

## 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

- Rapid diagnosis is essential to slowing and reducing the spread of COVID-19 in Canada.
- Health Canada opposes COVID-19 home testing, because it has not assessed or approved any home testing kits, which means that the results could be inaccurate.
- These kits damage the health system's ability to collect timely and accurate data on the spread of infection, which are key to managing a pandemic.
- Health Canada has only authorized the sale and import of COVID-19 diagnostic tests intended for exclusive use by health professionals or qualified technicians.
- Health Canada has not authorized diagnostic tests or sample collection kits that the general public can use to detect or self-diagnose COVID-19.
- The Government of Canada continues to work with Canadian and international companies to equip Canadians and health workers with the necessary tools to take care of Canadians and reduce the spread of COVID-19.

#### On the Interim Order concerning medical devices

- The [Interim order respecting the importation and sale of medical devices for use in relation to COVID-19](#) was made to allow for accelerated access to medical devices to combat COVID-19.
- With the Interim Order, new diagnostic tests can be easily accessed in Canada. The list is available on the [Health Canada website](#).
- The Interim Order ensures access to medical devices related to COVID-19 for the treatment, mitigation or prevention of the disease, as needed.

#### Questions and answers

##### Q1. What types of tests have been proposed for home use?

To date, Health Canada does not authorize diagnostic tests or sample collection kits for the general public to use to detect or self-diagnose COVID-19.

Lateral flow antibody tests, commonly known as “rapid tests” have been proposed illegally for home use. This type of test does not require any laboratory equipment and results are shown as a coloured band on a small stick. However, Health Canada has not authorized the importation

or sale of any tests of this type. They are not recommended, given that the patient has no access to a medical professional who could interpret the results.

Patients who receive a positive COVID-19 result must also be advised by a medical professional on how to care for themselves and reduce the spread of COVID-19 by self-isolating. Also, public health authorities must have access to the results of all tests to make decisions on fighting the spread of COVID-19 in Canada.

Based on current information, the World Health Organization recommends using rapid tests only in a research context.

## **Q2. What is Health Canada doing to prevent the sale of unauthorized rapid COVID-19 tests?**

Health Canada continues to monitor the use of home medical test kits that are not authorized, including for COVID-19, and it intervenes as necessary to stop the sale. When Health Canada becomes aware of a possible case of non-compliance with the [Food and Drugs Act](#) or its [Regulations](#), it takes the required action and informs Canadians if necessary.

For example, on April 21, 2020, Health Canada worked with the Royal Canadian Mounted Police in seizing more than 1,500 unauthorized kits in British Columbia.

On May 7, 2020, Health Canada issued an advisory telling Canadians not to use unauthorized COVID-19 test kits intended for sale or personal use and not to rely on them.

## **Q3. Are COVID-19 home test kits offered in other countries?**

No other international regulatory organization, including the Food and Drug Administration (FDA) in the United States, has approved COVID-19 home test kits.

It was recently mentioned in the media that the FDA had approved its first home test kit, but that is inaccurate. The FDA approved the COVID-19 RT-PCR test, for which only the collection of a fluid sample is performed at home. After collection, the swabs must be sent to a laboratory for analysis. They are subject to rigorous transportation requirements.

## **Q4. What types of COVID-19 screening tests are authorized by Health Canada or under review?**

Health Canada has [authorized](#) the importation and sale of COVID-19 diagnostic tests for exclusive use by health professionals or qualified technicians.

Health Canada has received submissions for serological tests for COVID-19 and is currently reviewing them. The department has issued an [industry guidance document](#) on requirements for serological antibody tests submitted under the COVID-19 Interim Order.