



IT'S YOUR HEALTH



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 can also present risks.



Background

Advances in technology have made it possible for Canadians to self test for a variety of medical conditions. Medical test kits for home use can help do the following:

- 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 give 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 of using home test kits are obvious. They can help you take an active role in monitoring and even improving your 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.

But 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 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. If you send money to companies that are not reliable and reputable, you may end up getting a defective product, or no product at all. A defective test kit may indicate a health condition when none is present. Worse, it may fail to identify a condition you do have.

Legitimate companies will market their products using legal distribution channels. An unlicensed test kit (bought from either a foreign or a Canadian supplier) very likely does not meet Canadian requirements of safety and effectiveness.

Even when test kits have been licensed by Health Canada, the



results may not be 100% accurate. Faulty results can happen if all of the directions for storing and using the test kits are not followed. Sometimes people try to save money by doing things like 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 you are less likely to end up with accurate results.

If you don’t consult a qualified health care professional, there is also a significant chance that you may interpret test results incorrectly and/or decide to change your treatment or lifestyle unnecessarily. Interpreting 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 a qualified health care professional. These tests are best used as part of an overall approach to health that is supervised by a qualified health care professional.

When buying a test:

- Always buy the test kit from a reliable source. If you are unsure, ask a health care professional for advice.
- Make sure that the product has been [licensed by Health Canada](#) (see [Need More Info?](#) below). Remember, buying an unlicensed test kit increases the chances that the test is unreliable, because it is not subject to Canadian standards.
- Check to see if there is an expiry date on the package.

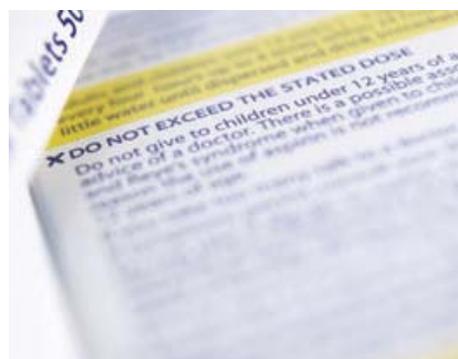
Read and follow the directions for storing the test kit. If you don’t store the test kit properly, it could affect the accuracy of the test results.

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 exactly as described.
- 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 qualified health care professional.





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- Do not take any action or make drastic changes to your treatment without first consulting your health care professional.
- 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 all medical devices imported and sold in Canada be safe, effective, and of quality manufacture. This is achieved through both a pre-market review of medical devices (before licensing), and post-market surveillance of problems and adverse events (after licensing).

Need More Info?

To report problems with medical devices, visit Health Canada's [Health Product and Food Branch Inspectorate](#) website at: www.health.gc.ca/inspectorate

For more information visit the following web pages:

- See Health Canada's [Medical Devices](#) web section at: www.health.gc.ca/medicaldevices
- To find out whether a Class II, III or IV medical device has a licence from Health Canada, do an online search of Health Canada's [Medical Devices database](#) at: <http://webprod.hc-sc.gc.ca/mdll-limh/index-eng.jsp>

If your specific device is not listed, check to see if similar devices have been licensed by typing the generic name (for example, "automatic blood pressure monitor") in the "device name" field. If there are similar licensed devices, it means that your device also requires a Canadian Medical Device Licence. You can also send your questions by e-mail to device_licensing@hc-sc.gc.ca or by fax to 613-957-6345.

- See Health Canada's [Advisories, Warnings and Recalls related to medical devices](#) at: www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/index_e.html

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- *It's Your Health*, Buying Medical Devices Over the Internet at www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/med_mat-eng.php
 - Medical Device Problem Reporting by Health Care Facilities, Medical Professionals and Other Device Users at www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/md_prob_rep-rap_incident_im_tc-tm-eng.php
 - *It's Your Health*, Medications listing at: www.hc-sc.gc.ca/hl-vs/iyh-vsv/alpha-eng.php#m

For safety information about food, health and consumer products, visit the [Healthy Canadians](http://www.healthycanadians.gc.ca) at: www.healthycanadians.gc.ca

For more articles on health and safety issues, go to the *It's Your Health* web section at: www.health.gc.ca/iyh

You can also call toll free at 1-866-225-0709 or TTY at 1-800-267-1245*