



PRODUCT INFORMATION LEAFLET

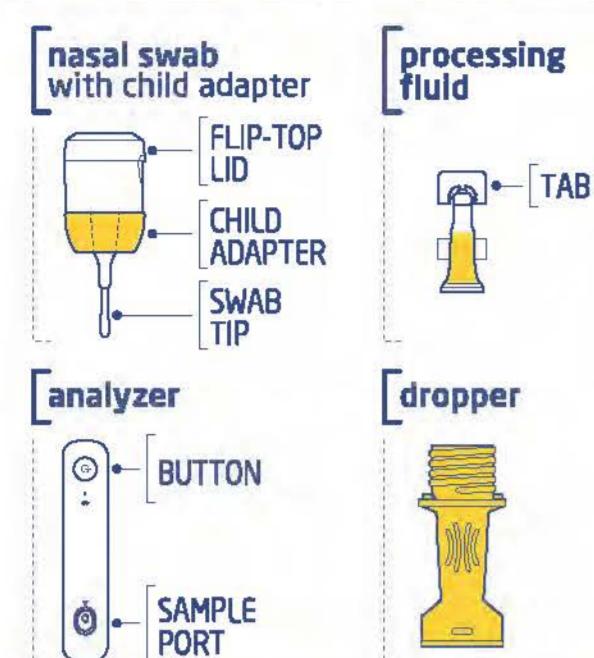
Refer to the Quick Start Guide for a summary of the key information of this leaflet.

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.

2 DURING THE TEST

Do's and don'ts

- 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.
- Only use the test components provided. Do not replace the processing fluid with any other fluid.
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- 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.

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 taken within the treatment window of 48 hours after onset of symptoms. The antiviral treatment is more effective the earlier it is initiated.

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.

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.

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.

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.

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.

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 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 What 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 What is the Theraflu Home Flu Test? The Theraflu Home Flu Test is a rapid test for influenza A and influenza B. It uses a nasal swab to detect the presence of influenza virus in the nose. The test results are available within 15 minutes.

10 How accurate is the Theraflu Home Flu Test? The Theraflu Home Flu Test has an overall accuracy of 95% for influenza A and 89% for influenza B.

11 What are the symptoms of the flu? The symptoms of the flu include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills, and fatigue. Some people may also experience vomiting and diarrhea.

12 How long does it take for the flu to spread from one person to another? Flu viruses are spread through 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.

13 How can I protect myself from the 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.

14 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.

15 Will antibiotics make me better? If you have flu, antibiotics will not make you better because flu (influenza) is a virus.

16 Manufacturer

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Customer helpline

If you have any questions about this flu test, please contact Theraflu toll free customer helpline on
1-855-328-5259

IVD No test components to be used inside the body
10035E-09-11/19
209-11-04
1059865PL