



Lateral flow test 7 pack

Nose only test

# Your step-by-step guide to Getein Biotech COVID-19 Self Testing

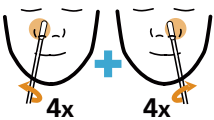
## Warning

Do not mix and match components from other test kits.

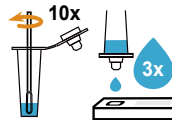
**Read this whole guide carefully before you start.**

This test may be different to other tests you have used before.

### Nose only test



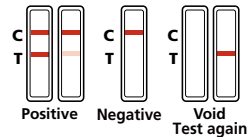
1. Swab both nostrils



2. Process sample



3. Wait



4. Results

**This instruction is a step-by-step guide to performing a Getein Biotech lateral flow COVID-19 test on yourself or another person. Additional instructions about when to take your test or reporting your result may be issued by your test provider.**

To access alternative language and other format versions of this instruction, go to:  
[gov.uk/covid19-self-test-help](https://www.gov.uk/covid19-self-test-help)

These instructions relate to Getein Biotech One Step Test for SARS-CoV-2 Antigen (Colloidal Gold), for self-testing, product code: CG206157.

# What you need to do

## Your step-by-step guide

Read through the instructions and follow the steps in the correct order.

## Why you should self-test

This COVID-19 self-test kit is a swab test for the nose to check if you have the virus and are infectious, even if you do not have symptoms.

## Inside this booklet

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# Guidance and precautions

- Do not use any test kit component if the packaging is damaged, has a broken seal, or if the component appears to be broken.
- Do not mix components from different test kit boxes. Only use the kit components provided in this kit, as liquid from one test type will not work with another test type.
- All parts of the test kit are for single use only except for the extraction tube holder. Do not reuse any parts other than the tube holder.
- These kits are designed for human use only.
- Store out of reach of children. The test kit contains small parts that may be a choking hazard.
- If you have one or more nose piercings, remove before swabbing.
- Do not use excessive force or pressure or bend the swab when collecting swab samples, as this may break the swab.
- If you experience a nose bleed during swabbing, stop swabbing. If there is blood on the swab, it cannot be used for the test. Wait 24 hours before doing a new test.
- Do not let the test cassette come into contact with any household cleaning products, as this may cause an incorrect result.
- Clean spills from the plastic tube using paper towels and household disinfectant.
- The test may not be suitable for people who have had facial or head surgery in the last 6 months, or anyone who is prone to nose bleeds.
- If you have problems with your hands or vision, you may need someone to assist you with the swabbing and testing process.

# About this test

## This test is suitable for:



### Adults aged 18 and over

Self-test, with assistance if needed.



### Adolescents aged 12 to 17

Self-test with adult supervision (and assistance if needed).



### Children

Children aged 11 and under should be tested by an adult.

## Storage and handling

- Store the test kit at normal room temperature or in a cool dry place (4°C to 30°C).
- Do not leave in direct sunlight and do not store in a freezer.
- The kit should be used at room temperature (15°C to 30°C). If the kit has been stored in an area below 15°C, leave at normal room temperature for 30 minutes before using.

## If you display new symptoms of COVID-19

Visit [nhs.uk/coronavirus](https://www.nhs.uk/coronavirus) for the most up-to-date advice.

### Warning



### If you're worried about your symptoms,

or if your symptoms get worse, contact a GP, visit the NHS **111** online service at **111.nhs.uk** or call **111** to speak to someone directly.

For a medical emergency, dial **999** immediately.

# Prepare your test area

**You'll need:** A timer such as a watch, clock or mobile device, tissues, surface cleaner, hand sanitiser or soap and warm water.



- 1 Read this instruction guide carefully.

if you need more help, go to:

[gov.uk/covid19-self-test-help](https://www.gov.uk/covid19-self-test-help)



- 2 Immediately before starting the test, clear, clean and dry a flat surface to place the test kit on.



- 3 Wash your hands thoroughly for 20 seconds, using soap and warm water or use hand sanitiser.

If doing more than one test, clean the surface and rewash your hands between each test.

# Check your kit contents

## Warning

Do not mix and match components from other test kits.

## In your test box you should have:

1x

Box with extraction tube holder hole



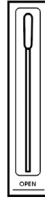
7x

Kit bags



7x

Sterile swabs



7x

SARS-CoV-2 antigen test card in sealed cassette pouch



7x

Extraction tube with sample extraction solution and tip



## Warning

Before you start, check the expiry date on the test kit box and the sealed pouch (EXP). Do not use the test kit if it has expired.

# Set up your test

## Important

Do not use the test device after its use-by date.



- 4 Take the test cassette out of the sealed pouch and place it onto the cleaned flat surface.

Once opened, start the test within 60 minutes.

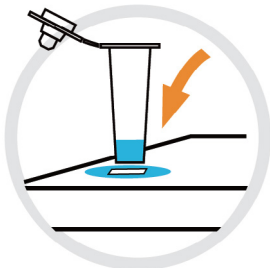


- 5 Keeping the extraction tube away from your face, gently peel off the sealing film from the extraction tube to avoid spilling any liquid.

## Warning

Do not try to rip the seal film off with your teeth.

Avoid getting the buffer solution on your skin. If the buffer solution gets on your skin or in your eyes, rinse well with water and seek medical advice if irritation occurs.



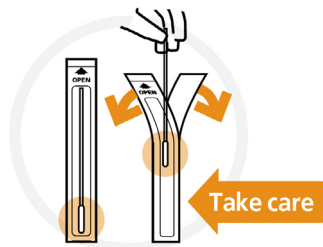
- 6 Place the extraction tube containing the buffer in the extraction tube holder hole in the box.



- 7 Gently blow your nose** into a tissue so excess mucus does not spoil the test. Throw the tissue away in a bin.  
If you are testing a child/dependent, help them blow their nose, if needed.



- 8 Wash your hands** thoroughly for 20 seconds using soap and warm water or hand sanitiser before handling the test kit to avoid contaminating it.  
If you are helping a child/dependent, **both of you must wash your hands** thoroughly for 20 seconds or use hand sanitiser.



- 9** Find the sterile swab in the sealed wrapper. When you are ready to start the test, peel open the swab package at the stick end.



Gently take out the swab. Be careful not to touch the fabric tip with your fingers.

**Warning**

Do not let the tip of the swab touch anything before you take your sample, or you will need to start again with a fresh swab.



# Doing a test on someone else

Children under 12 should be tested by an adult. Follow the guidelines on how to prepare and test a child or a person who requires assistance at:

[gov.uk/covid19-self-test-help](https://www.gov.uk/covid19-self-test-help)

Show the child the test kit and explain what you are going to do. If possible, sit them on someone's lap or have someone hold their hand.

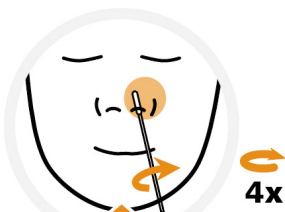
Ask the child to blow their nose into a tissue. Place the tissue in a bin then both wash your hands thoroughly for 20 seconds, using soap and warm water or hand sanitiser.

If you do not feel confident to conduct the test, or the child complains it hurts, do not continue with the test.



## 10 First nostril

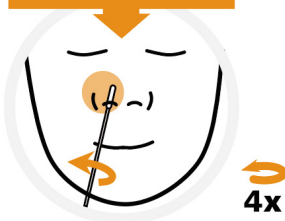
Gently place the fabric tip of the swab just inside the child's first nostril. Do not insert the swab more than 1.5cm into their nose.



## 11

Gently wipe the swab around inside the nostril 4 times in a circular motion. Make sure there is good contact between the fabric tip and the inside of the nostril.

Swab both nostrils



## 12 Second nostril

Place the fabric tip of the same swab just inside the child's second nostril. Repeat the circular motion 4 times with good contact between the fabric tip and the inside of the nostril.

# Take your swab sample

## Advice

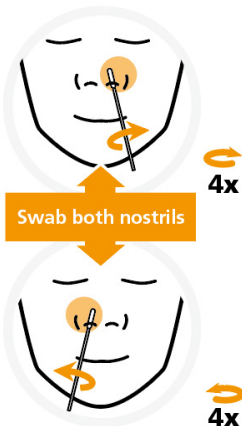
For best performance, place the swab in the extraction tube and buffer as soon as possible after swabbing the nostrils.



## 13 First nostril

Place the fabric tip of the swab inside the first nostril approximately 1.5 cm. You do not need to push it in far and no force is needed.

Gently wipe the swab around inside the nostril at least 4 times in a circular motion. Make sure there is good contact between the fabric tip and the inside of the nostril.



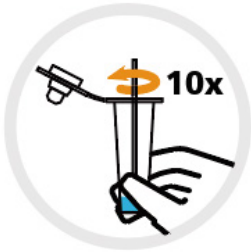
## 14 Second nostril

Place the fabric tip of the same swab inside the second nostril. Repeat the circular motion 4 times with good contact between the fabric tip and the inside of the nostril.

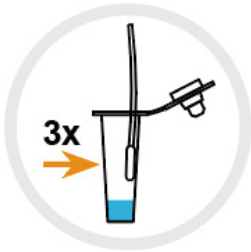
## Warning

If you, or a person you are swabbing, experience a nose bleed when swabbing, do not continue, as the sample cannot be tested. If bleeding persists, consult a doctor.

# Process the swab sample



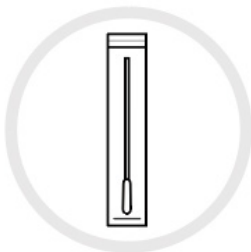
- 15** Place the fabric tip of the swab into the fluid in the extraction tube and rotate the swab **at least 10 times**.



- 16** Press the tip firmly against the inside of the tube **3 times**.



- 17** Remove the swab from the extraction tube.  
Push the nozzle cap tightly onto the extraction tube to avoid any leaks.



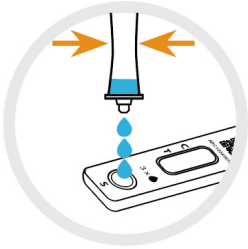
- 18** Place the swab into the plastic zip-lock bag.

## Advice

The individual zip-lock bag can be used as the waste bag.

## Advice

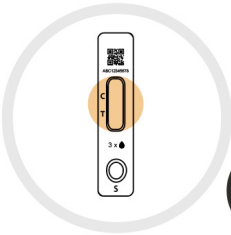
Make sure you place the test cassette on a flat and level surface. Do not move the test cassette during the test. Add the drops to the sample well (marked **S**) on the test cassette. Do not overfill.



**Only**  
  
**3x**

- 19** Gently squeeze the extraction tube to place **3 drops** of liquid into the sample well (marked **S**) on the test cassette.

Make sure you drop liquid and not an air bubble.



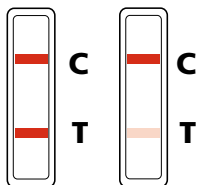
- 20** Set a timer and wait **10 minutes** before you read your result.

## warning

Do not leave the test to develop for longer than **20 minutes** as this will make the result void.

# Read your results

## If you test positive



### Two lines appear.

One coloured line should be in the control line region (**C**), and another coloured line should be in the test line region (**T**).

Two lines, one next to **C** and one next to **T**, even faint lines, show the test is positive.

If you get a positive result, you could be highly infectious.

### what to do next:

Follow the advice on staying at home and avoiding contact with other people.

Go to: [nhs.uk/stay-at-home](https://www.nhs.uk/stay-at-home)

If you can, tell people who you have been in close contact with about your positive test result.

## If you test negative

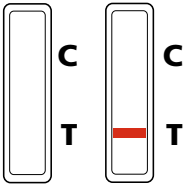


One coloured line appears in the control line region (**C**). No line appears in the test line region (**T**). If you get a negative result, it is likely you were not infectious at the time the test was taken.

A negative result is not a guarantee that you do not have COVID-19. You and your household should follow advice on how to avoid catching and spreading COVID-19.

Go to: [nhs.uk/how-to-avoid-covid](https://www.nhs.uk/how-to-avoid-covid)

## **Void result**



Control line (**C**) fails to appear, or just one red bar (**T**) appears, means the test is void.

**If you get a void result**, this means it is not possible to say if you had the virus when the test was done. To check if you have coronavirus, repeat the test from step one using a new kit. Do not reuse anything from the first test.



### **Safely dispose of your test kit**

Once your test is complete, put all of the used test kit contents in your general household waste. Wash your hands thoroughly after disposal.

### **Advice**

#### **Give feedback about your test or report harm**

If any part of your test kit is damaged or missing, do not use that test kit. You can still use the other test kits in the pack.

If you are harmed by a device or have feedback about your test kit, reporting it could help others.

Go to: [gov. uk/covid-19-test-feedback](https://www.gov.uk/covid-19-test-feedback).

## INTENDED USE

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended for the qualitative detection of the SARS-CoV-2 antigens in human nasal swab samples. This test is used for individuals suspected of having COVID-19 within the first seven days of the onset of symptoms, such as headache, fever, cough, sore throat, loss of sense of smell or taste, shortness of breath and muscle pain. The test can also be applied for individuals without symptoms. Results are for the identification of SARS-CoV-2 Antigen. Positive results indicate the presence of SARS-CoV-2 antigens, but individual history and other diagnostic information is necessary to determine infection status. Negative results do not rule out SARS-CoV-2 infection. Negative results for individuals with symptoms similar to COVID-19 infection for more than seven days should probably be treated as negative. If necessary, it should be confirmed by molecular assay. One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended to be used to help the diagnosis of SARS-CoV-2 infection. This test is used for self-testing.

## PRINCIPLE

The test uses anti-SARS-CoV-2 nucleocapsid protein (N protein) monoclonal antibody I conjugated with colloidal gold coated on the sample pad, and another anti-SARS-CoV-2 N protein monoclonal antibody II coated on test line. After the samples have been applied to the test strip, the colloidal gold-labelled anti-SARS-CoV-2 N protein monoclonal antibody I bind with SARS-CoV-2 antigens in sample and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on test line by anti-SARS-CoV-2 N protein monoclonal antibody II. The color intensity of each test line increases in proportion to the amount of SARS-CoV-2 antigen in sample.

## PERFORMANCE CHARACTERISTICS

### 1 Limit of Detection (LoD)

The LoD for nasal swab was established using heat-inactivated SARS-CoV-2 isolate strain. The strain was spiked with negative human nasal swab into a series of concentrations. The estimated LoD found from the initial twofold serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for nasal swab was 200 TCID<sub>50</sub>/mL.

### 2 Clinical Agreement Study

The clinical performance of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) was evaluated by testing a total of 480 nasal swab samples. It is compared to the results of RT-PCR assays. Overall study results were shown in the tables below.

Total		BG's RT-PCR kit		
		Positive	Negative	Subtotal
Getein's kit	Positive	165	4	169
	Negative	5	306	311
	Subtotal	170	310	480

Positive percent agreement (Diagnostic sensitivity) =  $165 / (165 + 5) \times 100\% = 97.06\%$  (95% CI: 93.30%-98.74%)

Negative percent agreement (Diagnostic specificity) =  $306 / (306 + 4) \times 100\% = 98.71\%$  (95% CI: 96.73%-99.50%)

Total percent agreement =  $(165 + 306) / 480 \times 100\% = 98.13\%$  (95% CI: 96.48%-99.01%)

### 3 Analytical Specificity

#### 3.1 Cross-Reactivity & Microbial Interference

Each organism and virus was tested in triplicate in the absence and presence of SARS-CoV-2 respectively. According to the test results, there was no cross-reactivity with the following viruses or organisms.

Viruses or organisms	Concentration
Human coronavirus 229E	1 x 10 <sup>5</sup> PFU/mL
Human coronavirus OC43	1 x 10 <sup>5</sup> PFU/mL
Human coronavirus NL63	9.87 x 10 <sup>3</sup> PFU/mL
MERS coronavirus	7930 PFU/mL
Adenovirus (e.g. C1 Ad.71)	1 x 10 <sup>5</sup> PFU/mL
Human Metapneumovirus (hMPV)	1 x 10 <sup>5</sup> PFU/mL
Parainfluenza virus Type 1	1 x 10 <sup>5</sup> PFU/mL
Parainfluenza virus Type 2	1 x 10 <sup>5</sup> PFU/mL
Parainfluenza virus Type 3	1 x 10 <sup>5</sup> PFU/mL
Parainfluenza virus Type 4a	1 x 10 <sup>5</sup> PFU/mL
Influenza A	1x10 <sup>5</sup> PFU/mL
Influenza B	2.92 x 10 <sup>4</sup> PFU/mL
Enterovirus	1 x 10 <sup>5</sup> PFU/mL
Respiratory syncytial virus	1 x 10 <sup>5</sup> PFU/mL
Rhinovirus	4.17 x 10 <sup>5</sup> PFU/mL
Haemophilus influenzae	1x10 <sup>5</sup> CFU/mL
Streptococcus pneumoniae	1x10 <sup>5</sup> CFU/mL

Streptococcus pyogenes	1x10 <sup>5</sup> CFU/mL
Candida albicans	1 x 10 <sup>5</sup> CFU/mL
Pooled human nasal wash	14% v/v
Bordetella pertussis	1 x 10 <sup>5</sup> CFU/mL
Mycoplasma pneumoniae	1 x 10 <sup>5</sup> CFU/mL
Chlamydia pneumoniae	1 x 10 <sup>5</sup> CFU/mL
Legionella pneumophila	1 x 10 <sup>5</sup> CFU/mL
Mycobacterium tuberculosis	1 x 10 <sup>5</sup> CFU/mL
Pneumocystis jirovecii	1x10 <sup>5</sup> CFU/mL
Pseudomonas Aeruginosa	1x10 <sup>5</sup> CFU/ml
Staphylococcus Epidermidis	1 x 10 <sup>5</sup> CFU/mL
Streptococcus Salivarius	1x10 <sup>5</sup> CFU/mL

### 3.2 Interferences

The potentially interfering substances that may be found in the upper respiratory tract in symptomatic subjects (including over the counter medications). No false positive or false negative results were seen at the following concentrations.

Potentially Interfering Substances	Concentration
Blood (human)	5%
Mucin	5 mg/mL
Nasal GEL(NeilMed)	5% v/v
CVS Nasal Drops (phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Zicam Cold Remedy	5% v/v
Homeopathic(Alkaloi)	10 % v/v
Sore Throat Phenol Spray	15% v/v
Tobramycin	3.3 mg/dL
Mupirocin	0.15 mg/dL
Fluticasone	5% v/v
Tamiflu (Osetamivir phosphate)	500 mg/dL
Biotin	0.35 mg/dL
Methanol	0.15% v/v
Diphenhydramine	0.0774 mg/dL
Dextromethorphan	0.00156 mg/dL
Dexamethasone	1.2 mg/dL

### 4. Precision

For reproducibility study, the agreement percent of both negative samples and positive samples are 100%. For reproducibility study, the agreement percent of both negative samples and positive samples are 100%.

## Symbols used



Store within  
4°C -30°C



Sterilized using  
ethylene oxide



Manufacturer



Lot number



Use-by date



In vitro diagnostic  
medical device



Keep away  
from sunlight



Date of  
manufacture



Do not re-use



Keep dry



Consult instructions  
for use



Caution



Contains sufficient  
for 7 tests



Do not use if  
package is damaged



Recyclable



CE mark



UK responsible person



Authorized representative  
in the European community



Latex free



Catalogue number

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EC Certificate No.1434-IVDD-195\_2022

### Swab manufacturer

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China

or

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