WHO Emergency Use Assessment SARS-CoV-2 IVDs
PUBLIC REPORT

Product: SARS-CoV-2 Antigen Rapid Test *(Flowflex)*
Manufacturer: Acon Biotech (Hangzhou) Co. Ltd
EUL Number: EUL 0597-021-00
Outcome: Accepted.

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: a desktop review of the manufacturer's Quality Management System documentation and specific manufacturing documents.
- Product Dossier Review: assessment of the documentary evidence of safety and performance. This evaluation of limited scope is to verify critical analytical and performance characteristics.

SARS-CoV-2 Antigen Rapid Test *(Flowflex)* with product codes L031-129R5, L031-129T5, L031-129U5, L031-129V5, L031-129W5, L031-129Y5, L031-129K5, L031-129M5, REF L031-129L5, and L031-129N5 CE mark regulatory version, manufactured by Acon Biotech (Hangzhou) Co. Ltd, No.210 Zhenzhong Road, West Lake District, Hangzhou 310030, China was listed as eligible for WHO procurement on 4 April 2022.

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the product under EUL, for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
2.0	1. Added new supplier of a swab from Jiangsu HanHeng Medical Technology Co., Ltd. and Goodwood Medical Care Ltd. 2. Added a new format of extraction buffer tube with aluminium foil sealed, resulting in 4 new product codes for new kit configuration with the prefilled buffer tube. 3. Changed the intended population to include asymptomatic individuals. 4. Labelling update for the above changes.	17 November 2022

Intended use:
According to the claim of intended use from Acon Biotech (Hangzhou) Co. Ltd, *" The 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 nasopharyngeal 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 can also test specimens from asymptomatic individuals.*
The SARS-CoV-2 Antigen Rapid Test is manually operated, visually read and intended for use by trained clinical laboratory personnel and individuals 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. 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."

Specimen types that were validated: Nasal and nasopharyngeal swab specimens.

Assay description:

According to the claim of assay description from Acon Biotech (Hangzhou) Co. Ltd, *"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 and nasopharyngeal 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 precoated 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."

Test kit contents:

Component	25 T/Kit (product code L031-129R5)	25 T/Kit (product code L031-129V5)	25 T/Kit (product code L031-129T5)	25 T/Kit (product code L031-129W5)	5 T/kit (product code L031-129U5)	5 T/kit (product code L031-129Y5)	25 T/Kit (product code L031-129K5	25 T/Kit (product code L031-129M5	5 T/kit (product code L031-129L5)	5 T/kit (product code L031-129N5)
Test cassettes	25	25	25	25	5	5	25	25	5	5
Positive control swab	1	1	1	1	\	\	1	1	1	1
Negative control swab	1	1	1	1	\	\	1	1	1	1
Disposable swabs	25 Nasal swabs	25 Nasopharyngeal swabs	25 Nasal swabs	25 Nasopharyngeal swabs	5 Nasal swabs	5 Nasopharyngeal swabs	25 Nasal swabs	25 Nasopharyngeal swabs	5 Nasal swabs	5 Nasopharyngeal swabs
Extraction buffer tubes	25	25	25	25	5	5	\	\	\	\
Extraction buffer	\	\	2 x 6mL vials	2 x 6mL vials	\	\	\	\	\	\
Prefilled extraction buffer with aluminium foil	\	\	\	\	\	\	25	25	5	5
Package insert	1	1	1	1	1	1	1	1	1	1
Specimen collection guide	1	1	1	1	1	1	1	1	1	1

Items required but not provided:

- Personal Protective Equipment
- Permanent marker pen and Timer

Storage:
The test kit must be stored at 2 - 30 °C.

Shelf-life upon manufacture:
24 months (stability studies are ongoing).

Warnings/limitations:

Please refer to the attached instructions for use (IFU).

Product dossier assessment

Acon Biotech (Hangzhou) Co. Ltd submitted a product dossier for the SARS-CoV-2 Antigen Rapid Test *(Flowflex)* as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_0347)"*. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and an external assessor appointed by WHO.

Post listing Commitments for EUL:

As a requirement to listing, the manufacturer is required to:

1. Estimate the limit of detection with the WHO international standard for SARS-CoV-2 Antigens when available.
2. Submit interim and final stability study reports by 31 December 2022.
3. Submit the final validation study report for the real-time stability of the proposed extraction buffer with an aluminium foil seal. Please submit this information as part of the EUL renewal application.

The risk-benefit assessment is acceptable.

Quality Management Systems Review

To establish eligibility for WHO procurement, Acon Biotech (Hangzhou) Co. Ltd was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff and external technical experts (assessors), it was established that sufficient information was provided by Acon Biotech (Hangzhou) Co. Ltd to fulfil the requirements described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid, PQDx_ 347 "*.

The quality management documentation assessment is acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods and processes is critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-prequalification activities are required to maintain the prequalification status:
1. Notification to WHO of any planned changes to a prequalified product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic" (document number PQDx_121*); and
2. Post-market surveillance activities, in accordance with "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics"*(ISBN 978-92-4-001531-9).

Acon Biotech (Hangzhou) Co. Ltd is also required to report complaints related to the product. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality and performance monitoring activities are in place, which are in accordance with WHO guidance "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics"*[1]

Scope and duration of procurement eligibility

[1] https://www.who.int/publications/i/item/9789240015319

The ARS-CoV-2 Antigen Rapid Test *(Flowflex)* with product codes L031-129R5, L031-129T5, L031-129U5, L031-129V5, L031-129W5, L031-129Y5, L031-129K5, L031-129M5, L031-129L5, and L031-129N5 manufactured by Acon Biotech (Hangzhou) Co. Ltd is considered to be eligible for WHO procurement for 12 months from the day of listing. The assay may be used for the detection of the Severe Acute Respiratory Coronavirus 2 (SARS-CoV-2) antigen. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO-prequalified.

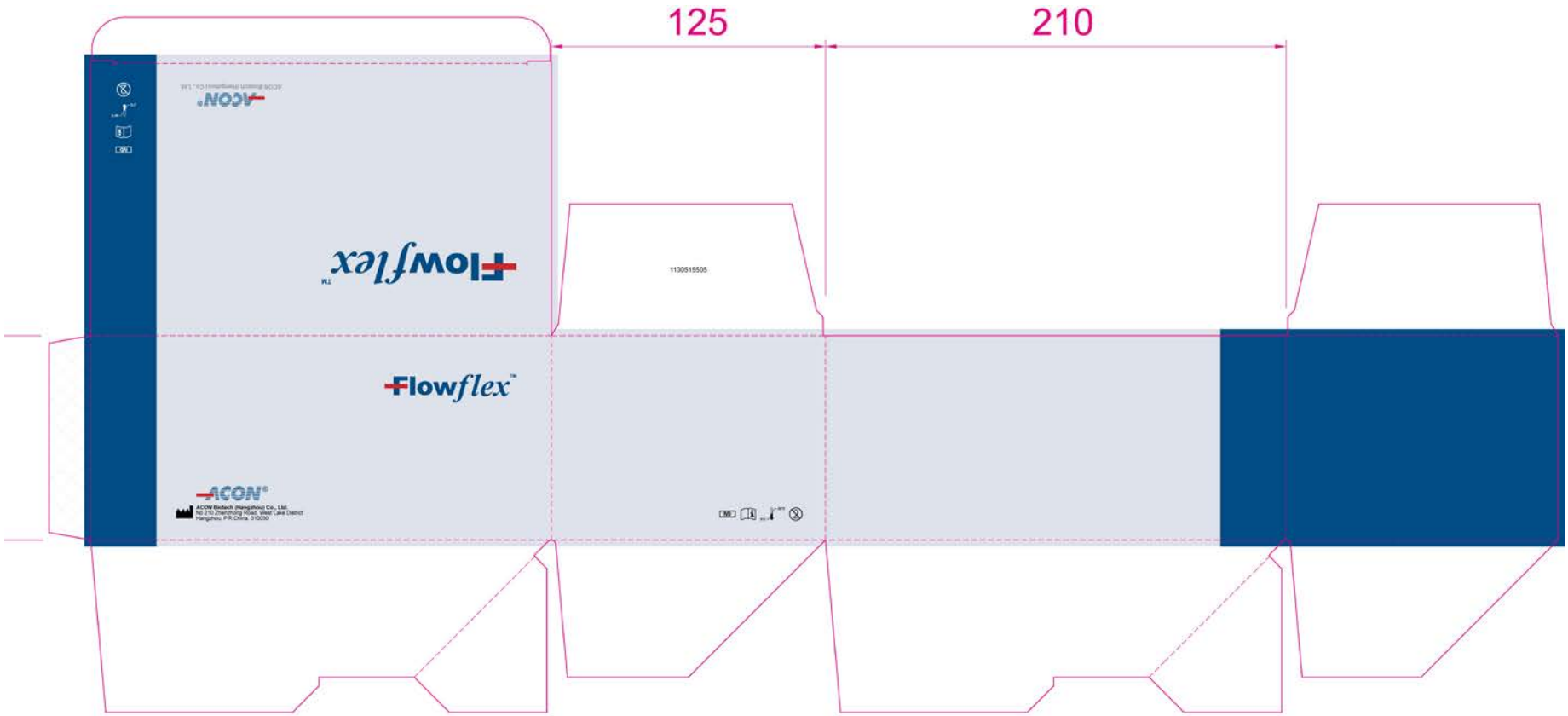
As part of the ongoing requirements for listing as eligible for WHO procurement, Acon Biotech (Hangzhou) Co. Ltd must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality, and performance requirements. Acon Biotech (Hangzhou) Co. Ltd is required to notify WHO of any complaints, including adverse events related to the use of the product within 7 days and any changes made to the product.

WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

Labelling

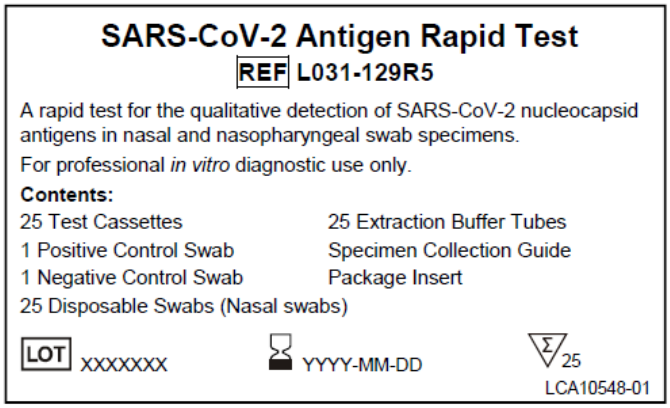
1. **Labels**
2. **Instructions for use**

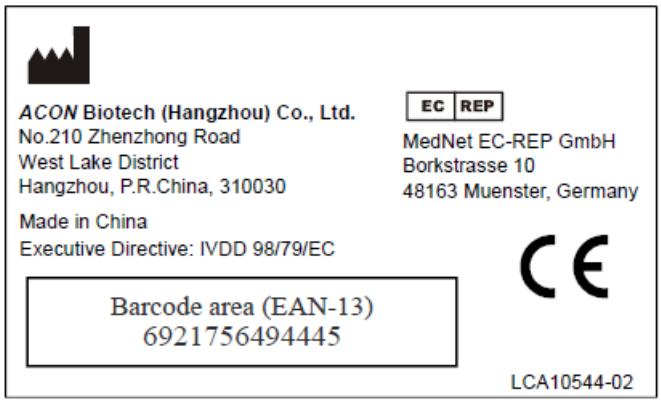
1.1.1 Kit box for product codes L031-129R5, L031-129V5, L031-129T5, L031-129W5 and L031-129M5



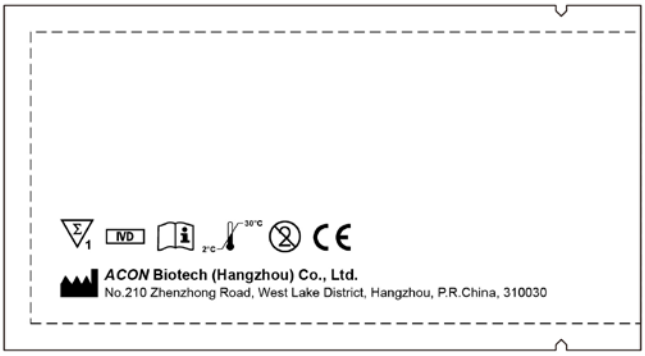
25 Tests (T)/Kit (product code L031-129R5) labels

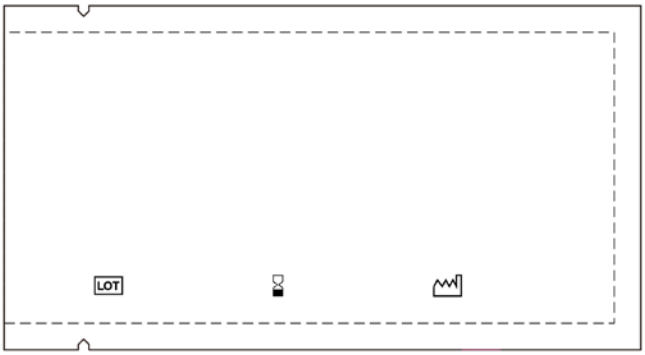
1.1.2 Kit box label



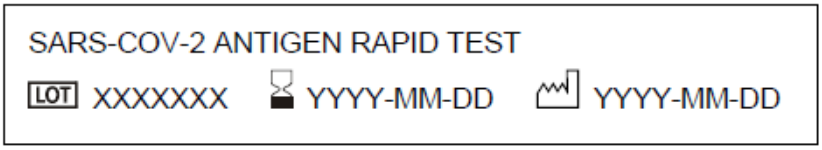


1.1.3 Cassette pouch for all product codes L031-129R5, L031-129V5, L031-129T5, L031-129W5, L031-129U5, L031-129Y5, L031-129K5, L031-129M5, L031-129L5, L031-129N5

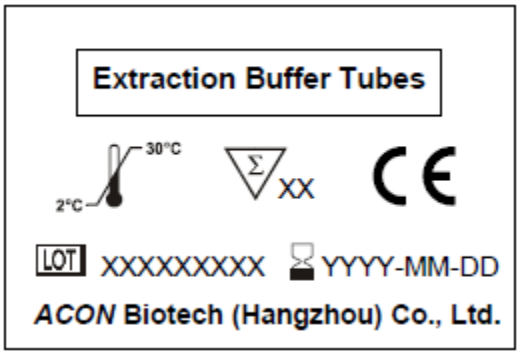




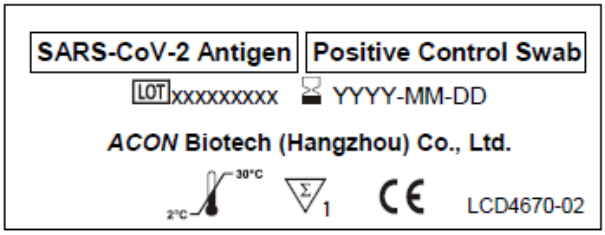
1.1.4 Pouch label for product codes L031-129R5, L031-129V5, L031-129T5, L031-129W5, L031-129U5, L031-129Y5, L031-129K5, L031-129M5, L031-129L5, L031-129N5



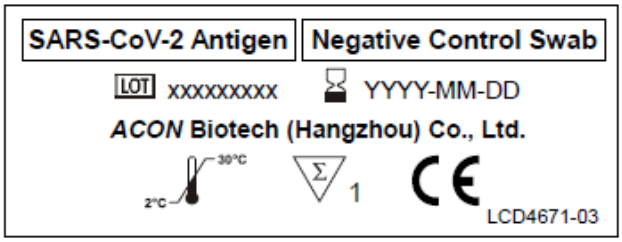
1.1.5 Extraction buffer tube bag label L031-129R5, L031-129V5, L031-129U5, L031-129Y5, L031-129K5, L031-129M5, L031-129L5, L031-129N5



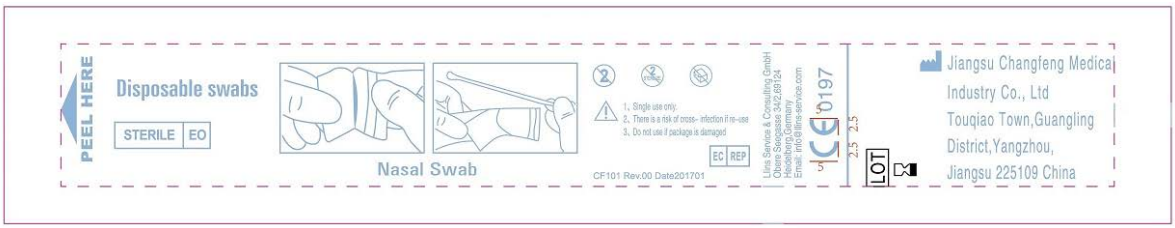
1.1.6 Positive control swab label for product codes L031-129R5, L031-129V5, L031-129T5, L031-129W5, L031-129K5, L031-129M5

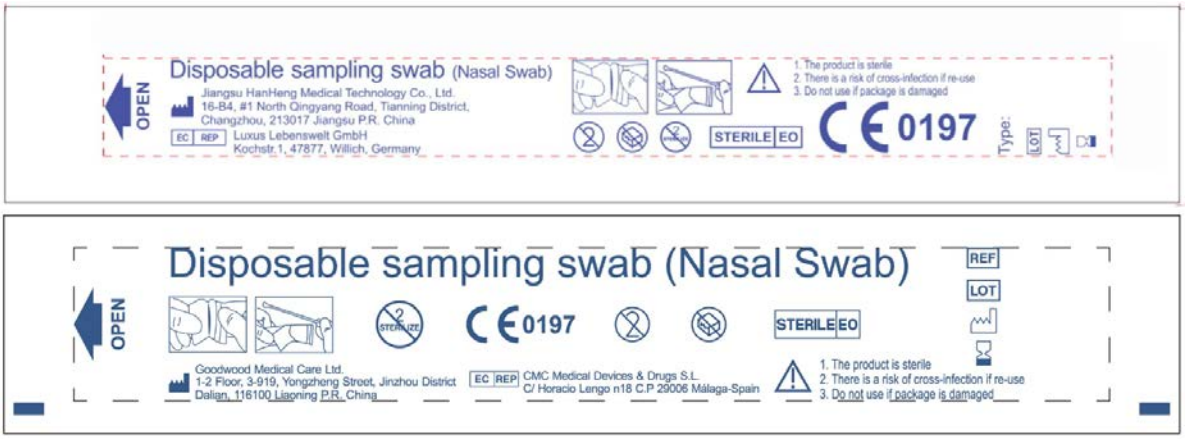


1.1.7 Negative control swab label for product codes L031-129R5, L031-129V5, L031-129T5, L031-129W5, L031-129K5, L031-129M5

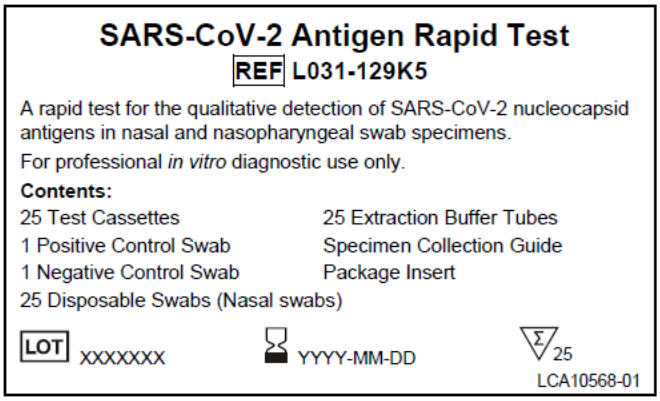


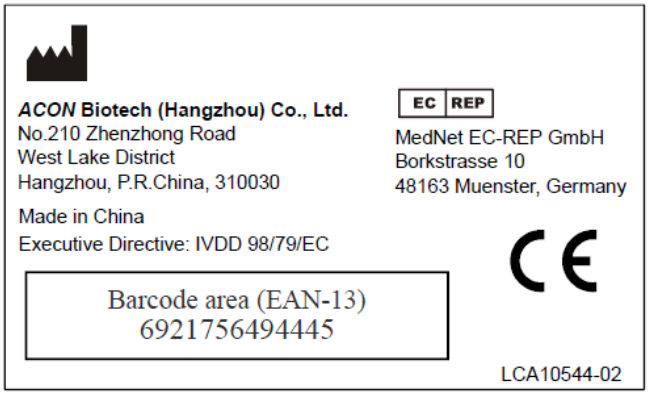
1.1.8 Nasal swab pouch label L031-129R5, L031-129T5, L031-129U5, L031-129K5 and L031-129L5





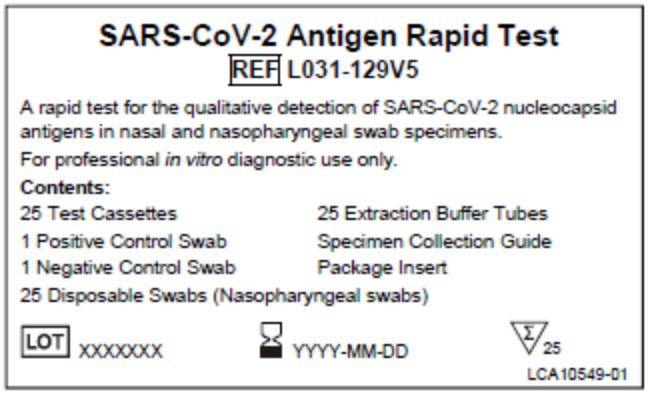
1.2 Kit box label (product code L031-129K5)

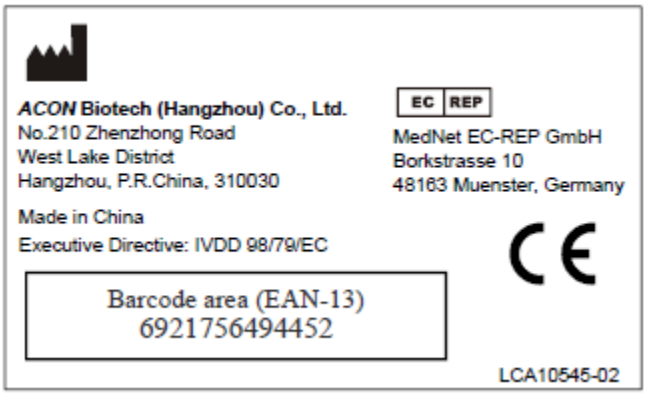




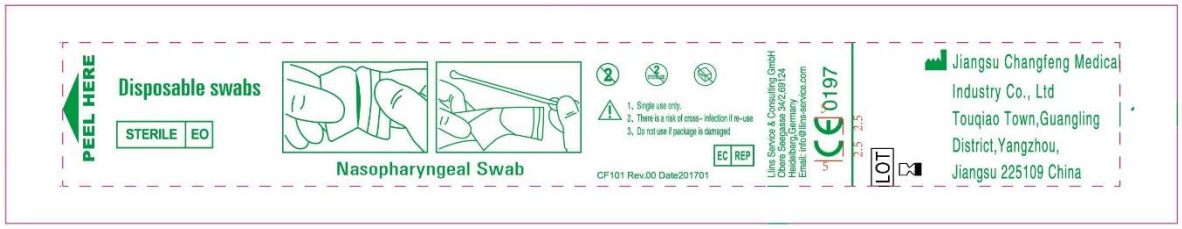
1.3 25 T/Kit(product code L031-129V5) labels

1.3.1 Kit box label

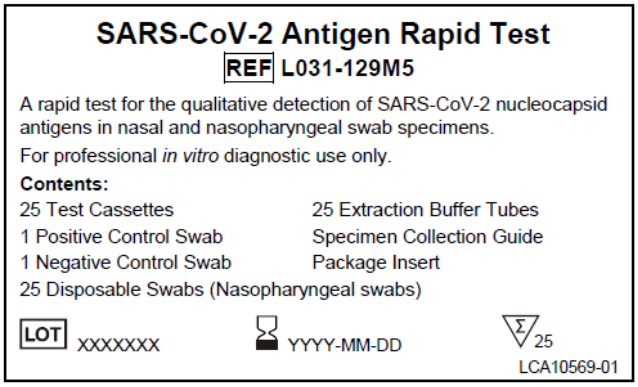


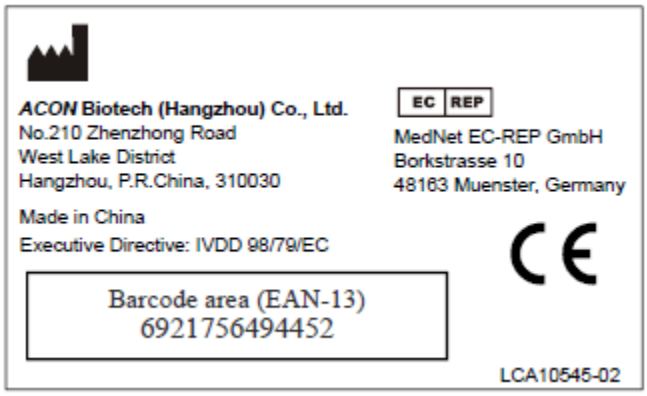


1.3.2 Nasopharyngeal swab label for product codes L031-129V5, L031-129W5, L031-129Y5, L031-129M5 and L031-129N5

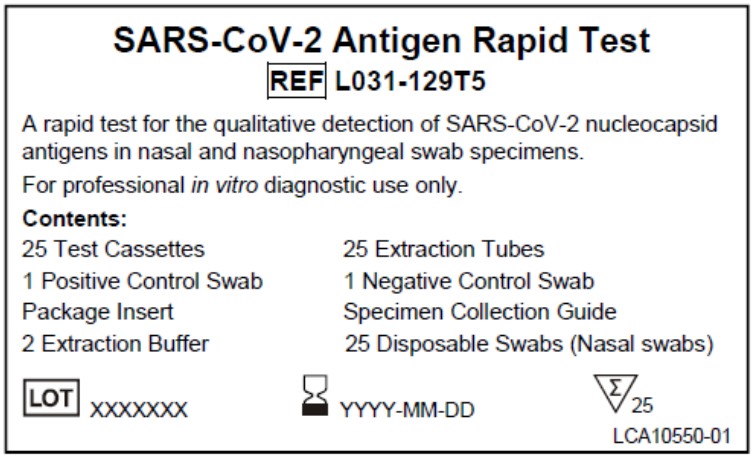


1.4 Kit box label (product code L031-129M5)

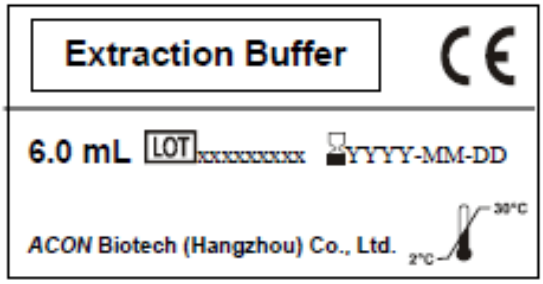




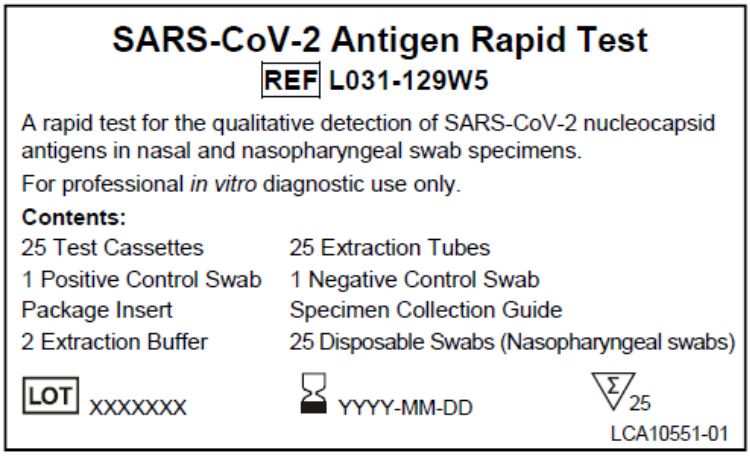
1.5 Kit box label (product code L031-129T5)



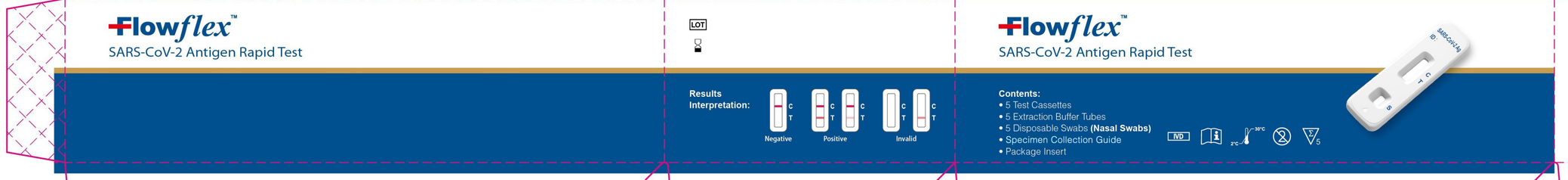
1.5.1 Extraction buffer label for product codes L031-129T5 and L031-129W5

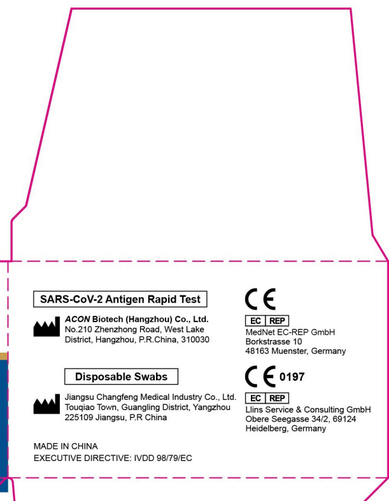


1.6 Kit box label (product code L031-129W5)



1.7 5 T/kit (product code L031-129U5, L031-129L5) kit box





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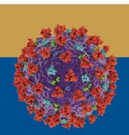
1.8 5 T/kit (product code L031-129Y5, L031-129N5) kit box



COVID-19 Test

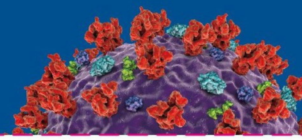
A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal and nasopharyngeal swab specimens.
For professional *in vitro* diagnostic use only.

Contents:
- 5 Test Cassettes
- 5 Extraction Buffer Tubes
- 5 Disposable Swabs **(Nasopharyngeal Swabs)**
- Specimen Collection Guide
- Package Insert

SARS-CoV-2 Antigen Rapid Test

Flowflex™

REF L031-129Y5

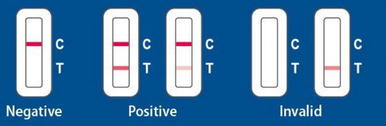


Flowflex™

SARS-CoV-2 Antigen Rapid Test

LOT

Results Interpretation:



Flowflex™

SARS-CoV-2 Antigen Rapid Test

Contents:
- 5 Test Cassettes
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- Specimen Collection Guide
- Package Insert

IVD 2°C 30°C 5

SARS-CoV-2 Antigen Rapid Test

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

CE

EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster, Germany

Disposable Swabs

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District, Yangzhou 225109 Jiangsu, P.R China

CE 0197

EC REP
Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124
Heidelberg, Germany

MADE IN CHINA
EXECUTIVE DIRECTIVE: IVDD 98/79/EC

FPO
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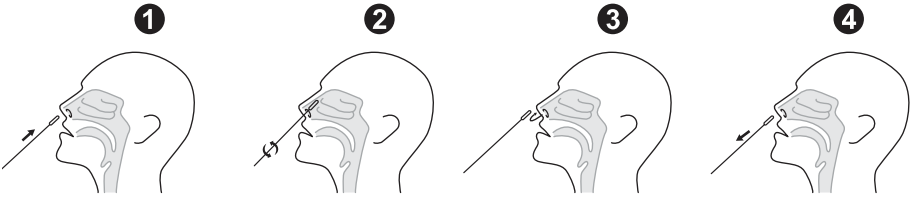
3.0 Instructions for use[2]

[2] English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

3.1 Nasal swab collection guide

Specimen Collection Guide - Nasal Swabs



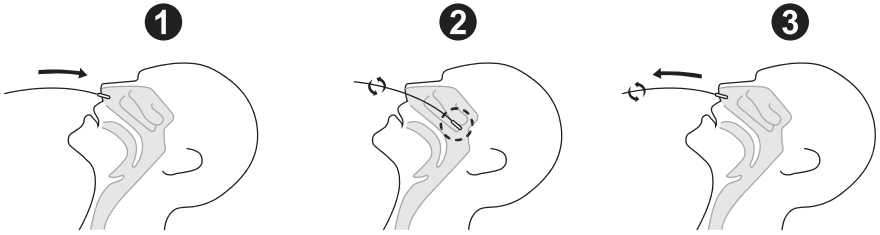
How to collect an anterior nasal swab sample:

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.

Number: 1151368901
Effective Date: 2022-04-25

3.2 Nasopharyngeal swab specimen collection guide

Specimen Collection Guide - Nasopharyngeal Swabs



How to collect a nasopharyngeal swab sample:

1. Tilt patient's head back 70 degrees. Gently and slowly insert a nasopharyngeal swab, provided with your kit, through the nostril parallel to the palate until resistance is encountered.
2. Gently rub and roll the swab, leaving it in place for several seconds to absorb secretions. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
3. Slowly remove swab while rotating it. The specimen is now ready for preparation using the extraction buffer tubes.

Number: 1151369001
Effective Date: 2022-04-25

3.3 Instructions for Use

Flowflex™ SARS-CoV-2 Antigen Rapid Test Package Insert

REF L031-129R5 (Nasal)	REF L031-129V5 (Nasopharyngeal)	English

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal and nasopharyngeal 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 of the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal 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 can also test specimens from asymptomatic individuals.

The SARS-CoV-2 Antigen Rapid Test is manually operated, visually read and intended for use by trained clinical laboratory personnel and individuals 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.

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.

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 and nasopharyngeal 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 15-30 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. 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.
- Do not mix and match components from other test kits.
- 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

Product code	L031-129R5	L031-129V5
Test Cassettes	25	25
Positive Control Swab	1	1
Negative Control Swab	1	1
Disposable Swabs*	25 Nasal Swabs	25 Nasopharyngeal Swabs
Extraction Buffer Tubes	25	25
Specimen Collection Guide	1	1
Package Insert	1	1

** The Disposable Swab is a medical device which produced by another manufacturer. Either Nasal swabs or nasopharyngeal swabs are supplied in the kit depending on the package you ordered.*

Materials Required But Not Provided

- Personal Protective Equipment
- Permanent marker pen and Timer

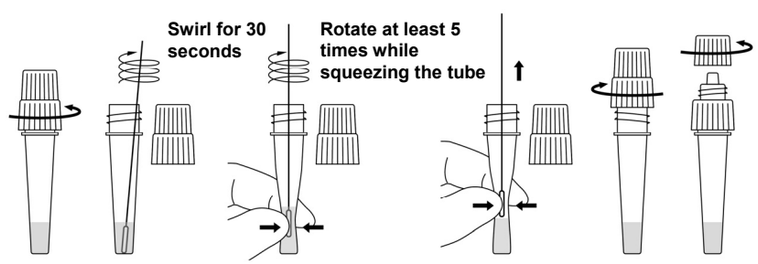
SPECIMEN COLLECTION AND PREPARATION

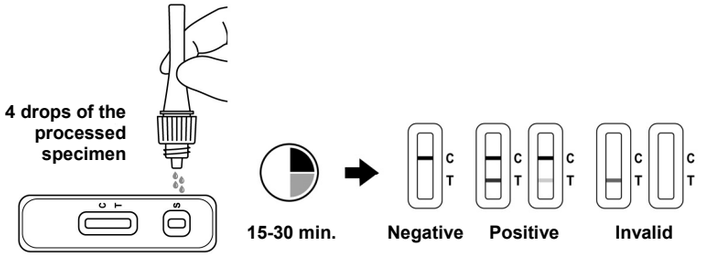
- The SARS-CoV-2 Antigen Rapid Test can be performed using nasal and nasopharyngeal swab specimens.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).
- Please refer to the Specimen Collection Guide provided with the kit for specimen collection details.

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. Label the test cassette with the patient identification number. 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. Set the timer for 15 minutes and 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.

The control swabs can be tested under any of the following circumstances:

1. When new lot of tests are used and/or when a new operator performs the test before testing patient specimens.
2. At periodic intervals as dictated by local requirements, and/or by the user's Quality Control procedures.

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 and nasopharyngeal 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.
10. The performance has been evaluated no diminished sensitivity with SARS-CoV-2 Variants of Concern (VoCs), such as Alpha, Beta, Gamma, Delta, Omicron. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
    (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 605 nasal swabs collected from individual 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
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 98.8% (n=161).
The clinical equivalency between nasopharyngeal and nasal swab specimen was evaluated by testing 70 paired RT-PCR positive nasopharyngeal swab specimens and nasal swab specimens from the same diagnosis of COVID-19 patients. The positive percent agreement of nasopharyngeal swab specimen compared to paired nasal swab specimen is 100% which indicated the SARS-CoV-2 Antigen Rapid Test has no difference when tested using nasopharyngeal swab specimens and nasal swab specimens.

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 nasopharyngeal sample pool into a series 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[1, 2]. 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 specimens and SARS-CoV-2 antigen positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision was determined using 60 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

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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 Buffer Tubes	Extraction Buffer Tubes
Disposable Swabs	Disposable Swabs
Nasal Swabs	Nasal Swabs
Nasopharyngeal Swabs	Nasopharyngeal Swabs
SARS-CoV-2 Antigen Rapid Test	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

Disposable Swabs

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District, Yangzhou
225109 Jiangsu, P.R. China

Or

Jiangsu HanHeng Medical Technology Co., Ltd.
16-B4, #1 North Qingyang Road, Tianning District
Changzhou, 213017 Jiangsu P.R. China

Or

Goodwood Medical Care Ltd.
1-2 Floor, 3-919, Yongzheng Street, Jinzhou District
Dalian, 116100 Liaoning P.R. China

CE EC REP

MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster, Germany

CE 0197 EC REP

Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124
Heidelberg, Germany

CE 0197 EC REP

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

CE 0197 EC REP

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo n18 C.P 29006
Málaga-Spain

Number: 1151368602
Effective Date: 2022-08-17

Flowflex™ SARS-CoV-2 Antigen Rapid Test Package Insert

REF L031-129T5 (Nasal)	REF L031-129W5 (Nasopharyngeal)	English

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal and nasopharyngeal 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 of the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal 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 can also test specimens from asymptomatic individuals.

The SARS-CoV-2 Antigen Rapid Test is manually operated, visually read and intended for use by trained clinical laboratory personnel and individuals 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.

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.

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 and nasopharyngeal 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 15-30 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. 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.
- Do not mix and match components from other test kits.
- 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

Product code	L031-129T5	L031-129W5
Test Cassettes	25	25
Positive Control Swab	1	1
Negative Control Swab	1	1
Disposable Swabs*	25 Nasal Swabs	25 Nasopharyngeal Swabs
Extraction Tubes	25	25
Extraction Buffer	2	2
Specimen Collection Guide	1	1
Package Insert	1	1

** The Disposable Swab is a medical device which produced by another manufacturer. Either Nasal swabs or nasopharyngeal swabs are supplied in the kit depending on the package you ordered.*

Materials Required But Not Provided

- Personal Protective Equipment
- Permanent marker pen and Timer

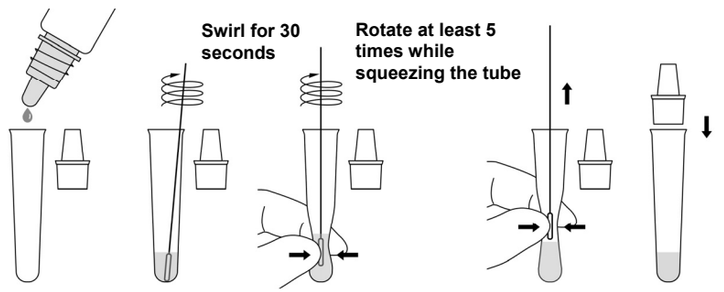
SPECIMEN COLLECTION AND PREPARATION

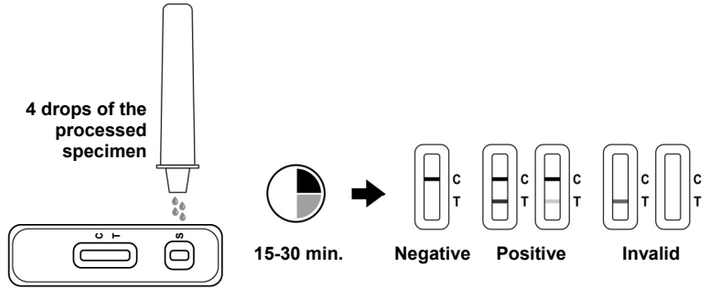
- The SARS-CoV-2 Antigen Rapid Test can be performed using nasal and nasopharyngeal swab specimens.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).
- Please refer to the Specimen Collection Guide provided with the kit for specimen collection details.

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 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. Label the test cassette with the patient identification number. 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. Set the timer for 15 minutes and 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.

The control swabs can be tested under any of the following circumstances:

1. When new lot of tests are used and/or when a new operator performs the test before testing patient specimens.
2. At periodic intervals as dictated by local requirements, and/or by the user's Quality Control procedures.

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 and nasopharyngeal 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.
10. The performance has been evaluated no diminished sensitivity with SARS-CoV-2 Variants of Concern (VoCs), such as Alpha, Beta, Gamma, Delta, Omicron. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
    (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 605 nasal swabs collected from individual 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
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 98.8% (n=161).
The clinical equivalency between nasopharyngeal and nasal swab specimen was evaluated by testing 70 paired RT-PCR positive nasopharyngeal swab specimens and nasal swab specimens from the same diagnosis of COVID-19 patients. The positive percent agreement of nasopharyngeal swab specimen compared to paired nasal swab specimen is 100% which indicated the SARS-CoV-2 Antigen Rapid Test has no difference when tested using nasopharyngeal swab specimens and nasal swab specimens.

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 nasopharyngeal sample pool into a series 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[1, 2]. 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 x 10^6 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Enterovirus	9.50 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Human coronavirus 229E	1.04 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
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	Parainfluenza virus 1	1.25 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
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	Rhinovirus	3.15 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Human coronavirus- HKU1	1 x 10^5 copies/mL	No (3/3 negative)	No (3/3 positive)
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	Chlamydia trachomatis	3.13 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 positive)
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	Mycoplasma pneumoniae	7.90 x 10^7 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Staphylococcus aureus	1.38 x 10^7 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Staphylococcus epidermidis	2.32 x 10^9 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Streptococcus pneumoniae	1.04 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Streptococcus pyogenes	4.10 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Pneumocystis jirovecii-S. cerevisiae	8.63 x 10^7 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Pseudomonas aeruginosa	1.87 x 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 x 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 specimens and SARS-CoV-2 antigen positive specimens. The specimens were correctly identified > 99% of the time.

Inter-Assay

Between-run precision was determined using 60 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

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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 Tubes	Extraction Tubes
Extraction Buffer	Extraction Buffer
Disposable Swabs	Disposable Swabs
Nasal Swabs	Nasal Swabs
Nasopharyngeal Swabs	Nasopharyngeal Swabs
SARS-CoV-2 Antigen Rapid Test	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

Disposable Swabs

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District, Yangzhou
225109 Jiangsu, P.R. China

Or

Jiangsu HanHeng Medical Technology Co., Ltd.
16-B4, #1 North Qingyang Road, Tianning District
Changzhou, 213017 Jiangsu P.R. China

Or

Goodwood Medical Care Ltd.
1-2 Floor, 3-919, Yongzheng Street, Jinzhou District
Dalian, 116100 Liaoning P.R. China

CE EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster, Germany

CE 0197 EC REP
Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124
Heidelberg, Germany

CE 0197 EC REP
Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

CE 0197 EC REP
CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo n18 C.P 29006
Málaga-Spain

Number: 1151368702
Effective Date: 2022-08-17

Flowflex™ SARS-CoV-2 Antigen Rapid Test Package Insert

REF L031-129U5 (Nasal)	REF L031-129Y5 (Nasopharyngeal)	English

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal and nasopharyngeal 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 of the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal 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 can also test specimens from asymptomatic individuals.
The SARS-CoV-2 Antigen Rapid Test is manually operated, visually read and intended for use by trained clinical laboratory personnel and individuals 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.
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.

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 and nasopharyngeal 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 15-30 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.
- Do not mix and match components from other test kits.
- 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

Product code	L031-129U5	L031-129Y5
Test Cassettes	5	5
Disposable Swabs*	5 Nasal Swabs	5 Nasopharyngeal Swabs
Extraction Buffer Tubes	5	5
Specimen Collection Guide	1	1
Package Insert	1	1

* *The Disposable Swab is a medical device which produced by another manufacturer. Either Nasal swabs or nasopharyngeal swabs are supplied in the kit depending on the package you ordered.*

Materials Required But Not Provided

- Personal Protective Equipment
- Positive Control Swab
- Permanent marker pen and Timer
- Negative Control Swab

Positive and negative control swabs are not supplied with this kit. Please contact ACON for purchasing information.

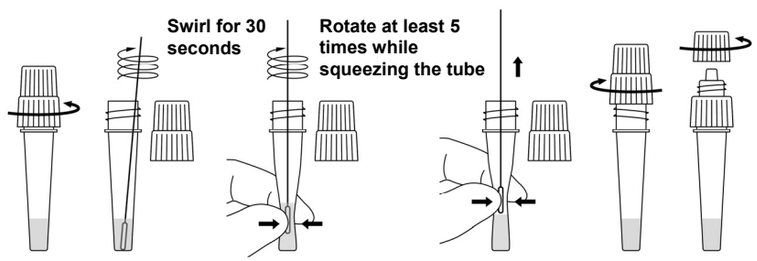
SPECIMEN COLLECTION AND PREPARATION

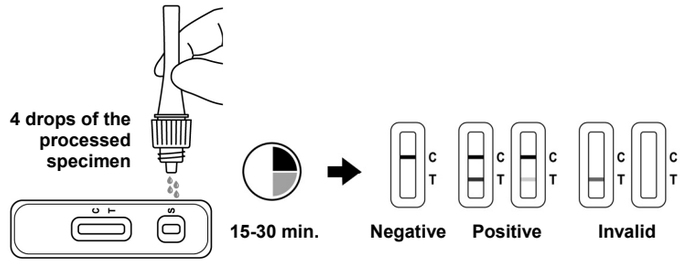
- The SARS-CoV-2 Antigen Rapid Test can be performed using nasal and nasopharyngeal swab specimens.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).
- Please refer to the Specimen Collection Guide provided with the kit for specimen collection details.

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. Label the test cassette with the patient identification number. 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. Set the timer for 15 minutes and 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

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	Staphylococcus epidermidis	2.32 x 10^9 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Streptococcus pneumoniae	1.04 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Streptococcus pyogenes	4.10 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Pneumocystis jirovecii-S. cerevisiae	8.63 x 10^7 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Pseudomonas aeruginosa	1.87 x 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 x 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 specimens and SARS-CoV-2 antigen positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision was determined using 60 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

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Nasopharyngeal Swabs	Nasopharyngeal Swabs
SARS-CoV-2 Antigen Rapid Test	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

Disposable Swabs

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District, Yangzhou
225109 Jiangsu, P.R. China

Or

Jiangsu HanHeng Medical Technology Co., Ltd.
16-B4, #1 North Qingyang Road, Tianning District
Changzhou, 213017 Jiangsu P.R. China

Or

Goodwood Medical Care Ltd.
1-2 Floor, 3-919, Yongzheng Street, Jinzhou District
Dalian, 116100 Liaoning P.R. China

CE EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster, Germany

CE 0197 EC REP
Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124
Heidelberg, Germany

CE 0197 EC REP
Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

CE 0197 EC REP
CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo n18 C.P 29006
Málaga-Spain

Number: 1151368802
Effective Date: 2022-08-17

Flowflex™ SARS-CoV-2 Antigen Rapid Test Package Insert

REF L031-129K5 (Nasal)	REF L031-129M5 (Nasopharyngeal)	English

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal and nasopharyngeal 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 of the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal 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 can also test specimens from asymptomatic individuals.

The SARS-CoV-2 Antigen Rapid Test is manually operated, visually read and intended for use by trained clinical laboratory personnel and individuals 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.

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.

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 and nasopharyngeal 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 15-30 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. 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.
- Do not mix and match components from other test kits.
- 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

Product code	L031-129K5	L031-129M5
Test Cassettes	25	25
Positive Control Swab	1	1
Negative Control Swab	1	1
Disposable Swabs*	25 Nasal Swabs	25 Nasopharyngeal Swabs
Extraction Buffer Tubes	25	25
Specimen Collection Guide	1	1
Package Insert	1	1

* *The Disposable Swab is a medical device which produced by another manufacturer. Either Nasal swabs or nasopharyngeal swabs are supplied in the kit depending on the package you ordered.*

Materials Required But Not Provided

- Personal Protective Equipment
- Permanent marker pen and Timer

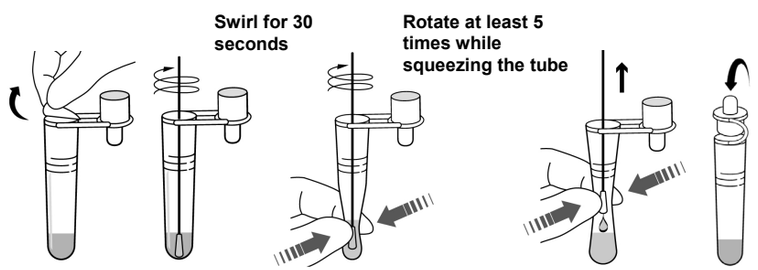
SPECIMEN COLLECTION AND PREPARATION

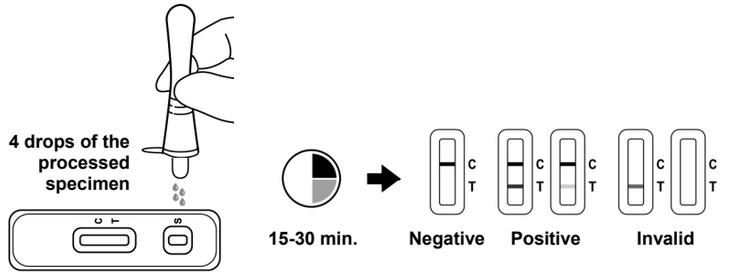
- The SARS-CoV-2 Antigen Rapid Test can be performed using nasal and nasopharyngeal swab specimens.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).
- Please refer to the Specimen Collection Guide provided with the kit for specimen collection details.

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. Label the test cassette with the patient identification number. 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. Set the timer for 15 minutes and 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.

The control swabs can be tested under any of the following circumstances:

1. When new lot of tests are used and/or when a new operator performs the test before testing patient specimens.
2. At periodic intervals as dictated by local requirements, and/or by the user's Quality Control procedures.

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 and nasopharyngeal 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.
10. The performance has been evaluated no diminished sensitivity with SARS-CoV-2 Variants of Concern (VoCs), such as Alpha, Beta, Gamma, Delta, Omicron. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
    (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 605 nasal swabs collected from individual 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
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 98.8% (n=161).
The clinical equivalency between nasopharyngeal and nasal swab specimen was evaluated by testing 70 paired RT-PCR positive nasopharyngeal swab specimens and nasal swab specimens from the same diagnosis of COVID-19 patients. The positive percent agreement of nasopharyngeal swab specimen compared to paired nasal swab specimen is 100% which indicated the SARS-CoV-2 Antigen Rapid Test has no difference when tested using nasopharyngeal swab specimens and nasal swab specimens.

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 nasopharyngeal sample pool into a series 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[1, 2]. 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 specimens and SARS-CoV-2 antigen positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision was determined using 60 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
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Nasal Swabs	Nasal Swabs
Nasopharyngeal Swabs	Nasopharyngeal Swabs
SARS-CoV-2 Antigen Rapid Test	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

Disposable Swabs

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District, Yangzhou
225109 Jiangsu, P.R. China

Or

Jiangsu HanHeng Medical Technology Co., Ltd.
16-B4, #1 North Qingyang Road, Tianning District
Changzhou, 213017 Jiangsu P.R. China

Or

Goodwood Medical Care Ltd.
1-2 Floor, 3-919, Yongzheng Street, Jinzhou District
Dalian, 116100 Liaoning P.R. China

CE
EC REP

MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster, Germany

CE 0197
EC REP

Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124
Heidelberg, Germany

CE 0197
EC REP

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

CE 0197
EC REP

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo n18 C.P 29006
Málaga-Spain

Number: 1151453701
Effective Date: 2022-08-17

Flowflex™ SARS-CoV-2 Antigen Rapid Test Package Insert

REF L031-129L5 (Nasal)	REF L031-129N5 (Nasopharyngeal)	English

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal and nasopharyngeal 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 of the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal 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 can also test specimens from asymptomatic individuals.

The SARS-CoV-2 Antigen Rapid Test is manually operated, visually read and intended for use by trained clinical laboratory personnel and individuals 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.

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.

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 and nasopharyngeal 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 15-30 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.
- Do not mix and match components from other test kits.
- 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

Product code	L031-129L5	L031-129N5
Test Cassettes	5	5
Disposable Swabs*	5 Nasal Swabs	5 Nasopharyngeal Swabs
Extraction Buffer Tubes	5	5
Specimen Collection Guide	1	1
Package Insert	1	1

* *The Disposable Swab is a medical device which produced by another manufacturer. Either Nasal swabs or nasopharyngeal swabs are supplied in the kit depending on the package you ordered.*

Materials Required But Not Provided

- Personal Protective Equipment
- Positive Control Swab
- Permanent marker pen and Timer
- Negative Control Swab

Positive and negative control swabs are not supplied with this kit. Please contact ACON for purchasing information.

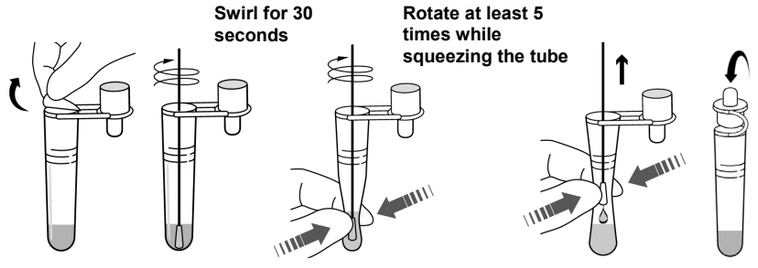
SPECIMEN COLLECTION AND PREPARATION

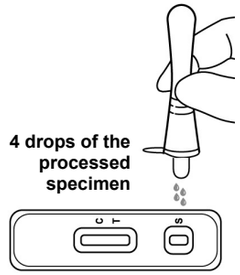
- The SARS-CoV-2 Antigen Rapid Test can be performed using nasal and nasopharyngeal swab specimens.
- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).
- Please refer to the Specimen Collection Guide provided with the kit for specimen collection details.

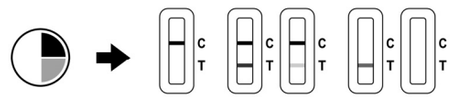
DIRECTIONS FOR USE

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. Label the test cassette with the patient identification number. 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. Set the timer for 15 minutes and 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 and nasopharyngeal 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.
10. The performance has been evaluated no diminished sensitivity with SARS-CoV-2 Variants of Concern (VoCs), such as Alpha, Beta, Gamma, Delta, Omicron. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
    (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 605 nasal swabs collected from individual 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
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 98.8% (n=161).
The clinical equivalency between nasopharyngeal and nasal swab specimen was evaluated by testing 70 paired RT-PCR positive nasopharyngeal swab specimens and nasal swab specimens from the same diagnosis of COVID-19 patients. The positive percent agreement of nasopharyngeal swab specimen compared to paired nasal swab specimen is 100% which indicated the SARS-CoV-2 Antigen Rapid Test has no difference when tested using nasopharyngeal swab specimens and nasal swab specimens.

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 nasopharyngeal sample pool into a series 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[1, 2]. 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 x 10^6 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Enterovirus	9.50 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Human coronavirus 229E	1.04 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Human coronavirus OC43	2.63 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Human Metapneumovirus	1.25 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	MERS-coronavirus	7.90 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Influenza A	1.04 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Influenza B	1.04 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Parainfluenza virus 1	1.25 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Parainfluenza virus 2	3.78 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Parainfluenza virus 3	1.0 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Parainfluenza virus 4	2.88 x 10^6 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Respiratory syncytial virus	3.15 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Rhinovirus	3.15 x 10^5 $TCID_{50}$/mL	No (3/3 negative)	No (3/3 positive)
	Human coronavirus- HKU1	1 x 10^5 copies/mL	No (3/3 negative)	No (3/3 positive)
Bacteria	Bordetella pertussis	2.83 x 10^9 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Chlamydia trachomatis	3.13 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Haemophilus influenza	1.36 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Legionella pneumophila	4.08 x 10^9 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Mycobacterium tuberculosis	1.72 x 10^7 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Mycoplasma pneumoniae	7.90 x 10^7 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Staphylococcus aureus	1.38 x 10^7 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Staphylococcus epidermidis	2.32 x 10^9 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Streptococcus pneumoniae	1.04 x 10^8 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Streptococcus pyogenes	4.10 x 10^6 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Pneumocystis jirovecii-S. cerevisiae	8.63 x 10^7 CFU/mL	No (3/3 negative)	No (3/3 positive)
	Pseudomonas aeruginosa	1.87 x 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 x 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 specimens and SARS-CoV-2 antigen positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision was determined using 60 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

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SARS-CoV-2 Antigen Rapid Test

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

Disposable Swabs

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District, Yangzhou
225109 Jiangsu, P.R. China

Or

Jiangsu HanHeng Medical Technology Co., Ltd.
16-B4, #1 North Qingyang Road, Tianning District
Changzhou, 213017 Jiangsu P.R. China

Or

Goodwood Medical Care Ltd.
1-2 Floor, 3-919, Yongzheng Street, Jinzhou District
Dalian, 116100 Liaoning P.R. China

EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster, Germany

CE 0197
EC REP
Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124
Heidelberg, Germany

CE 0197
EC REP
Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

CE 0197
EC REP
CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo n18 C.P 29006
Málaga-Spain

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