



## Home Care

### Tips for Effective At-home Testing

Always see your doctor if you are feeling sick or worried about a medical condition, or if any test result indicates you should do so. Use the tips below to ensure any at-home diagnostic test you use is safe and effective.

- ✓ Only use tests that have been cleared by the U.S. Food and Drug Administration (FDA) for home use. If any test has not been cleared by the FDA, it means that the U.S. government has not determined the product to be reasonably safe or effective, or substantially equivalent, to another legally marketed product.
- ✓ If you have questions about the test that are not answered by the product's label or package insert, call the test's manufacturer before administering it.
- ✓ To get the best results, read the label and instructions to be sure you understand:
  - What the test is and is not for
  - How to store the test before you use it
  - How to collect and store the sample
  - When and how to run the test, including any specific timing requirements
  - How to interpret the results

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### Issue Highlights

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## Home Diagnostic Tests: Help or Hurt?

**The market for at-home diagnostic tests used to be dominated by pregnancy tests and ovulation predictors. Now, increased attention to rapidly rising health care costs, privacy demands and a greater focus on preventive care is driving demand for similar products that can screen for serious diseases. But do these tests really provide reliable information, or do they cause undue worry and delay professional medical care?**

Home diagnostic tests or medical devices allow at-home access to information about your health status. These include pieces of equipment, machines, test kits, and other articles intended to diagnose, heal, manage, or prevent diseases or conditions.

Such tests provide a variety of benefits to patients. They can lead to early treatment and lower the chances of future complications, encourage patients to take immediate action about a condition even when no signs of the condition are present, and lead to changes in treatment for existing conditions. In addition, home diagnostic

tests provide convenient, cost-effective, confidential and fast results for users.

Unfortunately, in many cases, the risks and limitations of home diagnostic tests far outweigh the benefits. It is hard to find fault with home pregnancy tests or blood sugar monitors, but other tests for more complicated conditions can lead to problems if performed incorrectly.

Home tests alone cannot provide a full medical picture or diagnosis. All diagnostic tests need to be integrated with additional information from your doctor or health care provider. Home tests cannot replace the knowledge or expertise of a physician who has performed a complete physical exam and who knows your medical history. Individuals who rely solely on home test kits will miss out on pre- and post-test counseling from their physician, who can offer information, support, interpretation, and follow-up advice. Moreover, if the test indicates a positive presence of a serious disease or condition, the psychological reaction can be complicated if a physician is not there to discuss a patient's options.

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# Home Diagnostic Tests

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Other potential risks and limitations include:

- Misinterpretation, which can lead to delayed treatment
- False positive or false negative results (“false positive” results indicate a condition is present when it is not; “false negative” results are those that do not identify a condition as present when it actually is)
- Internet sites that sell unapproved devices and make fraudulent claims about their products
- Inaccurate results due to a user’s failure to follow instructions

## Buying Diagnostic Tests Online

The prevalence of Internet marketing has led to an alarming increase in the sale of fraudulent and potentially harmful medical devices and test kits. Many reputable companies, such as

pharmacies and manufacturers, use the Internet to market FDA-cleared medical products. Other products, however, are being sold illegally, and may be ineffective or even harmful. Most diagnostic tests are designed for use by healthcare professionals, but many Internet sites advertise that these tests are appropriate for in-home use. Other potential problems with online purchasing include receiving a contaminated product, receiving the wrong product or receiving no product at all.

The FDA recommends checking with a health care provider before buying a medical device or obtaining medical services from the Internet. Just like a prescription drug, if a device requires a prescription, it should only be used under a doctor’s supervision. ◇

## FDA Clearance

FDA-cleared home diagnostic tests have undergone extensive study and review by the manufacturer to satisfy the FDA’s requirements. They are as safe and accurate for consumer use as their laboratory counterparts are for professional use. For any in-home test, the manufacturer must convince the FDA that the results of a test will benefit the user and that users have the knowledge necessary to decide whether testing themselves is appropriate.

To determine if a test has been cleared by the FDA, cleared for home use or cleared for use in the United States, visit the FDA’s device database at [www.fda.gov](http://www.fda.gov) or call the Division of Industry and Consumer Education at 800-638-2041. You can also contact the manufacturer of a diagnostic product to determine if it has been reviewed by the FDA. If you are unable to reach a reliable party, it may be a signal that it is not a reliable product.

Do your part by reporting any problems you experience with a home diagnostic test. Report false marketing claims to the Federal Trade Commission at 877-FTC-HELP (382-4357). ◇

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## Tips for Effective At-home Testing

- What might interfere with performing the test or the accuracy of the results
- ✓ Follow all instructions carefully. Most tests require several, relatively simple procedures. (The FDA requires kits to be simple enough for an average consumer to use at home without doctor supervision.)
- ✓ Keep good records of any tests you perform and their results.
- ✓ Never change medications or dosages based on a home test result without first checking with your doctor.
- ✓ Never store a test where it can be exposed to extreme temperatures. This may cause product deterioration and invalid results.
- ✓ Always check the expiration date. Chemicals in an outdated kit may no longer work properly.
- ✓ Be sure to read and follow the test’s instructions for the timing of a urine sample; different times of the day can alter the urine’s composition.

If you have any doubts about the test or its results, contact your physician. ◇

