Flowflex™

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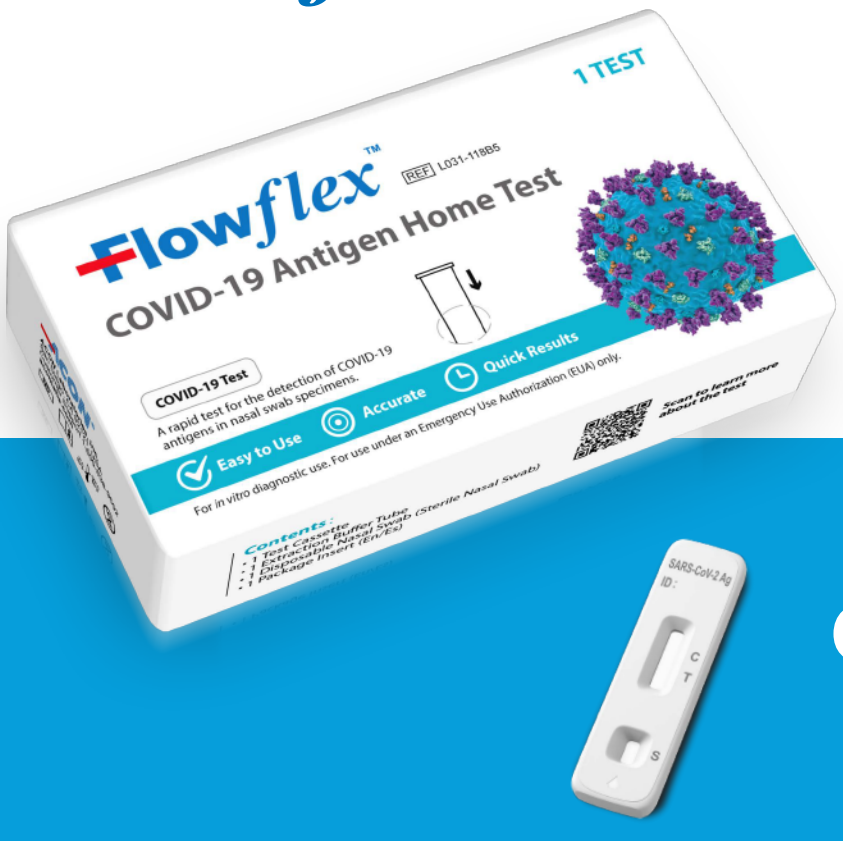


COVID-19 Antigen Home Test

A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection.

ACON®

ACON Laboratories, Inc.

Flowflex COVID-19 Antigen Home Test

Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older. **The Flowflex COVID-19 Antigen Home Test does not require serial testing.**

- Anterior nasal swab specimens
- Results in 15 minutes
- 12 Months shelf life
- Store between 36 to 86° F
- Sample self-collection ages 14 and older
- Sample collection by an adult in **children ages 2 to 13**
- Excellent performance when compared to an FDA authorized molecular SARS-CoV-2 test.

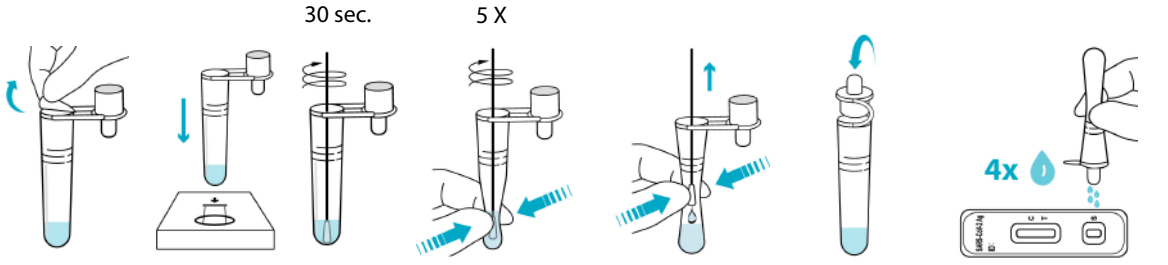
Clinical Performance

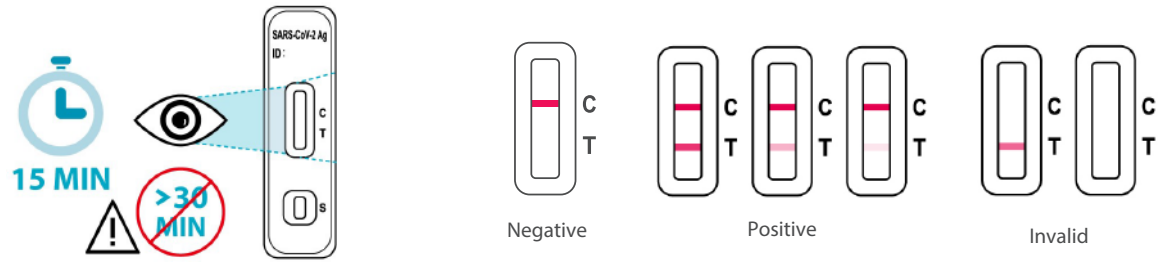
The Flowflex COVID-19 Antigen Home Test was compared to an FDA authorized molecular SARS-CoV-2 test. The Flowflex COVID-19 Antigen Home Test correctly identified 93% of positive specimens and 100% of negative specimens.

Materials Provided

- Test Cassette(s)
- Package Insert
- Extraction Buffer Tube(s)
- Nasal Swab(s)
- External Tube Holder - Package of 25 tests

Test Procedure and Interpretation





Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
Flowflex COVID - 19 antigen Home Test	L031-118B5	Cassette	Nasal swabs	1 Test/Kit

- This product has not been FDA cleared or approved but has been authorized by FDA under an EUA.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of IVDs for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparednessand-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19
- For detailed instructions, please visit: www.aconlabs.com

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Concordance #	349090
Contact Info.	(Name) (Phone) (Email)

PN: 2210033702 • Date 10/2021

Flowflex™ COVID-19 Antigen Home Test Package Insert

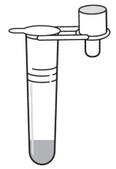
REF L031-118B5	REF L031-125M5	REF L031-125N5	REF L031-125P5	English

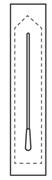
A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens. For self-testing use. For use under an Emergency Use Authorization (EUA) only.

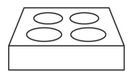
Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

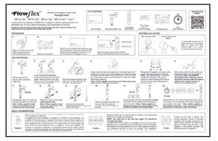
KIT CONTENTS


Test Cassette


Extraction Buffer Tube


Disposable Nasal Swab


Tube Holder (only for 25 test quantity)


Package Insert


Timer (Not included)

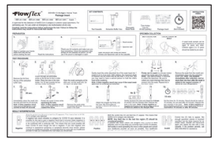
INSTRUCTION VIDEO:

PREPARATION

1.


Wash or sanitize your hands. Make sure they are dry before starting the test.

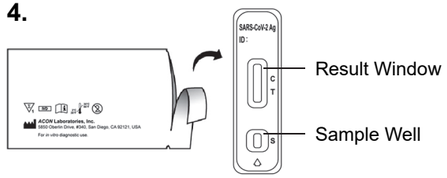
2.


Read the instructions.

3.


Check your kit contents and make sure you have everything. Check the expiration date printed on the cassette foil pouch. Do not use if the pouch is damaged or open.

4.

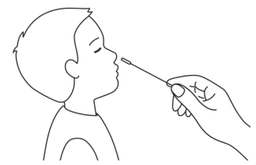


Open the pouch and locate the Result Window and Sample Well on the cassette.

SPECIMEN COLLECTION

SELF COLLECTION

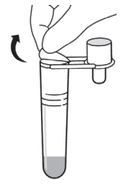
COLLECTION BY AN ADULT



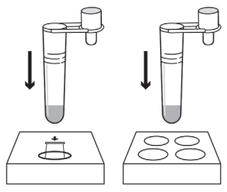
A nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.

TEST PROCEDURE

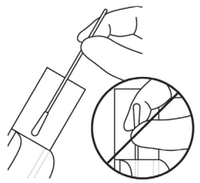
1.


Remove the foil from the top of the extraction buffer tube.

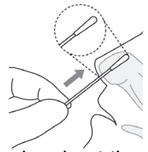
2.


Punch through the perforated circle on the kit box to form a tube holder. Place the tube in the tube holder. For 25 test quantity kit box the tube holder is provided.

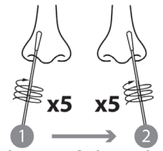
3.


Open the swab packaging at the stick end, not the swab end. Do not touch the swab head.

4.

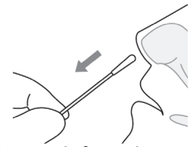

Gently insert the entire absorbent tip of the swab head into 1 nostril (½ to ¾ of an inch). With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.
Note: A false negative result may occur if the nasal swab specimen is not properly collected.

5.

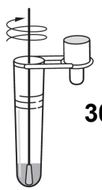


Firmly rub the **swab** in a circular motion around the inside wall of the nostril **5 times**. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril.

6.

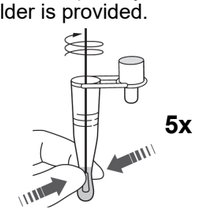

Remove the swab from the nostril and immediately place into the extraction buffer tube. ***Note: Test samples immediately after collection, and no more than one hour after the swab is added to the reagent solution, if stored at room temperature.***

7.



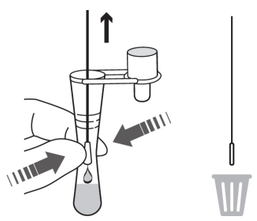
Immediately place the swab into the tube and swirl for 30 seconds. ***Note: A false negative result may occur if the swab is not swirled at least 30 seconds.***

8.

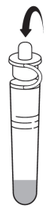


Rotate the swab 5 times while **squeezing the tube**. ***Note: A false negative result may occur if the swab is not rotated five times.***

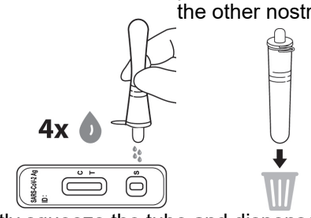
9.


Remove the swab while **squeezing the tube**. Dispose the swab in the trash.

10.

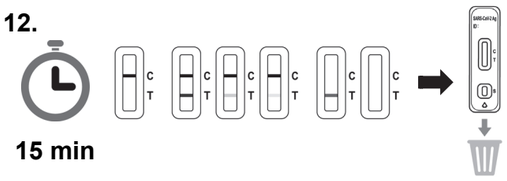

Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.

11.



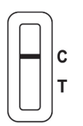
Gently squeeze the tube and dispense **4 drops** of solution into the Sample Well. Dispose the tube in the trash. ***Note: A false negative or invalid result may occur if less than 4 drops of fluid are added to the Sample Well.***

12.

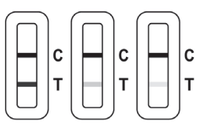


Set the timer for 15 minutes. Result should be read at 15 minutes. Do not read after 30 minutes. Dispose the test cassette in the trash. ***Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.***

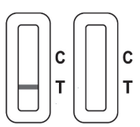
RESULT INTERPRETATION


Negative

Only the control line (C) and no test line (T) appears. This means that no SARS-CoV-2 antigen was detected.
A negative test result indicates no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience symptoms or symptoms become more severe, please consult your healthcare provider. It is important that you work with your healthcare provider to help you understand the next steps you should take.


Positive

Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
NOTE: Any faint line in the test line region (T) should be considered positive.
A positive test result means that antigens from COVID-19 were detected, and it is very likely you currently have COVID-19 disease. Self-isolate to avoid spreading the virus to other people and consult your healthcare provider as soon as possible. Your healthcare provider will work with you to determine how best to care for you.


Invalid

Control line (C) fails to appear. Not enough specimen volume or incorrect operation are the likely reasons for an invalid result. Review the instructions again and repeat the test with a new cassette. If the problem persists, call (800) 838-9502 for assistance.

FOR FDA EMERGENCY USE AUTHORIZATION (EUA) ONLY

- This product has not been FDA cleared or approved but has been authorized by FDA under an EUA.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of IVDs for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparednessand-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19
- For detailed instructions, please visit: www.aconlabs.com

INTENDED USE

The Flow*flex* COVID-19 Antigen Home Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older. The Flow*flex* COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. This antigen is generally found in anterior nasal swabs 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.

Individuals who test positive should self-isolate and consult their healthcare provider as additional testing may be necessary and for public health reporting.

Negative results are presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. Healthcare providers will report all test results they received from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The Flow*flex* COVID-19 Antigen Home Test is intended for self-use or lay user testing another in a non-laboratory setting. The Flow*flex* COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY

The new coronaviruses belong to the beta genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the new coronavirus are the main source of infection; infected people without symptoms can also infect others. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Read the Flow*flex* COVID-19 Antigen Home Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.
- The Test is intended to aid in the diagnosis of a current COVID-19 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
- Keep test kit and materials out of the reach of children and pets before and after use.
- Do not use on anyone under two years of age.
- Do not open the kit contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
- Do not use the test after the expiration date shown on the test cassette pouch.
- Do not use the test if the pouch is damaged or open.
- Do not reuse any kit components. Do not use with multiple specimens.
- Make sure there is sufficient light when testing.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Remove any piercings from the nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Inadequate or improper nasal swab sample collection may yield false negative test results.
- Do not touch the swab head when handling the swab.
- The test is intended to be read at 15 minutes. If the test is read before 15 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test cassette.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.
- The chemicals in the reagent solution are hazardous to the skin and eye. Please see the below table for safety recommendations for skin and eye irritation. No personal protective equipment is recommended for use.

Hazard Category (mixture)	Hazard Statement for mixture	Labeling of Harm(s)
Not classified	Acute oral or dermal toxicity	None
Category 2	Eye irritation	May cause eye irritation
Category 3	Skin irritation	Causes mild skin irritation

- If the reagent solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice. https://www.poison.org/contact-us or 1-800-222-1222

FREQUENTLY ASKED QUESTIONS

Q: WILL THIS TEST HURT?

A: No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?

A: Potential **risks** include:

- Possible discomfort during sample collection.
- Possible incorrect test results (see Result Interpretation section).

Potential **benefits** include:

- The results, along with other information, can help you and your healthcare provider make informed decisions about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

A: There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests, such as the Flow*flex* COVID-19 Antigen Home Test detect proteins from the virus. Antigen tests are very specific for the COVID-19 virus but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test is necessary and if you should continue isolating at home.

Q: HOW ACCURATE IS THIS TEST?

A: The performance of Flow*flex* COVID-19 Antigen Home Test was established in an all-comers clinical study conducted between March 2021 and May 2021 with 172 nasal swabs self-collected or pair-collected by another study participant from 108 individual symptomatic patients (within 7 days of onset) suspected of COVID-19 and 64 asymptomatic patients. All subjects were screened for the presence or absence of COVID-19 symptoms within two weeks of study enrollment. The Flow*flex* COVID-19 Antigen Home Test was compared to an FDA authorized molecular SARS-CoV-2 test. The Flow*flex* COVID-19 Antigen Home Test correctly identified 93% of positive specimens and 100% of negative specimens.

Q: WHAT IF YOU TEST POSITIVE?

A: A positive test result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19 disease. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

Q: WHAT IF YOU TEST NEGATIVE?

A: A negative test result indicates no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19, and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact your healthcare provider.

IMPORTANT

This test is intended to be used as an aid in the clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting.

HEALTHCARE PROVIDERS

Please visit www.aconlabs.com to obtain the complete instructions for use and fact sheet for healthcare providers.

Index of Symbols

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

***ACON* Laboratories, Inc.**
San Diego, CA 92121, USA
aconlabs.com
Customer Support: 1-800-838-9502

Number: 1151297701
Effective Date: 2021-10-17

Flowflex™

Prueba casera de antígeno del COVID-19
Prospecto

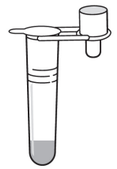
REF L031-118B5	REF L031-125M5	REF L031-125N5	REF L031-125P5	Español

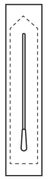
Una prueba rápida para la detección de antígenos del SARS-CoV-2 en muestras de las fosas nasales anteriores. Para pruebas autoadministradas. Solo para uso bajo una Autorización de Uso de Emergencia (EUA, por sus siglas en inglés).

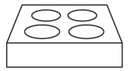
Lea con cuidado las instrucciones antes de realizar la prueba. No seguir las instrucciones puede dar resultados de prueba inexactos.

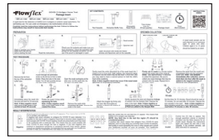
CONTENIDOS DEL KIT


Cartucho de prueba


Tubo de tampón de extracción


Hisopo nasal descartable


Soporte para tubos (solo para una cantidad de 25 pruebas)

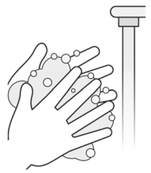

Prospecto


Temporizador (No incluido)

VIDEO DE INSTRUCCIONES:

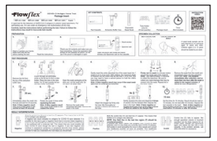
PREPARACIÓN

1.



Lávese o desinfecte las manos. Asegúrese de que estén secas antes de comenzar la prueba.

2.

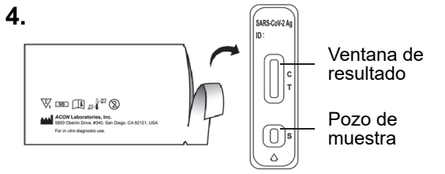


Lea las instrucciones.

3.

Verifique los contenidos del kit y asegúrese de que tenga todo. Verifique la fecha de vencimiento impresa en el estuche de aluminio del cartucho. No use si el estuche estuviera dañado o abierto.

4.

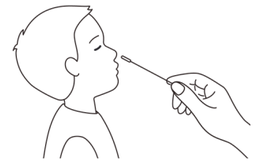


Abra el estuche y ubique la ventana de resultado y el pozo de muestra en el cartucho.

RECOLECCIÓN DE MUESTRAS

AUTORECOLECCIÓN

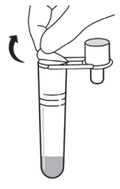
RECOLECCIÓN POR UN ADULTO



Una persona de 14 años o más puede recolectar su propia muestra de las fosas nasales. Las pruebas de los niños de 2 a 13 años deben ser administradas por un adulto.

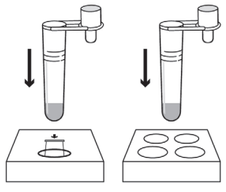
PROCEDIMIENTO DE PRUEBA

1.



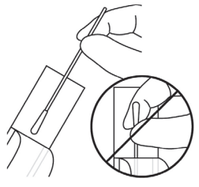
Retire el aluminio de la parte superior del tubo de tampón de extracción.

2.



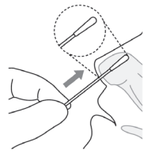
Perfore el círculo perforado en la caja del kit para formar un soporte para tubos. Coloque el tubo en el soporte para tubos. En la caja del kit con una cantidad de 25 pruebas, se proporciona el soporte para tubos.

3.



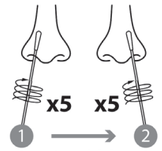
Abra el empaque del hisopo por el extremo del palillo, no por el extremo del hisopo. No toque la cabeza del hisopo.

4.



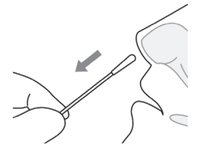
Inserte suavemente toda la punta absorbente de la cabeza del hisopo en 1 fosa nasal (de ½ a ¾ de pulgada). En el caso de los niños, la profundidad máxima de inserción en la fosa nasal puede ser inferior a ¾ de pulgada, y es posible que necesite una segunda persona para sujetar la cabeza del niño mientras realiza el hisopado. ***Nota: Puede producirse un resultado falso negativo si la muestra del hisopo nasal no se recolecta correctamente.***

5.



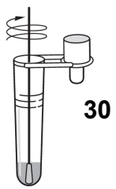
Frote firmemente el **hisopo** con un movimiento circular alrededor de la pared interior de la fosa nasal **5 veces**. Tómese aproximadamente 15 segundos para recolectar la muestra. Asegúrese de recoger cualquier drenaje nasal que pueda haber en el hisopo. Repita esto en la otra fosa nasal.

6.



Retire el hisopo de la fosa nasal y colóquelo inmediatamente en el tubo de tampón de extracción. ***Nota: Analice las muestras inmediatamente después de la recolección y no más de una hora después de agregar el hisopo a la solución de reactivo, si se almacena a temperatura ambiente.***

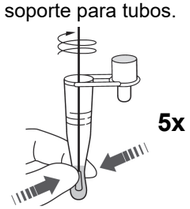
7.



30 segundos

Inserte de inmediato el hisopo en el tubo y gírelo durante 30 segundos. ***Nota: Puede producirse un falso negativo si no gira el hisopo durante al menos 30 segundos.***

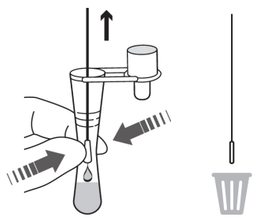
8.



5x

Rote el hisopo 5 veces mientras **aprieta el tubo.** ***Nota: Puede producirse un falso negativo si no rota el hisopo cinco veces.***

9.



Retire el hisopo mientras **aprieta el tubo**. Deseche el hisopo en la basura.

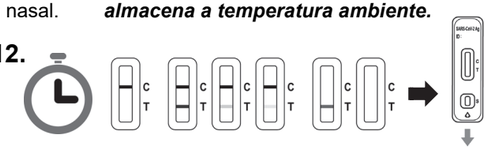
10.

Coloque el gotero firmemente en el tubo. Mezcle bien girando o sacudiendo la parte inferior del tubo.

11.

Apriete suavemente el tubo y dispense **4 gotas** de solución en el pozo de muestra. Deseche el tubo en la basura. ***Nota: Puede producirse un resultado falso negativo o no válido si se agregan menos de 4 gotas de líquido en el pozo de muestra.***

12.



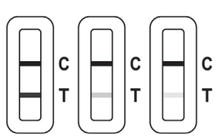
15 minutos

Configure el temporizador en 15 minutos. El resultado debe leerse a los 15 minutos. No lea después de 30 minutos. Deseche el cartucho de prueba en la basura. ***Nota: Puede producirse un resultado falso negativo o falso positivo si lee el resultado de la prueba antes de los 15 minutos o después de 30 minutos.***

INTERPRETACIÓN DE RESULTADOS

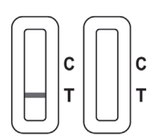
Negativo

Solo aparece la línea de control (C) y ninguna línea de prueba (T). Esto significa que no se detectó ningún antígeno del SARS-CoV-2.
Un resultado negativo de la prueba indica que no se detectaron antígenos de COVID-19. Es posible que esta prueba dé un resultado negativo incorrecto (falso negativo) en algunas personas con COVID-19, y los resultados negativos son presuntos y es posible que deban confirmarse con una prueba molecular. Esto significa que aún es posible que tenga COVID-19 aunque la prueba sea negativa. Si el resultado de la prueba es negativo y continúa experimentando síntomas o los síntomas se agravan, consulte a su proveedor de atención médica. Es importante que trabaje con su proveedor de atención médica para ayudarlo a comprender los próximos pasos que debe seguir.



Positivo

Aparecen tanto la línea de control (C) como la línea de prueba (T). Esto significa que se detectó el antígeno de SARS-CoV-2.
NOTA: Cualquier línea tenue en la región de línea de prueba (T) debe considerarse un resultado positivo.
Un resultado positivo de la prueba significa que se detectaron antígenos de COVID-19 y es muy probable que actualmente tenga la enfermedad de COVID-19. Debe aislarse para evitar la transmisión del virus a otras personas y consulte a su proveedor de atención médica lo antes posible. Su proveedor de atención médica trabajará con usted para determinar cuál es la mejor manera de atenderlo a usted.



Inválido

No aparece la línea de control (C). Un volumen de muestra insuficiente o una operación incorrecta son las posibles razones de un resultado no válido. Revise las instrucciones nuevamente y repita la prueba con un nuevo cartucho. Si el problema persiste, llame al (800) 838-9502 para obtener ayuda.

SOLO PARA AUTORIZACIÓN DE USO DE EMERGENCIA (EUA)

- Este producto no ha sido autorizado ni aprobado por la FDA, pero ha sido autorizado por la FDA bajo una EUA.
- Este producto ha sido autorizado solo para la detección de proteínas del SARS-CoV-2, no para otros virus o patógenos.
- El uso de emergencia de este producto solo está autorizado mientras dure la declaración de que existen circunstancias que justifiquen la autorización del uso de emergencia de IVD para la detección o diagnóstico del COVID-19 en virtud del Artículo 564 (b)(1) de la Ley Federal de Alimentos, Medicamentos y Cosméticos, 21 USC § 360bbb-3(b)(1), a menos que finalice la declaración o la autorización se revoque antes.
- Para obtener más información sobre EUA, visite: https://www.fda.gov/emergency-preparednessand-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Para la información más actualizada sobre el COVID-19, visite: www.cdc.gov/COVID19
- Para instrucciones detalladas, visite: www.aconlabs.com

USO PREVISTO

La prueba casera de antígeno del COVID-19 Flow*flex* es un inmunoensayo cromatográfico de flujo lateral destinado a la detección cualitativa del antígeno de la proteína nucleocápside del SARS-CoV-2 en muestras de hisopos de fosas nasales anteriores tomadas directamente en personas dentro de los 7 días de la aparición de los síntomas o sin síntomas u otras razones epidemiológicas para sospechar una infección del COVID-19. Esta prueba está autorizada para uso en el hogar sin receta con muestras de hisopos de fosas nasales anteriores autorecolectadas directamente en personas de 14 años o más o con muestras de fosas nasales anteriores recolectadas por adultos directamente en niños de 2 años o más. La prueba casera de antígeno del COVID-19 Flow*flex* no diferencia entre el SARS-CoV y el SARS-CoV-2.

Los resultados son para la identificación del antígeno de la proteína nucleocápside del SARS-CoV-2. En general, este antígeno se encuentra en las fosas nasales anteriores durante la fase aguda de la infección.

Los resultados positivos indican la presencia de antígenos virales, pero es necesaria una correlación clínica con el historial del paciente y otra información de diagnóstico para determinar el estado de la infección. Los resultados positivos no descartan infección bacteriana o coinfección con otros virus. Es posible que el agente detectado no sea la causa definitiva de la enfermedad.

Las personas que den positivo en la prueba deben aislarse y consultar a su proveedor de atención médica, ya que pueden ser necesarias pruebas adicionales e informes de salud pública.

Los resultados negativos son presuntos y se puede realizar la confirmación con un ensayo molecular, si es necesario para el manejo del paciente. Los resultados negativos no descartan la infección del SARS-CoV-2 y no deben usarse como la única base para el tratamiento o las decisiones de manejo del paciente, incluso para tomar decisiones de control de infecciones. Los resultados negativos deben considerarse en el contexto de las exposiciones recientes de la persona, el historial y la presencia de signos y síntomas clínicos compatibles con COVID-19.

Las personas deben proporcionar todos los resultados obtenidos con este producto a su proveedor de atención médica para los informes de salud pública. Los proveedores de atención médica informarán a las autoridades de salud pública pertinentes todos los resultados de las pruebas que recibieron de las personas que utilizan el producto autorizado, en conformidad con los requisitos locales, estatales y federales, mediante los códigos LOINC y SNOMED apropiados, como lo define el código para el mapeo de pruebas para las pruebas de SARS-CoV-2 de laboratorio de Diagnósticos In Vitro (LIVD) proporcionado por los CDC.

La prueba casera de antígeno del COVID-19 Flow*flex* está destinada al uso propio o para usuarios no especializados que les realizan la prueba a otros en un lugar distinto a un laboratorio. La prueba casera de antígeno del COVID-19 Flow*flex* solo se utiliza en conformidad con la Autorización de Uso de Emergencia de la Administración de Medicamentos y Alimentos.

RESUMEN

Los nuevos coronavirus pertenecen al género beta. El COVID-19 es una enfermedad respiratoria infecciosa aguda. Actualmente, los pacientes infectados con el nuevo coronavirus son la principal fuente de infección. Las personas infectadas que son asintomáticas también pueden infectar a otras. Basado en lo que se conoce actualmente, el período de incubación es de 1 a 14 días, en su mayoría de 3 a 7 días. Los principales síntomas incluyen fiebre, cansancio y tos seca. En algunos casos, se puede apreciar la congestión nasal, el goteo nasal, el dolor de garganta, el dolor muscular y la diarrea.

ADVERTENCIAS, PRECAUSIONES E INFORMACIÓN DE SEGURIDAD

- Lea el prospecto de la prueba casera de antígeno del COVID-19 Flow*flex* cuidadosamente antes de realizar la prueba. No seguir las indicaciones podrá generar que los resultados de las pruebas sean imprecisos.
- La prueba tiene el propósito de ayudar a diagnosticar la infección por COVID-19 actual. Por favor, comuníquese con un profesional de la salud para hablar sobre sus resultados y respecto a si se necesitan pruebas adicionales.
- Mantenga el kit para pruebas y los materiales fuera del alcance de los niños y mascotas antes y después del uso.
- No lo utilice en ninguna persona menor de dos años de edad.
- No abra los contenidos del kit hasta que esté listo para utilizarlos. Si el cartucho de prueba permanece abierto por una hora o más, es posible que los resultados de las pruebas sean inválidos.
- No utilice la prueba luego de la fecha de vencimiento indicada en la bolsa del cartucho de prueba.
- No utilice la prueba si la bolsa está dañada o abierta.
- No vuelva a utilizar ninguno de los componentes del kit. No lo utilice con varias muestras.
- Asegúrese de que haya suficiente luz cuando realice la prueba.
- No utilice espráis nasales durante al menos 30 minutos antes de recoger una muestra nasal.
- Quite toda perforación de la nariz antes de comenzar la prueba.
- No lo utilice en nadie que sea propenso a las hemorragias nasales o que haya tenido lesiones faciales o lesiones/cirugía en la cabeza en los últimos seis meses.
- Recoger muestras con un hisopo nasal de forma inadecuada o incorrecta puede generar resultados de la prueba negativos falsos.
- No toque la cabeza del hisopo cuando lo manipule.
- La prueba debe leerse después de 15 minutos. Si la prueba se lee antes de los 15 minutos o después de 30 minutos, pueden generarse resultados negativos o positivos falsos y deberá repetirse la prueba con un nuevo cartucho de prueba.
- No ingiera ninguno de los componentes del kit.
- Evite exponer su piel, ojos, nariz o boca a la solución que se encuentra en el tubo de extracción.
- Los químicos en la solución reactiva son peligrosos para la piel y los ojos. Por favor, consulte el cuadro a continuación para ver las recomendaciones de seguridad por la irritación de la piel y los ojos. No se recomienda utilizar equipo de protección personal.

Categoría de peligro (mezcla)	Indicación de peligro de la mezcla	Identificación del/de los daño(s)
Sin clasificar	Toxicidad aguda oral o cutánea	Ninguna
Categoría 2	Irritación de los ojos	Puede causar irritación de los ojos
Categoría 3	Irritación cutánea	Causa irritación cutánea leve

- Si la solución reactiva entra en contacto con la piel o los ojos, enjuague con bastante agua. Si la irritación continúa, busque asesoramiento médico. https://www.poison.org/contact-us o 1-800-222-1222

PREGUNTAS FRECUENTES

P: ¿ESTA PRUEBA DOLERÁ?

R: No, el hisopo nasal no está afilado y no debe doler. En ocasiones, es posible que el hisopo se sienta ligeramente incómodo. Si siente dolor, detenga la prueba y solicite el asesoramiento de su proveedor de salud.

P: ¿CUÁLES SON LOS POSIBLES RIESGOS Y BENEFICIOS DE ESTA PRUEBA?

R: Los posibles **riesgos** incluyen:
- Posible incomodidad durante la recogida de muestras.
- Posibles resultados de pruebas incorrectos (consulte la sección Interpretación de resultados).

Los posibles **beneficios** incluyen:
- Los resultados, junto con otra información, pueden ayudarlo a usted y a su proveedor de salud a tomar decisiones bien fundadas sobre su atención.
- Los resultados de esta prueba pueden ayudar a limitar el contagio del COVID-19 a su familia y otras personas en su comunidad.

P: ¿CUÁL ES LA DIFERENCIA ENTRE UNA PRUEBA DE ANTÍGENO Y UNA MOLECULAR?

R: Existen distintas pruebas para detectar COVID-19. Las pruebas moleculares (también conocidos como las pruebas PCR) detectan el material genético del virus. Las pruebas de antígeno, como la prueba casera de antígeno del COVID-19 Flow*flex* detectan proteínas del virus. Las pruebas de antígeno son muy específicas para el virus del COVID-19, pero no son tan sensibles como las pruebas moleculares. Esto significa que un resultado positivo es altamente preciso, pero que un resultado negativo no descarta la infección. Si la prueba arroja resultados negativos, debe hablar con su proveedor de atención médica respecto a si es necesaria una prueba molecular adicional y si debe continuar aislándose en su hogar.

P: ¿QUÉ TAN PRECISA ES ESTA PRUEBA?

R: Realizar la prueba casera de antígeno del COVID-19 Flow*flex* se estableció en un estudio clínico general realizado entre marzo de 2021 y mayo de 2021 con 172 hisopados nasales recogidos por uno mismo o de a dos por otro participante del estudio de 108 pacientes sintomáticos particulares (en los 7 días siguientes al inicio) que se cree tienen COVID-19 y 64 pacientes asintomáticos. Se examinó a todos los sujetos para detectar la presencia o ausencia de síntomas del COVID-19 en el plazo de dos semanas desde la inscripción en el estudio. La prueba casera de antígeno del COVID-19 Flow*flex* se comparó con una prueba molecular para SARS-CoV-2 autorizada por la FDA. La prueba casera de antígeno del COVID-19 Flow*flex* identificó correctamente 93% de muestras positivas y 100% de muestras negativas.

P: ¿QUÉ SUCEDE SI SU PRUEBA RESULTA POSITIVA?

R: Un resultado positivo de la prueba significa que se detectaron antígenos de COVID-19 y es muy probable que actualmente tenga la enfermedad de COVID-19. Existe una muy pequeña posibilidad de que esta prueba pueda arrojar un resultado positivo que sea incorrecto (un resultado positivo falso). Si su resultado es positivo debe aislarse en su casa según las recomendaciones de los CDC, a fin de evitar contagiar a terceros con el virus. Por favor, consulte las recomendaciones de los CDC respecto al aislamiento en www.cdc.gov/coronavirus. Busque atención de seguimiento con su proveedor de atención médica de inmediato. Su proveedor de atención médica trabajará con usted para determinar cuál es la mejor manera de atenderlo a usted según el/los resultado(s) de su prueba junto con su historia clínica y sus síntomas.

P: ¿QUÉ SUCEDE SI SU PRUEBA RESULTA NEGATIVA?

R: Un resultado negativo de la prueba indica que no se detectaron antígenos de COVID-19. Es posible que esta prueba dé un resultado negativo incorrecto (falso negativo) en algunas personas con COVID-19, y los resultados negativos son presuntos y es posible que deban confirmarse con una prueba molecular. Esto significa que aún es posible que tenga COVID-19 aunque la prueba sea negativa. Si su prueba arroja un resultado negativo y sigue teniendo síntomas de fiebre, tos y/o falta de aire, debe buscar atención de seguimiento con su proveedor de atención médica de inmediato. Su proveedor de atención médica podrá sugerirle que necesita otra prueba para determinar si contrajo el virus que causa COVID-19. Si está preocupado sobre el estado de su infección por COVID-19 luego de la prueba o cree que podría necesitar una prueba de seguimiento, por favor, comuníquese con su proveedor de atención médica.

IMPORTANTE

Esta prueba tiene el propósito de ser utilizada como una ayuda para el diagnóstico clínico de una infección por COVID-19 actual. No utilice esta prueba como la única guía para controlar su enfermedad. Por favor, consulte a su proveedor de atención médica si sus síntomas continúan, se agravan o si se preocupa en algún momento.

Las personas deben proporcionar todos los resultados obtenidos con este producto a su proveedor de atención médica para los informes de salud pública.

PROVEEDORES DE ATENCIÓN MÉDICA

Visite www.aconlabs.com para obtener las instrucciones de uso completas y la hoja de datos de los proveedores de atención médica.

Índice de símbolos

	Fabricante		Fecha de fabricación
	Contiene suficiente para <*n*> pruebas	REF	Número de catálogo
IVD	Dispositivo médico de diagnóstico *in vitro*		Usar para la fecha
	Consulte las instrucciones de uso	LOT	Código de lote
	Límite de temperatura		No reutilizar

***ACON* Laboratories, Inc.**
San Diego, CA 92121, USA
aconlabs.com
Customer Support: 1-800-838-9502

Número: 1151395801
Fecha Efectiva: 2021-10-19

FACT SHEET FOR HEALTHCARE PROFESSIONALS

ACON Laboratories, Inc. **October 4, 2021**

Flow*flex* COVID-19 Antigen Home Test

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Flow*flex* COVID-19 Antigen Home Test.

The Flow*flex* COVID-19 Antigen Home Test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal samples from individuals 14 years or older or adult collected anterior nasal samples from individuals age 2 years or older.

All individuals who use this assay are required to receive and should carefully review the Flow*flex* COVID-19 Antigen Home Test Instructions for Use before they use the test.

What are the symptoms of COVID-19?
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

This test is for use at home with self-collected anterior nasal swab specimens from individuals within 7 days of symptom or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal samples from individuals 14 years or older or adult collected anterior nasal samples from individuals age 2 years or older.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

- The Flow*flex* COVID-19 Home Antigen Test can be used to test directly collected Anterior Nasal Swab specimens
- The Flow*flex* COVID-19 Antigen Home Test can be used to test individuals within 7 days of symptom or without symptoms or other epidemiological reasons to suspect COVID-19 infection.
- The Flow*flex* COVID-19 Antigen Home Test is for non-prescription home use with self-collected anterior nasal samples from individuals 14 years or older or adult collected anterior nasal samples from individuals age 2 years or older.

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that nucleocapsid antigens from SARS-CoV-2 were detected, and the patient is infected with the virus and presumed to be contagious. COVID-19 test results should always be considered in the context of clinical observations and epidemiological data such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

management decisions should be made by a healthcare provider and follow current CDC guidelines.

The Flow*flex* COVID-19 Antigen Home Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All healthcare providers must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that nucleocapsid antigens from SARS- CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 7 of illness may be more likely to be negative compared to a RT-PCR assay Therefore, negative results should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings (Interim Guidance) (see links provided in "*Where can I go for updates and more information?*" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March and May 2021.The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Negative results, particularly in asymptomatic individuals, should be considered to be presumptive and additional testing with a highly sensitive molecular SARS-CoV-2 test may be necessary to help rule out infection.

What is an EUA?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs)

for the detection and/or diagnosis of the virus that causes COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19. The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?
There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medicaldevices/device-advice-comprehensive-regulatoryassistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatoryand-policy-framework/emergency-use-authorization.

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/coronavirus/2019-ncov/index.html
Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to fact sheet for individuals and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

Manufacturer Information:

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

Customer Support:
+1 800-838-9502
support@aconlabs.com

Technical Support:
+1 800 838-9502
support@aconlabs.com

Safety Data Sheet – Flow*flex* COVID-19 Antigen Home Test

SAFETY DATA SHEET

This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

SECTION 1: INDENTIFICATION

1.1 Identification

Product form: Mixture

Product name: Flow*flex*™ COVID-19 Antigen Home Test

Product code: REF L031-118B5, REF L031-125M5, REF L031-125N5, REF L031-125P5

1.2 Recommended use and restrictions on use

Recommended use: For medical diagnostic use.

Restrictions on use: Restricted to users aged 14 years and older

1.3 Supplier:

Name: ACON Laboratories, Inc.

Address: 5850 Oberlin Drive, # 340
San Diego, CA 92121, USA

Customer Support: 1-800-838-9502

E-mail: info@aconlabs.com

1.4 Emergency telephone number: 1-800-838-9502

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Classification of substance or mixture

GHS US classification: Not classified

2.2 GHS Label elements, including precautionary statements

GHS US labeling: No labeling applicable

2.3 Other hazards which do not result in classification

No additional information available.

2.4 Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: COMPOSITION /INFORMATION ON INGREDIENTS

3.1 Substance

Not Applicable.

3.2 Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of HazCom 2012.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

First-aid measures after inhalation: Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact: Wash skin with plenty of water.

First-aid measures after eye contact: Rinse eyes with water as a precaution.

First-aid measures after ingestion: Call a poison center/doctor/physician if you feel unwell.

4.2 Most important symptoms and effects (acute and delayed)

No additional information available.

4.3 Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Water spray. Dry powder. Foam.

5.2 Special hazards arising from the chemical

Reactivity: The product is non-reactive under normal conditions of use, storage and transport.

5.3 Special protective equipment and precautions for firefighters

Protection during firefighting: Do not attempt to take action without suitable protective equipment.

Self -contained breathing apparatus. Complete protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Take up liquid spill into absorbent material.

Other information: Dispose of materials or solid residues at an authorized site.

Reference to other sections: For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Product must only be kept in the original packaging. Keep cool.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No additional information available

8.2 Appropriate engineering controls

Appropriate engineering controls: Ensure good ventilation of the work station.

Environmental exposure controls: Avoid release to the environment.

8.3 Individual protection measures/Personal protective equipment

Personal protective equipment:

Gloves. Safety glasses. Protective clothing.

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

A risk assessment is required

Personal protective equipment symbol(s):

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	:	Liquid
Color	:	No data available
Odor	:	Not applicable
Odor threshold	:	No data available
pH	:	No data available
Melting point	:	No data available
Freezing point	:	Not applicable
Boiling point	:	No data available
Flash point	:	Not applicable
Relative evaporation rate (butyl acetate=1)	:	No data available
Flammability (solid, gas)	:	Non flammable
Vapor pressure	:	No data available
Relative vapor density at 20 °C	:	No data available
Relative density	:	Not applicable
Solubility	:	No data available
Log Pow	:	No data available
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosion limits	:	Not applicable
Explosive properties	:	No data available
Oxidizing properties	:	No data available

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5 Incompatible material

No additional information available.

10.6 Hazardous decomposition products

Not established.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity (oral): Not classified

Acute toxicity (dermal): Not classified

Acute toxicity (inhalation): Not classified

Skin corrosion/irritation: Not classified

Serious eye damage/irritation: Not classified

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

Specific target organ toxicity – single exposure: Not classified

Specific target organ toxicity – repeated exposure: Not classified

Aspiration hazard: Not classified

Viscosity, kinematic: No data available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ecology – general: No additional data.

12.2 Persistence and degradability

No additional information available.

12.3 Bioaccumulative potential

No additional information available.

12.4 Mobility in soil

No additional information available.

12.5 Other adverse effects

No additional information available.

Safety Data Sheet – Flow*flex* COVID-19 Antigen Home Test

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Disposal methods

Waste treatment methods: Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: TRANSPORT INFORMATION

Department of Transportation (DOT)

In accordance with DOT

Other information : No supplementary information available.

Transportation of Dangerous Goods

Transport by sea

Air transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal regulations

No additional information available.

15.2 International regulations

CANADA: No additional information available

EU-Regulations: No additional information available

National regulations: No additional information available

15.3 US State regulations

No additional information available

SECTION 16: OTHER INFORMATION

This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

Indication of changes: Date of issue. 2021 10 22

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

October 4, 2021

Qiyi Xie
ACON Laboratories, Inc.
5850 Oberlin Drive, #340,
San Diego, CA 92121

Device:	Flow*flex* COVID-19 Antigen Home Test
EUA Number:	EUA210494
Company:	ACON Laboratories, Inc.
Indication:	Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older.

Dear Qiyi Xie:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to ACON Laboratories, Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the Flow*flex* COVID-19 Antigen Home Test, used for the indication identified above.
[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the "Flow*flex* COVID-19 Antigen Home Test Package Insert" Healthcare Provider instructions for use identified below.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a lateral flow test intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older. It does not differentiate between SARS-CoV and SARS-CoV-2.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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. Individuals who test

[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

positive with your product should self-isolate and consult their doctor as additional testing may be necessary and for public health reporting.

Negative results are presumptive, and confirmation with a molecular assay, if necessary for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID19.

Individuals should provide all results obtained with this product to their doctor or healthcare provider for public health reporting. Doctors or healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

Your product is performed using anterior nasal samples from individuals aged 14 years or older or adult-collected anterior nasal samples from individuals age 2 years or older. When using your product the individual unpacks all the test components, before removing the test cassette from its pouch. The extraction buffer tube is then opened and inserted into the tube holder. The swab is then removed from its packaging and the individual collects an anterior nasal swab sample by inserting the swab into the nostril firmly rubbing the swab in a circular motion around the inside wall of the nostril 5 times before repeating in the second nostril. The swab is then immediately inserted into the extraction tube and swirled for 30 seconds before rotating the swab 5 times while squeezing the tube. The swab is then removed and the tube capped with the dropper cap. The contents of the extraction vial is then mixed before four drops of the solution are applied to the sample well Test Cassette. When the anterior nasal swab specimen migrates in the test strip, SARS-CoV-2 antigens, if present in the specimen, will react with the colored anti-SARS-CoV-2 antibody-coated particles, which have been pre-coated on the test strip. The antigen-antibody complex then migrates toward the membrane by capillary action. This complex is then captured by anti-SARS-CoV-2 monoclonal antibodies immobilized at the test line region, and a red line appears on the membrane. Test results are interpreted visually after 15 minutes based on the presence or absence of visually detectable colored lines at the control line (C) and/or test line (T). Upon completion of the test and result interpretation the user should share their results with their healthcare provider.

The Flow*flex* COVID-19 Antigen Home Test kit includes the following materials or other authorized materials: Test Cassettes, Disposable Nasal Swabs, Extraction Buffer Tubes, Tube Holder, and Package Insert.

Your product includes an internal control test line ("C") that must generate the expected result for a test to be considered valid, as outlined in the "Flow*flex* COVID-19 Antigen Home Test Package Insert" and the "Flow*flex* COVID-19 Antigen Home Test Package Insert for Healthcare Providers."

The labeling entitled "Flow*flex* COVID-19 Antigen Home Test Package Insert for Healthcare

Providers" instructions for use, the "Flowflex COVID-19 Antigen Home Test Package Insert" lay user instructions for use, and the "Flow*flex* COVID-19 Antigen Home Test" box labels (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the following fact sheet pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Professionals[5]: ACON Laboratories, Inc. - Flow*flex* COVID-19 Antigen Home Test

The above described product, with the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart

[5] Note that the information typically found in a Fact Sheet for Individuals is contained in the authorized "Flow*flex* COVID-19 Antigen Home Test Package Insert" lay user instructions for use, that will be available to end users as set forth in the Conditions of Authorization (Section IV).

H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

ACON Laboratories, Inc. (You) and Authorized Distributor(s)[6]

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the Flow*flex* COVID-19 Antigen Home Test Package Insert" lay user instructions for use in the shipped kit using the "Flow*flex* COVID-19 Antigen Home Test" box labels and make these two documents electronically available on your website.

C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and

[6] "Authorized Distributor(s)" are identified by you, ACON Laboratories, Inc., in your EUA submission as an entity allowed to distribute your product.

Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributor(s) using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

ACON Laboratories, Inc. (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "Flow*flex* COVID-19 Antigen Home Test Package Insert for Healthcare Providers" instructions for use and the "Fact Sheet for Healthcare Professionals" electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "Flow*flex* COVID-19 Antigen Home Test Package Insert for Healthcare Providers" instructions for use and "Fact Sheet for Healthcare Professionals" in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit your lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide them within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[7] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must develop a mobile phone application or website to further facilitate results reporting by the individual using your product, and submit to FDA such application or website within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the mobile phone application or website to, and review of and concurrence with the developed mobile phone application or website by FDA, you must update the authorized labeling. Such labeling updates will be made in consultation with, and require concurrence of, FDA.

R. You must evaluate the clinical performance of your product in additional asymptomatic individuals in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You must further develop your video instructions for end users and submit to FDA within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH), prior to making the video instructions available for use. After submission of the video instructions and review of and concurrence with the developed video instructions by FDA, you must update the authorized labeling. Such labeling updates will be made in consultation with, and require concurrence of, FDA.

T. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling accordingly. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

U. You must submit your product for any FDA-recommended independent evaluation to confirm the performance characteristics of your test, if requested by FDA. After submission to and concurrence with the data by FDA, you will update your labeling to

[7] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

V. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately.

W. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Conditions Related to Printed Materials, Advertising and Promotion

X. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

Y. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

Z. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens; and,
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure