

**"FDA Questions Drug Store Tests for Sexually Transmitted Diseases"
New York Times (11.05.10):: Andrew Pollack**

On Thursday, the Food and Drug Administration sent a letter warning Identigene that its over-the-counter test to detect chlamydia and gonorrhea has not been approved by the agency. The product is being sold at most Rite Aid stores.

Steve Smith, Identigene's executive director, said the company has already responded to FDA. The test, developed by Gen-Probe, was previously approved, he said. "There's no reason for Rite Aid or anyone to discontinue selling the test," Smith said Friday.

The product is a urine collection kit that retails for \$20. The consumer mails the urine sample, along with a \$99 laboratory processing fee, to Identigene's lab. Results are made available two to three days after Identigene receives the sample, according to the Salt Lake City-based company.

However, FDA's director of in-vitro diagnostics, Dr. Alberto Gutierrez, said Friday that even Identigene's urine sample collection kit needs to be approved. In addition to the social implications of potential false results, FDA is concerned that people who test positive will not have access to a doctor. Identigene has contracted with doctors who will approve each test ordered and release the result, Smith said, but the company cannot ensure that doctors would talk to patients.

Chlamydia and gonorrhea diagnoses must be reported to CDC, and it is not clear who would be responsible for that with the home test.

FDA has been moving toward more oversight of tests offered directly to consumers, either through retailers or online. In addition, states can impose regulations; the Identigene test is not being sold in Rite Aid's New York stores.