REF L031-12535	Italiano

Test rapido per la rilevazione qualitativa degli antigeni nucleocapsidici del virus SARS-CoV-2 in campioni di tampone nasale o saliva.
Solo per uso diagnostico professionale in vitro.

USO PREVISTO

Il test antigenico rapido per SARS-CoV-2, è un test immunologico cromatografico a flusso laterale per la rilevazione qualitativa dell'antigene della proteina nucleocapsidica del virus SARS-CoV-2, in campioni di tampone nasale o saliva, prelevati direttamente da individui con sospetta infezione da COVID-19 dal loro medico, entro i primi sette giorni dalla comparsa dei sintomi. Il test antigenico rapido per SARS-CoV-2 può essere usato per analizzare campioni di soggetti asintomatici. Il test antigenico rapido per SARS-CoV-2 non distingue tra SARS-CoV e SARS-CoV-2.
Un risultato positivo evidenzia la presenza dell'antigene nucleocapsidico SARS-CoV-2. Questo antigene è generalmente rilevabile nei campioni delle vie respiratorie superiori durante la fase acuta dell'infezione. Come ricordato, risultati positivi indicano la presenza di antigeni virali, ma è necessaria la correlazione clinica con l'anamnesi del paziente e altre informazioni diagnostiche per determinare lo stato dell'infezione. Risultati positivi non escludono infezioni batteriche o co-infezioni da altri virus. L'agente rilevato potrebbe non essere la causa definitiva della malattia.
Risultati negativi, in pazienti con sintomi oltre i sette giorni, dovrebbero essere trattati come presunti negativi e confermati con un test molecolare per una corretta gestione del paziente. Risultati negativi non escludono un'infezione da SARS-CoV-2 e non devono essere utilizzati come unico riferimento per le decisioni di trattamento o di gestione del paziente, comprese le decisioni su cui basare l'approccio clinico all'infezione. I risultati negativi devono essere considerati nel contesto delle esposizioni recenti del paziente, dell'anamnesi e della presenza di segni e sintomi clinici coerenti con COVID-19.
Il test antigenico rapido per SARS-CoV-2 è destinato all'uso da parte di personale di laboratorio clinico addestrato e di operatori sanitari qualificati presso centri di assistenza. Il Test Rapido Antigenico SARS-CoV-2 è destinato ad essere utilizzato come ausilio nella diagnosi di infezione da SARS-CoV-2.

RIASSUNTO

I nuovi coronavirus appartengono al genere β. COVID-19 è una malattia infettiva respiratoria acuta. Gli esseri umani sono generalmente soggetti a tale infezione. Attualmente, i pazienti infettati dal nuovo coronavirus sono la principale fonte di infezione ma le persone infette asintomatiche possono rappresentare anch'essi una fonte di infezione. Sulla base dell'attuale indagine epidemiologica, il periodo di incubazione è compreso tra 1 e 14 giorni, principalmente tra 3 e 7 giorni. Le principali manifestazioni sono febbre, stanchezza e tosse secca, perdita dell'olfatto, insufficienza respiratoria. In alcuni casi sono presenti congestione nasale, rinorrea, mal di gola, mialgia e diarrea.

PRINCIPIO

Il test antigenico rapido per SARS-CoV-2 è un test immunologico cromatografico qualitativo su membrana, per la rilevazione qualitativa dell'antigene proteico nucleocapsidico del virus SARS-CoV-2, in campioni di tampone nasale o saliva umana.
Quando i campioni estratti vengono processati e dispensati nella cassetta per il test, gli antigeni del SARS-CoV-2, se presenti nel campione, reagiscono con le particelle rivestite con anticorpi anti-SARS-CoV-2, che sono presenti sulla linea di test (T). La miscela migra quindi attraverso la membrana per azione capillare. I complessi antigene-coniugato migrano attraverso la striscia di test verso l'area di reazione e vengono catturati da una linea di anticorpi legati sulla membrana. I risultati dei test vengono interpretati visivamente dopo 15e non oltre 30 minuti in base alla presenza o all'assenza di linee colorate visibili.
Quale esclusivo controllo procedurale, nella regione della linea di controllo (C) viene sempre visualizzata una linea colorata che indica che è stato aggiunto il volume corretto del campione e che si è verificata corretta imbibizione della membrana.

REAGENTI

La cassetta per il test contiene anticorpi anti-SARS-CoV-2.

PRECAUZIONI

- Solo per uso diagnostico professionale *in vitro*. Non utilizzare oltre la data di scadenza.
- Non mangiare, bere o fumare nella zona in cui vengono manipolati i campioni o il kit.
- Non utilizzare il test se l'involucro esterno è danneggiato.
- Maneggiare tutti i campioni come se contenessero agenti infettivi. Osservare le precauzioni stabilite contro i pericoli biologici durante i test e seguire le procedure standard per il corretto smaltimento dei campioni.
- Indossare indumenti protettivi, ad esempio camici da laboratorio, guanti usa e getta, maschere e protezioni per gli occhi quando vengono testati i campioni.
- Il test utilizzato deve essere smaltito in conformità alle normative locali. Il test utilizzato deve essere considerato potenzialmente infetto e smaltito in conformità alle normative locali.
- Umidità e temperatura possono influire negativamente sui risultati.
- Leggere attentamente il foglietto illustrativo prima di eseguire il test. La mancata osservanza delle istruzioni precisate nel foglietto illustrativo potrebbe non permettere di ottenere risultati di test precisi.
- La linea del test per un campione con carica virale alta potrebbe diventare visibile entro 15 minuti, o non appena il campione supera l'area della linea del test.
- La linea del test per un campione con carica virale bassa diventa visibile dopo 30 minuti.

STOCCAGGIO E STABILITÀ

- Il kit deve essere conservato a temperature comprese tra 2 - 30 °C.
- Il test è stabile fino alla data di scadenza stampata sull'involucro esterno sigillato.
- Il test deve rimanere nell'involucro sigillato fino all'uso.
- NON CONGELARE.
- Non utilizzare oltre la data di scadenza.

MATERIALI

Materiali forniti

- Cassette per il test
- Tamponi monouso*
- Foglietto illustrativo
- Provette contenenti la soluzione tampone di estrazione
- Contenitori per la raccolta della saliva

** I tamponi monouso sono realizzati da un altro produttore.*

Materiali necessari ma non forniti

- Dispositivi di protezione individuale
- Timer

PRELIEVO E PREPARAZIONE DEI CAMPIONI

- Il test deve essere eseguito immediatamente dopo il prelievo del campione, o al massimo entro un'ora (1) dal prelievo del campione stesso, a condizione che sia conservato a temperatura ambiente (15-30°C).
- Il prelievo del campione con tampone nasale può essere eseguito da un professionista oppure da soli, ma sempre sotto la supervisione di un professionista sanitario.
- Per i bambini con meno di 12 anni di età, la raccolta dei campioni deve essere eseguita da un professionista sanitario. I bambini di età compresa tra 12 e 17 anni devono essere sorvegliati da adulti se prelevano da soli il campione nasale. Gli adulti (dai 18 anni in su) possono eseguire autonomamente il prelievo del campione nasale. Seguire le linee guida locali per la raccolta dei campioni da parte dei bambini.

PRELIEVO DA PARTE DI PROFESSIONISTI SANITARI **PRELIEVO AUTONOMO**

- **Come prelevare un campione nasale anteriore con un tampone**

1. Inserire con cautela uno dei tamponi nasali monouso inclusi nel kit in una narice. Ruotandolo delicatamente, spingere il tampone all'interno del naso di non oltre 2,5 cm (1 pollice) dall'estremità della narice.

2. Strusciare la parte cotonata del tampone nasale sulla superfice interna della narice (mucosa) praticando movimenti rotatori, sia in un senso che nell'altro, per cinque volte consecutive.

3. Utilizzando lo stesso tampone nasale, ripetere la procedura nell'altra narice per assicurarsi che venga raccolto un campione adeguato da entrambe le cavità nasali.

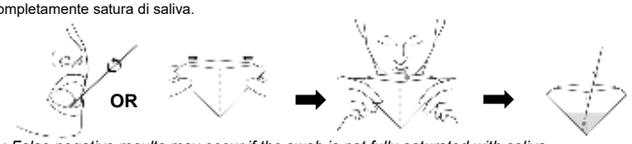
4. Rimuovere il tampone dalla cavità nasale. Ora il campione è pronto per la preparazione utilizzando le provette contenenti la soluzione tampone di estrazione.

- **Come raccogliere un campione di saliva:**

NON mangiare, bere, fumare, masticare gomme o lavarsi i denti 30 minuti prima di raccogliere un campione di saliva.

1. Prima di raccogliere un campione di saliva, massaggiare delicatamente le guance per 15-30 secondi. Appoggiare la lingua contro le radici dei denti dell'arcata inferiore e lasciare che la saliva si raccolga in quella zona.
2. Inserire un tampone cotonato monouso (presente nel KIT) in bocca, e mantenerlo per almeno 30 secondi, fino a quando la punta del tampone non sia completamente satura di saliva.

In alternativa, la saliva può essere raccolta sputando con attenzione nel contenitore di raccolta della saliva incluso nel KIT. Quando si utilizza il contenitore di raccolta della saliva per raccogliere la saliva, immergere la punta assorbente del tampone monouso nel contenitore di raccolta medesimo fino a quando la punta del tampone non sia completamente satura di saliva.

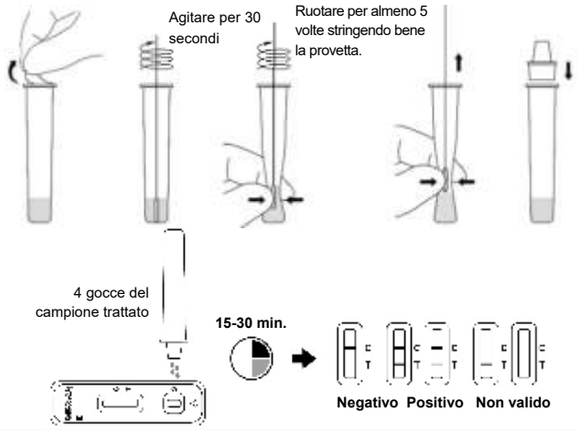


Note: *False negative results may occur if the swab is not fully saturated with saliva.*

ISTRUZIONI PER L'USO

Lasciare che il campione e la soluzione tampone di estrazione raggiungano la temperatura ambiente (15-30 °C) prima di eseguire il test.

1. Utilizzare una provetta contenente la soluzione tampone di estrazione per ciascun campione da testare ed etichettare ciascuna provetta in modo appropriato.
2. Rimuovere il foglio di alluminio dall'estremità superiore della provetta contenente la soluzione tampone di estrazione.
3. Inserire il tampone nella provetta ed agitare per 30 secondi. Quindi ruotare il tampone almeno 5 volte stringendo bene i lati della provetta. Prestare attenzione a non spruzzare il contenuto fuori dalla provetta.
4. Rimuovere il tampone premendo i lati della provetta per estrarre il liquido dal tampone.
5. Fissare saldamente la punta del contagocce sulla provetta del tampone di estrazione contenente il campione. Mescolare accuratamente ruotando e sfiorando il fondo della provetta.
6. Rimuovere la cassetta per il test dalla busta di alluminio e utilizzarla al più presto.
7. Posizionare la cassetta per il test su una superficie piana e pulita.
8. Aggiungere il campione elaborato al relativo pozzetto della cassetta per il test.
   a. Rovesciare la provetta contenente la soluzione tampone di estrazione e il campione con la punta del contagocce rivolta verso il basso, mantenendola in posizione verticale.
   b. Premere delicatamente la provetta, versando 4 gocce del campione trattato nel pozzetto di campionamento.
9. Attendere lo sviluppo delle linee colorate. Il risultato deve essere letto dopo 15-30 minuti. **Non leggere il risultato dopo 30 minuti.**



INTERPRETAZIONE DEI RISULTATI

(Si rimanda all'illustrazione di cui sopra)

NEGATIVO: Nella regione della linea di controllo (C) viene visualizzata una sola linea colorata. Nella regione della linea di test (T) non viene visualizzata alcuna linea colorata visibile. Significa che non è stato rilevato alcun antigene SARS-CoV-2.
POSITIVO:* Vengono visualizzate due linee colorate distinte. Una linea nella regione della linea di controllo (C) e l'altra-nella regione della linea di test (T). Significa che è stato rilevato l'antigene SARS-CoV-2.
***NOTA:** L'intensità del colore della linea di test (T) può variare a seconda del livello di antigene SARS-CoV-2 presente nel campione. Pertanto, qualsiasi tonalità di colore nella regione della linea di test (T) deve essere considerata positiva.
NON VALIDO: Non viene visualizzata alcuna linea di controllo. Volume del campione insufficiente o errato utilizzo sono le ragioni più probabili della mancata comparsa della linea di controllo. Rivedere la procedura e ripetere il test con una nuova cassetta per test. Se il problema persistesse, non utilizzare ulteriormente il kit e contattare il distributore locale.

CONTROLLO DI QUALITÀ

I controlli procedurali interni sono inclusi nel test. Una linea colorata visualizzata nella regione della linea di controllo (C) rappresenta un controllo procedurale interno. Conferma il volume del campione sufficiente e la corretta tecnica procedurale.
Questo kit non include tamponi di controllo; si raccomanda tuttavia, come buona pratica di laboratorio, di analizzare campioni positivi e negativi per assicurare che il test a cassetta e la procedura del test abbiano funzionato correttamente.

LIMITAZIONI

1. Il test antigenico rapido per SARS-CoV-2 è destinato al solo uso diagnostico *in vitro*. Il test deve essere utilizzato per la rilevazione degli antigeni del virus SARS-CoV-2 in campioni di tampone nasale o saliva. L'intensità della linea di test non è necessariamente correlata al titolo virale SARS-CoV-2 presente nel campione.
   Si noti che la carica virale nel campione di saliva è relativamente bassa, quindi si consiglia di utilizzare un campione nasale. Se il campionamento nasale non è possibile, può essere utilizzato il campione di saliva.
2. I campioni devono essere testati il più rapidamente possibile dopo il prelievo del campione stesso e al massimo entro l'ora successiva al prelievo.
3. L'uso di mezzi (terreni) di conservazione e stabilizzazione per il trasporto del campione può comportare una riduzione della sensibilità al test.
4. Potrebbe essere ottenuto un test falso negativo se la concentrazione di antigene in un campione risultasse inferiore al limite di rilevazione del test o se il campione fosse stato raccolto in modo errato.
5. I risultati dei test devono essere correlati con altri dati clinici a disposizione del medico.

6. Un risultato positivo del test non esclude co-infezioni da altri patogeni.
7. Un risultato positivo del test non distingue tra SARS-CoV e SARS-CoV-2.
8. Un risultato negativo del test non intende escludere altre infezioni virali o batteriche.
9. Un risultato negativo, su un paziente con l'insorgenza di sintomi oltre i sette giorni, dovrebbe essere trattato come presunto negativo e confermato con un test molecolare, in base al quale stabilire il trattamento clinico. (Qualora fosse necessaria la differenziazione di virus e ceppi SARS specifici, si dovrà procedere ad ulteriori test.)

CARATTERISTICHE DEL METODO

Sensibilità relativa, Specificità relativa ed Accuratezza

Campioni di tamponi nasali

Le prestazioni del test antigenico rapido per SARS-CoV-2 sono state definite in base all'analisi di 605 tamponi nasali prelevati da singoli pazienti sintomatici con sospetta infezione da COVID-19. I risultati mostrano che la sensibilità e la specificità relativa sono le seguenti:

Metodo		RT-PCR		Risultati totali
Test antigenico rapido per SARS-CoV-2	Risultati	Negativo	Positivo	
	Negativo	433	5	438
	Positivo	2	165	167
Risultati totali		435	170	605

Sensibilità relativa: 97,1% (93,1%-98,9%)* Specificità relativa: 99,5% (98,2%-99,9%)*
Accuratezza: 98,8% (97,6%-99,5%)* *95% Intervalli di confidenza
La stratificazione dei campioni positivi successivamente alla comparsa dei sintomi tra 0-3 giorni presenta una percentuale di concordanza positiva (PPA) pari al 98,8% (n=81) e tra 4-7 giorni presenta una percentuale di concordanza positiva (PPA) pari al 96,8% (n=62).
I campioni positivi con valore Ct ≤33 presentano una percentuale di concordanza positiva (PPA) superiore o pari al 98,7% (n=153).

Campioni di saliva

Le prestazioni del test antigenico rapido per SARS-CoV-2, sono state stabilite attraverso la valutazione di 341 campioni di saliva raccolti da singoli pazienti sintomatici con sospetta infezione da COVID-19. I risultati mostrano che la sensibilità relativa e la specificità relativa sono le seguenti:

Metodo		RT-PCR		Risultati totali
Test antigenico rapido per SARS-CoV-2	Risultati	Negativo	Positivo	
	Negativo	235	9	244
	Positivo	1	96	97
Risultati totali		236	105	341

Sensibilità relativa: 91.4% (84.3%-95.6%)* Specificità relativa: 99,6% (97,4% - 99,9%)*
Accuratezza: 97.1% (94.6% - 98.5%)* *95% Intervalli di confidenza

Limite di rilevazione (LOD)

Il limite di rilevamento del test antigenico rapido per SARS-CoV-2 è stato determinato usando diluizioni limitate di un campione virale inattivato. Il campione virale è stato addizionato ad una serie di campioni di saliva e nasali umani negativi, a diverse concentrazioni.Ogni livello è stato testato per 30 repliche.
I risultati mostrano che il LOD corrisponde a $1,6*10^2$ $TCID_{50}$/mL.

Reattività crociata (specificità analitica) e Interferenza microbica

La reattività crociata è stata valutata testando un panel di patogeni e microorganismi correlati che potrebbero potenzialmente essere presenti nella cavità nasale. Ogni organismo e virus è stato testato in assenza o in presenza del virus SARS-CoV-2 inattivato termicamente con bassa positività.
Non è stata osservata reattività crociata o interferenza con i seguenti microorganismi quando testati alle concentrazioni precisate nella tabella allegata sottostante. Il test antigenico rapido per SARS-CoV-2 non distingue tra SARS-CoV e SARS-CoV-2.

Potenziale cross-reattivo		Concentrazione del test	Reattività crociata (in assenza del virus SARS-CoV-2)	Interferenza (in presenza del virus SARS-CoV-2)
Virus	Adenovirus	1,14 x 10^6 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Enterovirus	9,50 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Coronavirus umano 229E	1,04 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Coronavirus umano OC43	2,63 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Coronavirus umano NL63	1,0 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Metapneumovirus umano	1,25 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	MERS-coronavirus	7,90 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Influenza A	1,04 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Influenza B	1,04 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Parainfluenza virus 1	1,25 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Parainfluenza virus 2	3,78 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Parainfluenza virus 3	1,0 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Parainfluenza virus 4	2,88 x 10^6 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Virus respiratorio sinciziale	3,15 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Rinovirus	3,15 x 10^5 $TCID_{50}$/mL	No 3/3 negativo	No 3/3 positivo
	Coronavirus umano-HKU1	1 x 10^5 copies/mL	No 3/3 negativo	No 3/3 positivo
Batteri	Bordetella pertussis	2,83 x 10^9 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Chlamydia trachomatis	3,13 x 10^8 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Haemophilus influenzae	1,36 x 10^8 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Legionella pneumophila	4,08 x 10^9 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Mycobacterium tuberculosis	1,72 x 10^7 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Mycoplasma pneumoniae	7,90 x 10^7 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Staphylococcus aureus	1,38 x 10^7 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Staphylococcus epidermidis	2,32 x 10^9 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Streptococcus pneumoniae	1,04 x 10^8 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Streptococcus pyogenes	4,10 x 10^6 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Pneumocystis jirovecii-S. cerevisiae	8,63 x 10^7 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Pseudomonas aeruginosa	1,87 x 10^8 CFU/mL	No 3/3 negativo	No 3/3 positivo
	Chlamydia pneumoniae	1×10^6 IFU/ml	No 3/3 negativo	No 3/3 positivo
Candida	Candida albicans	1,57 x 10^8 CFU/mL	No 3/3 negativo	No 3/3 positivo
Lavaggio nasale umano in pool			No 3/3 negativo	No 3/3 positivo

Sostanze interferenti

Sono state valutate le seguenti sostanze naturalmente presenti nei campioni respiratori o che sono state artificialmente introdotte nella cavità nasale o nel rinofaringe. Ogni sostanza è stata testata in assenza o in presenza del virus SARS-CoV-2 a bassa positività. La concentrazione finale delle sostanze testate è precisata nella tabella seguente e non sembra influenzare le prestazioni del test.

Sostanza interferente	Principio attivo	Concentrazione	Risultati (in assenza del virus SARS-CoV-2)	Risultati (in presenza del virus SARS-CoV-2)
Endogeno	Biotina	2,4 mg/mL	3/3 negativo	3/3 positivo
	Mucina	0,5% w/v	3/3 negativo	3/3 positivo
	Sangue intero	4% v/v	3/3 negativo	3/3 positivo
Spray nasale Afrin Original	Oxymetazoline	15% v/v	3/3 negativo	3/3 positivo
Spray nasale sollievo allergia ALKALOL	Omeopatico	1:10 Diluizione	3/3 negativo	3/3 positivo
Pastiglie per mal di gola Max Chloraseptic	Mentolo, Benzocaina	1,5 mg/mL	3/3 negativo	3/3 positivo
Spray nasale a base di fluticasone propionato CVS Health	Fluticasone propionato	5% v/v	3/3 negativo	3/3 positivo
Spray nasale ad azione rapida Equate	Fenilefrina	15% v/v	3/3 negativo	3/3 positivo
Spray anestetico orale fenolico per mal di gola Equate	Fenolo	15% v/v	3/3 negativo	3/3 positivo
Pastiglie per la gola al mentolo extra-forte Original	Mentolo	1,5 mg/mL	3/3 negativo	3/3 positivo
Spray nasale NasalCrom	Cromolina	15% v/v	3/3 negativo	3/3 positivo
Nasogel per mucose secche Neilmed	Ialuronato di sodio	5% v/v	3/3 negativo	3/3 positivo
Pastiglie per il mal di gola	Idrocloruro di diclonina	1,5mg/mL	3/3 negativo	3/3 positivo
Rimedio per il raffreddore Zicam	Galphimia glauca, Luffa operculata, Sabadilla	5% v/v	3/3 negativo	3/3 positivo
Antibiotico	Mupirocina	10 mg/mL	3/3 negativo	3/3 positivo
Tamiflu	Oseltamivir Fosfato	5 mg/mL	3/3 negativo	3/3 positivo
Antibiotico	Tobramicina	4 µg/mL	3/3 negativo	3/3 positivo
Spray nasale al mometasone furoato	Mometasone furoato	5%v/v	3/3 negativo	3/3 positivo
Soluzione di lavaggio con soluzione salina	NaCl	15%v/v	3/3 negativo	3/3 positivo

PRECISIONE

Intra-dosaggio

La precisione durante l'esecuzione è stata determinata utilizzando 60 repliche di campioni: campioni negativi e campioni positivi dell'antigene SARS-CoV-2. I campioni sono stati identificati correttamente >99% delle volte.

Inter-dosaggio

La precisione durante l'esecuzione è stata determinata utilizzando 60 dosaggi indipendenti sullo stesso campione negativo e campione positivo dell'antigene SARS-CoV-2. Con questi campioni sono stati testati tre diversi lotti del test antigenico rapido per SARS-CoV-2. I campioni sono stati identificati correttamente >99% delle volte.

BIBLIOGRAFIA

1. Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, June 2016, vol. 24, No. 6: 490-502
2. Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Volume 81: 85-164

Indice dei simboli

	Fabbricante	Σ	Contenuto sufficiente per <*n*> test		Limite di temperatura
IVD	Dispositivo medico diagnostico *in vitro*		Data di scadenza		Non riutilizzare
	Consultare le istruzioni per l'uso	LOT	Codice lotto	REF	Numero di catalogo
EC REP	Rappresentante autorizzato nella Comunità Europea				Data di produzione

Indice dei contenuti

SARS-CoV-2 Antigen	Antigene SARS-CoV-2
Extraction Buffer Tubes	Provette contenenti la soluzione tampone di estrazione
Disposable Swabs	Tamponi monouso
Nasal Swabs	Tamponi nasali
Saliva Collection Container	Contenitori per la raccolta della saliva
SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)	Test Antigenico Rapido per SARS-CoV-2 (nasale/salivare)

***ACON* Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego, CA 92121, USA
www.aconlabs.com

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Distributed by:
Nevia Biotech S.r.l
Via Piedipastini,14
83048 Montella (AV)
ITALY

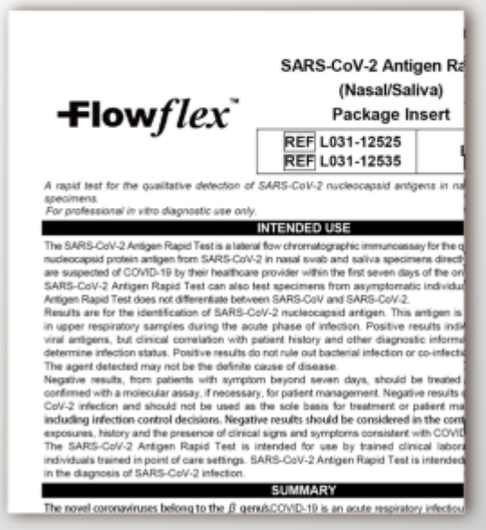
Numero: 1151318501
Data di rilascio: 2021-xx-xx

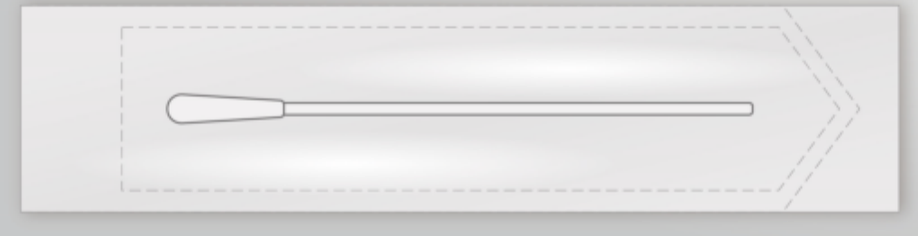

Flowflex™
(REF) L031-12525
SARS-CoV-2 Antigen Rapid Test
(Nasal/Saliva)
Contents:
• 1 Test Cassette
• 1 Extraction Buffer Tube
• 1 Disposable Swabs
• 1 Saliva Collection Container
• Package Insert
COVID-19 Test
A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab and saliva specimens.
For professional in vitro diagnostic use only.
Italiano
Test antigenico rapido per SARS-CoV-2
Contenuti:
• Cassette per il test
• Provette del tampone di estrazione
• Tamponi monouso
• Contenitore per la raccolta della saliva
• Foglietto illustrativo


NUOVA GOOD LUCK


IVD
ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego, CA 92121, USA
For in vitro diagnostic use.


SARS-CoV-2 Ag
ID:
C
T
S


Flowflex™
SARS-CoV-2 Antigen Ra
(Nasal/Saliva)
Package Insert
REF L031-12525
REF L031-12535
A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in na
specimens.
For professional in vitro diagnostic use only.
INTENDED USE
The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the q
nucleocapsid protein antigen from SARS-CoV-2 in nasal swab and saliva specimens direct
are suspected of COVID-19 by their healthcare provider within the first seven days of the on
SARS-CoV-2 Antigen Rapid Test can also test specimens from asymptomatic individua
Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.
Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is
in upper respiratory samples during the acute phase of infection. Positive results indi
viral antigens, but clinical correlation with patient history and other diagnostic informa
determine infection status. Positive results do not rule out bacterial infection or co-infecti
The agent detected may not be the definite cause of disease.
Negative results, from patients with symptom beyond seven days, should be treated
confirmed with a molecular assay, if necessary, for patient management. Negative results
CoV-2 infection and should not be used as the sole basis for treatment or patient ma
including infection control decisions. Negative results should be considered in the cont
exposures, history and the presence of clinical signs and symptoms consistent with COVI
The SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical labora
individuals trained in point of care settings. SARS-CoV-2 Antigen Rapid Test is intended
in the diagnosis of SARS-CoV-2 infection.
SUMMARY
The novel coronaviruses belong to the β genusCOVID-19 is an acute respiratory infectiou



Ministero della Salute

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM:
Codice attribuito dal fabbricante:
Nome commerciale e modello: **FLOWFLEX SARS-COV-2 ANTIGEN RAPID TEST (NASAL/SALIVA)**
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:03/04/2021

DISPOSITIVO MEDICO/ASSEMBLATO	FABBRICANTE/ASSEMBLATORE

TIPOLOGIA DISPOSITIVO	IDENTIFICATIVO DI REGISTRAZIONE BD/RDM	ISCRITTO AL REPERTORIO	CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE CE	DATA PRIMA PUBBLICAZIONE	DATA FINE IMMISSIONE IN COMMERCIO	RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
Dispositivo	2086636	S	L031-12515	FLOWFLEX SARS-COV-2 ANTIGEN RAPID TEST (NASAL/SALIVA)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	01/04/2021		FABBRICANTE	ACON LABORATORIES, INC.			US
									MANDATARIO	MDSS GMBH		177346163	DE
Dispositivo	2087441	S	L031-12525	Flowflex SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	01/04/2021		FABBRICANTE	ACON LABORATORIES, INC.			US
									MANDATARIO	MDSS GMBH		177346163	DE
Dispositivo	2087442	S	L031-12535	Flowflex SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	01/04/2021		FABBRICANTE	ACON LABORATORIES, INC.			US
									MANDATARIO	MDSS GMBH		177346163	DE

<< < Pagina:1 > >> Num. Pagine:1 Num. Dispositivi:3

Certificate of CE-Registration

MDSS Medical Device Safety Service

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC and the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Acon Laboratories, Inc.
5850 Oberlin Drive, #340
San Diego, CA 92121
USA

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and medical devices and has allocated registration numbers shown in:

Annex A dated 2021-03-15

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices and medical devices fulfill the applicable requirements of Directives 98/79/EC and 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2021-03-15

Dr. Philipp Hohenbrink
Senior Consultant
MDSS GmbH

Annex A: 2021-03-15
Manufacturer: ACON Laboratories, Inc

REF	Device Names (notified)	Optional Information/Category Code	Nomenclature	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
L031-11011	Malaria P.f/P.v Antigen Rapid Test Cassette (Whole Blood)		15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/091-01
L031-10911	Malaria P.f/Pan Antigen Rapid Test Cassette (Whole Blood)		15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/091-01
F131-10211	FIAflex™ Influenza A/B FIA		15 70 90 04	Influenza A and /or B - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/104
L031-11915	Flowflex™ Influenza A/B Rapid Test		15 70 90 04	Influenza A and /or B - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/104
L031-11211	ACON® Dengue NS1 Antigen Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/094-01
L031-11311	ACON® Dengue IgG/IgM Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/094-01
L031-11511	ACON® Dengue NS1 Ag & IgG/IgM Combo Rapid Test Cassette (Serum/Plasma/Whole Blood)		15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/094-01
L031-11815 L031-11825 L031-11845	Flowflex™ SARS-CoV-2 Antigen Rapid Test		15 70 90 08	Coronavirus – RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/100-03
L031-11813F L031-11843F	Ritter® Easy Check SARS-CoV-2 Antigen Rapid Test		15 70 90 08	Coronavirus – RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/100-03
L031-11865, L031-11875, L031-11885, L031-11895, L031-118D5, L031-118E5	Flowflex™ SARS-CoV-2 Antigen Rapid Test Strip		15 70 90 08	Coronavirus – RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/100-03
L031-12515, L031-12525 L031-12535,	Flowflex™ SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)		15 70 90 08	Coronavirus – RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/100-03
L031-11711	ACON® SARS-CoV-2 IgG/IgM Rapid Test		15 70 90 90	Other Other Virology - RT & POC	"Other"	N/A	DE/CA09/0170/A10/IVD/095

Declaration of Conformity

ACON Laboratories, Incorporated
5850 Oberlin Drive, #340
San Diego, CA 92121, USA

We, the manufacturer, declare under our sole responsibility that the *in vitro* diagnostic device:

Flowflex™ SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)

classified as Others in the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

The self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 1 day of March, 2021
in San Diego, CA, USA

Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.

Clinical Study Report
for
SARS-CoV-2 Antigen Rapid Test
(Nasal/Saliva)

I. Intend for Use

The SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab and saliva specimens directly from individuals who are suspected of COVID-19 by their healthcare provider. The SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) does not differentiate between SARS-CoV and SARS-CoV-2.

II. Objective

A multi-site clinical study was conducted in China to evaluate the performance of the SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) when compared to RT-PCR method.

III. Clinical Study Site and Study Period

Sample collection sites in China	Testing sites in China
Site 1: Shenzhen CDC No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China	Site 1: Shenzhen CDC No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China
Site 2: Adicon No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China	Site 2: Adicon No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China

Study Period

Study Initiation Date: Nov, 2020

Study Completion Date: Mar, 2021

IV. Study acceptance criteria

Total Sensitivity: ≥85%

Total Specificity: ≥98%

V. Study Procedure:

The clinical performance of the SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) was evaluated at two (2) investigational sites in China using a total of 341 Saliva specimens collected from the patients at multiple sites in China.

Material:

- SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva), Lot# 202009001
- RT-PCR, Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing), FDA authorized RT-PCR test for emergency use, manufactured by Sansure BioTech Inc.
- Saliva samples from infected patients and non-infected patients

Procedure:

A total of 341 Saliva specimens were collected from the patients at multiple sites in China. The patients presenting the COVID-19 like symptoms within 14 days of symptom onset at the collection sites are enrolled.

The Saliva specimens were randomized and blinded tested by operators following product package insert.

A companion nasopharyngeal (NP) swab was also collected from the same patient and confirmed as positive or negative and validated with Ct counts by the FDA EUA RT-PCR as a comparator method.

Also the RT-PCR test results were confirmed by the clinical diagnostic result. RT-PCR positive specimens were all from diagnosis of COVID-19 patients and RT-PCR negative specimens were all from non COVID-19 patients.

Test results:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Test Results	Negative	235	9	244
	Positive	1	96	97
	Total	236	105	341

Relative Sensitivity: 91.4% (95% CI: 84.3%-95.6%)
Relative Specificity: 99.6% (95% CI: 97.4% - 99.9%)
Accuracy: 97.1% (95% CI: 94.6%-98.5%)

Positive results to be reported by different Ct value range

Ct value	RT-PCR Positive (+)	Proportion	SARS-CoV-2 Antigen Rapid Test Positive (+)	PPA
≤25	59	56.2%	59	100%
25-30	42	40%	36	85.7%
>30	4	3.8%	1	25%

Comparing with RT-PCR, the positive percent agreement (PPA) of the SARS-CoV-2

Antigen Rapid Test (Nasal/Saliva) is 100% for samples with Ct value ≤25, 85.7% for samples with Ct value from >25 to 30. And 25% for samples with Ct value >30.

Positive results to be reported by days since symptom onset

Days Since Symptom Onset	RT-PCR Positive (+)	Proportion	SARS-CoV-2 Antigen Rapid Test Positive (+)	PPA
0-3	46	43.8%	42	91.3%
4-7	45	42.9%	42	93.3%
>7	9	8.6%	7	77.8%

Note: There are 5 patients is asymptomatic individuals.

Saliva specimens obtained early (≤7 days) after symptom onset may contain higher viral concentration.

VI. Conclusions:

Using a total of 341 specimens tested at multiple sites in China, the SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) has sensitivity of 91.4%, specificity of 99.6%, and accuracy of 97.1% when comparing with FDA EUA RT-PCR.

Flowflex™ SARS-CoV-2 Antigen Rapid Test

Evaluation Report

December 2020

Flow*flex* SARS-CoV-2 Antigen Rapid Test Evaluation Report

The Flow*flex* SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The Flow*flex* SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples 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.
Negative results from patients with more than seven days post symptom onset should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. 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 Flow*flex* SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

1. **Purpose:** To evaluate the performance of the Flow*flex* SARS-CoV-2 Antigen Rapid Test

2. **Study procedure and results**

2.1 Imprecision/reproducibility Study

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#1:202009101, Lot#2:202009001, Lot#3:202009201
- Extraction Buffer, Lot1#:202008001, Lot2#:202008002, Lot3#:202008003
- SARS-CoV-2 Antigen Negative Sample Lot#: COVAG200904N
- SARS-CoV-2 Antigen Low Positive Sample P3 Lot#: COVAG200904P3
- SARS-CoV-2 Antigen Middle Positive Sample P2 Lot#: COVAG200904P2
- SARS-CoV-2 Antigen High Positive Sample P1 Lot#: COVAG200904P1

Procedure:

3 Lots of SARS-CoV-2 Antigen Rapid Test were tested according to the package insert by 3 operators. Each operator performed 2 tests on each control for 5 days in 2 sites in China. Total 180 tests were performed per each control: 2 replicates X 5 days X 3 lots X 3 operators X 2 sites = 180 tests.

Test results:

SARS-CoV-2 Samples	Lot 1	Lot 2	Lot 3
High Pos	+ / 60 replicates	+ / 60 replicates	+ / 60 replicates
Mid Pos	+ / 60 replicates	+ / 60 replicates	+ / 60 replicates
Low Pos	+ / 60 replicates	+ / 60 replicates	+ / 60 replicates
Neg	- / 60 replicates	- / 60 replicates	- / 60 replicates

Conclusions:

All three lots identified the samples 100% correctly as negative or positive.

2.2 Limit of Detection (LOD)

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#1:202009101, Lot#2:202009001, Lot#3:202009201
- Extraction Buffer, Lot1#:202008001, Lot2#:202008002, Lot3#:202008003
- SARS-CoV-2 viral culture

Procedure:

1. Sample Application Method: Apply 4 drops of sample to the sample well on the test cassette, then start the timer, read the result at 15 minutes and 30 minutes.
2. Dilute the high concentration SARS-CoV-2 viral culture with the Extraction Buffer.
3. Use 3 lots of SARS-CoV-2 antigen rapid test to test the samples, and every sample is tested in 10 replicates. Calculate the detectable rate for each sample.
4. The minimum concentration with ≥95% detectable rate is defined as the minimum detectability (LOD).

Test results:

Culture sample:

Concentration	Lot	Test Result	Detectable rate
2.56×10^3 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	
1.28×10^3 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	
6.4×10^2 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	

3.2 x 10^2 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	
1.6 x 10^2 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	96.7% (29/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ 9 replicates / - 1 replicate	
8 x 10 $TCID_{50}$/mL	**Lot 1**	- / 10 replicates	0% (0/30)
	Lot 2	- / 10 replicates	
	Lot 3	- / 10 replicates	

Conclusion:

According to the test result, the LOD is 1.6 x 10^2 $TCID_{50}$/mL.

2.3 **Clinical study – nasal swabs**

A multi-site clinical study was conducted to evaluate the performance of the SARS-CoV-2 Antigen Rapid Test, and the results are shown below.

2.3.1 Study in China

Clinical site:

Sample collection and testing site	Responsible person/Qualification	Coordinator/Qualification
Shenzhen CDC No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China	Renli Zhang, MD	Fangli Tong, Technologist
Adicon No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China	Cheng Zeng, Technologist	

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Jiangsu Changfeng Medical nasal swabs
- Comparison method: RT-PCR, Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing), manufactured by Sansure BioTech Inc.
- Extraction Buffer, Lot1#:202008001

- Nasal swab samples from infected patients and non-infected patients

Procedure:

1. Study was conducted in China
    - 452 clinical nasal swabs were collected from patients who were suspected of COVID-19. All the samples were confirmed with RT-PCR.
    - 70 positive clinical nasal swabs collected from patients. 63 samples with Ct counts <33, 7 samples with Ct counts ≥33.

2. Following product package insert, performed the test and read the result at reading time.

Test results:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Flow*flex* Test Results	Negative	381	2*	383
	Positive	1	68	69
	Total	382	70	452

***2 samples with PCR CT value 34-35**

2.3.2 Clinical Study in USA

Clinical sites:

- Sample collection sites in USA:

Patient sample collection site	Responsible person/Qualification	Coordinator/Qualification
Boca Raton 6877 SW 18th Street Boca Raton, FL 33433	Dr. Peter Miller, MD	David Cantor, CRO
COVID CLINIC Westminster (WM) 2109 Westminster Mall Westminster, CA 92683	Dr. Matthew Abinante, DO, MPH	
COVID CLINIC La Mesa (LM) 5601 Grossmont Center Drive La Mesa, CA 91942		
COVID CLINIC Downtown San Diego 1350 Third Avenue San Diego, CA 92101		

- Testing sites in USA:

Testing sites	Operator name/Qualification	Coordinator /Qualification
7200 Parkway Drive, Suite 117 La Mesa, CA 91942	Dr. Shannyn Fowl, MD	David Cantor, CRO
COVID CLINIC Westminster (WM) 2109 Westminster Mall Westminster, CA 92683	Dr. Matthew Abinante, DO, MPH	
COVID CLINIC La Mesa (LM) 5601 Grossmont Center Drive La Mesa, CA 91942		
COVID CLINIC Downtown San Diego 1350 Third Avenue San Diego, CA 92101		

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Puritan Medical Products nasal swabs (#25-1506 1PF 100), and Jiangsu Changfeng Medical nasal swabs
- Comparison method: TaqPath COVID-19 Combo Kit, FDA authorized RT-PCR test for emergency use, manufactured by Thermo Fisher Scientific, Inc.
- Nasal swab samples from infected patients and non-infected patients

Procedure:

1. Study is being conducted in multiple U.S. sites in California and Florida, and it is ongoing. So far, 125 clinical nasal swabs were collected from patients who were suspected of COVID-19. All the samples were confirmed with RT-PCR method.
2. Following product package insert, performed the test and read the result at reading time.

Test results:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Flow*flex* Test Results	Negative	32	3*	35
	Positive	1	89	90
	Total	33	92	125

***3 samples with PCR CT value 32.9-33**

2.3.3 Summary of combined clinical studies at all sites:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Flow*flex* Test Results	Negative	413	5	418
	Positive	2	157	159
	Total	415	162	577

2.3.4 Conclusions:

The sensitivity, specificity, and accuracy are meeting MHRA acceptable requirement, which has sensitivity greater than 80% and specificity greater than 95%.

	Performance	95% CI
Sensitivity	96.9% (157/162)	92.8%-98.9%
Specificity	99.5% (413/415)	98.1%- 99.9%
Accuracy	98.8% (570/577)	97.5% -99.5%

2.4 Cross Reactivity (Analytical Specificity)

To demonstrate the related pathogens and microorganisms that are reasonably likely to be present in the nasal cavity do not interfere with test performance of Flow*flex* SARS-Cov-2 Antigen Test.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#202009001
- Extraction Buffer, Lot#102820
- Pooled human negative matrix

Procedure: Cross-Reactivity Wet Testing

Samples were prepared by spiking each stock microorganism into the pooled human negative matrix. Each microorganism was tested in triplicate with Flow*flex* SARS-CoV-2 Antigen Rapid Test.

Test Results:

No cross-reactivity was observed with the following bacteria and viruses when tested at the concentration presented in the table below.

Potential Cross -Reactant		Test Concentration	Cross-Reactivity (in the absence of SARS-CoV-2 virus)
Virus	Adenovirus	1.14×10^6 $TCID_{50}$/mL	No 3/3 negative
	Enterovirus	9.50×10^5 $TCID_{50}$/mL	No 3/3 negative
	Human coronavirus 229E	1.04×10^5 $TCID_{50}$/mL	No 3/3 negative
	Human coronavirus OC43	2.63×10^5 $TCID_{50}$/mL	No 3/3 negative
	Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No 3/3 negative
	Human Metapneumovirus	1.25×10^5 $TCID_{50}$/mL	No 3/3 negative
	MERS-coronavirus	7.90×10^5 $TCID_{50}$/mL	No 3/3 negative
	Influenza A	1.04×10^5 $TCID_{50}$/mL	No 3/3 negative
	Influenza B	1.04×10^5 $TCID_{50}$/mL	No 3/3 negative
	Parainfluenza virus 1	1.25×10^5 $TCID_{50}$/mL	No 3/3 negative
	Parainfluenza virus 2	3.78×10^5 $TCID_{50}$/mL	No 3/3 negative
	Parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL	No 3/3 negative
	Parainfluenza virus 4	2.88×10^6 $TCID_{50}$/mL	No 3/3 negative
	Respiratory syncytial virus	3.15×10^5 $TCID_{50}$/mL	No 3/3 negative
	Rhinovirus	3.15×10^5 $TCID_{50}$/mL	No 3/3 negative
Bacteria	Bordetella pertussis	2.83×10^9 CFU/mL	No 3/3 negative
	Chlamydia trachomatis	3.13×10^8 CFU/mL	No 3/3 negative
	Haemophilus influenzae	1.36×10^8 CFU/mL	No 3/3 negative
	Legionella pneumophila	4.08×10^9 CFU/mL	No 3/3 negative
	Mycobacterium tuberculosis	1.72×10^7 CFU/mL	No 3/3 negative
	Mycoplasma pneumoniae	7.90×10^7 CFU/mL	No 3/3 negative
	Staphylococcus aureus	1.38×10^7 CFU/mL	No 3/3 negative

	Staphylococcus epidermidis	2.32 x 10^9 CFU/mL	No 3/3 negative
	Streptococcus pneumoniae	1.04 x 10^8 CFU/mL	No 3/3 negative
	Streptococcus pyogenes	4.10 x 10^6 CFU/mL	No 3/3 negative
	Pneumocystis jirovecii-S. cerevisiae	8.63 x 10^7 CFU/mL	No 3/3 negative
	Pseudomonas aeruginosa	1.87 x 10^8 CFU/mL	No 3/3 negative
Yeast	Candida albicans	1.57 x 10^8 CFU/mL	No 3/3 negative

Flow*flex* SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

2.5 Microbial Interference Studies

To demonstrate that false negatives will not occur with Flow*flex* SARS-Cov-2 Antigen Test when SARS-CoV-2 is present in a specimen with other microorganisms.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Heat inactivated SARS-CoV-2 virus: Isolate USA-WA1/2020, Cat# 0810587CFHI, Lot#324615
- Extraction Buffer, Lot#102820
- Pooled human negative matrix

Procedure:

The samples were prepared by spiking each microorganism and the heat inactivated SARS-CoV-2 virus into the pooled human negative matrix. Each microorganism in the presence of low concentration of the heat inactivated SARS-CoV-2 virus was tested in triplicate with Flow*flex* SARS-CoV-2 Antigen Rapid Test.

Test Results:

No interference was observed in the presence of heat inactivated SARS-CoV-2 virus with the following bacteria and viruses when tested at the concentration presented in the table below.

Potential Cross -Reactant		Test Concentration	Interference (in the presence of SARS-CoV-2 virus)
Virus	Adenovirus	1.14×10^6 $TCID_{50}$/mL	No 3/3 positive
	Enterovirus	9.50×10^5 $TCID_{50}$/mL	No 3/3 positive
	Human coronavirus 229E	1.04×10^5 $TCID_{50}$/mL	No 3/3 positive
	Human coronavirus OC43	2.63×10^5 $TCID_{50}$/mL	No 3/3 positive
	Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No 3/3 positive
	Human Metapneumovirus	1.25×10^5 $TCID_{50}$/mL	No 3/3 positive
	MERS-coronavirus	7.90×10^5 $TCID_{50}$/mL	No 3/3 positive
	Influenza A	1.04×10^5 $TCID_{50}$/mL	No 3/3 positive
	Influenza B	1.04×10^5 $TCID_{50}$/mL	No 3/3 positive
	Parainfluenza virus 1	1.25×10^5 $TCID_{50}$/mL	No 3/3 positive
	Parainfluenza virus 2	3.78×10^5 $TCID_{50}$/mL	No 3/3 positive
	Parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL	No 3/3 positive
	Parainfluenza virus 4	2.88×10^6 $TCID_{50}$/mL	No 3/3 positive
	Respiratory syncytial virus	3.15×10^5 $TCID_{50}$/mL	No 3/3 positive
	Rhinovirus	3.15×10^5 $TCID_{50}$/mL	No 3/3 positive
Bacteria	Bordetella pertussis	2.83×10^9 CFU/mL	No 3/3 positive
	Chlamydia trachomatis	3.13×10^8 CFU/mL	No 3/3 positive
	Haemophilus influenzae	1.36×10^8 CFU/mL	No 3/3 positive
	Legionella pneumophila	4.08×10^9 CFU/mL	No 3/3 positive
	Mycobacterium tuberculosis	1.72×10^7 CFU/mL	No 3/3 positive
	Mycoplasma pneumoniae	7.90×10^7 CFU/mL	No 3/3 positive
	Staphylococcus aureus	1.38×10^7 CFU/mL	No 3/3 positive

	Staphylococcus epidermidis	2.32 x 10^9 CFU/mL	No 3/3 positive
	Streptococcus pneumoniae	1.04 x 10^8 CFU/mL	No 3/3 positive
	Streptococcus pyogenes	4.10 x 10^6 CFU/mL	No 3/3 positive
	Pneumocystis jirovecii-S. cerevisiae	8.63 x 10^7 CFU/mL	No 3/3 positive
	Pseudomonas aeruginosa	1.87 x 10^8 CFU/mL	No 3/3 positive
Yeast	Candida albicans	1.57 x 10^8 CFU/mL	No 3/3 positive

Conclusion:

Based on the data generated by this study, the microorganisms tested do not cross-react or interfere with Flow*flex* SARS-CoV-2 Antigen Rapid Test.

2.6 Endogenous Interfering Substances

To determine if the substances that naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity interfere with Flow*flex* SARS-CoV-2 Antigen Rapid Test.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Heat inactivated SARS-CoV-2 virus: Isolate USA-WA1/2020, Cat# 0810587CFHI, Lot#324615
- Extraction Buffer, Lot# 102820
- Pooled human negative matrix

Procedure 1: Test the endogenous substances in the absence of heat inactivated SARS-Cov-2 virus.

The samples were prepared by spiking each substance into the human negative matrix to the test concentration listed in the table below. Each sample was tested in triplicate with Flow*flex* SARS-CoV-2 Antigen Rapid Test according to the package insert.

Test Results:

No cross-reactivity was observed with the endogenous interfering substances when tested at the concentration presented in the table below.

Procedure 2: Test the endogenous substances in the presence of heat inactivated SARS-CoV-2 virus.

The samples were prepared by spiking each substance and heat inactivated SARS-Cov-2 virus into the human negative matrix to the test concentration in the presence of low concentration of heat inactivated SARS-CoV-2 virus. Each sample was tested in triplicate according to the package insert.

Test Results:

No interference was observed.

Endogenous Interference Substances Study Results

Interfering Substance	Active Ingredient	Concentration	Test Results (in the absence of SARS-CoV-2 virus)	Test Results (in the presence of SARS-CoV-2 virus)
Endogenous	Biotin	2.4 mg/mL	3/3 negative	3/3 positive
	Mucin	0.5% w/v	3/3 negative	3/3 positive
	Whole Blood	4% v/v	3/3 negative	3/3 positive
Afrin Original Nasal Spray	Oxymetazoline	15% v/v	3/3 negative	3/3 positive
ALKALOL Allergy Relief Nasal Spray	Homeopathic	1:10 Dilution	3/3 negative	3/3 positive
Chloraseptic Max Sore Throat Lozenges	Menthol, Benzocaine	1.5 mg/mL	3/3 negative	3/3 positive
CVS Health Fluticasone Propionate Nasal Spray	Fluticasone propionate	5% v/v	3/3 negative	3/3 positive
Equate Fast-Acting Nasal Spray	Phenylephrine	15% v/v	3/3 negative	3/3 positive
Equate Sore Throat Phenol Oral Anesthetic Spray	Phenol	15% v/v	3/3 negative	3/3 positive
Original Extra Strong Menthol Cough Lozenges	Menthol	1.5 mg/mL	3/3 negative	3/3 positive
NasalCrom Nasal Spray	Cromolyn	15% v/v	3/3 negative	3/3 positive
NeilMed NasoGel for Dry Noses	Sodium Hyaluronate	5% v/v	3/3 negative	3/3 positive
Throat Lozenge	Dyclonine Hydrochloride	1.5mg/mL	3/3 negative	3/3 positive
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5% v/v	3/3 negative	3/3 positive
Antibiotic	Mupirocin	10 mg/mL	3/3 negative	3/3 positive
Tamiflu	Oseltamivir Phosphate	5 mg/mL	3/3 negative	3/3 positive
Antibiotic	Tobramycin	4 µg/mL	3/3 negative	3/3 positive

Conclusion:

Based on the data generated by this study, the endogenous interfering substances tested do not cross-react or interfere with Flow*flex* SARS-CoV-2 Antigen Rapid Test.

2.7 Hook effect

To evaluate if the false negative result can be observed when test very high levels of heat inactivated SARS-CoV-2 virus with Flow*flex* SARS-Cov-2 Antigen Rapid Test.

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Heat inactivated SARS-CoV-2 virus: Isolate USA-WA1/2020, Cat# 0810587CFHI, Lot#324615
- Extraction Buffer, Lot#102820
- Pooled human negative clinical matrix

Procedure:

The nasal swabs from healthy donors were collected and eluted with PBS buffer. The swab eluates were combined and mixed thoroughly to create a negative clinical matrix pool. The heat-inactivated SARS-CoV-2 virus was diluted in the negative clinical matrix pool to generate a positive sample.

For each test, 50 µL of the positive sample was added to a nasal swab. The spiked swab was processed in the extraction buffer tube and tested on the Flow*flex* SARS CoV-2 Antigen Rapid Test according to the package insert. The testing concentration for the heat-inactivated SARS-CoV-2 virus was 1.43×10^5 $TCID_{50}$/mL.

Conclusion:

No high dose hook effect was observed when tested with up to a concentration of 1.43×10^5 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus with Flow*flex* SARS-CoV-2 Antigen Rapid Test.

2.8 Read Time Flex

To demonstrate that the test result is stable when read within the recommended time window.

Material:

SARS-CoV-2 Antigen Rapid Test, Lot# COV0110005
Buffer, Lot#: TDE20110009
SARS-CoV-2 Antigen Negative Sample Lot#: 20201104
SARS-CoV-2 Antigen Low Positive Control Lot#: COVAG200930L
SARS-CoV-2 Antigen Middle Positive Control Lot#: COVAG200930M
ACON Rapid Flow Test Color Card, Lot#20200112

Procedure:

SARS-CoV-2 Antigen negative, high, middle and low positive sample are tested with SARS-CoV-2 Antigen Rapid Test according to package insert. Each test was performed in triplicate. The test results were recorded at 5, 10, 15, 20 and 30 mins.

Test results:

SARS-CoV-2 Samples	5 min	10 min	15 min	20 min	30 min
Neg	- / 3 replicates	- / 3 replicates	- / 3 replicates	- / 3 replicates	- / 3 replicates
Low Pos	- / 3 replicates	+/ 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates
Mid Pos	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates
High Pos	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates	+ / 3 replicates

Conclusion:

The results are stable when read between 10 minutes to 30 minutes.

2.9 Stability Study

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot#1:202009101, Lot#2:202009001, Lot#3:202009201
- Extraction Buffer, Lot1#:202008001, Lot2#:202008002, Lot3#:202008003
- SARS-CoV-2 Antigen Negative Sample Lot#: COVAG200904N
- SARS-CoV-2 Antigen Low Positive Sample P3 Lot#: COVAG200904P3
- SARS-CoV-2 Antigen Middle Positive Sample P2 Lot#: COVAG200904P2
- SARS-CoV-2 Antigen High Positive Sample P1 Lot#: COVAG200904P1
- SARS-CoV-2 Antigen positive control swab, Lot#1: 202009003P-1, Lot#2: 202009003P-2, Lot#3: 202009003P-3
- SARS-CoV-2 Antigen negative control swab, Lot#1: 202009003N-1, Lot#2: 202009003N-2, Lot#3: 202009003N-3

2.9.1 Accelerated stability

Estimate the shelf life for SARS-CoV-2 Antigen Rapid Test, Extraction Buffer and Control Swabs basing on the accelerate stability study.

Procedure:

Accelerated stability study for three lots (including tests in individual pouches, control swabs in individual pouches, extraction buffer in tube) will be stored at 55°C/65°C to estimate product stability. Tests will be assayed according to package insert at designated time points. For each device lot, run 3 replicates per sample at each time points. Read the results according to package insert.

Test results:

Result of SARS-CoV-2 Antigen Rapid Test

55°C

SARS-CoV-2 Samples	0 day	7 days	14 days
Neg	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots
Low Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Mid Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
High Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots

65°C

SARS-CoV-2 Samples	0 day	7 days	14 days
Neg	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots
Low Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Mid Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
High Pos	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots

Result of SARS-CoV-2 Antigen Control swab:

55°C

Samples	0 day	7 days	14 days
Positive Control Swab	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Negative Control Swab	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots

65°C

Samples	0 day	7 days	14 days
Positive Control Swab	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
Negative Control Swab	- / 3 tests x 3 lots	- / 3 tests x 3 lots	- / 3 tests x 3 lots

Conclusion:

SARS-CoV-2 Antigen Rapid Test, extraction buffer and SARS-CoV-2 Antigen Control Swabs are stable at 65°C for 14 days, so the shelf life can be estimated at least 24 months.

2.9.2 Real time stability

Estimate the shelf life for SARS-CoV-2 Antigen Rapid Test, Extraction Buffer and Control Swabs basing on the real time stability study.

Procedure:

Real time stability study for three lots (including tests in individual pouches, control swabs in individual pouches, extraction buffer in tube) will be stored at 2-8°C/30°C to estimate product stability. Tests will be assayed according to package insert at designated time points every 3 months until the timepoints that performance does not meet the acceptance criteria. For each device lot, negative and different levels of positive samples will be tested, run 3 replicates per sample at each time points. Read the results according to package insert.

Acceptance criteria:

Negative sample will generate negative result

Low positive, medium positive and high positive sample will generate positive results

Test results:

Result of SARS-CoV-2 Antigen Rapid Test:

2-8°C

SARS-CoV-2 Samples	Neg	Low Pos	Mid Pos	High Pos
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months				
6 months				
9 months				
12 months				

30°C

SARS-CoV-2 Samples	Neg	Low Pos	Mid Pos	High Pos
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months				
6 months				
9 months				
12 months				

Result of SARS-CoV-2 Antigen Control swab:

2-8°C

SARS-CoV-2 Samples	Neg control swab	Pos control swab
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months		
6 months		
9 months		
12 months		

30°C

SARS-CoV-2 Samples	Neg control swab	Pos control swab
0 day	- / 3 tests x 3 lots	+ / 3 tests x 3 lots
3 months		
6 months		
9 months		
12 months		

Conclusion:

The real time stability of SARS-CoV-2 Antigen Rapid Test, extraction buffer and SARS-CoV-2 Antigen Control Swab are still in process. It is scheduled to finish in December 2022.

4.0 Mimicking Shipping Study

To evaluate the performance of Flow*flex* SARS-CoV-2 Antigen Rapid Test by mimicking shipping conditions.

Materials:

	SARS-CoV-2 Antigen Rapid Test, Lot1	SARS-CoV-2 Antigen Rapid Test, Lot2	SARS-CoV-2 Antigen Rapid Test, Lot3
Test lot number	Lot 202009101	Lot 202009001	Lot 202009201
Negative control swab	Lot 202009003N-1	Lot 202009003N-2	Lot 202009003N-3
Positive control swab	Lot 202009003P-1	Lot 202009003P-2	Lot 202009003P-3

Heat-inactivated SARS-CoV-2 virus: ZeptoMetrix Corporation, Lot#324615

Dry ovens

Refrigerator, -20℃

Method:

1) Study at 3XFT/25°C:

SARS-CoV-2 Antigen Rapid Tests were stored at -20°C for 24 hours and then stored at RT for 24 hours. 3 freeze/thaw cycles were repeated to mimic harsh shipping conditions. At the last thaw, the products were stored at 65°C for a certain period. Performed the tests with control swabs, negative and positive samples in 5 replicates at designated timepoints as below:

Temperature	Day 0	Day 7	Day 14
65°C	X	X	X

The nasal swabs from healthy volunteers were collected and eluted with PBS buffer. The swab eluates were combined and mixed thoroughly to create a negative clinical matrix pool. The heat-inactivated SARS CoV-2 virus was spiked in the negative clinical matrix pool to generate a positive sample.

50 ul of negative clinical matrix pool and spiked positive sample were applied to each swab, respectively. The swab was inserted to the extraction buffer tube, processed and tested with SARS CoV-2 Antigen Rapid Test following package insert at different time point and different mimic shipping condition. Each sample was tested in 5 replicates.

2) Shipping under condition of 55°C for two days.

Accelerated stability study at 55°C was performed for 35 days in a separated study report, which supports that product still maintain good stability after 55°C/2 days shipping condition.

Accepted Criteria:

Negative control swab and negative sample should generate negative results.

Positive control swab and positive sample should generate positive results.

Results:

Test Result of 3XFT/25°C:

1) Accelerated stability study results with lot 1:

Results with quality control swabs:

65°C stability with Lot 1	Day 0	Day 7	Day 14
Negative control swab	- (5/5)	- (5/5)	- (5/5)
Positive control swab	+ (5/5)	+ (5/5)	+ (5/5)

The results at 15min were the same as at 30min

Results with contrived samples:

65°C stability with Lot 1	Day 0	Day 7	Day 14
Negative specimen	- (5/5)	- (5/5)	- (5/5)
Low positive specimen	+ (5/5)	+ (5/5)	+ (5/5)

The results at 15min were the same as at 30min

2) Accelerated stability study results with lot 2:

Results with quality control swabs:

65°C stability with Lot 2	Day 0	Day 7	Day 14
Negative control swab	- (5/5)	- (5/5)	- (5/5)
Positive control swab	+ (5/5)	+ (5/5)	+ (5/5)

The results at 15min were the same as at 30min

Results with contrived samples:

65°C stability with Lot 2	Day 0	Day 7	Day 14
Negative specimen	- (5/5)	- (5/5)	- (5/5)
Low positive specimen	+ (5/5)	+ (5/5)	+ (5/5)

The results at 15min were the same as at 30min

3) Accelerated stability study results with lot 3:

Results with quality control swabs:

65°C stability with Lot 3	Day 0	Day 7	Day 14
Negative control swab	- (5/5)	- (5/5)	- (5/5)
Positive control swab	+ (5/5)	+ (5/5)	+ (5/5)

The results at 15min were the same as at 30min

Results with contrived samples:

65°C stability with Lot 3	Day 0	Day 7	Day 14
Negative specimen	- (5/5)	- (5/5)	- (5/5)
Low positive specimen	+ (5/5)	+ (5/5)	+ (5/5)

The results at 15min were the same as at 30min

4) Study with storage temperature at 55°C:

Product performance met the acceptable criteria under the shipping condition of 55°C for two days (detailed results are available in **3.9.1** Accelerated stability study).

6. Conclusion:

The study results of mimicking shipping condition support that the shelf life of SARS-CoV-2 Antigen Rapid Test is over two years under mimic harsh shipping conditions.

SAFETY DATA SHEET

SECTION 1: INDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

1.1 Product identifier

Product name: SARS-CoV-2 Antigen Rapid Test

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses:

The SARS-CoV-2 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal and nasopharyngeal swab specimens. The SARS-CoV-2 Antigen Rapid Test is for professional in vitro diagnostics use only.

Uses advised against:

None.

1.3 Details of the supplier of the safety data sheet

Manufacturer:

Name: ACON Biotech (Hangzhou) Co., Ltd.

Address: No.210 Zhenzhong Road,
West Lake District, Hangzhou,
P.R. China, 310030

Phone: +86 571 87 96 35 69

E-mail: info@aconlabs.com

Authorized Representative in the EU:

Name: MedNet GmbH

Address: Borkstrasse 10
48163 Muenster, Germany

Phone: +49 251 32266-0

1.4 Emergency telephone number: +49 030/19240

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2 Label elements

The product does not need to be labelled according to Regulation (EC) No. 1272/2008.

2.3 Other Hazards

The product does not contain any substance that meet the criteria for PBT/vPvB according to Annex XIII of Regulation (EC) No. 1907/2006.

SECTION 3: COMPOSITION /INFORMATION ON INGREDIENTS

3.1 Substance

Not Applicable.

3.2 Mixtures

3.2.1 Hazardous ingredients in Test Cassette

As per the Regulation (EC) No 1907/2006, the cassette is defined as an "Article" for which an SDS is not legally required. Thus, no substance need to be listed in this Section.

3.2.2 Hazardous ingredients in Buffer:

Extraction Buffer solution is accompanied with the SARS-CoV-2 Antigen Rapid Test in the kit box. Then concentration of the hazardous ingredients in the buffer is shown in below table:

Components	CAS number	Concentration	Classification according to Regulation (EC) No. 1278/2008 (CLP)	Specific Concentration. Limits, M-factors
Sodium azide	26628-22-8	0.02%	Acute Tox. 2 * (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	N/A

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

If INHALATION: Move to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

If SKIN Contact: Take off immediately all contaminated clothing. Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention is required.

If EYE Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention immediately.

If INGESTION: Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep airways free. Pulmonary failure possible after aspiration of vomit. Call a physician or Poison Control Center immediately.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact: May cause skin irritation, corrosion and dermatitis. Drying-out effect resulting in rough and chapped skin.

Symptoms/effects after eye contact: May cause eye damage and corneal clouding.

Symptoms/effects after ingestion: May cause vomit.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Use water spray, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

No data available.

5.3 Advice for firefighters

Wear protective eyewear, gloves and clothing. Ensure self-safety.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Not applicable.

6.2 Environmental precautions

Dispose the tests as medical rubbish.

6.3 Methods and material for containment and cleaning up

Dispose the tests as medical rubbish.

6.4 Reference to other sections

None.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Wear suitable laboratory coat and gloves. Avoid contacting with skin, eyes and mucous membranes. Take care not to splash, spill or splatter the buffer. Do not eat, drink or smoke in laboratory areas. Do not pipette the buffer by mouth. Wash hands and remove contaminated clothing after use.

7.2 Conditions for safe storage, including any incompatibilities

Store in the sealed package either at room temperature or refrigerated (2-30℃) and keep out of direct sunlight to ensure the product quality.

7.3 Specific end use(s)

No specific uses.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limit Values:

Substance:	**Sodium azide**				
CAS No.	**26628-22-8**				
Country	**Limit Value-Eight hours**		**Limit Value-Short term**		**Legal basis**
	ppm	**mg/m^3**	**ppm**	**mg/m^3**	
Belgium		0.1		0.3	Data from GESTIS

Denmark		0.1		0.2	Database
European Union		**0.1**		**0.3 (1)**	
Finland		0.1		0.3 (1)	
France		**0.1**		**0.3**	
Germany (AGS)		0.2		0.4 (1)	
Germany (DFG)		0.2 inhalable aerosol		0.4 inhalable aerosol	
Hungary		0.1		0.3	
Ireland		0.1		0.3 (1)	
Italy		0.1		0.3	
Latvia		0.1		0.3 (1)	
Poland		0.1		0.3	
Spain		0.1		0.3	
Sweden				0.29 (1)	
Switzerland		0.2 inhalable aerosol		0.4 inhalable aerosol	
The Netherlands		0.1		0.3	
Turkey		0.1		0.3 (1)	
United Kingdom		0.1		0.3	

	Remarks
European Union	Bold-type: Indicative Occupational Exposure Limit Values and Limit Values for Occupational Exposure Binding Occupational Exposure Limit Value - BOELV ~ (1) 15 minutes average value
Finland	(1) 15 minutes average value
France	Bold type: Restrictive statutory limit values
Germany (AGS)	(1) 15 minutes average value
Germany (DFG)	STV 15 minutes average value
Ireland	(1) 15 minutes reference period
Italy	skin
Latvia	(1) 15 minutes average value
Spain	Skin
Sweden	(1) Ceiling Limit value
Turkey	(1) 15 minutes average value

8.1.2 Biological Limit Values:

No data available.

8.1.3 Monitoring Methods:

No data available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Use with adequate ventilation.

8.2.2 Personal protective equipment:

Use with adequate ventilation.

Eye/face protection: Not applicable.

Skin protection:

Hand protection: Not applicable.

Body protection: Not applicable.

Respiratory protection: Not applicable.

Thermal hazards: Not applicable.

8.2.3 Environmental exposure controls:

Do not allow to enter into surface water or drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

The below data applies to the buffer solution:

Appearance	colorless Liquid
Odor	odorless
Odor threshold	No data available
pH	8.0~9.0
Melting point/freezing point	No data available
Initial boiling point and boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Solubility (ies)	No data available
Partition coefficient: n-octanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidising properties	No data available

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Sodium azide (CAS No. 26628-22-8)	
Reaction	No data available.

10.2 Chemical stability

No known instability under normal conditions of use or storage.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Keep away from open flames, hot surfaces and sources of ignition. Avoid dust formation.

10.5 Incompatible material

Acids, Oxidizing agents, Peroxides, Acid chlorides, Metals.

10.6 Hazardous decomposition products

Nitrogen oxides (NOx), Sodium oxides, Carbon monoxide (CO), Carbon dioxide (CO2).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Sodium azide (CAS No. 26628-22-8)	
LD_{50} Oral (Mouse)	27 mg/kg
LC_{50} Inhalation (Rats)	0.054 and 0.52 mg/L
LD_{50} Dermal (Rabbits)	500-1000mg/kg

Skin corrosion/irritation No data available.

Serious eye damage/irritation No data available.

Respiratory or skin sensitization No data available.

Germ cell mutagenicity No data available.

Carcinogenicity No component in this product is confirmed carcinogenicity by ACGIH, IARC, NTP or OSHA.

Reproductive toxicity Sodium azide has a drastically toxic effect on the in vitro growth of mouse embryos at concentrations of 10^{-4} mol/L in the petri dish or greater.

STOT-single exposure No data available.

STOT-repeated exposure No data available.

Aspiration hazard No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Sodium azide (CAS No. 26628-22-8)	
LC_{50} (Fish 1)	0.7 mg/L (96h, Lepomis macrochirus)
LC_{50} (Fish 2)	5.46 mg/L (96h, flow-through (Pimephales promelas)
LC_{50} (Fish 3)	0.8 mg/L (96h, Oncorhynchus mykiss)

12.2 Persistence and degradability

Sodium azide (CAS No. 26628-22-8)	
Persistence and degradability	Soluble in water Persistence is unlikely based on information available.

12.3 Bioaccumulative potential

Sodium azide (CAS No. 26628-22-8)	
Bioaccumulative potential	No data available.

12.4 Mobility in soil

Sodium azide (CAS No. 26628-22-8)	
Mobility in soil	Will likely be mobile in the environment due to its water solubility.

12.5 Results of PBT and vPvB assessment

This product does not contain any substances that are assessed to be PBT or vPvB.

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Dispose as medical rubbish after being used

Contaminated packaging

Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

This product is not regulated for transport.

14.2 UN proper shipping name

This product is not regulated for transport.

14.3 Transport hazard class (es)

This product is not regulated for transport.

14.4 Packing group

This product is not regulated for transport.

14.5 Environmental hazards

No data available.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

No data available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Not data available.

15.2 Chemical safety assessment

No data available.

SECTION 16: OTHER INFORMATION

16.1 Indication of Changes:

Version 1 Revision 0: First version, document in accordance with requirements for safety data sheets introduced by Regulation (EC) No 1907/2006 (REACH).

Version 2 Revision 0: Correct the PH value from “8.0” to “8.0~9.0” in section 9.1.

Version 3 Revision 0: Update the Relevant identified uses in section 1.2 to add the specimen type of “nasopharyngeal swab”.

16.2 Abbreviations and acronyms:

Acute Tox. 2: Acute Toxicity, Category 2

Aquatic Acute 1: Hazard to the aquatic environment – Acute, category 1

Aquatic Chronic 1: Hazard to the aquatic environment – Chronic, category 1

PBT: Persistent, Bioaccumulative and Toxic;

vPvB: Very Persistent and Very Bioaccumulative

16.3 Classification and procedure used to derive the classification for mixtures according to Regulation (EC) No 1272/2008 (CLP):

The product is not classified as a hazard mixture as per Regulation (EC) No 1272/2008 (CLP).

16.4 Relevant H-statements (number and full text):

H300 Fatal if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

16.5 Further information

This information is based upon the present state of our knowledge.

This SDS has been compiled and is solely intended for this product.