

Media Lines

COVID-19 home test kits

Issue Statement: Health Canada continues to receive inquiries about the availability of COVID-19 home test kits. Health Canada does not support home testing for COVID-19, because home test kits can provide inaccurate results. Lastly, they also make it hard for the health care system to collect timely and accurate data on the spread of infection, which are key for managing a pandemic.

Key Messages:

- Early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada.
- Health Canada does not support home testing for COVID-19, because no home test kits have been reviewed by Health Canada and authorized, therefore they can provide inaccurate results.
- They also make it hard for the health care system to collect timely and accurate data on the spread of infection, which are key for managing a pandemic.
- Health Canada has authorized the sale and importation of COVID-19 diagnostic tests intended for use only by health care professionals or trained operators.
- Health Canada has not authorized any diagnostic tests or sample collection kits intended for use by the general public to detect or self-diagnose COVID-19.
- The Government of Canada continues to work with companies across the country and internationally to ensure Canadians and health care workers have the tools they need to care for Canadians and reduce the spread of COVID-19.

About the Interim Order for medical devices:

- As an emergency public health measure, the [Interim order respecting the importation and sale of medical devices for use in relation to COVID-19](#) allows for expedited access to COVID-19-related medical devices.
- With the Interim Order, new diagnostic tests are being made readily accessible in Canada. They are listed on [Health Canada's website](#).
- The Interim Order will also ensure that other COVID-19-related medical devices are available to treat, mitigate or prevent COVID-19, as necessary.

Questions and Answers:

Q1. What kind of tests have been promoted for use at home?

To date, Health Canada has not authorized the importation or sale of any diagnostic tests or sample collection kits intended for use by the general public to detect or self-diagnose COVID-19.

Lateral-flow antibody tests, commonly referred to as “rapid tests” have been illegally promoted for home use. This type of test does not require laboratory equipment, and the result is

displayed as a coloured band on a small stick-style device. However, Health Canada has not authorized any tests of this type for sale or importation and this type of home testing is not recommended because the patient would not have the support of a medical professional to interpret the results.

Patients who test positive for COVID-19 also need to be advised by a medical professional on how to care for themselves and how to help reduce the spread of COVID-19 by self-isolating. In addition, public health authorities need access to the results of all testing to make decisions relating to the spread of COVID-19 in Canada.

Based on the current available information, the World Health Organization recommends the use of rapid tests only in research settings.

Q2. What is Health Canada doing to stop the sale of unauthorized COVID-19 test kits?

Health Canada continues to monitor the use of unlicensed medical test kits, including for COVID-19, and takes appropriate action to stop their sale as required. When Health Canada identifies or is notified of non-compliance with the [Food and Drugs Act](#) or its [Regulations](#), it takes action and informs Canadians as necessary.

For example, on April 21, 2020, Health Canada worked with the RCMP to seize over 1500 unauthorized test kits in B.C.

On May 7, 2020, Health Canada issued an advisory notifying Canadians not to use or rely on unauthorized COVID-19 test kits presented for individual sale or personal use.

Q3. Are COVID-19 home test kits available in other jurisdictions?

Other international regulators, including the U.S. Food and Drug (FDA) Administration, have not approved home test kits for COVID-19.

There was recent media coverage claiming that the U.S. FDA had approved its first home test kit; however, this is not accurate. The U.S. FDA has approved the COVID-19 RT-PCR Test for which only the collection of a fluid sample is done at home. The swab then needs to be sent to a laboratory for testing. These are subject to strict transportation requirements.

Q4. What type of COVID-19 tests have been authorized by Health Canada or are under consideration?

Health Canada has [authorized](#) the sale and importation of COVID-19 diagnostic tests intended for use only by health care professionals or trained operators.

Health Canada has received submissions for serological tests for COVID-19, which are under review. Health Canada has published [guidance for industry](#) on Requirements for Serological Antibody Tests submitted under the COVID-19 [Interim Order](#).