

# The FDA Warns Against Use of Previously Owned Test Strips or Test Strips Not Authorized for Sale in the United States: FDA Safety Communication

## Date Issued

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## Audience

- People who use test strips to monitor for some diseases or health conditions, particularly people who use test strips with **Blood Glucose Meters** (<https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/glucosetestingdevices/default.htm>) or **Warfarin INR Test Meters** (<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/WarfarinINRTesMeters/default.htm>).
- Caregivers of people who use home use test strips.
- Health care providers who manage the care of people who use test strips.

## Medical Specialties

Internal Medicine, Nursing, General Practice, Endocrinology, Hematology, Cardiology

## Product

Test strips are part of many **home use tests** (<https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/homeusetests/default.htm>) that allow people to test for or monitor some diseases or health conditions at home. For example, a person with diabetes may apply blood to a test strip to measure their blood glucose (sugar) level or people on warfarin therapy may apply blood to a test strip to obtain their International Normalized Ratio (INR).

There are various at home tests that use test strips to monitor diseases or conditions, such as pregnancy or cholesterol.

## Purpose

The FDA is warning people who use test strips and their caregivers that using test strips from a previous owner (pre-owned test strips) or test strips not authorized for sale in the United States (U.S.) may lead to inaccurate test results, potentially cause infection, and should **not** be used.

Incorrect results from home use tests may increase the risk of serious patient injury, including death.

## Summary of Problem and Scope

The FDA is aware that some sellers are marketing pre-owned test strips or test strips not authorized for sale in the U.S. to consumers. These test strips may be sold through online marketplaces such as Amazon, eBay, and Craigslist, or directly from the seller.

Pre-owned test strips may not be safe to use because:

- The test strips may not be stored properly. For example, they may have been removed from their original packaging or not stored within the recommended temperature and humidity conditions. This could lead to inaccurate results.
- The expiration dates might have been changed or covered up. The use of expired test strips could lead to inaccurate results.
- The test strips may have been tampered with and could be damaged causing them to not work properly.
- If a user receives an inaccurate result from a test strip and uses this result as a basis for their treatment, they could take too much medication or not enough medication, potentially leading to serious patient injury, including death.
- The test strip vials may have small amounts of blood from the previous owner on them, which can put users at risk for infection.

Test strips that are not authorized for sale in the U.S. may not be safe to use because:

- They could be faulty or poor quality.
- Their ability to provide an accurate result is unknown. Certain test strips require review by the FDA prior to being authorized for sale in the U.S. to provide a reasonable assurance of safety and effectiveness of the test strips when used as intended. Test strips not authorized for sale in the U.S. have not been reviewed by the FDA, and their ability to provide an accurate result is unknown.
- If a user receives an inaccurate result from a test strip and uses this result as a basis for their treatment, they could take too much medication or not enough medication potentially leading to serious patient injury, including death.
- Test strips that are not authorized for sale in the U.S. are not following FDA requirements such as FDA reporting requirements. When manufacturers don't follow these requirements, the FDA may not become aware of product malfunctions or safety issues.

## Recommendations for People Who Use Test Strips

- Do not buy or use previously owned test strips. Look for signs that may indicate your test strips are pre-owned, for example:
  - Pre-owned test strips are often sold through online marketplaces such as Amazon, eBay, and Craigslist, or directly from another user.
  - The packaging of the test strip (for example the box or vial of test strips) may have been opened or the labels may have been removed. The test strips may have been moved from their original packaging to a different package or vial.
  - The expiration dates on the package, box, or vial may appear scratched off, changed, or tampered with.

- The packaging may look pre-owned, discolored, or otherwise second-hand.
- If you typically need a prescription (such as for test strips for use with warfarin INR meters), and the seller does not verify your prescription, beware. The seller could be selling test strips that pre-owned.
- Do not buy or use test strips that are not authorized for sale in the U.S. Look for signs that may indicate your test strips are not authorized for sale in the U.S., for example:
  - Test strips that are not authorized for sale in the U.S. are often sold through online marketplaces such as Amazon, eBay, and Craigslist, or directly from the seller.
  - If instructions are not in English or the strips look different than other strips from the same brand, this can be a sign of unsafe strips.
  - If you typically need a prescription (such as for test strips for use with warfarin INR meters), and the seller does not verify your prescription, beware. The seller could be selling test strips that are not authorized for sale in the U.S.
- Always buy unopened vials of test strips designed for your test meter through a trusted source such as your local pharmacy or through the test strip manufacturer. If you are unsure about where to buy safe test strips, talk to your health care provider or pharmacist.
- Talk to your health care provider, pharmacist, or test strip manufacturer if you cannot afford to buy the test strips recommended for use with your meter.
  - There may be patient assistance programs through test strip manufacturers or consumer advocacy organizations that help provide financial assistance to people who cannot afford to buy test strips. Some test strip manufacturers also offer coupons or prescription cards that may help reduce the cost.
- Some test meters used with test strips include a quality control check test that the user can run to make sure the test strips and meter are working properly together. If your test meter includes this, the FDA recommends that users regularly evaluate their home use test using the control solution. Read the test meter instructions for use to see how often you should test with control solutions.
- The FDA strongly discourages you from reselling or giving away your unused test strips because this may put the buyer at risk for infection or inaccurate results.

## Recommendations for Health Care Providers

- Talk to your patients about the risks of using pre-owned test strips or test strips not authorized for sale in the U.S.
- Talk to patients or caregivers about safe and affordable options such as patient assistance programs through test strip manufacturers or other consumer advocacy organizations.

## FDA Actions

The FDA is closely monitoring adverse event reports associated with this issue and will keep the public informed if significant new information becomes available.

## Reporting Problems to the FDA

If you experience an injury or problem with test trips, the FDA encourages you to file a voluntary report by phone at 1-800-FDA-1088 or online at [MedWatch, the FDA Safety Information and Adverse Event Reporting program](https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm) (<https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>). Please include the following information in your reports: