



MEDICAL TEST KITS FOR HOME USE

The Issue

A growing number of Canadians are using medical test kits in their homes to diagnose or monitor certain health conditions. These test kits are considered to be medical devices. Like all medical devices, they provide potential benefits, but they also pose potential risks.

Background

Advances in technology have made it possible for consumers to conduct self-testing for a variety of medical conditions. Medical test kits for home can perform one of the following tasks:

Diagnose a health condition: An example of this type of kit is a home pregnancy test.

Monitor an illness: These kits monitor health conditions and provide information about whether treatment may need to be adjusted. An example is glucose testing to monitor blood sugar levels in people with diabetes.

Screen for an illness or a health condition: These kits are intended to screen for health conditions or diseases in people who appear to be healthy. For example, people might use this type of kit to measure cholesterol or triglyceride levels. Depending on the readings, they might then make choices to help minimize their risk for heart disease.

Some of the benefits associated with home-use test kits are obvious. They can help Canadians take an active role in monitoring and perhaps improving their health. They offer privacy because the tests are conducted at home. In many cases, the tests also provide quick results, sometimes in a matter of minutes.

However, health and sickness are very complex issues. It is important to realize that do-it-yourself medical tests are not a replacement for professional health care. Medical kits for self-testing are best used when they are part of a comprehensive program that is supervised by a doctor or other health care professional.

The Safety and Effectiveness of Home-Use Test Kits

Home-use test kits are medical devices, and medical devices must be licensed by Health Canada before companies can sell them in Canada. The licence from Health Canada provides the assurance that the product is safe and effective when used as directed. It is important to be sure that the product being used is licensed by Health Canada. (See the [Need More Info?](#) section for more on this.)

Risks associated with Home-Use Medical Tests

Some companies advertise and sell test kits over the Internet and/or by mail order. In some cases, the products they offer may not be licensed for sale in Canada. Sending money to companies that are not reliable and reputable may result in receipt of a defective product, or no product at all. For example, a defective test kit may indicate a health condition when none is present. Worse, it may fail to identify a condition.

Legitimate companies will market their products using legal channels. An unlicensed test kit purchased from a foreign or Canadian supplier very likely does not meet Canadian requirements of safety and effectiveness for licensing.

Even when test kits have been licensed by Health Canada, there is still a risk that the results may not be 100% accurate. Faulty results are more likely to occur if all of the directions for storing and using the test are not followed. Sometimes people try to save money by doing things such as cutting glucose test strips in half so they will last twice as long, or trying to "mix and match" parts from different kits. Tampering with the contents of a test kit means a reduced likelihood of ending up with accurate results.



There is also a significant chance that people may interpret test results incorrectly and/or decide to change their treatment or lifestyle unnecessarily, if they don't consult a qualified health care provider. Interpretation of test results should always be part of a comprehensive health assessment.

Minimizing Your Risk

The following steps will help to minimize the risks associated with home-use medical tests.

- Remember that do-it-yourself tests are not a replacement for professional health care. These tests are best used as part of an overall approach to health that is supervised by a doctor or other licensed health care provider.

When buying a test:

- Buy the test from a reliable source. If you are uncertain, ask your doctor or pharmacist for advice.
- Make sure that the product has been licensed by Health Canada. Remember, buying an unlicensed test increases the chances that the test is unreliable, because it is not subject to Canadian regulatory controls.
- Check to see if there is an expiry date on the package.
- Read and follow the directions for storing the test. Incorrect storage could affect the accuracy of the test results.

Before using the test:

- Read the label and directions carefully. Be sure you understand exactly what you are supposed to do and follow the directions to the letter.
- Become familiar with the limitations of the test. Be aware of what alarms and error messages mean. Make sure you know what to do if the device fails.

After conducting the test:

- Remember that tests may not be 100% accurate. Test results should always be evaluated in the context of your overall health and in consultation with a licensed health care provider.
- Do not take any action or make drastic changes to your treatment without first consulting your health care provider.
- See your doctor if you are feeling sick or worried, or if the test instructions recommend it.
- Report any problems with test kits to Health Canada's Medical Devices Inspectorate Hotline, at 1-800-267-9675 (toll-free in Canada). Health Canada does follow-up on reported problems, and your call can help ensure that the medical devices available in Canada are safe and effective.

Health Canada's Role

Medical devices, including test kits for home use, must be licensed by Health Canada before companies are allowed to import and sell them in this country. The Medical Devices Regulations require that the medical devices imported and sold in Canada be safe, effective, and of quality manufacture. This is achieved by a combination of a pre-market review prior to licensing, and post-market surveillance of adverse events after licensing.

Need More Info?

To find out if a medical test kit has a licence from Health Canada, contact: Medical Devices Bureau, Health Canada Building 3, Tunney's Pasture Ottawa, Ontario K1A 0K9 Telephone: (613) 957-1909 Fax: (613) 957-6345 or do an online search of Health Canada's Medical Devices database, at www.mdall.ca

You can also find more information at the following Health Canada sites:

Medical Devices Web site at : http://www.hc-sc.gc.ca/dhp-mps/md-im/index_e.html

Medical Device Problem Reporting by Health Care Facilities, Medical Professionals and other device users, at : http://www.hc-sc.gc.ca/dhp-mps/compli-conform/index_e.html

and Guidance on reporting, at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/activit/index_e.html

For a list of Health Canada advisories and warnings about medical devices and other health products, see : http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index_e.html

For additional articles on health and safety issues go to the It's Your Health Web site at: www.healthcanada.gc.ca/iyh You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245*