Prominex dCliP SARS-CoV-2 Assay

QUICK REFERENCE INSTRUCTIONS

For research use only.

For demonstration purposes only

The performance characteristics of this product have not been established.

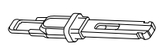
For use with anterior nasal swab specimens.

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

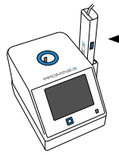
An anterior nasal swab sample can be self-collected by an individual aged 14 years or older. Children aged 2-13 years should be tested by an adult.

MATERIALS PROVIDED

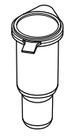

Sterile Nasal Swab

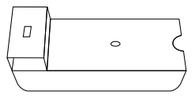

Test Cassette
(in sealed pouch)


Collection Vial


Reader
Wand

Reusable Reader

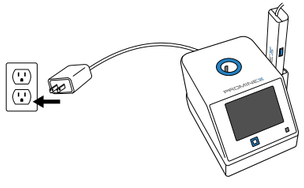

Reaction Vial


Tube Holder

PREPARING FOR THE TEST

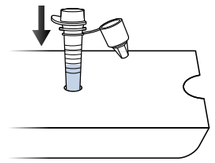
NOTE: Do not open the test contents until ready for use. If the Test Cassette is open for an hour or longer, invalid test results may occur.

1. **Check the test's expiration date printed on the outer test packaging.** For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.
2. Wash your hands with soap and water for 20 seconds and dry the thoroughly, or use hand sanitizer.
3. Connect the Reader to a power outlet. The Reader will say "Initializing".

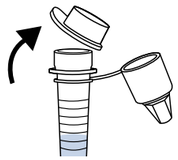


PREPARING FOR THE TEST (CONT'D)

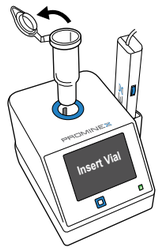
4. Insert the Collection Vial into the tube holder. Ensure that the tube is stable and upright.



5. Uncap the Collection Vial carefully so as to not spill the buffer (liquid).

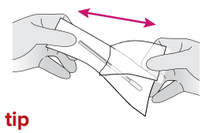


6. Uncap the Reaction Vial and insert it into the Reader. The Reader will say "Dispense sample then press button."



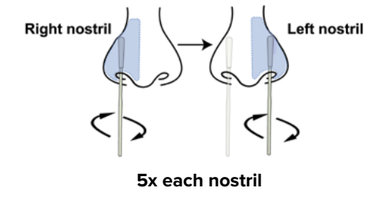
SAMPLE COLLECTION

1 Remove the swab from the pouch. Carefully insert the sterile swab no more than 3/4 inch (1.5 cm) into the nostril.



⚠ **Be careful not to touch the swab tip (soft end) with hand.**

2 Slowly rotate the swab **at least 5 times** against the nostril wall. Remove the swab and repeat in the other nostril using the same swab.

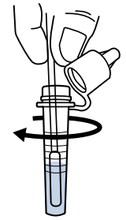


5x each nostril

Note: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing.

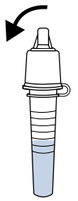
RUNNING THE TEST

3 Insert Swab into the Collection Vial and rotate Swab for 15 seconds. Then Remove and dispose of the used Swab.

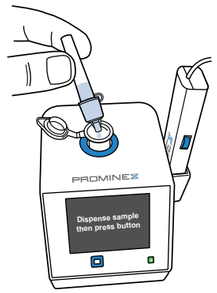


⚠ **Sample must be mixed with the buffer in the Collection Vial within 1 hour of sample collection.**

4 Cap the Collection Vial with attached Dropper Cap.



Invert the capped Collection Vial and dispense all of the sample into the Reaction Vial.



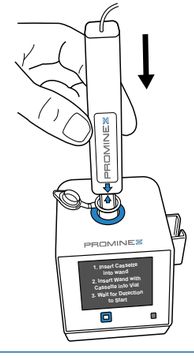
5 Press the button on the front of the Reader. The reader will say "Heating." This process takes approximately one minute.

6 Remove the Test Cassette from its packaging. When prompted by the Reader, remove the Wand from the Reader and insert the Test Cassette into the Wand. The arrow on the Test Cassette and the arrow on the Wand will face each other.

7 Insert the Wand with Cassette into Reaction Vial. You can let go of the Wand.

Wait for detection to start. This may take up to 30 seconds. The light on the Reader will change from blinking green to a solid blue when detection begins.

Wait for test results.



UNDERSTANDING YOUR RESULTS

The Reader will visually display and audibly announce your test results. You can press the button on the reader to hear your results again.

Invalid
The test could not tell whether or not you have COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

Cov:Neg-
The virus from COVID-19 was not detected in the sample. A negative result does not mean it is certain that you do not have COVID-19. There is a higher chance of false negative results with home tests compared to laboratory-based molecular tests. If you tested negative and continue to experience COVID-19 symptoms, you should seek follow-up care with your healthcare provider.

Cov:Pos+
The COVID-19 virus was detected in your sample. It is very likely that you have COVID-19 and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive).

Flu:Neg-
The virus from Flu A and/or Flu B was not detected in the sample. A negative result does not mean it is certain that you do not have Flu A, and/or Flu B. There is a higher chance of false negative results with home tests compared to laboratory-based molecular tests. If you tested negative and continue to experience COVID-19 symptoms, you should seek follow-up care with your healthcare provider.

Flu:Pos+
The virus from Flu A and/or Flu B was detected in your sample. It is very likely that you have Flu A or Flu B and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive).

AFTER YOUR TEST & RESULTS REPORTING

To report your dCliP COVID-19 Test results to public health agencies, please visit: https://report.makemytestcount.org/

If symptoms persist or if you are concerned about your health, please seek follow-up care from a healthcare professional.

For free support, or to obtain a physical copy of the product information free of charge, please call us at 1.858.412.3030 or email us at info@prominex.com.

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID-19.

INTENDED USE

The Prominex OTC Respiratory Assay is a single use (disposable) home test kit test for the simultaneous qualitative detection and differentiation of SARS-CoV-2 and influenza RNA in anterior nasal swab (NS) specimens collected with the Prominex Collection Swab. The Prominex OTC Respiratory Assay is intended for use in individuals 14 years or older (self-collected) or individuals 2 years or older (collected by an adult) with symptoms consistent with respiratory tract infection, including COVID-19 and flu . Clinical symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. It is authorized for non-prescription home use.

The Prominex OTC Respiratory Assay is intended for use in the differential diagnosis of SARS-CoV-2, influenza A, and influenza B in clinical specimens. The test will not differentiate influenza A from influenza B and is not intended to detect influenza C. SARS-CoV-2, influenza A, and influenza B viral nucleic acids are generally detectable in anterior nasal swab samples during the acute phase of infection.

Positive results indicate the presence of viral nucleic acid, 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 pathogens not detected by the test. The virus detected may not be the definitive cause of disease. Individuals who test positive with the Prominex OTC Respiratory Assay should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

Negative results for SARS-CoV-2 and influenza are presumptive, meaning that they should be confirmed, if necessary for patient management, with an authorized or cleared molecular test performed in a CLIA-certified laboratory that meets requirements to perform high or moderate complexity tests. Negative results do not rule out SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for treatment or other management decisions, including infection control decisions.

Negative results should be considered in the context of current prevalence of infection, an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with respiratory infection. Individuals who test negative and continue to experience symptoms of fever, cough and/or shortness of breath may still have a respiratory infection and should seek follow up care with their healthcare provider.

INTENDED USE CONT.

Individuals should report all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. 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 and 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 Prominex OTC Respiratory Assay is intended for non-prescription home use. The test is performed using the Prominex OTC Instrument. The Prominex OTC Respiratory Consumable, the Prominex Nasal Swab and the Prominex Collection Device all of which are included in the Prominex OTC Respiratory Assay Kit. The Prominex OTC Respiratory Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

Prominex understands that additional limitations may be required depending on the performance data submitted.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- For Research Use Only (RUO).
- This product has not been FDA cleared or approved; this is for research use only
- Single use only. Do not use if kit is visibly damaged.
- Follow all instructions carefully. Correct use is required for accuracy.
- Only use the test components provided. Do not re-use any components for another test. Only the Prominex Reader may be reused multiple times.
- Touch only the handle of the swab with your hands to avoid contaminating the soft tip.
- Positive Covid results are indicative of the presence of SARS-CoV-2 RNA.
- Positive Influenza results are indicative of the presence of Influenza A and/or Influenza B RNA.
- Do not ingest any of the kit contents. Keep away from children. Avoid contact with skin and eyes.
- If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION CONT.

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

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.

STORAGE AND STABILITY

- Store between 36 °F and 86 °F (2 °C to 30 °C).
- Do not open kit components until you are ready to perform testing.
- Do not use the Prominex dCliP Test past the Use By Date.

RISK/BENEFITS

- Potential risks of this test include: (1) Possible discomfort during sample collection, (2) Possible incorrect test results.
- Potential benefits of this test include: (1) The results, along with other information, can help your healthcare provider make informed recommendations about your care, (2) The results of this test may help limit the spread of COVID-19 to your family and others in your community.

SYMBOLS

	Do not re-use		Use-by date (Expiration date)		Keep dry
LOT	Batch code		Consult instructions for use		Keep away from sunlight
	Store at 36~86°F /2~30°C		Manufacturer	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use				

PROMINEX

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