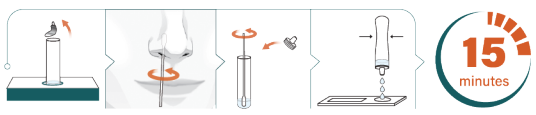
REF R0182CHT

IMMUVIEW® COVID-19 Antigen Home Test
Instructions For Use

For Emergency Use Authorization (EUA) Only. | For *in vitro* diagnostic use.

Scan to access product website



- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

BEFORE OPENING THE TEST

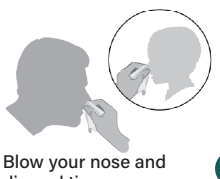
If you are testing more than one person, always clean the test space and wash your hands between each test.

1

You will need (not included in kit):
- **Watch or timer**
- Tissues
- Soap and water or hand sanitizer
- Mirror (optional)

2

Clean and dry a **flat, well-lit** surface, such as a table or counter top.

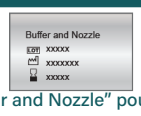


3 Blow your nose and discard tissue.

4 Wash your hands thoroughly and **DRY** them.

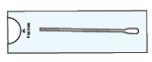
PREPARE FOR TESTING

Do not use the kit if the items are damaged, missing, or expired. Use buffer and cassette within 30 minutes of opening pouches. For 2, 5 and 20 test kits, do not throw the kit box away until all tests are used up.



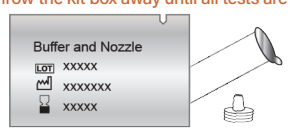
"Buffer and Nozzle" pouch

Cassette pouch

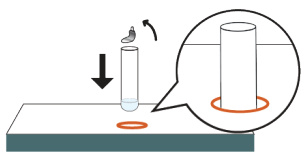


Swab

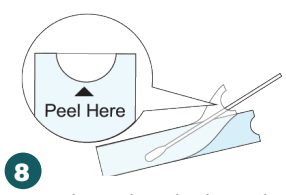
5
- Remove all items needed for 1 test.
- Check that the seal is still intact in all items. Check the expiration dating of the kit. For current information on the expiration dating of the product please visit: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests#list



6 Open the pouch labeled "Buffer and Nozzle".



7
- Push in the perforated circle on the kit box and place buffer tube.
- Slowly peel off the buffer tube seal.
- Place the open tube in the **rack.**



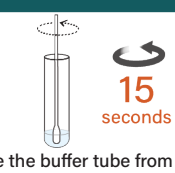
8 Open the swab packaging and hold the swab by its handle. **DO NOT** touch the fabric tip.

COLLECT SAMPLE

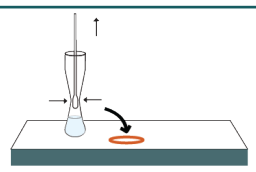
Children ages 14 to 17 may self-test with adult supervision. Do not touch your cheeks, teeth, gums, or any other surfaces with the fabric tip of the swab, or it might contaminate your sample. DO NOT touch the fabric tip of the swab with your hands.

9
- Carefully insert fabric tip of the swab ½ to ¾ of an inch into first nostril.
- 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.
- **DO NOT** insert the swab any deeper if you feel strong resistance or pain. If self-testing, use a mirror to help.
- Slowly rub swab in a complete circle around the inside of the nostril at least 5 times.
- Using the **SAME SWAB**, repeat process in the second nostril.
- **Children under age 14 should be tested by an adult (wear a face cover when swabbing others).**

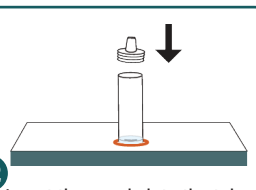
PROCESS THE SWAB SAMPLE



10
- Remove the buffer tube from the rack.
- Insert the fabric tip of the swab into the tube.
- Swirl the swab in the liquid for 15 seconds.



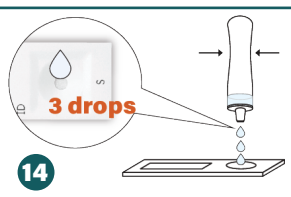
11
- Remove the swab from the tube while squeezing tube into the swab tip to press out excess liquid.
- Place the tube back into tube rack.



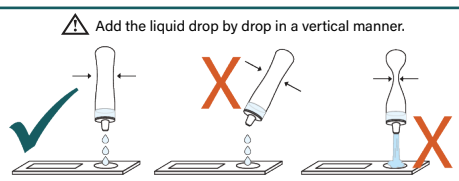
12 Insert the nozzle into the tube while holding the tube with your other hand. It should fit snug like a cork.

TEST THE SAMPLE

13
- Open the pouch labeled "COVID-19 Antigen Home Test" and remove the test cassette. Do not use after the test cassette has been opened for more than 30 minutes.
- Lay the cassette on clean, flat, well-lit surface.



14
- Invert the buffer tube over the cassette and gently squeeze to **slowly** add 3 drops of the liquid into the sample well (S), avoiding forming bubbles.
- **Immediately start timing 15 minutes and wait. DO NOT** move the cassette during the test.



READ THE RESULT

15

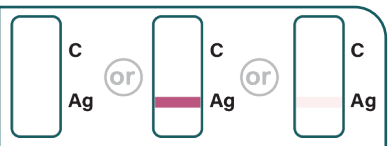
Read result after 15 minutes.
You must read the result after 15 minutes, but not past 30 minutes.

Negative

If the Control (C) line is visible, but the Antigen (Ag) line is not visible, the test is negative. To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours if you have symptoms on the first day of testing. Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.
A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

Positive

If the Control (C) line and the Antigen (Ag) line are visible, the test is positive. Any faint visible red test (Ag) line with the control line (C) should be read as positive. You do not need to perform repeat testing if you have a positive result at any time.
A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).



Invalid

If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

TEST INTERPRETATION

- Repeat testing is needed to improve test accuracy. Please follow the table when interpreting test results for COVID-19.
- 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. **Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.**

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

SAFELY DISPOSE OF USED TEST

16

When done testing, dispose of used items (except Instructions For Use) in a trash can (not recycling) or according to your local guidelines. Thoroughly wash or sanitize your hands and any surfaces and items used during testing.

INTENDED USE

The ImmuView® COVID-19 Antigen Home Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The ImmuView® 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, which is generally detectable in anterior nasal (nares) swab specimens 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 positive with the ImmuView® COVID-19 Antigen Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All 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 measures such as isolating from others and wearing masks. 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 who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All 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.

The ImmuView® COVID-19 Antigen Home Test is intended for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years of age or older in a non-laboratory setting. The ImmuView® COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

FREQUENTLY ASKED QUESTIONS

Q: WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?
A: Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

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

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19.
For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the ImmuView® COVID-19 Antigen Home Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

Q: HOW ACCURATE IS THIS TEST?
A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at https://immuviewathome.com.

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?
A: A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?
A: A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

WARNINGS, PRECAUTIONS & SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. 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 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.**
- **If you have had symptoms for longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.**
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within 30 minutes.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-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: https://immuviewathome.com.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, and mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, or mouth, flush with large amounts of water. **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name	Harms (GHS Code) for each ingredient at stock for reference only:	Concentration
Tergitol 15 S-9	H302, H332, H315, H318, H401	0.4%
ProClin 300	H302, H312, H314, H317, H332, H411	0.1%
Sodium azide	H300, H400, H410	0.095%

LIMITATIONS

- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March, 2022 and August, 2022. The clinical performance has not been established for 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

HEALTHCARE PROVIDERS

Please visit https://immuviewathome.com to obtain the complete instructions for use and fact sheet for healthcare providers.

STORE

1. In a dry place, at 35°F-86°F (2°C-30°C).
2. Keep away from direct sunlight and do not store it in a freezer.
3. If you stored the kit in an area colder than 59°F (15°C), leave it at room temperature for 30 minutes before starting the test.

PI-R0182CHT Rev A3.3
12/2022

CTK Biotech, Inc.
support@immuview.com
Call center 1-833-919-0617
https://immuviewathome.com

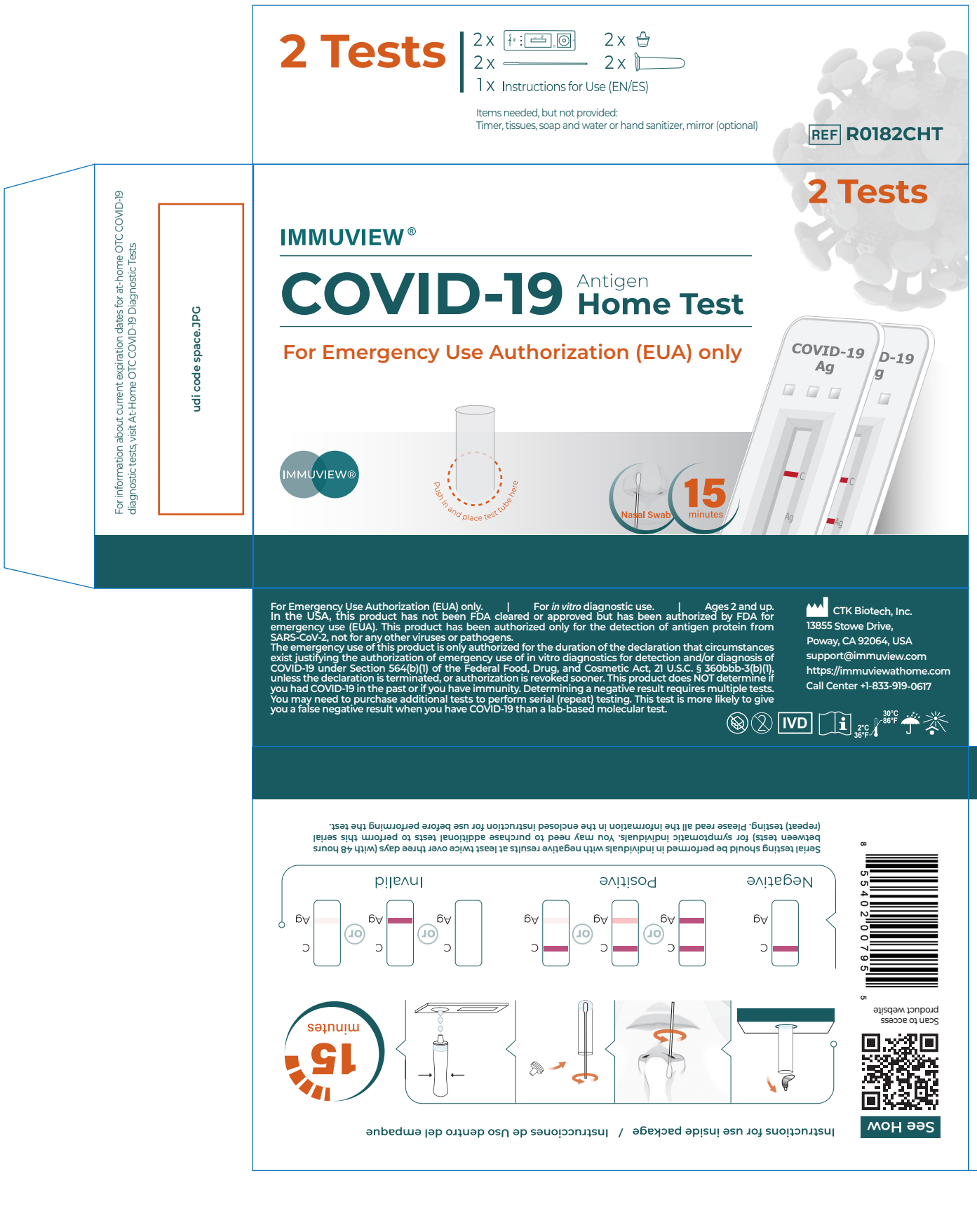
PM-R0182CHT-2T Rev. B2.1

kit box design for COVID-19 Ag Home Test, 2 test/kit, Revision B2.1.

size 135 x 80 x 30mm

C 80
M 30
Y 40
K 45

C 0
M 75
Y 98
K 13



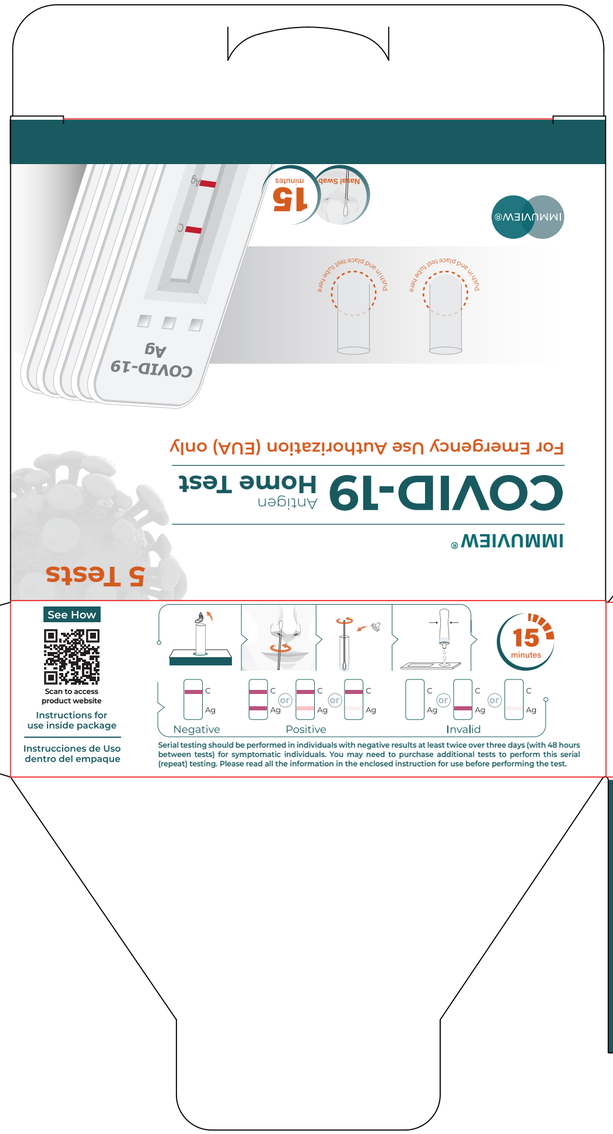
PM-R0182CHT-5T Rev. B2.1

Kit box design for COVID-19 Ag Home Test, 5 test/kit, Revision B2.1.

size 135 x 110 x 40 mm

C 80
M 30
Y 40
K 45

C 0
M 75
Y 98
K 13



See How

Scan to access product website

Instructions for use inside package

Instrucciones de Uso dentro del empaque

Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing. Please read all the information in the enclosed instruction for use before performing the test.

For Emergency Use Authorization (EUA) only. | For *in vitro* diagnostic use. | Ages 2 and up.
In the USA, this product has not been FDA cleared or approved but has been authorized by FDA for emergency use (EUA). This product has been authorized only for the detection of antigen protein 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 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. This product does NOT determine if you had COVID-19 in the past or if you have immunity. Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

CTK Biotech, Inc.
13855 Stowe Drive,
Poway, CA 92064, USA
support@immuview.com
https://immuviewathome.com
Call Center +1-833-919-0617

IVD

36°C 97°F
2°C 36°F

IMMUVIEW®

COVID-19 Antigen **Home Test**

For Emergency Use Authorization (EUA) only

5 Tests

For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit At-Home OTC COVID-19 Diagnostic Tests

udi code space.JPG

8 55402 00796 2

REF R0182CHT

Store in a dry place, at 35°F-86°F (2-30°C)
Keep away from direct sunlight and do not store it in a freezer.
If you stored the kit in an area colder than 59°F (15°C), leave it at room temperature for 30 minutes before starting the test.

5 Tests

5x
5x
1x Instructions for Use (EN/ES)
5x
5x

Items needed, but not provided:
Timer, tissues, soap and water or hand sanitizer, mirror (optional)

40mm

PM-R0182CHT-20T Rev. B2.1

Kit box design for COVID-19 Ag Home Test, 20 test/kit, Revision B2.1.

size 220.5 x 135.5 x 80.5 mm

C 80
M 30
Y 40
K 45

C 0
M 75
Y 98
K 13

udi code space.JPG

For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit At-Home OTC COVID-19 Diagnostic Tests

IMMUVIEW®

COVID-19 Antigen Home Test

For Emergency Use Authorization (EUA) only

20 Tests

Store in a dry place, at 35°F-86°F (2-30°C)
Keep away from direct sunlight and do not store it in a freezer.
If you stored the kit in an area colder than 59°F (15°C), leave it at room temperature for 30 minutes before starting the test.

REF R0182CHT

IMMUVIEW®

For Emergency Use Authorization (EUA) only. | For *in vitro* diagnostic use. | Ages 2 and up.

In the USA, this product has not been FDA cleared or approved but has been authorized by FDA for emergency use (EUA). This product has been authorized only for the detection of antigen protein 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 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.

This product does NOT determine if you had COVID-19 in the past or if you have immunity. Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

CTK Biotech, Inc.
13855 Stowe Drive,
Poway, CA 92064, USA
support@immuview.com
https://immuviewathome.com
Call Center +1-833-919-0617

IVD

2°C 36°F 30°C 86°F

See How

Scan to access product website

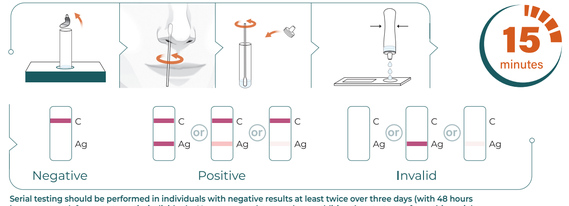
20 Tests

20 x 20 x
20 x 20 x
4 x Instructions for Use (EN/ES)

Items needed, but not provided: Timer, tissues, soap and water or hand sanitizer, mirror (optional)

Instructions for use inside package / Instrucciones de Uso dentro del empaque

15 minutes



Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing. Please read all the information in the enclosed instruction for use before performing the test.