GenuIN COVID-19 Rapid PCR Test
Instruction for Use

IVD

[PRODUCT NAME]
GenuIN COVID-19 Rapid PCR Test

[PACKING SPECIFICATION]
Σ1 REF U202025-1

[INTENDED USE]
The GenuIN COVID-19 Rapid PCR Test is a single-use test kit intended to detect SARS-CoV-2 that causes COVID-19.
This test is for home use with self-collected anterior nasal swab specimens in individuals aged 14 years and older (self-collected) or individuals aged 2~13 years (collected by an adult) with suspected COVID-19. The assay is only used for auxiliary diagnosis of SARS-CoV-2 infection.
This assay applies isothermal amplification and the nucleic acid lateral flow assay to detect and identify specific sequences of SARS-CoV-2 RNA. This assay is similar to a PCR test in that it utilizes a molecular amplification technology for the detection of SARS-CoV-2 viral RNA. SARS-CoV-2 viral RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. In general, in vitro testing for SARS-CoV-2 infection is most accurate in the first week after symptom onset. Individuals diagnosed with COVID-19 within 3 months are recommended to first seek medical advice of testing because SARS-CoV-2 RNA is detectable in upper respiratory tract specimens even for weeks after the onset of symptoms.
Persons who test positive with the GenuIN COVID-19 Rapid PCR Test should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.
COVID-19 is an acute respiratory infectious disease. All individuals infected COVID-19 are a source of infection.
Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.
It is difficult to differentiate between COVID-19 and respiratory infections caused by other pathogens through clinical manifestations because the symptoms of respiratory infections caused by these pathogens are similar.
Results of the assay are for clinical reference only, and shall not be used as the sole basis for diagnosing or excluding cases.

[TEST PRINCIPLE]
The assay applies cross priming amplification (CPA) and nucleic acid lateral flow to qualitatively detect the specific sequence of SARS-CoV-2 RNA (genes ORF1ab and N). With the self-driven heating module, the assay can perform isothermal amplification reactions through specific amplification primers, probes, RNA reverse transcriptase, and DNA polymerase with high strand displacement activity. The viral RNA was first transferred to DNA with RNA reverse transcriptase and then amplified with DNA polymerase. The assay consists of a module preloaded with nucleic acid amplification reagent and corresponding lateral flow strip.
The paper strip is used for rapid detection of nucleic acid amplification products by

chromatographic double antibody sandwich method. Biotin and FAM probe are modified at both ends of one specific primer in the reaction system. For positive samples, due to capillary forces, reported nucleic acid fragment flow from sample pad side to detection pad, then the FAM end of nucleic acid will combine with colloidal gold particles and binds specifically to the T-line with secondary antibody. In the process of chromatography, the other end is captured by streptavidin (line C), so line C with T line color at the same time. For negative samples, only one end of modified biotin is captured by streptavidin (line C) during chromatography, so only C line is colored. If there is an operation error, only T, or both T and C are not colored, the result is regarded as invalid.

[MATERIALS PROVIDED]

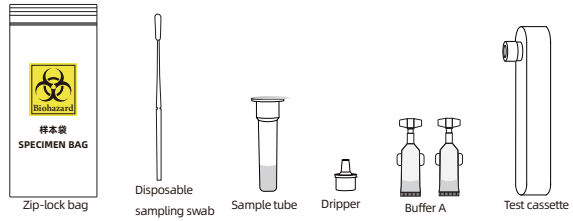
No.	Materials Provided	Quantity
1	Disposable sampling swab	1
2	Sample tube (Prefilled with lysis buffer)	1
3	Dripper	1
4	Buffer A (Prefilled in bubbles)	2
5	Test cassette	1
6	Zip-lock bag	1

Note:
1. Do not mix materials from different lots.
2. Do not reuse the materials of the assay.

[STORAGE CONDITIONS & VALIDITY PERIOD]
1.Usage: the kit should be used at 2~30℃.
2.Storage: the kit should be stored at 2~8℃.
3.Validity period: 6 months. Refer to the package for the production date and expiry date.
4.Transportation: The kit performance will not be affected by temperature 2~30℃ transportation within 15 days.

[SAMPLE COLLECTION AND HANDLING]
1. Sample types: anterior nasal swabs
2. Sample storage
The samples should be sent for testing as soon as possible after collection.

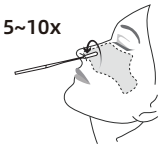
[TEST PROCEDURE]
Note: Read this IFU carefully before using.
1. Prepare for test



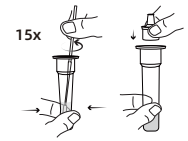
-Take out all components from the package.

2. Tear off the seal of the sample tube.

3. Swab Both Nostrils

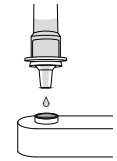


-Take out the swab and hold with handle end.
-Tilt head back and **gently insert swab tip (about 18mm) until it is fully inside your nostril.**
-Roll the swab tip 5~10 times around the inside walls of your nostril.
-The swab tip should be touching the walls of the nostril as you rotate.
-**Repeat swab step in the other nostril.**

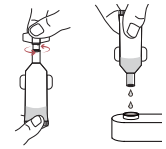


Insert swab into the sample tube and **make sure the swab tip is fully immersed in the lysis buffer.**
-Stir the swab and press the tube bottom for 15 times to release the sample fully.
-Dispose of the swab into the ziplock bag.
-Put on the dripper.

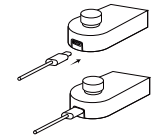
4. Load Sample and Run Test



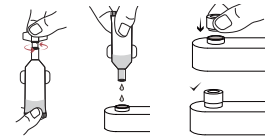
-Take out the test cassette and place it on a clean flat surface with the side of sample hole facing up.
-Open the cap of sample hole.
-Press the sample tube lightly to add only one drop lysis buffer into the sample hole.



-Open one bubble of buffer A and add all of it into the sample hole.



-Cover the cap of test cassette.
-Connect the cassette with power supply by the USB Type-C cable and connector (output voltage: 5V).
-If the blue light is on, the cassette is working; otherwise, please change the power supply.
-Do not move the cassette when the test is running.
-Wait 35 minutes.



-Pull out the Type-C connector and open the cap of sample hole.
-Open another bubble of Buffer A and add all of it into the hole, then close with the cap again.
-The result can be read in 5 min.

5. Reading the result
Read the test result according to the notice provided on the test cassette.
Note: Please make sure to check the test result within 30 minutes after adding the second bubble of Buffer A.

[INTERPRETATION OF RESULTS]
The result of COVID-19 test is shown in the "Test" area of result window. The kit contains internal control material to confirm the lateral flow worked. The result of internal control is shown in the "Control" area of result window.

Positive:
If a clear visible line is seen in "Test" area of the result window, the nucleic acid of SARS-CoV-2 is detected in the sample, namely the result is positive. In positive results, sometimes the lines in "control" area could be light. In this case, the results are still valid.
Negative:
If there is only one line presented in "Control" area and no visible line is seen in "Test" area, the nucleic acid of SARS-CoV-2 is not detected in the sample, namely the result is negative.
Invalid:
If there is no visible line in both areas of the result window, test is failed and the result is invalid.

[LIMITATIONS]

1. Persons who test positive with the GenuIN COVID-19 Rapid PCR Test should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.
2. Inappropriate collection, transport and treatment of samples or low titer of pathogens may yield false negative result.
3. This product has been validated for current known mutations. Future mutations of target nucleic acid may yield false negative result.
4. Interference or amplification inhibitors other than those presented in [PERFORMANCE CHARACTERISTICS] 3.2 Interfering substances may yield false negative result.
5. Users are advised not to eat, drink or take unnecessary nasal drugs before self-testing.
6. Positive results do not rule out co-infection of bacteria or other viruses.

[PERFORMANCE CHARACTERISTICS]

1. Limit of detection

3000 copies/mL

2. Precision

2.1 Intra-batch precision

Through the analysis on the results of repeatability samples from the same batch within 20 days, the detection rates of medium positive samples, weak positive samples and negative samples are all 100%, and the coincidence rate of negative samples is 100% (n ≥ 20).

2.2 Within-batch precision

Through the analysis of the 20-day test results of the same operator in different batches, the 20-day detection rates of medium positive samples were all 100%, the detection rate of weak positive samples was 100%, and the coincidence rate of negative samples = 100% (n ≥ 20).

3. Specificity

3.1 Cross-reactivity

Cross-reactivity (organisms tested in the absence of SARS-CoV-2)

The specificity of the assay was evaluated in cross-reactivity testing using 25 commensal organisms. The cross-reactivity testing confirmed that none of the 25 organisms were cross reactive with the GenuIN COVID-19 Rapid PCR Test at the concentrations tested. The 25 commensal organisms are listed below:

Bacteria and viruses	Test concentration	Bacteria and viruses	Test concentration
Bordetella pertussis	10^6 bacteria/mL	*Staphylococcus aureus*	10^6 bacteria/mL
Respiratory Syncytial virus	10^6 copies/mL	*Chlamydia pneumoniae*	10^6 ccu/mL
Adenovirus	10^6copies/mL	*Rhinovirus*	10^6 copies/mL
Influenza A virus	10^6 copies/mL	*Bocavirus*	10^6 copies/mL
Influenza B virus	10^6 copies/mL	*Coronavirus NL63*	10^6 copies/mL
Parainfluenza virus	10^6 copies/mL	*Mycoplasma pneumoniae*	10^6 ccu/mL
Epstein-Barr virus	10^6 copies/mL	*Coronavirus 229E*	10^6 copies/mL
Coronavirus OC43	10^6 copies/mL	*Coronavirus HKU1*	10^6 copies/mL
Legionella pneumophila	10^6 bacteria/mL	*MERS coronavirus*	10^6 copies/mL
Streptococcus pneumonia	10^6 bacteria/mL	*SARS CoV-1*	10^6 copies/mL
Human Metapneumovirus	10^6 copies/mL	*Candida albicans*	10^6 bacteria/mL
Klebsiella pneumonia	10^6 bacteria/mL	*Staphylococcus epidermidis*	10^6 bacteria/mL
Haemophilus influenzae	10^6 bacteria/mL	/	/

3.2 Interfering substances

The following substances have no effects on test results of this product.

3.2.1 Endogenous interfering substances: human plasma (1% v/v), human mucoprotein (1% v/v), Human genome DNA (300ng).

3.2.2 Exogenous interfering substances: Phenylephedrine, Methotrexate, Sodium chloride, Beclomethasone, Dexamethasone, Flunisolide, Triamcinolone acetonide, Budesonide, Mometasone,Fluticasone,Histamine hydrochloride, Interferon α, Zanamivir, Oseltamivir, Peramivir, Arbidol, Lopinavir, Ritonavir, Mupirocin, Levofloxacin, Azithromycin, Ccephalosporin, Minocycline, Tobramycin, Azelastine, Vitamin A ointment, D-panthenol ointment, Biotin

4. Clinical performance

Clinical performance of GenuIN COVID-19 Rapid PCR Test was determined by testing 109 positive and 508 negative specimens. 95.413% of individuals with positive real-time PCR tests were tested positive by GenuIN COVID-19 Rapid PCR Test. 99.803% of individuals with negative real-time PCR tests were tested negative by GenuIN COVID-19 Rapid PCR Test. And the total coincidence rate was 99.028%

		RT-PCR		Total
		Positive	Negative	
GenuIN COVID-19 Rapid PCR Test	Positive	104	1	105
	Negative	5	507	512
Total		109	508	617

Relative Sensitivity: 95.413% (95%CI: 89.619% ~ 98.494%)
Relative Specificity: 99.803% (95%CI: 98.908% ~ 99.995%)
Accuracy: 99.028% (95%CI: 97.895% ~ 99.642%)

[PRECAUTIONS]

Please make sure to read this Instruction for Use carefully before use.

IVD This product is for auxiliary diagnosis in vitro only. It shall not be used as the only basis for confirmed diagnosis.
Please integrate other test methods or clinical symptoms for comprehensive consideration.

- **Testing**

This product is for disposable use. Please use it in accordance with this instruction.
1. Do not squeeze or press the test cassette while operating it.
2. Do not move the test cassette while testing.
3. Read test results within 30 minutes after adding the second bubble of buffer A, otherwise it may yield false positive result.

- **Operation**

The sample and other components contacted with the sample (e.g. used fragment of the tabletop, timer surface) may be a source of infection even if the test is negative and should be disinfected. Hands also should be washed or disinfected. Throughout the testing process, users are advised to wear masks and gloves to prevent infection.
This test kit is a disposable in vitro diagnostic product. Any experimental wastes such as test cassettes, gloves, unused samples or reagent, etc., which have potential biological hazards, should be disposed of in accordance with biological safety regulations, environmental protection regulations or medical waste regulations.
1. If the reagent mistakenly enters the eyes or mouth or sprays on the skin, please wash with clean water and seek help from doctors if necessary.
2. Please make sure there is no liquid or other matters affixed on the outside surface of the test cassette before test.
3. Proper sample collection and sample handling are essential for correct results.

- **Storage and use**

1. This product must be stored at the condition as required in this instruction.
2. Do not use the expired product.
3. Before test, please make sure there is no rift on the test cassette or leakage of the liquid.
4. Please do not use this product for purposes not described in this instruction.
5. Please store the product properly and prevent children from touching it.

- **Disposal**

1. The pollution level of this kit is PD1 (No pollution or only dry non-conductive pollution).
2. The used product should be sealed in the zip-lock bag and be disposed of as the medical waste.

- **Caution**

FCC Compliance Statement:
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 18 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference,
(2) this device must accept any interference received, including interference that may cause undesired operation.

[EXPLANATION OF SYMBOLS]

IVD	*In vitro* diagnostic medical device		Do not re-use
	Use-by date		Consult instructions for use
	Caution		Manufacturer
	Temperature limit	LOT	Batch code
EC REP	Authorized representative in the European Community		Keep dry
	Keep away from sunlight		Do not use if package is damaged
	Date of manufacture		Biological risks
	Contains sufficient for <*n*> tests	REF	Catalogue number

GenuIN Biotech LLC
Address: 2270 Kraft Drive, Suite 1311, Blacksburg, VA 24060, USA
Customer service: +01-540-605-9777
CAUTION - Investigational device. Limited by Federal law to investigational use.

[INSTRUCTION VERSION AND MODIFICATION DATE]

Approved on April 25, 2022. Version: A0