



**NEW YORK CITY DEPARTMENT OF HEALTH AND
MENTAL HYGIENE**

Thomas R. Frieden, MD, MPH
Commissioner

HEALTH DEPARTMENT STATEMENT REGARDING RAPID HIV TESTING

NEW YORK CITY – June 22, 2008 – Oral testing increases the number of people who can get tested for HIV. Overall, less than a third of one percent – 0.3% – of the more than 130,000 oral tests performed at the Health Department’s STD clinics have yielded false positives. The FDA’s standard for HIV screening tests allows false positive rates of up to 2%.

Between October 2007 and April 2008, the Health Department documented a higher-than-usual percentage of false positive oral HIV tests in STD clinics, with the false-positive rate reaching 1.1% in some months. This rate is below the FDA threshold of 2% but higher than expected. A similar phenomenon was observed in December of 2005 but resolved within a few months. Data for the month of May 2008 showed that the oral test’s specificity (the accuracy of positive results) had returned to the usual level of 99.9% for the nearly 5,000 oral tests administered that month.

Some false positives are inevitable with any test, so any positive screening test must be confirmed with a second, more definitive test. In addition to a confirmatory lab test, which typically takes 3 to 5 days, anyone who receives a preliminary positive oral HIV test is also offered a rapid blood test before leaving the clinic. This identifies likely false positives, because rapid blood tests are slightly more accurate than those using oral fluid. If a rapid oral test is positive and the rapid blood test is negative, patients are told that the negative result is far more likely to be valid. All patients with positive rapid HIV tests are offered referral to HIV primary care.

Since October, 2007 an unusually large number of people have required two tests. The Department’s STD clinics switched to rapid blood tests while investigating the problem. The reason for slight increase in false positive tests is not clear, but the Health Department is working with CDC and the manufacturer to identify the cause. So far, false positive tests have not been linked to test kit handling, storage conditions, lot numbers, clinic sites or test operators.

OraSure’s rapid test can be performed with blood or oral fluid. Though the Health Department’s STD clinics have stopped testing oral fluid, they still use the rapid test to screen blood samples.

HIV testing in New York City remains safe, convenient, and highly accurate – and false positives are rare. The Health Department provided close to 60,000 HIV rapid oral tests in 2007 – twice the number given in 2003. Even with recent fluctuations in test performance at some Health Department STD clinic sites, the accuracy of rapid oral tests has remained well above 98% citywide.

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