The ImmutaVax® 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 specimens from persons aged 14 years or older. Children age 14 to 17 years may self-test with adult supervision.

SARS-CoV-2 Tests provided by CDC. You must read the result after 15 minutes or after 30 minutes. For 2 test kits, do not throw the kit box away until all tests are used.

Start the test:

1. Thoroughly wash or sanitize your hands. Do not touch your nose, mouth, or other visible body areas.
2. Make sure all test components are in their original packaging.

Read all instructions carefully before performing the test. Failure to follow the instructions may result in a false negative or false positive result.

Serial testing should be performed in all individuals with symptoms of COVID-19. If you test negative, you may need to perform additional tests to confirm your diagnosis. If you have symptoms of COVID-19 and both your first and second test results are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

If your test is positive, then proceed from the stage that causes COVID-19 have been detected in your sample and you likely have COVID-19. You should follow-up with your healthcare provider.

If your test is invalid, then proceed from the stage that causes COVID-19 have been detected in your sample and you likely do not have COVID-19. You should follow-up with your healthcare provider.

The COVID-19 Antigen Home Test is intended for non-prescription use and as an aid in your decision-making process. It is not intended to replace routine medical consultations or visits to a healthcare provider. The results of this test should be used in conjunction with clinical evaluation and other diagnostic methods. Positive test results will not rule out a bacterial infection or co-infection. Always consult a healthcare provider for appropriate medical care. For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19.
For Emergency Use Authorization (EUA) only. For 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.

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

For Emergency Use Authorization (EUA) only

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 serial (repeat) testing. Please read all the information in the enclosed instructions for use before performing the test.

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.

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For the protection of all, please wash your hands before opening the kit.