THERAFLU

fluTEST

HOME DIAGNOSTIC KIT

PRODUCT INFORMATION LEAFLET

Refer to the Quick Start Guide for a summary of the key information of this leaflet.

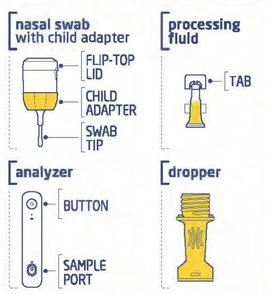
GENERAL TEST INFORMATION

Please read this leaflet before using the test.

You must follow the Theraflu App when performing the test.

This test is intended to be used as an aid in the diagnosis of flu (influenza). If your test detects flu please consult a healthcare professional. If your test does not detect flu but you are becoming increasingly unwell, are not recovering, or if you are concerned about your health, please see a healthcare professional.

Home diagnostic kit:



When to use this test:

! Use this test if you have all 3 of the below:

- You have had a fever or have felt feverish within the last 24 hours, AND;
- You have a runny or blocked nose, AND;
- You have had flu-like symptoms for 3 days or less.

✕ Do not use this test:

- On anyone under 2 years of age;
- If you have been unwell for 4 days or more;
- If you are prone to nose bleeds;
- If you have had a flu nasal spray mist vaccine in the last 7 days, OR;
- If you have had a facial or head injury or surgery in the last 6 months.

1 BEFORE THE TEST

Preparing to do the test

- ✓ **Ensure you have an internet connection.** You will need to download the Theraflu App. The app will require an Internet connection to email you your test result record.
- ✓ **Ensure you are using a compatible smartphone.** For a full list visit: www.theraflu.com
- ✓ **Ensure your phone is charged** (at least 20% battery) or is charging.
- ✓ **Ensure your test is at room temperature.** 59-77°F (15-25°C).
- ✓ **Ensure all packaging is intact.** Do not use the test if there is visible damage to the foil packaging.
- ✓ **Only open the foil packaging when you are ready to do the test.** Use test within 1 hour after opening.
- ✓ **Wash your hands before using the test.**
- ✓ **Keep the swab clean.** Avoid touching the swab tip and ensure it does not touch any surfaces before use.

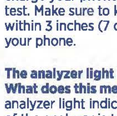
! STEP-BY-STEP INSTRUCTIONS

This leaflet only describes the key steps of the test. Step-by-step instructions on how to perform this test are in the Theraflu App.

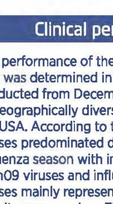
6 key steps of the test

1. **UNBOX COMPONENTS**
 Only open foil packaging when you are ready to do the test. Use within 1 hour.
2. **DOWNLOAD AND OPEN THE APP**
 Find the free Theraflu App on the Google Play Store, the App store, or use your smartphone's web browser to visit: **www.theraflu.com**

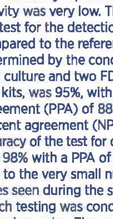
 Google Play App Store
3. **ANSWER QUESTIONS**
 This will select the right video and instructions for you.
4. **WATCH INFO VIDEO**
 The video will provide an overview of what to expect. There will be separate step-by-step instructions later in the app.



5. **FOLLOW INSTRUCTIONS**
 Separate step-by-step instructions will be available within the app after the video.



6. **YOUR TEST RESULT**
 After finishing the testing process wait 12 minutes for your result to appear on your phone screen.



Menu **Once you have your result, you can use the Menu icon to start a new test, access past test results or use the telemedicine consultation** (refer to Post Result Service section).

2 DURING THE TEST

Do's and don'ts

- ✓ **Follow the app's instructions carefully.** Incorrect use or use in the wrong order may result in a test failure or an incorrect result.
- ✓ **For children under the age of 16 years, the test must be performed by an adult.**
- ✓ **Children aged 2-12 years must be swabbed with the child adapter in place.**
- ✓ **Keep out of reach of children.** Small kit parts may be a choking hazard.
- ✓ **Only use the test components provided.** Do not replace the processing fluid with any other fluid.
- ✓ **Keep the swab clean.** Avoid touching the swab tip and ensure it does not touch any surfaces before use. A contaminated swab is a health hazard.
- ✓ **Screw the swab into the dropper immediately after taking the sample.**
- ✓ **Keep your phone within 3 inches of the analyzer until the test result is available.** Answer calls on speaker.
- ✓ **Keep the analyzer on a flat surface until the result is available.** Tilting the analyzer could result in a test error.
- ✓ **Keep foreign substances away from the test during the testing process.** Contact with foreign substances may result in an incorrect test result.
- ✕ **Do not drop the analyzer. Handle with care.**
- ✕ **Do not perform the test in direct sunlight.**
- ✕ **Avoid contact with processing fluid.** Do not insert swab into your nose once it has been in contact with processing fluid and do not ingest processing fluid.
- ✕ **Do not perform your test within 30 feet of another Theraflu test.**
- ✕ **Do not close the Theraflu App during processing as it will cause an error and you will need a new test kit.**

THIS TEST INVOLVES TAKING A SAMPLE FROM DEEP INSIDE YOUR NOSE. When doing the test, pay particular attention to the instructions on how to swab your nose. Incorrect swabbing may lead to an inaccurate test result.
SWABBING A SMALL CHILD. We recommend swabbing small children with the help of a second adult. One adult should hold & reassure the child while the other takes the swab.

3 AFTER THE TEST

Your result and what it means for you

The Theraflu App will show one of the following results on your phone's screen:

+ YOUR TEST DETECTED FLU

Your test is positive for flu (influenza) A or B.

Flu is a viral infection of the nose, mouth, throat and sometimes lungs.

It is treatable with antiviral medicines if treated within the treatment window of 48 hours after onset of symptoms. The antiviral treatment is more effective the earlier it is initiated.

You are contagious and can give the flu to other people – please read about stopping the spread of influenza in the Flu and You section.

We recommend consulting a healthcare professional as soon as possible. This is particularly important if:
•You are in a high-risk group (refer to the User Safety section), OR;
•You are in the treatment window, OR;
•You are concerned about your health.

Please tell the healthcare professional that you have had a positive flu test.

Press the YOUR RESULT & WHAT IT MEANS button in the app to find out more about your result.

! IMPORTANT

This test is intended to be used to aid a clinical diagnosis. Do not use this test as the only guide to manage your illness. Please consult a healthcare professional if your symptoms persist or become more severe, or if you are concerned at any time.

– YOUR TEST DID NOT DETECT FLU

Your test is negative for flu (influenza).

So what could be making you sick? Other viruses cause flu-like symptoms. These illnesses typically resolve by themselves within 2-4 days, but sometimes they can cause more severe illness, especially in children or people at high risk (refer to User Safety section).

Sometimes more serious conditions can cause flu-like symptoms. These include bacterial infections of the throat, sinuses and lungs.

If you feel worse, you don't get better, or you are concerned about your health, please consult a healthcare professional.

! A TEST ERROR HAS OCCURRED

Your test has experienced an error.

Please call the Theraflu's toll free customer helpline and have your test result and the test packaging handy. We will need the Error Code under the circle on the result screen as well as the Lot Number and Analyzer ID of your test. You will need to test again with a new test or consult a healthcare professional for further care.

Testing outside the flu season

As with all flu tests, test results are slightly less reliable when there are very few flu cases in the community (outside the flu season). Please consult a healthcare professional if you are concerned about your health, if your symptoms persist, or if symptoms become more severe.

Post result services

Telemedicine Service

The Theraflu Home Flu Test enables you to connect to a telemedicine consultation directly through the app. This allows you to discuss your illness with a healthcare professional. If the healthcare professional believes a prescription medication is needed, this will be sent electronically to you or your pharmacy. The healthcare professional may also write a flu certificate for your employer if appropriate. To arrange a telemedicine consultation simply press the VIDEO CALL A DOCTOR button on the result screen and follow the prompts. The telemedicine consultation has an extra fee, some or all of which may be covered by your health insurance.

Test Results Record

A record of your test result and detailed information regarding your result will be emailed to you automatically. This record can be used as a proof of test result for your doctor, pharmacist or employer. If required, your employer can log on to verify the record's authenticity. Acceptance is at your employer's discretion.

Buy over the counter medicine in app

When you are sick, the last thing you want to do is drag yourself out of the house to buy more medicine. The Theraflu App works with retailers to deliver to you the over-the-counter medication you need, when you need it, all from the comfort of your home. Simply press the BUY OVER THE COUNTER MEDICINE button on the result screen, and follow the prompts to get medication delivered to your door in as little as a few hours. Additional charges for delivery may apply. Theraflu over the counter medicine are not antiviral.

! ATTENTION ALL USERS

If you are not recovering, feeling worse, or are concerned about your health, please consult a healthcare professional.

! AT ALL TIMES

Flu safety

High Risk Groups

Users who fall into one of the following groups are at high risk of complications from the flu and are recommended to see a healthcare professional regardless of their test result:

- Children under the age of 5 and especially under 2 years of age
- Adults 65 years and older
- People under 19 years of age who are on long-term aspirin or salicylate containing medications
- Pregnant women
- American Indians and Alaska Natives
- People who live in nursing homes and other long-term care facilities

Or individuals who suffer from:

- Asthma
- Neurologic and neurodevelopment conditions
- Blood disorders
- Chronic lung disease
- Endocrine disorders
- Heart disease
- Kidney disorders
- Liver disorders
- Metabolic disorders
- Weakened immune system due to disease or medication
- Obesity (with a body mass index [BMI] of 40 or more)

For most current information on high risk groups refer to:

https://www.cdc.gov/features/fluhighrisk/index.html

! ATTENTION ALL USERS

If you are not recovering, feeling worse, or are concerned about your health, please consult a healthcare professional.

Warning Signs

The following are signs of severe flu (influenza) infection. Please seek medical attention if any of these apply to you at any time:

Adults

- Difficulty breathing or shortness of breath
- Persistent pain or pressure in the chest or abdomen
- Persistent dizziness, confusion, inability to arouse
- Seizures
- Not urinating
- Severe muscle pain
- Severe weakness or unsteadiness
- Fever or cough that improve but then return or worsen
- Worsening of chronic medical condition

Children

- Fast breathing or trouble breathing
- Bluish lips or face
- Ribs pulling in with each breath
- Chest pain
- Severe muscle pain (child refuses to walk)
- Dehydration (no urine for 8 hours, dry mouth, no tears when crying)
- Not alert or interacting when awake
- Seizures
- Fever above 104° F (40°C)
- In children less than 12 weeks, any fever
- Fever or cough that improve but then return or worsen
- Worsening of chronic medical conditions

For most current information on warning signs refer to:

https://www.cdc.gov/flu/consumer/symptoms.html

Frequently asked questions (FAQs)

1. **How does the Theraflu Home Flu Test work?** When you have flu, the virus causing your symptoms is present in your nasal secretions. The Theraflu Home Flu Test can detect small amounts of flu (influenza) virus in your nasal secretions.
2. **How accurate is the Theraflu Home Flu Test?** No rapid flu test is 100% accurate. The Theraflu Home Flu Test has an overall accuracy of 95% for Flu A and 89% for Flu B.
3. **What should I do if my phone cannot connect with the analyzer?** Contact Theraflu's toll free customer helpline for assistance.
4. **Why is the app asking me for my name and email address?** The app will automatically email you a record of your test result. You can share this record as a proof of influenza testing with your doctor, pharmacist or employer. For the app to be able to generate this record and email it to you it requires the patient's name and an email address.
5. **Whats should I do if my phone runs out of charge during the test?** It is ok to charge your phone while performing the test. Make sure to keep the analyzer within 3 inches (7 centimeters) of your phone.
6. **The analyzer light is flashing red. What does this mean?** A flashing red analyzer light indicates that the battery of the analyzer is too low to perform the test.
7. **The analyzer light is solid red. What does this mean?** A solid red analyzer light indicates that the analyzer is faulty.
8. **I have a nose bleed after swabbing my nose. What should I do?** In the unlikely event your nose starts bleeding, apply pressure to your nose and consult a healthcare professional. Do not insert the swab again.
9. **I am trying to squeeze the fluid into the sample port but no fluid is coming out. What should I do?** Ensure the swab is screwed into the dropper as tightly as possible. Some force will be required to do this. Then try again holding the dropper completely vertical. If this does not solve the problem, call Theraflu's toll free customer helpline for assistance.

For further FAQs visit www.theraflu.com

Clinical performance

The performance of the Theraflu Home Flu Test was determined in a clinical study conducted from December 2018 to April 2019 at geographically diverse sites throughout the USA. According to the CDC, influenza A viruses predominated during the 2018/2019 influenza season with influenza A(H1N1) pdm09 viruses and influenza A(H3N2) viruses mainly represented. Influenza B activity was very low. The overall accuracy of the test for the detection of influenza A when compared to the reference result, as determined by the concordance between viral culture and two FDA cleared molecular test kits, was 95%, with positive percent agreement (PPA) of 88% and negative percent agreement (NPA) of 98%. The overall accuracy of the test for detection of influenza B was 98% with a PPA of 83% and NPA of 98%. Due to the very small number of influenza B cases seen during the season, additional bench testing was conducted using stored clinical samples. The overall accuracy of the test for detection of influenza B when using these samples was 91% with 86% PPA and 97% NPA. The results for the annual reactivity panel provided by the CDC can be found on our website www.theraflu.com

If you or your healthcare professional would like to know more about how the test works you will find more details in the Test Result Record that was emailed to you. Alternatively you or a healthcare professional can contact Theraflu's toll free customer helpline at any time.

Warnings and precautions

- ✓ Store in a dry location between 36-86°F (2-30°C)
- ✓ Keep out of direct sunlight
- ✓ Use at room temperature 59-77°F (15-25°C)
- ✓ Keep out of reach of children
- ✕ Do not use after expiry date
- ✕ Do not use if any of the packaging is opened or damaged
- ✕ Do not re-use; this is a single use test
- ✕ Do not use this test as the only guide to manage your illness, particularly if your test has not detected flu. Please consult a healthcare professional if symptoms persist or become more severe
- ! Avoid performing the test in a very dry environment (very low humidity) to prevent a build up of static electricity that could damage the electronics of the test
- ! A test result will be less reliable when there is very little flu in the community (outside flu season, and in the very early and very late stages of the flu season). Please consult a healthcare professional if you are concerned about your health, if your symptoms persist, or if symptoms become more severe
- ! No test components to be used inside the body except the nasal swab
- ! High levels of blood in your nasal swab sample may interfere with the test
- ! Individuals who received nasally administered flu vaccine may test positively for the virus for up to seven days after vaccination

Test disposal

Before disposal of the analyzer, we recommend removing the battery using the following steps:

- Locate the gap at the end (short side) close to power button of the analyzer
- Place a coin in the gap
- Twist the coin to break off the bottom end of the analyzer along the perforation in the plastic
- Lift up the little metal battery holder and turn the analyzer so the battery can slide out
- Dispose of the battery according to local regulations
- Keep the battery out of reach of children
- Dispose the remainder of the test in general waste
- Do not incinerate

More about the test

- Some technologies inside the test are licensed from Thermo Fisher.
- This product contains small amounts of animal sourced materials.
- This device complies with the emission and immunity requirements described in EN61326-2-6. Interference from other electronically driven equipment is not expected.

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

Warning: Any changes or modifications not expressively approved by GSK could void the user's authority to operate this equipment

For a Glossary of Symbols please refer to www.theraflu.com

Flu and you

1. **What is flu?** Flu is a serious and common contagious illness caused by a viral infection of the nose, throat and lungs.
2. **How does flu spread?** Flu viruses are mainly spread by tiny droplets made when people with flu cough, sneeze, blow their nose and talk. A person might also get flu by touching a surface or object that has flu virus on it and then touching their own eyes, mouth or nose.
3. **How long can a sick person spread flu to others for?** People infected with flu may infect others from about 1 day before feeling sick to 5-7 days after symptoms appear. Some people are infectious for longer, including children and people with weakened immune systems.
4. **How severe is illness caused by flu?** Different flu viruses affect people differently. Even healthy children and adults can get very sick or even die from flu.
5. **Does flu have complications?** Sometimes people who have flu get a delayed bacterial infection, usually of the lungs. This usually occurs within 5 days of symptoms and is caused by the flu virus making the person more susceptible to infection. Antibiotics are likely to help these people and it is recommended that you consult a healthcare professional if you think your flu infection has led to a subsequent bacterial lung infection.
6. **How can I avoid catching flu?** Try to avoid close contact with sick people. Wash your hands often and avoid touching your mouth, nose and eyes. Face masks help reduce the spread of flu. Clean and disinfect surfaces and objects that may be contaminated with germs like the flu.
7. **I had flu last year, why have I got it again?** Each year, the flu virus changes slightly. This means that you are not protected from getting influenza this year just because you had it last year.
8. **I got the flu vaccine this year, why do I have a positive flu test?** You may have been exposed to a flu virus shortly before or after getting vaccinated. Or you may have been exposed to a flu virus that is not included in the seasonal flu vaccine. There is also a small chance of becoming infected with a flu virus the flu vaccine is designed to protect against, despite getting vaccinated.
9. **How can I protect myself from flu?** Vaccination is widely regarded as the best method of preventing flu (influenza) infection. Each year, flu viruses change a little, so flu experts change the flu vaccine to match the new viruses. It is important to get vaccinated every year, especially if you are in a high risk group, or you live and work with people in high risk groups.
10. **Will antiviral drugs make me better?** If started within 2 days (48 hours) antiviral drugs may help you get better sooner and make your illness less severe. Antiviral medicines also decrease the chance you will have complications of flu (influenza). For people in high risk groups, there might be benefits in treatment even if you have been sick for longer than 2 days. Antiviral medicines are not a replacement for vaccination – prevention is better than treatment.
11. **Will antibiotics make me better?** If you have flu, antibiotics will not make you better because flu (influenza) is a virus.

Customer helpline

If you have any questions about this flu test, please contact Theraflu toll free customer helpline on

1-855-328-5259

Manufacturer

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IVD No test components to be used inside the body except the nasal swab as directed.

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