Flowflex™

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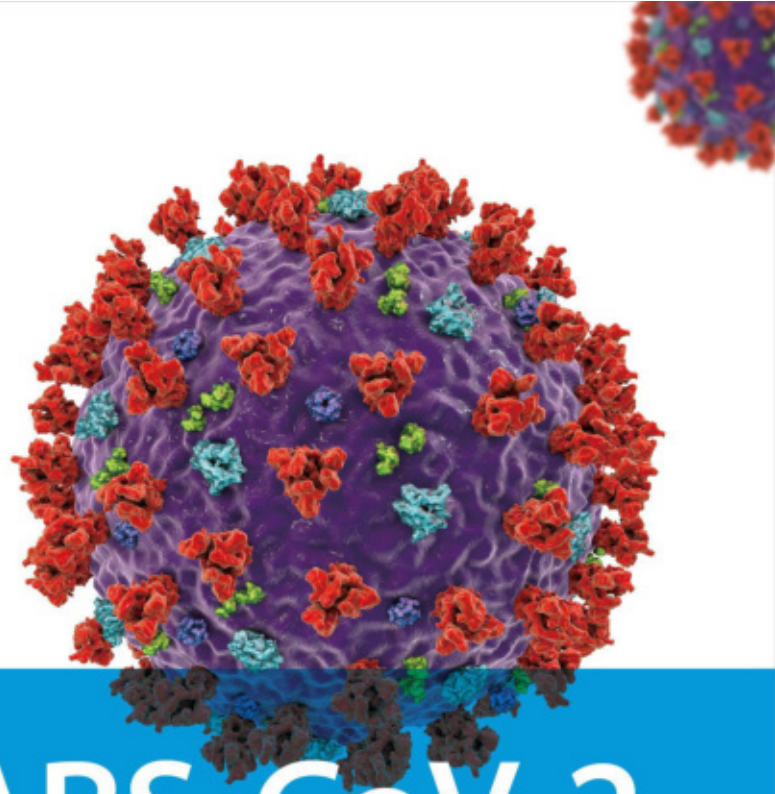


SARS-CoV-2

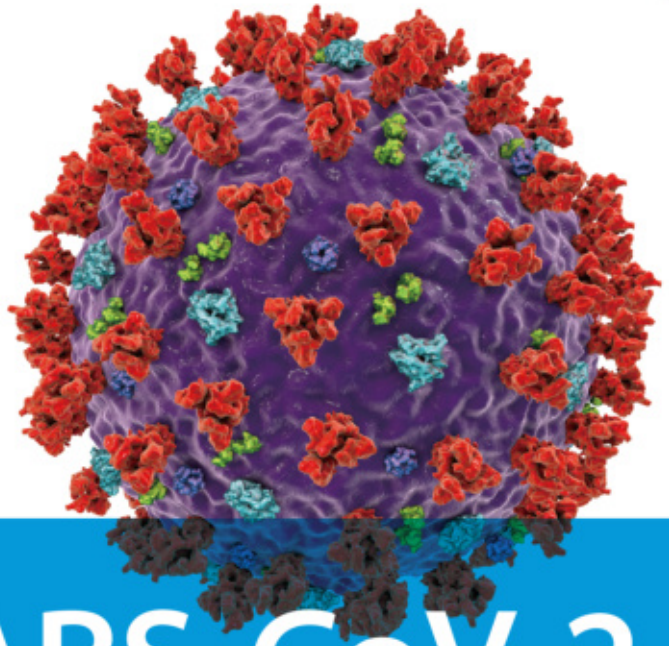
Antigen Rapid Test

INDEX

Flowflex™

NeVia BIOTECH

Official European Distributor
Exclusive distributor in Italy



SARS-CoV-2
Antigen Rapid Test

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.

The King of Rapid Test with 25 Years Experience.

Fast | Reliable | Easy to Use | User friendly | CE Marked

ACON®

ACON Biotech (Hangzhou) Co., Ltd.

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

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 and nasopharyngel 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.

- **Nasal and nasopharyngel swab specimens**
- **Results in 15 minutes**
- **Excellent performance compared to molecular methods**
- **Room temperature storage**

Clinical Performance

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:

Clinical Performance for SARS-CoV-2 Antigen Rapid Test

Method		RT-PCR		Total Results
	Results	Negative	Positive	
SARS-CoV-2 Antigen Rapid Test	Negative	433	5	438
	Positive	2	165	167
Total Results		435	170	605
PPA: 97.1%(93.1%-98.9%)*	NPA: 99.5%(98.2%-99.9%)*	OPA: 98.8%(97.6%-99.5%) *		

PPA-Positive Percent Agreement; **NPA**- Negative Percent Agreement; **OPA**-Overall Percent Agreement, *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).

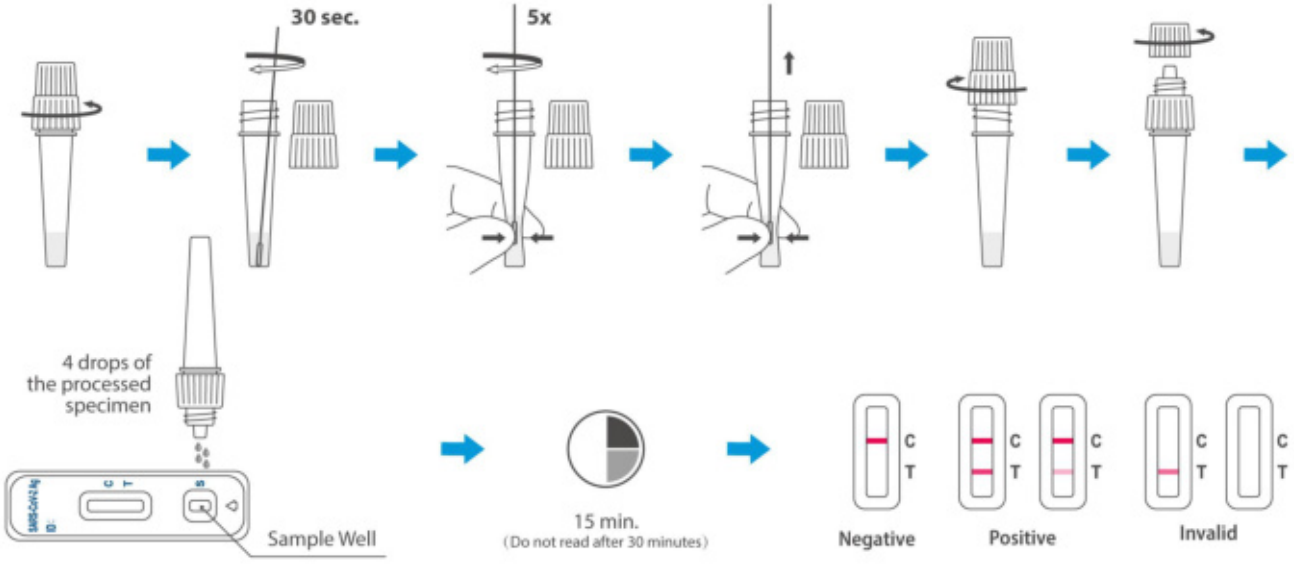
Positive samples with Ct value ≤33 has a higher positive percent agreement (PPA) of 98.7% (n=153) .

Materials Provided

- Test Cassettes
- Extraction Buffer Tubes
- Positive Control Swab
- Negative Control Swab
- Disposable Swabs*
- Package Insert

* The Disposable Swabs are produced by another manufacturer.

Test Procedure and Interpretation



Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flow*flex* SARS-CoV-2 Antigen Rapid Test	L031-11815 √	Cassette	Nasal and nasopharyngel swabs	25 Tests/Kit

√ CE marked

ACON®

www.aconbio.com

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Website: www.neviabiotech.it – e-mail: info@neviabiotech.it

PRODUCT DESCRIPTION

PRODUCT: **FLOWFLEX – Antigen Rapid test for SARS-COV-2**

Items	PHOTO	NAME OF ITEM	MINSAN	ITEM DESCRIPTION	RDM ITALIAN MINISTRY OF HEALTH ---------- CND	Box specification (pieces for box)
L031-11815 L031-11825		FlowflexSARS-CoV-2 Antigen Rapid Test	981452459	Antigen Rapid Test for the detection of specific antigens for SARS COV-2, taken with swabs	2027050 ---------- W0105099099	25 TEST cassette 25 swabs 25 extraction tubes 2 bottles of buffer solution if not contained in the extraction tubes 1 positive control swab 1 negative control swab

ANTIGEN RAPID TEST FLOWFLEX for SARS-COV-2 – ACON
Antigen Rapid Test for the detection of specific antigens for SARS COV-2, taken with swabs.

QUALITATIVE TECHNICAL CHARACTERISTICS:
immunochromatographic antigen rapid test on cassette
1) specificity: 99,5%
2) sensitivity: 97,1%
3) accurancy: 98,8%
4) limit of detection: LOD = 1,6x10^2 (160 TCID50/ml)

The detection limit of the antigen was substantially confirmed with an independent Italian study carried out by:
DIMES - University of Bologna (Italy)
Microbiology Operating Unit
Unique Laboratory of the Service Center
AUSL della Romagna
Piazza della Liberazione, 60
47522 Pievesestina (FC)
tel. +39 0547 39 4906

RISULTATI DELLO STUDIO

numero copie RNA/uL N gene	TCID50/ml	Flowflex
10^7	10^5.4 (251.188,64)	P
10^6	10^4.4 (25.118,86)	P
10^5	10^3.4 (2.511,88)	P
10^4	10^2.4 (251,18)	DP
10^3	10^1.4 (25,12)	N
10^2	10^0.4 (2,51)	N
10^1	10^0.04 (1,096)	N
1	10^0.004 (1,009)	N

Flowflex

LOD dichiarata (TCID50/mL) 1.6x10^2 (160,00)

P = positivo

CONTENTS OF THE KIT:

The KIT box contains everything necessary for the execution of the tests, with the following specifications of the swabs:

- swabs material: FOAM or flocked cotton
- Shaft material: shockproof polyester
- free from interference with the search for DNA / RNA belonging to the pathogens sought

PRODUCT DESCRIPTION:

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.

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 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 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.

The test provides the result within 15 minutes of taking the sample.

The test allows you to operate in safe conditions without the obligation of a Biohazard hood.

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 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 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.

REAGENTS:
The test cassette contains anti-SARS-CoV-2 antibodies coated particles on the membrane. The positive control swab contains SARS-CoV-2 recombinant antigen pre-coated on the swab.

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. Positive and Negative control swabs are supplied with each kit. These control swabs should be used to ensure that the test cassette and that the test procedure is performed correctly. Follow the "DIRECTIONS FOR USE" section to perform the control test.

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 specimens only. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.
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.)

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.

The expiry of the product is 24 months.
For anything not specified, see the package leaflet and the safety data sheet of the product.

Montella, 18 February 2021

Flowflex™

SARS-CoV-2 Antigen Rapid Test
Package Insert

REF L031-11825	English

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab 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 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 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.

SUMMARY

The novel coronaviruses belong to the β genus.[1] 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 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 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 coated particles on the membrane. The positive control swab contains SARS-CoV-2 recombinant antigen pre-coated on the swab.

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, 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.

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
- Positive Control Swab
- Disposable Swabs*
- Package Insert
- Extraction Tubes
- Negative Control Swab
- Extraction Buffer

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

Materials Required But Not Provided

- Personal Protective Equipment
- Timer

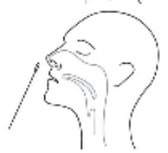
SPECIMEN COLLECTION AND PREPARATION

- The SARS-CoV-2 Antigen Rapid Test can be performed using nasal swab specimens.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection.
- To collect a nasal swab sample:

1. Carefully insert a Disposable Swab, **provided with your kit**, into one nostril. 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 to ensure sufficient specimen collection.

3. Using the same swab, repeat this process in the other nostril to ensure that an adequate amount of sample is collected from both nasal cavities.

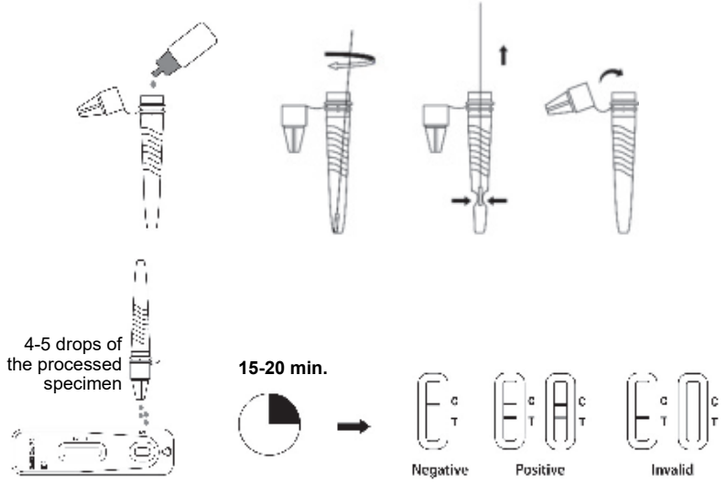


4. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer tubes

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. Hold the extraction buffer bottle upside down vertically, then add approximately 300 µL (10~12 drops) of extraction buffer to the extraction tube.
3. Insert the swab into the tube and swirl it for at least 15 seconds. Then roll 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. Best results will be obtained if the assay is performed as close as possible to collection time, and **at most within the hour** following the specimen collection.
7. Place the test cassette on a flat and clean surface.
8. Add the specimen to the test cassette well
   a. Invert the extraction buffer tube with the dropper tip pointing downwards and hold it vertically (approximately one inch above the sample well).
   b. Gently squeeze the tube, dispensing 4-5 drops (approximately 100~125 µL) of the processed specimen into the sample well.
9. Wait for the colored line(s) to appear. The result should be read at 15 minutes. **Do not read the result after 20 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.

Positive and Negative control swabs are supplied with each kit. These control swabs should be used to ensure that the test cassette and that the test procedure is performed correctly. Follow the "**DIRECTIONS FOR USE**" section to perform the control test.

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 specimens only. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.
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

The performance of SARS-CoV-2 Antigen Rapid Test was established with 304 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

Clinical Performance for SARS-CoV-2 Antigen Rapid Test

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test	**Results**	Negative	Positive	
	Negative	269	1	270
	Positive	1	33	34
Total Results		270	34	304

Relative Sensitivity: 97.1% (83.8%-99.9%)* Relative Specificity: 99.6% (97.7%-99.9%)*

Accuracy: 99.3% (97.5%-99.9%)* *95% Confidence Intervals

Limit of Detection (LoD)

The LOD of SARS-CoV-2 Antigen Rapid Test was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The viral sample was spiked with negative human nasal 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.

Sample SARS-CoV-2 Concentration	% Positive (Tests)
$1.28*10^3$ $TCID_{50}$/mL	100% (30/30)
$6.4*10^2$ $TCID_{50}$/mL	100% (30/30)
$3.2*10^2$ $TCID_{50}$/mL	100% (30/30)
$1.6*10^2$ $TCID_{50}$/mL	96.7% (29/30)
$8*10$ $TCID_{50}$/mL	0% (0/30)

Cross-Reactivity and Interference

No cross reactivity was observed with specimens from patients infected with coronavirus-229E, coronavirus-NL63, coronavirus-OC43, coronavirus-HKU1[1, 2], parainfluenza virus type (Type 1, Type 2, Type 3 and Type 4), Influenza A/B, Human rhinovirus, Human Bocavirus, Human respiratory syncytial virus, Human metapneumovirus, Human adenovirus, Enterovirus , Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Candida albicans, MERS-coronavirus, Pneumocystis jirovecii.

The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

The interfering substances (Whole Blood, Dafenlin Oxymetazoline Hydrochloride Spray, Mometasone Furoate Nasal Spray, Fluticasone Propionate, Physiological Seawater Nasal Cleaner) with a certain concentration have no interference on the test of SARS-CoV-2 Antigen Rapid Test.

PRECISION

Intra-Assay

Within-run precision was determined using 10 replicates of specimens: negative control and SARS-CoV-2 antigen positive controls. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision was determined using 10 independent assays on the same specimen: 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	2	Do not reuse
	Consult instructions for	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community				Date of manufacture

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SARS-CoV-2 Antigen	SARS-CoV-2 Antigen
Negative Control Swab	Negative Control Swab
Positive Control Swab	Positive Control Swab
Extraction Tube	Extraction Buffer Tube
Extraction Buffer	Extraction Buffer
Disposable Swabs	Disposable Swabs
SARS-CoV-2 Antigen Rapid Test	SARS-CoV-2 Antigen Rapid Test

***ACON* Biotech (Hangzhou) Co., Ltd.**
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R.China, 310030

EC REP

CE

NeVia BIOTECH

Number: 1151242701
Effective date: 2020-11-03

Flowflex™

SARS-CoV-2 Antigen Rapid Test
Package Insert

REF L031-11815	English

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab 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 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 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.

SUMMARY

The novel coronaviruses belong to the β genus.[1] 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 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 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 coated particles on the membrane. The positive control swab contains SARS-CoV-2 recombinant antigen pre-coated on the swab.

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, 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
- Positive Control Swab
- Disposable Swabs*
- Extraction Buffer Tubes
- Negative Control Swab
- Package Insert

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

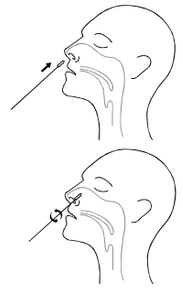
Materials Required But Not Provided

- Personal Protective Equipment
- Timer

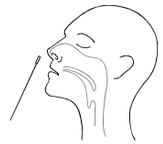
SPECIMEN COLLECTION AND PREPARATION

- The SARS-CoV-2 Antigen Rapid Test can be performed using nasal swab specimens.
- 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).
- To collect a nasal swab sample:

1. Carefully insert a Disposable Swab, **provided with your kit**, into one nostril. 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 to ensure sufficient specimen collection.



3. Using the same swab, repeat this process in the other nostril to ensure that an adequate amount of sample is collected from both nasal cavities.

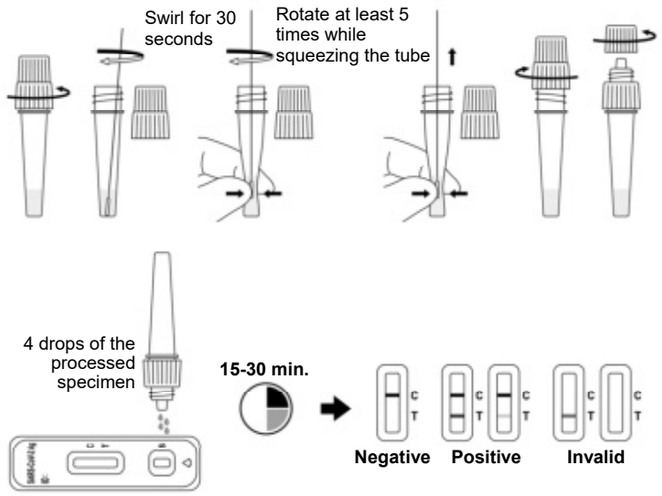


4. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer tubes.

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. Unscrew the dropper cap from the extraction buffer tube without squeezing.
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. Screw the dropper cap 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. Unscrew the small cap from the dropper tip.
   b. Invert the extraction buffer tube with the dropper tip pointing downwards and hold it vertically.
   c. 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.

Positive and Negative control swabs are supplied with each kit. These control swabs should be used to ensure that the test cassette and that the test procedure is performed correctly. Follow the "**DIRECTIONS FOR USE**" section to perform the control test.

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 specimens only. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.
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

The performance of SARS-CoV-2 Antigen Rapid Test was established with 304 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

Clinical Performance for SARS-CoV-2 Antigen Rapid Test

Method		RT-PCR		Total Results
SARS-CoV-2 Antigen Rapid Test	Results	Negative	Positive	
	Negative	269	1	270
	Positive	1	33	34
Total Results		270	34	304

Relative Sensitivity: 97.1% (83.8%-99.9%)* Relative Specificity: 99.6% (97.7%-99.9%)*

Accuracy: 99.3% (97.5%-99.9%)* *95% Confidence Intervals

Limit of Detection (LoD)

The LOD of SARS-CoV-2 Antigen Rapid Test was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The viral sample was spiked with negative human nasal 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.

Sample SARS-CoV-2 Concentration	% Positive (Tests)
$1.28*10^3$ $TCID_{50}$/mL	100% (30/30)
$6.4*10^2$ $TCID_{50}$/mL	100% (30/30)
$3.2*10^2$ $TCID_{50}$/mL	100% (30/30)
$1.6*10^2$ $TCID_{50}$/mL	96.7% (29/30)
$8*10$ $TCID_{50}$/mL	0% (0/30)

Cross-Reactivity and Interference

No cross reactivity was observed with specimens from patients infected with coronavirus-229E, coronavirus-NL63, coronavirus-OC43, coronavirus-HKU1[1, 2], parainfluenza virus type (Type 1, Type 2, Type 3 and Type 4), Influenza A/B, Human rhinovirus, Human Bocavirus, Human respiratory syncytial virus, Human metapneumovirus, Human adenovirus, Enterovirus , Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Candida albicans, MERS-coronavirus, Pneumocystis jirovecii.

The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

The interfering substances (Whole Blood, Dafenlin Oxymetazoline Hydrochloride Spray, Mometasone Furoate Nasal Spray, Fluticasone Propionate, Physiological Seawater Nasal Cleaner) with a certain concentration have no interference on the test of SARS-CoV-2 Antigen Rapid Test.

PRECISION

Intra-Assay

Within-run precision was determined using 10 replicates of specimens: negative control and SARS-CoV-2 antigen positive controls. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision was determined using 10 independent assays on the same specimen: 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

Index of Contents

SARS-CoV-2 Antigen	SARS-CoV-2 Antigen
Negative Control Swab	Negative Control Swab
Positive Control Swab	Positive Control Swab
Extraction Buffer Tubes	Extraction Buffer Tubes
Disposable Swabs	Disposable Swabs
SARS-CoV-2 Antigen Rapid Test	SARS-CoV-2 Antigen Rapid Test

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

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1151256801
Effective date: 2020-12-01

Ministero della Salute

Stampa | Scarica il dataset

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: **2027050**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:07/11/2020

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	2027050	S	L031-11825	FLOWFLEX SARS-COV-2 TEST RAPIDO ANTIGENICO	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	IVD - Altro tipo di IVD	06/11/2020		FABBRICANTE	ACON BIOTECH (HANGZHOU) CO., LTD			CN
									MANDATARIO	MEDNET GMBH		DE126042714	DE

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

Declaration of Conformity

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R. China, 310030

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

Flowflex SARS-CoV-2 Antigen Rapid Test

classified as Others according to the Annex II of 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

This declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
MedNet GmbH
Borkstrasse 10
48163 Muenster, Germany

This Declaration of Conformity is valid until 25 May, 2022.

Signed this 28 day of 9, 2020
in Hangzhou, China

Junny You
International Regulatory Affairs Senior Director
ACON Biotech (Hangzhou) Co., Ltd.

ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R. China, 310030
Tel: +86-571-87963569 Fax: +86-571-87963570 E-mail: css@aconlab.com.cn

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 042074 0031 Rev. 01

Holder of Certificate: **Acon Biotech (Hangzhou) Co., Ltd.**
No.210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District, 310030 Hangzhou,
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Test Kits and Related Instruments, Lancet and Lancing Device**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1910622

Valid from: 2019-07-15
Valid until: 2022-07-14

Date, 2019-07-09

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R.China, 310030
Tel: +86-571-87963569 Fax: +86-571-87963570 E-mail: css@aconlab.com.cn

November 2, 2020

Declaration Letter

To whom it may concern:

We, ACON Biotech(Hangzhou) Co., Ltd., manufacturer of ***Flowflex*** **SARS-CoV-2 Antigen Rapid Test,** hereby declare that not any natural rubber latex was used as a material in the manufacturing of this product.

Sincerely,

Jianxi Kong
BioChemistry R&D
ACON Biotech (Hangzhou) Co., Ltd.,

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	

3.2×10^2 $TCID_{50}$/mL	**Lot 1**	+ / 10 replicates	100% (30/30)
	Lot 2	+ / 10 replicates	
	Lot 3	+ / 10 replicates	
1.6×10^2 $TCID_{50}$/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 1.6×10^2 $TCID_{50}$/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.

February 16, 2021

To Whom It May Concern:

Thank you for your interest in the Flow*flex* SARS-CoV-2 Antigen Rapid Test.

ACON has developed this product through the collaboration of ACON personnel at our San Diego, USA and Hangzhou, China facilities. We have registered the same product (REF# L031-11815; L031-11825) as ACON Laboratories, Inc. and separately as ACON Biotech (Hangzhou) Co. Ltd. for global distribution purposes.

The ACON Laboratories version of the Flow*flex* SARS-CoV-2 Antigen Rapid Test is equivalent to the ACON Biotech version of the Flow*flex* SARS-CoV-2 Antigen Rapid Test. The specifications and performance of the test are identical.

We at ACON are monitoring the emergence of multiple new strains of SARS-CoV-2 which have become prevalent in some communities. These new variants of SARS-CoV-2 all feature mutations in the spike protein, including the receptor binding domain, the furin cleavage site, or other locations with unknown effects. The Flow*flex* SARS-CoV-2 Antigen Rapid Test specifically detects the nucleocapsid protein, so we do not anticipate that these spike protein mutations will have any effect on test performance. We will continue monitoring for any variants which may have mutations in the nucleocapsid protein, and assess the impact on test performance.

Sincerely,

Michael Lynch
Director of Strategic Marketing

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/m³**	**ppm**	**mg/m³**	
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.