

# FDA Patient Safety News: Show #28, June 2004

## First Rapid Oral Fluid Test for HIV

FDA recently approved the first rapid HIV diagnostic test that uses oral fluids instead of blood. The OraQuick Rapid HIV-1/2 Antibody Test provides HIV-1 antibody results with over 99% accuracy in as little as 20 minutes. The test is manufactured by OraSure Technologies, Inc.

The original version of this rapid test was approved in 2002 to detect HIV-1 antibodies in blood samples. Since then, it's also been approved to detect HIV-2 in blood. But this latest approval is important because now oral fluid can be used to screen for HIV-1 antibody instead of blood.

The person being tested for HIV-1 takes the device, which has an exposed absorbent pad at one end, and places the pad above the teeth, against the outer gum. The person gently swabs completely around the outer gums, both upper and lower, one time around. The device is then inserted into a vial containing a solution. In as little as 20 minutes, the test device will indicate if HIV-1 antibodies are present in the solution by displaying two reddish-purple lines in a small window on the device.

Knowing that this test is available, people who are afraid of a needle stick or finger puncture might be less reluctant to be tested. And the risk of infection to healthcare workers performing the test is greatly reduced since they won't be exposed to blood.

The test is approved only for preliminary screening to help diagnose HIV infection, not to screen blood donors. And, as with all screening tests for HIV, if the OraQuick test gives a preliminary positive result, this must be confirmed with a more specific blood test.

### Additional Information:

FDA/CBER: Product Approval Information - OraQuick Rapid HIV-1/2 Antibody Test.

<http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm091919.pdf>

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## More Duragesic Patches Recalled

In an earlier program, we told you that one lot of DURAGESIC 75 mcg/h transdermal patches was being recalled by Janssen Pharmaceutica. The recall has now been expanded to include four more manufacturing lots. Recalled DURAGESIC 75 mcg/h patches now include lot numbers 0327192 (exp. 10/05); 0327193 (exp. 10/05); 0327294 (exp. 11/05); 0327295 (exp. 11/05); and 0330362 (exp. 12/05).

These patches deliver the opioid fentanyl, used to treat severe chronic pain. These lots are being recalled because of a concern that a small percentage of the patches may leak medication because of an improper seal along one edge of the patch.

If the medication leaks from the patch directly onto the patient's skin, overdosing may occur. This can cause nausea, sedation, drowsiness, or potentially life-threatening complications. Caregivers can also be exposed, so anyone who comes in contact with the leaked medication should rinse the exposed skin thoroughly with water. Don't use soap, because this could increase the drug's absorption through the skin.

Patients could also be underdosed as a result of a leaking patch. In an opioid tolerant patient, this can lead to withdrawal symptoms, such as sweating, sleeplessness and abdominal discomfort.

If you have any product with these lot numbers, stop using, administering or distributing it. Go to our web site to find Janssen Pharmaceutica's instructions on how to return the product, and on helping patients who may have the product. Or you can call Janssen directly at 1-800-Janssen.

### Additional Information:

FDA MedWatch Safety Alert - Duragesic (fentanyl transdermal system).

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm166410.htm>

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## Warning about Hyperglycemia and Atypical Antipsychotic Drugs

FDA has asked manufacturers of all atypical antipsychotic drugs to add a new warning to the drugs' labels about the increased risk of

hyperglycemia and diabetes. Atypical antipsychotics include: Clozaril ® (clozapine), Risperdal ® (risperidone), Zyprexa ® (olanzepine), Seroquel ® (quetiapine), Geodon ® (ziprasidone), and Abilify ® (aripiprazole).

Epidemiologic studies suggest that the risk of hyperglycemia and diabetes is increased in patients taking Clozaril, Risperdal, Zyprexa and Seroquel, although the relationship isn't completely understood. In some cases, the hyperglycemia was extreme and associated with ketoacidosis or hyperosmolar coma or death. Geodon and Abilify weren't marketed at the time the study was conducted.

For some patients, the hyperglycemia resolved when the drug was discontinued, but others required continuing treatment for their diabetes even after they stopped taking the drug.

The warning recommends that patients with diabetes who are started on atypical antipsychotics be monitored regularly for worsening of glucose control.

Patients starting on these drugs who have diabetes risk factors, such as obesity or a family history of diabetes, should have fasting blood glucose testing at the start of treatment and periodically thereafter.

And all patients treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, such as excessive thirst, excessive appetite, frequent urination, or weakness. If they develop symptoms of hyperglycemia while on these drugs, they should have a fasting blood glucose test.

**Additional Information:**

FDA MedWatch Safety Alert - Abilify (aripiprazole).  
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm153025.htm>

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## Recall of Certain Vitek Gram Positive Sensitivity Cards

Here's news about a recall of certain cards used for antimicrobial sensitivity testing. The product is the VITEK GPS-107 gram positive sensitivity card, manufactured by bioMerieux, Inc. and used with the company's VITEK system. Two lots are currently being recalled. Those lot numbers are M83X and B28E.

Some of these cards were stamped with an incorrect code, which could cause them to read and report the cards incorrectly. Inaccurate test results could lead to the choice of an ineffective antibiotic, with potentially life-threatening consequences.

FDA has asked the company to work with clinical laboratories to notify physicians who ordered this test about the problem. If you have VITEK GPS-107 cards in your facility from the recalled lots, you should stop using them and contact the company.

**Additional Information:**

FDA MedWatch Safety Alert: VITEK GPS-107 gram positive susceptibility cards.  
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm161337.htm>

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**Avoiding Errors with Parenteral Nutrition**

Parenteral nutrition can be a life-saving therapy, but it can also be especially vulnerable to errors. In a recent newsletter, the USP's Center for the Advancement of Patient Safety describes a wide variety of ways that errors can occur when prescribing, compounding, dispensing and administering these solutions.

USP points out that many health care facilities now have performance improvement programs to monitor the appropriate use of parenteral nutrition, the accuracy of orders, and complications from the procedure. But despite these improvement programs, errors continue to occur.

Let's start with prescribing errors. USP cites examples of incomplete orders that omitted a base solution or an essential component like protein, dextrose or electrolytes. Or, the order didn't specify a total volume or flow rate.

There are other kinds of prescribing errors. In one report, a neonate was prescribed parenteral nutrition containing less than 1% protein as well as both calcium and phosphorous electrolytes. Even though the pharmacy told the prescriber that the calculated protein wasn't high enough to prevent calcium phosphate from precipitating, the physician didn't change the order. So shortly after the parenteral nutrition was hung, precipitate formed in the solution. The infusion was stopped and the order changed. The patient wasn't harmed in this case, but precipitates of calcium phosphate are one of the most dangerous incompatibilities, and they've sometimes caused fatal embolisms.

Dispensing errors occur in preparing the parenteral nutrition, using automated compounding devices, and labeling the bag. And a significant number of errors can occur when administering parenteral nutrition. For example, an IV pump can be incorrectly programmed. USP cites a case where an infusion was supposed to occur at 80 mL/hour, but the IV pump was programmed for 802 mL/hour. The entire bag infused in only 2 hours and 45 minutes. The patient experienced muscle spasms and shortness of breath as a result of fluid overload, and had to undergo additional diuresis.

Sometimes parenteral nutrition can mistakenly be administered peripherally, when it was ordered as a central line infusion. In one report, a central hyperalimentation IV was administered through a peripheral line and ran for 42 hours before the error was discovered. The patient developed phlebitis at the IV site. Capillary blood glucose levels weren't monitored, and the patient's glucose level peaked at 331.

USP's article contains a number of recommendations to prevent these kinds of errors -- from suggestions on standardizing order forms to visually inspecting the formulation for particulates or phase separation.

**Additional Information:**

USP Patient Safety: CAPSLink (February 2004): Assessing the Safety of Parenteral Nutrition.  
<http://www.usp.org/pdf/EN/patientSafety/capsLink2004-02-01.pdf>

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**Advising Patients about Pregnancy Tests**

It's been estimated that about a third of U.S. women have used home pregnancy tests. They allow women direct access to highly sensitive and personal information, and because they can provide results quickly, these tests can give pregnant women an earlier opportunity to get prenatal care. Patients often ask about the accuracy of home pregnancy tests, and that can be a confusing issue.

Some of the tests are labeled as up to 99 percent accurate. But that's sometimes misunderstood by patients. It's important to understand that FDA judges the accuracy of these home pregnancy tests by comparing them to standard lab tests for pregnancy. FDA looks specifically at the test's ability to measure human chorionic gonadotropin, which is the standard marker for pregnancy. So when a home test is labeled "99 percent accurate," that means it's 99 percent as accurate as the standard lab test. It doesn't necessarily mean that the home test will detect pregnancy 99 percent of the time.

The actual ability to detect pregnancy in any particular woman could be lower than 99 percent, depending on the amount of hCG she's secreting. And that can depend on the stage of pregnancy, and on the woman's individual biology. And the tests vary in their

ability to detect low levels of hCG.

It's important to let patients know that there's a possibility of both false positive and false negative results with home pregnancy tests. Of course, the woman finds out about a false positive when she has a period, and she finds out about a false negative when she fails to have a period or shows signs of pregnancy.

The bottom line for patients is "Don't jump to conclusions." Most importantly, they shouldn't jump to the conclusion that they're not pregnant if they get a negative result. Until they know for sure that they're not pregnant, women should avoid behaviors that could harm a fetus, like smoking, drinking, poor nutrition, and taking certain medications.

**Additional Information:**

FDA Lab Safety Tip - Home Pregnancy Tests – How to Use a Popular Test Wisely.  
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109396.htm>

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## Teaching Patients about Counterfeit Drugs

We've had several stories over the past few months on the growing problem of counterfeit drugs, in which we've alerted health professionals about specific cases of counterfeiting and how to spot the counterfeit product. But there's a role for the patient in this fight against counterfeiting, too. A recent FDA report lists several steps that patients can take to help assure that they're not using bogus pills or medical devices.

Of course, in order to help identify a counterfeit drug or device, the patient first has to know what the genuine product is supposed to look like. But patients who use a particular product over a long period of time actually become quite expert on the way it should look, or taste, or smell. And that familiarity is the key to their being able to spot a counterfeit product.

The FDA report lists several things that patients should be instructed to look for. The most obvious is to tell the physician or pharmacist if the product looks or tastes or smells differently than the one they're accustomed to.

For a prescription medication, that difference could simply be due to the pharmacist's changing the brand. But it could also be due to counterfeiting, or possibly to a medication error, and both of those things should be reported.

The FDA report lists several other things that patients should report. First, they should report new or unusual side effects with a drug they're accustomed to taking. They should report a recurrence of their original symptoms despite taking the medication. And, if it's an injectable, they should report unusual pain or redness at the injection site.

**Additional Information:**

COMBATING COUNTERFEIT DRUGS - A Report of the Food and Drug Administration February 2004.  
[http://www.fda.gov/oc/initiatives/counterfeit/report02\\_04.html](http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html)

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