



DEPARTMENT OF THE ARMY  
OFFICE OF THE SURGEON GENERAL  
5109 LEESBURG PIKE  
FALLS CHURCH, VA 22041-3258

REPLY TO  
ATTENTION OF

DASG-PPM-NC

24 MAR 2003

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Rapid HIV Antibody Testing Prior to Smallpox Vaccination for Deployment

1. This memorandum provides guidance on the use of the OraQuick® Rapid HIV-1 Antibody Test. This guidance applies when OraQuick® is considered for use in personnel who require HIV testing prior to receiving smallpox vaccine at deployment processing sites. Other rapid HIV tests developed in the future may be used IAW this guidance as long as such tests have equivalent or better performance characteristics, are approved by the FDA, and are waived from CLIA compliance by the FDA.
2. The OraQuick® test is a highly accurate test and has recently received a waiver from the Food and Drug Administration for compliance with Clinical Laboratory Improvement Amendments (CLIA) requirements. This waiver allows the test to be performed and interpreted in a physician's office or other settings without submission to a CLIA-certified laboratory.
3. Medical stations preparing soldiers for deployment will find this test of great value when a quick result is necessary. This situation occurs when a soldier must deploy within 4 or 5 days, requires smallpox vaccine, and the last HIV test result is more than two years old. In such a situation, use of a rapid test supports medical readiness and is warranted.
4. Because rapid HIV tests are 3 to 4 times more expensive than tests processed through our existing HIV force-testing contract and consume substantial local human resources, discipline is required in their use. Adhere to the guidelines in Enclosure 1. Particularly, assure primary reliance upon the HIV force-testing contract; use the rapid test for exceptional circumstances only. Comply with the FDA requirement to provide individuals with the "Subject Information" pamphlet (Encl 2). Include this test as part of the "Point of Care" testing program managed by your supporting laboratory. Assure that results are posted in the health record and that a separate blood specimen is concurrently submitted through the standard force-testing channels.
5. My POC for this guidance is COL Jeffrey D. Gunzenhauser at: Commercial (703) 681-3160, DSN 761-3160, or email Jeffrey.Gunzenhauser@otsg.amedd.army.mil.

- 2 Encls
1. Info Paper - Guidelines
  2. "Subject Information" pamphlet

JAMES B. PEAKE, M.D  
Lieutenant General  
The Surgeon General

DASG-PPM-NC

SUBJECT: Rapid HIV Antibody Testing Prior to Smallpox Vaccination for Deployment

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## Information Paper

SUBJECT: Guidelines - Rapid HIV Antibody Testing Prior to Smallpox Vaccination for Deployment

1. References.

a. AR 600-110, Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus (HIV), 1 June 1996.

b. Centers for Disease Control. Notice to readers: approval of a new rapid test for HIV antibody. MMWR 2002;51(46):1051-1052, 11 November 2002.

c. Food and Drug Administration waiver from Clinical Laboratory Improvement Amendments at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Detail.cfm?ID=26002> - 1 January 2003.

2. This guidance applies only to situations in which OraQuick® is considered for use in personnel who require HIV testing prior to receiving smallpox vaccine at deployment processing sites.

3. Background.

a. Infection with HIV is a serious condition. Failure to identify infected persons prior to receiving live virus vaccines, including smallpox vaccine, may lead to serious adverse reactions. Conversely, inaccurate labeling of a person as "HIV-infected" when this is not true can have serious, immediate health and social consequences and may inappropriately affect soldier deployment. Consequently, accurate diagnosis of HIV infection is extremely important.

b. HIV test results must be verified prior to live virus vaccine administration. Per reference 1.a. above, live virus vaccines (including smallpox vaccine) may be administered provided there is a record of a previous negative HIV test within the preceding 24 months.

c. In November 2002, OraQuick® was licensed by the Food and Drug Administration (FDA) to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1). On 31 January 2003, the FDA waived compliance with Clinical Laboratory Improvement Amendments (CLIA) requirements. This waiver allows this test to be performed and interpreted in a physician's office or other settings without submission to a CLIA-certified laboratory. OraQuick® is a highly accurate test, with an estimated sensitivity of 98.5% - 99.9% (ie, rare false negatives) and an estimated specificity of 99.7% - 100% (ie, extremely rare false positives).

4. Criteria for use. In order to allow timely administration of smallpox vaccine prior to deployment, the OraQuick® test may be used as a supplement to routine contract-supported HIV testing when the following criteria are met:

- a. The individual is required to receive smallpox vaccine prior to deployment.
- b. The individual is scheduled to deploy OCONUS within 5 days.
- c. The individual has received and read the "Subject Information" pamphlet (enclosure) prior to specimen collection.
- d. The testing site is prepared to notify and counsel individuals IAW reference 1.a. in the event of a positive test.

Encl 1

SUBJECT: Guidelines for the Use of Rapid HIV Antibody Tests

e. The senior medical officer supporting the medical processing section has determined that the HIV support contract cannot meet the individual's requirements and approves the use of the rapid HIV test.

f. The senior medical officer has ensured that staff are adequately trained to perform the Rapid HIV-1 Antibody Test and are under the auspices of the Point Of Care (POC) testing program managed by the supporting laboratory.

5. Other requirements.

a. If the OraQuick® test is used, smallpox vaccine will only be administered after a negative result is obtained.

b. Results of the OraQuick® test will be posted in the individual's health record.

c. The OraQuick® test will be used only on an "exceptional" basis. Medical sections providing support to deployment processing stations will use existing support contracts to the maximum extent possible, including testing prior to live virus vaccination. Existing HIV antibody testing contracts have a superior record of testing accuracy. The vast majority of deploying personnel who require pre-vaccination HIV tests can be tested through these contracts. Medical sections providing support should ensure the smallpox and other immunizations are planned greater than 72 hours from the time of the shipment of the HIV specimens to the existing contract laboratory. Direct coordination with deploying unit commanders to provide adequate time between HIV specimen collection and immunizations is required. Only when the unit commander and the senior medical officer determine planning cannot meet this requirement, will the rapid test be used.

d. Whenever the OraQuick® test is used, concurrently submit a blood specimen for HIV antibody testing through existing support contracts. This assures that HIV test results are recorded at the Army Medical Surveillance Activity and in MedPROS. Also, assuming concurrence of OraQuick® with standard HIV testing, this assures that positive OraQuick® tests are confirmed by Western Blot.

e. The senior medical officer will ensure that adequate staff are available to prepare HIV samples for shipment to the contracting laboratory on the same day of collection but no longer than 24 hours after collection. The senior medical officer will also work with the contracted lab or the contracting officer to ensure all means possible for the quickest return of results are provided. In some cases, other local contracting or local MTF automated testing can be approved to minimize use of rapid testing at SRP sites. Any results taking over 72 hours from the time of collection to the time of results should be reported immediately to the contracting officer representative by the senior medical officer.

f. Processing stations will write a local SOP for the management of personnel with "positive" OraQuick® test results. This SOP will be coordinated with the Preventive Medicine Officer at the supporting medical treatment facility.

g. Point-of-Care Testing. The laboratory POC team will monitor the testing on a daily basis. Any deviation from the standard operating procedures and the manufacturer's testing guidelines will result in immediate suspension of the rapid test. The POC team will ensure all staff performing the test have been trained to perform the test and training and competency assessments are documented. Any deviations will be reported immediately to the senior medical officer.

COL Gunzenhauser, (703) 681-3160



## SUBJECT INFORMATION

### What You Should Know About HIV and the OraQuick® Rapid HIV-1 Antibody Test Prior to Being Tested

#### ■ What should I know before I get tested?

Your healthcare provider is the best person to answer your questions about HIV, the OraQuick® Rapid HIV-1 Antibody Test, and other testing options.

You have a choice of the type of test to use. When you are tested for HIV, a specimen will be collected and checked for HIV antibodies. The presence of HIV antibodies in your body means that you have been infected with the virus that causes AIDS.

You should be aware that the presence of HIV antibodies can be detected in many ways. Ask your healthcare provider for the information you need to make good choices. Some questions answered in this pamphlet are:

- What are HIV and AIDS?
- How does someone get HIV?
- How can I avoid becoming infected?
- Why should I get tested?
- What is the OraQuick® Rapid HIV-1 Antibody Test and how is it done?
- What does a preliminary positive result mean?
- What does a negative result mean?
- Where can I get more information?

#### ■ What are HIV and AIDS?

HIV is the human immunodeficiency virus. HIV is the virus that causes AIDS (acquired immunodeficiency syndrome). It is possible for a person to have the virus for months or years before any signs of illness appear. The virus weakens the body's ability to fight off infections. As a result, people with AIDS develop serious infections and cancers. These illnesses make them very sick and can eventually kill them.

#### ■ How does someone get HIV?

HIV spreads through contact with blood, semen, vaginal fluids, or breast milk from infected people. Contact can come from unsafe sex. It can also come from sharing used needles and syringes. Infected women can pass the virus to their babies during pregnancy, childbirth, and breast feeding. It is also possible to become infected with HIV through a blood transfusion, although this is now very rare.

People do not become infected with HIV through everyday casual contact with people at school, work, home, or anywhere else. The virus is not spread from contact with

sweat, tears, saliva, or a casual kiss from an infected person (deep, or "French" kissing is not advised). Nor can people become infected from contact with forks, cups, clothes, phones, toilet seats, or other things used by someone who is infected with HIV. People do not become infected from eating food prepared by an HIV-infected person. People have not become infected with HIV through insect bites.

#### ■ How can I avoid becoming infected?

The best way to avoid getting HIV is to avoid activities that would allow the virus to be passed to you. By following these suggestions, you will lower your risk of getting HIV:

- The only way to avoid sexual exposure to HIV is to have sex with an uninfected partner or to abstain.
- If you are not certain that your sex partner is uninfected, you should use a latex condom correctly every time you have sex.
- Do not share needles or syringes.

#### ■ Why should I get tested?

You cannot generally tell by looking at someone whether he or she has an HIV infection. A person can be infected with HIV and not know it. The virus may take time to show its effects. A person can have HIV for ten years or more before the symptoms of AIDS appear. The only way to be confident that you are not infected is to get an HIV test.

It is important to find out if you are infected with HIV so that you do not infect someone else. If you know you are infected with HIV, you can avoid any activity that may pass it on.

It is also important to find out if you are infected with HIV so that you can receive good medical care. There are medicines that can help keep you healthy even though you are infected with the HIV virus.

#### ■ What are my options for HIV testing?

OraQuick® provides a rapid HIV test result (in as little as 20 minutes) and in some settings a result is needed quickly, such as in hospital emergency rooms. However, in settings where a rapid HIV test is not needed, alternative tests can be done. You also have a choice of having another type of test that would require you to wait about a week for your results. This type of test can be done using a sample of blood taken from your vein, a sample of oral fluid taken from your mouth, or a sample of urine.

#### ■ What is the OraQuick® Rapid HIV-1 Antibody Test and how is it done?

The OraQuick® Rapid HIV-1 Antibody is used to see if a sample of your blood contains HIV antibodies. If you decide to have an OraQuick® test, your healthcare provider will take a small droplet of blood from your finger, run the test, and give the results to you

during the same visit. The OraQuick® test is very accurate. However, additional testing is necessary to confirm a preliminary positive result.

Complete information about the OraQuick® Rapid HIV-1 Antibody Test device is available from your testing counselor or healthcare provider.

#### ■ What does a PRELIMINARY POSITIVE result mean?

A PRELIMINARY POSITIVE result suggests that antibodies to HIV may be present in your blood. If you receive a PRELIMINARY POSITIVE result on the test, you will need to have another test to confirm the OraQuick® test result. You will also be encouraged to take precautions to avoid any chance of spreading HIV until your test result is confirmed.

If you are found to be infected, you may benefit from special medical care. New treatments can help keep you healthy, even though you are infected with HIV. See a doctor, even if you don't feel sick. A doctor can help you to live longer. Other tests can tell you how strong your immune system is and what treatments might be best for you. Some people stay healthy for a long time with HIV. Others may become ill more rapidly. Be careful not to pass HIV on to others.

#### ■ What does a NEGATIVE result mean?

A NEGATIVE result means that this test did not detect HIV antibodies in your blood. However, in some cases HIV infection cannot be ruled out completely. If you recently (within 3 months) had any of the contacts described in the "How does someone get HIV?" section of this pamphlet it is still possible that you are infected with HIV. This is because your body can take several months after you are infected to make HIV antibodies. If you became infected only recently, there may not have been enough time to develop antibodies that can be detected by the test. You should consider getting tested again in three to six months to be sure you are not infected. If you had none of the contacts that transmit HIV in the three months before your test, a negative test result means you were not infected with HIV at the time of testing. Ask your healthcare provider to help you understand what your result means for you.

#### ■ Where can I get more information?

If you have any questions, ask your healthcare provider. You can also call the National AIDS Hotline at 1-800-342-AIDS (1-800-342-2437) to talk with an HIV specialist. They can give you quick, private answers at any time, day or night. Your local health department is another place to go for information. An AIDS service organization near you can also be a good source for information, education, and help.

The OraQuick® Rapid HIV-1 Antibody Test is manufactured by:



**OraSure Technologies, Inc.**

*diagnostic solutions for the new millennium*

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[www.orasure.com](http://www.orasure.com)

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