Pilot™ COVID-19 At-Home Test
Quick Reference Instructions for patients

For In Vitro Diagnostic (IVD) use.
For use under the Emergency Use Authorization (EUA) only.

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

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.

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

For use under the Emergency Use Authorization (EUA) only.
For In Vitro Diagnostic (IVD) use.

Materials Provided

- Sterile Swab
- Tube with Liquid (inside foil pouch 2)
- Nozzle Cap
- Tube Holder

**NOTE:** This test comes in a 1, 4 or 25 test quantity. The number of items supplied in the kit will vary depending on which kit is purchased.

Storage and Stability

Store the kit at 36-86 °F / 2-30 °C and protect from direct sunlight. The expiry date of the materials is indicated on the external packaging. Do not freeze the kit.

Prepare to perform the test

2. Wash your hands with soap and water, or use hand sanitizer before performing the test. Make sure you rinse thoroughly and your hands are dry before starting.
3. Check test expiry date on the back of the foil pouches. Do not use if the expiry date has passed.
4. Open foil pouch 1 by tearing along the tear-line. Remove the test device and desiccant package from the foil pouch. Place the test device on a flat surface.
5. Ensure that the test device is intact and that there are no green beads in the desiccant package (white and yellow beads are expected). Do not open the desiccant package.

Test Procedure

1. Open foil pouch 2 and place one tube and one nozzle cap on the table.
2. Remove the swab from the packaging. Ensure that you only touch the handle of the swab and not the soft pad at the tip.
3. Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately ⅛ of an inch.
4. **"Swab Both Nostrils"**
   - Firmly and slowly rotate the swab at least 8 times, brushing against the inside walls of the nostril, for a total of 15 seconds.
   - **"Do not just spin the swab."**
   - Gently remove the swab and, using the same swab, repeat in the second nostril with the same end of the swab.
   - **NOTE:** With children, the maximum depth of insertion into the nostril may be less than ⅛ of an inch, and you may need to have a second person to hold the child’s head while swabbing.
5. Insert the swab into the tube until the soft pad is in the liquid. Squeeze the tube at the bottom and hold it tight. Then stir the swab more than 10 times. This is to transfer the biological material from the swab to the liquid.
6. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

**WARNING:** Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

7. Dispose of the swab and seal the tube securely with the nozzle cap.
8. Hold the tube upright above the sample well. Drop 4 drops onto the sample well.

**"Do not apply the liquid in the rectangular result window"**

9. Set the timer and read the test result at 20 minutes. Do not read the result after 30 minutes.

Read and interpret the results

**WARNING:** Inaccurate test interpretations may occur if results are read before 20 minutes or after 30 minutes.

- **Negative result**
  - If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, this means that the result is negative. It is unlikely that you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures. If you suspect that you have an infection (i.e., if you have prolonged symptoms or if your symptoms worsen), contact your doctor or primary care physician. You may have another infection, or your test result may be false. Negative results do not rule out COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If you do not have COVID-19 symptoms and your result is negative, you should test again with at least 24 hours and no more than 48 hours between tests.

- **Positive result**
  - If a test line (T) is visible together with a control line (C), this means that the result is positive. Look carefully at the result: The test should be considered positive if two lines are visible - even if they are faint. A positive test result means it is very likely that you have COVID-19. Please contact your doctor or primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a molecular PCR test to confirm the result. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

- **Invalid result**
  - If a control line (C) is not visible, the result must be considered invalid. The test is not working correctly and you should perform another test using a different test kit. You may have performed the test incorrectly. Carefully read the Quick Reference Instructions and repeat the test. If your test result is still invalid, please contact your doctor or a COVID-19 test center.

**WARNING:** Do not move or lift the test device during this time.

**NOTE:** Dispose of the used test in the household trash. Do not flush or your test liquids down a drain.
Ilustrações e diagramas não foram fornecidas em texto natural.
For in vitro diagnostic use only.
Store between 36-86 °F (2-30 °C) until use.

Contents:
- Test device x 1
- Extraction buffer tube x 1
- Nozzle cap x 1
- Sterile swab x 1
- Tube holder x 1
- Quick Reference Instructions (en) x 1
- Quick Reference Instructions (es) x 1

Needed but not provided:
- Timer

Para uso diagnóstico in vitro exclusivamente.
Conservar entre 36-86 °F (2-30 °C) hasta el uso.

Contenido:
- Casete de test x 1
- Tubo de tampón de extracción x 1
- Capuchón de aguja x 1
- Torunda estéril x 1
- Soporte para tubo x 1
- Instrucciones de referencia rápida (en) x 1
- Instrucciones de referencia rápida (es) x 1

Requerido adicionalmente (no suministrado):
- Cronómetro

For more information on the Pilot™ COVID-19 At-Home Test, please scan this QR code or visit the website provided below.

https://go.roche.com/COVID-Home-Test


• The Pilot™ COVID-19 At-Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 6 days of symptom onset or those with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

• If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. 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.

• In the USA, this product has not been FDA cleared or approved; but has been authorized for use 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.

• This test does NOT determine if you had COVID-19 in the past or if you have immunity.

• 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.
Pilot COVID-19 At-Home Test

Rapid antigen test
for ages 2 and up

In just 20 minutes or less
EASY TO USE
With a simple nasal swab
QUICK RESULTS
In as few as 20 minutes
EASY TO USE
With a simple nasal swab

Distribution by:
Roche Diagnostics, Indianapolis, IN
www.diagnostics.roche.com

GTIN
Roche Order No.: 09666672160
9901-NCOV-10G

For in vitro diagnostic use only.
Store between 36-86 °F (2-30 °C) until use.
Contents:
Test device x 4, Extraction buffer tube x 4, Nozzle cap x 4, Sterile swab x 4, Tube holder x 1, Quick Reference Instructions (en) x 1, Quick Reference Instructions (es) x 1, Needed but not provided: Timer

• The Pilot COVID-19 At-Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 6 days of symptom onset or those with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

• If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. 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.

• In the USA, this product has not been FDA cleared or approved; but has been authorized for use 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.

• This test does NOT determine if you had COVID-19 in the past or if you have immunity.

• 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.

For more information on the Pilot COVID-19 At-Home Test, please scan this QR code or visit the website provided below.

https://go.roche.com/COVID-Home-Test
The PilotTM COVID-19 At-Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 6 days of symptom onset or those with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. 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.

In the USA, this product has not been FDA cleared or approved; but has been authorized for use 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.

This test does NOT determine if you had COVID-19 in the past or if you have immunity.

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. For more information on the PilotTM COVID-19 At-Home Test, please scan this QR code or visit the website provided below.

https://go.roche.com/COVID-Home-Test

For symbol glossary, refer to Instructions for Use.