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.

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. Open the seal of the tube carefully without spilling the liquid inside the tube. Place the tube in the tube holder. If any liquid spills, do not use the tube.
3. Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately ¼ of an inch.
4. **“Swab Both Nostrils”**
   - Firmly and slowly rotate the swab at least 5 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.

WARNING! Inaccurate test results may occur if the used test in the household trash. Do not flush or pour test liquids down a drain.

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.

10. Read and interpret the results

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

   **Positive result**
   - If a test line (T) is visible together with a control line (C), the test is positive.

   **Negative result**
   - If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, the result is negative.

   **Invalid result**
   - If a control line (C) is not visible, the result is invalid.

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

WARNING: 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 pour test liquids down a drain.

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. Open the seal of the tube carefully without spilling the liquid inside the tube. Place the tube in the tube holder. If any liquid spills, do not use the tube.
3. Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately ¼ of an inch.
4. **“Swab Both Nostrils”**
   - Firmly and slowly rotate the swab at least 5 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.

WARNING! Inaccurate test results may occur if the used test in the household trash. Do not flush or pour test liquids down a drain.

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.

10. Read and interpret the results

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

   **Positive result**
   - If a test line (T) is visible together with a control line (C), the test is positive.

   **Negative result**
   - If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, the result is negative.

   **Invalid result**
   - If a control line (C) is not visible, the result is invalid.

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

WARNING: 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 pour test liquids down a drain.

Materials Provided
- Sterile Swab
- Tube with Liquid (inside foil pouch 1)
- 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.

WARNING! Do not apply the liquid in the rectangular result window.
The Pilot™ COVID-19 At-Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 virus in human nasal swab samples. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.

This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.

The Pilot™ COVID-19 At-Home Test does not differentiate between SARS-CoV-1 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of the antigen 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 antigen detected may not be the definitive cause of disease. Individuals who test positive with the Pilot™ COVID-19 At-Home Test should seek advice and seek follow-up care with their healthcare provider or healthcare professional as additional testing may be necessary.

Negative results should be treated as presumptive and confirm 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary. If there is a high likelihood of COVID-19, such as in individuals with known exposures to COVID-19 or in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should be reminded to use the test after the expiry date shown on the test device pouch.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the product. The results are relevant public health information in accordance with local state, and federal requirements. Each manufacturer provides appropriate CDRH and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The Pilot™ COVID-19 At-Home Test is authorized for non-prescription self-use and/or as applicable an adult lay user another person 2 years or older in a non-hospital setting, and is intended to be used as an aid in the clinical diagnosis of a current SARS-CoV-2 infection. Do not use the 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.

The Pilot™ COVID-19 At-Home Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

**Intended Use**

The Pilot™ COVID-19 At-Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 virus in human nasal swab samples. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.

This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 6 days of symptom onset.

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Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of the antigen 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 antigen detected may not be the definitive cause of disease. Individuals who test positive with the Pilot™ COVID-19 At-Home Test should seek advice and seek follow-up care with their healthcare provider or healthcare professional as additional testing may be necessary.

Negative results should be treated as presumptive and confirm 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.

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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

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.

For symbol glossary, refer to Instructions for Use.

UDI Label
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