**User Instructions**

Genabio COVID-19 Rapid Self-Test Kit

A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal swab specimens. For self-testing use. For use under an Emergency Use Authorization (EUA) only. Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

If you have any questions regarding the use of this product or if you want to report a test system problem, please contact Genabio Diagnostics Inc. (via Email: info@genabio.com, or via Phone: 1-800-614-3365). Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (Phone: 800-FDA-1088; Fax: 800.FDA.0178; http://www.fda.gov/medwatch).

**Step by Step Instructions**

1. **Prepare Materials**
   - Open the package and take out the COVID-19 Test Pouch, Pre-filled Tube, Anterior Nasal Swab, and the Instruction for Use.
   - If stored refrigerated, allow test components (COVID-19 Test Pouch and Pre-filled Tube) to equilibrate to room temperature (15-30°C or 59-86°F) before starting the Test Procedure.

2. **Preparation**
   - Clean your hands thoroughly with hand sanitizer or soap for at least 20 seconds and make sure they are dry before you start the test.
   - Open the package and take out the COVID-19 test pouch, pre-filled tube, anterior nasal swab, or anterior nasal swab kit.
   - Carefully read the instructions.

3. **Specimen Collection**
   - An anterior nasal swab sample can be self-collected by adults. Children 2-13 years old should be tested by an adult.
   - Note: This product comes in a 1-test, 2-test, 5-test, or 25-test configuration.
   - Note: Failure to swab properly may cause a false negative result.

4. **Test Procedure**
   - Place the swab into the collection tube immediately and stir for 30 seconds.
   - Insert the entire soft end of the swab into your nostril no more than ¾ of an inch (1.5 cm) into your nose.
   - For children the maximum depth of insertion of swabs into the nostril may be less than ¾ of an inch. You may need additional help from the other person to hold the child’s head for swab sampling.
   - Gently remove the swab, use the SAME SWAB and repeat steps in your other nostril with the SAME end.
   - Once opened, use the test cassette within 1 hour.
   - Place the swab into the collection tube immediately and stir for 30 seconds.
   - Insert the collection tube with sample, squeeze and add 3 drops to the sample well of the test cassette.
   - Start the timer for 15 minutes. Do not move the cassette.
This product has been authorized only for the detection of SARS-CoV-2 virus, not for any other viruses or pathogens.

- An anterior nasal swab sample can be self-collected by an individual age 2 years and older. Children 2 to 11 years should be tested by a healthcare provider.

The emergency use of this product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of emergency use of ICDs 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(1), as declared by the HHS Secretary, for public health needs. All healthcare providers will report all tests to a database from individuals who use this product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as established by the Laboratory Diagnostics (VDI) Test Code Mapping for COVID-19 Tests provided by CDC.

The Genabio COVID-19 Rapid Self-Test Kit is intended for non-prescription self-use and/or, as applicable, for an adult by adult testing another person aged 2 or older.

The Genabio COVID-19 Rapid Self-Test Kit is only for use by the Food and Drug Administration’s Emergency Use Authorization.

Warning and Precaution

- Do not touch test package
- Do not perform immediately after opening the pouch
- To ensure correct results, follow the instructions for use
- Use only the contents provided in the test kit
- Test components are single use. Do not reuse.

A: 2019-nCoV is an acute respiratory infectious disease caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, both by individuals with symptoms of COVID-19 and by infected people without symptoms. SARS-CoV-2 is mostly spread person-to-person, both by individuals with symptoms of COVID-19 and by infected people without symptoms. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 4-5 days. Symptoms include fever, fatigue, cough. For a full list of symptoms, please visit the following website:


Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?

A: Potential risks include:
• Possible discomfort during sample collection.
• Possible incorrect test results (See result interpretation section).
Potential benefits include:
• The results, along with other information, can help you and your healthcare provider make informed decisions about your care.
• The results of this test help limit the spread of COVID-19 to your family and others in your community.

Q: WILL THIS TEST HURT?

A: The test kit is designed to be as fast and as painless as possible.

Q: WHAT IS SERIAL TESTING?

A: Serial testing is when person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and within your ‘test window’ when you test negative. If you test negative every day (or every other day) it is more likely to detect COVID-19. If you do not have any symptoms, testing should be performed at least twice over three days with two negative results in a 48-hour period. You may need to purchase additional tests to perform this serial (repeat) testing.

Q: HOW ACCURATE IS THIS TEST?

A: Based on the interim results of a clinical study where the COVID-19 Antigen Test was compared to an FDA authorized high sensitivity SARS-CoV-2 rapid test, COVID-19 Antigen Test correctly identified 98% of positive samples and 100% of negative samples. The performance of this test is still being studied in patients without COVID-19 symptoms. Some patients may perform better for antigen and for serial screening. Performance may differ in these populations. Based on this performance, the test is still being studied in patients without COVID-19 symptoms and for serial screening. Performance may differ in these populations.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

A: There are different kinds of tests for COVID-19. Molecular tests (also known as PCR test) detect genetic material from the virus. Antigen tests detect proteins from SARS-CoV-2, but are very specific for the virus, but not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not necessarily mean you do not have COVID-19. It is important to discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular test. This means that there is a higher chance of false negative results with laboratory-based molecular test.

Q: WHAT IS THE PERFORMANCE OF THIS TEST?

A: This test is intended to be used as an aid in clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your health. 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.

Healthcare Providers

Please visit www.genabio.com to obtain the complete instructions for use and fact sheet for healthcare professionals.

Storage and Stability

Store the Genabio COVID-19 Rapid Self-Test Kit between 2-30 °C (36-86 °F). Ensure that all kits are at room temperature before use. Kits are stable until the expiration date printed on the packaging. Do not use beyond the expiration date. The Test Cassette must remain in the sealed pouch until use.

In the USA

1. This test is intended to be used as an aid in clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your health.

2. In USA - This product has not been FDA cleared or approved but has been authorized by FDA under Emergency Use Authorization (EUA). Genabio Diagnostics has been authorized only for the detection of proteins from SARS-CoV-2, not for any other pathogens.

3. The performance of this test is still being studied in patients without COVID-19 symptoms and for serial screening. Performance may differ in these populations.

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The Genabio COVID-19 Rapid Self-Test Kit is a lateral flow chromatographic immunoassay method intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or with epidemiological reasons to suspect COVID-19. For use under the Emergency Use Authorization (EUA) only. For ages 2 through 13, an adult must collect and test the anterior nasal specimen. This test does NOT determine if you had COVID-19 in the past or if you have immunity. 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.

Invitrodiagnostic medical device
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