

RAPID HIV TESTING IN SUBSTANCE ABUSE TREATMENT FACILITIES

Rapid HIV tests are screening tests used to detect HIV infection. These tests provide negative results and preliminary positive results in minutes, compared with traditional or conventional HIV test results that can take 1 to 2 weeks to obtain. The faster availability of HIV test results enables substance abuse treatment providers to more quickly provide appropriate referrals for HIV treatment for clients. This *Advisory* contains basic, introductory information about the benefits of and requirements for incorporating rapid HIV testing (RHT) into substance use disorder (SUD) treatment programs. Additional sources of information are included on page 7.

Why Test for HIV in SUD Treatment?

People entering substance abuse treatment are at high risk for having HIV infection. For example, in 2006, people who injected drugs accounted for 18.5 percent of people infected with HIV (15.9 percent of men and 26.3 percent of women).¹ Further, most heterosexual transmission, as well as transmission between men having sex with men, involves alcohol or drug use. Testing in an SUD treatment facility provides an opportunity to address the broad role of alcohol and drug use that places people at risk for HIV transmission and provides those people with prevention counseling. The Centers for Disease Control and Prevention (CDC) estimates that approximately 20 percent of Americans who are HIV positive are unaware of their infection.² However, the CDC revised its HIV testing and counseling recommendations in 2006 to include testing of all adults (especially pregnant women) and adolescents during routine medical care.³ Despite clients in SUD treatment being at higher risk of having HIV infection than is the general population, less than 30 percent of SUD treatment facilities reported testing for HIV.⁴ Hospital inpatient treatment facilities (79 percent) are reported to be more likely than nonhospital residential

facilities (41 percent) or outpatient treatment facilities (24 percent) to provide HIV testing.⁴ Facilities that provide medication-assisted treatment for opioid use disorders and hospital-based treatment facilities have higher rates of testing than do other types of SUD treatment facilities, such as those that provide intensive outpatient treatment.

What Is Rapid HIV Testing?

Rapid HIV tests are Food and Drug Administration- (FDA-) approved HIV diagnostic devices that provide test results in less than 20 minutes, upon applying the sample to the device. These devices are typically small in size, thus portable, and their operation does not necessitate sophisticated instrumentation. The devices can be used in SUD treatment facilities, healthcare and HIV outreach clinics, needle-exchange programs, healthcare providers' offices, sexually transmitted disease clinics, perinatal clinics, emergency departments, and other venues. Sophisticated instrumentation is not needed to perform the tests. Depending on which RHT device is used, negative and preliminary positive test results can be obtained in 20 to 40 minutes. Negative results are considered final, except during the *window period*. This is the period after infection but before antibodies can be detected by an HIV test. It varies from approximately 8 to 12 weeks, depending on the type of test.⁵ If the person could be in the window period, another sample should be taken at the confirmatory facility after a few weeks to allow HIV antibodies to mature. People at high risk—such as those who inject drugs—need to be tested annually³ and people who think they may be in the window period need to be retested.

What Are the Benefits of RHT?

Increased access to HIV services

Much HIV testing is performed using a traditional laboratory test, which requires the person to return a

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In the recent Substance Abuse and Mental Health Services Administration- (SAMHSA-) funded Targeted Capacity Expansion Program for Substance Abuse Treatment and HIV/AIDS Services (TCE/HIV) awards, grant recipients were required to offer all clients rapid HIV preliminary antibody testing during outreach, pretreatment, or program enrollment. Data collection is ongoing and includes obtaining information on type of treatment site (e.g., inpatient, outpatient), treatment population demographics (e.g., gender, ethnicity, race, age), prior HIV testing history, reasons for taking or refusing HIV testing, rapid HIV test results, confirmatory HIV test results, and type of services provided.

Between November 2009 and August 2010, 3,692 TCE/HIV grantee clients were tested for HIV. Client information was coded and entered into a secure database to ensure client HIV information remained confidential. Preliminary findings indicate that 6.7 percent (248 clients) of those tested were HIV positive (SAMHSA Unpublished Data, 2010). Of those who were HIV positive:

- 37.1 percent reported any drug or alcohol risk behavior in the last 30 days.
- 27.4 percent reported cocaine use in the last 30 days.
- 23.0 percent reported marijuana use in the last 30 days.
- 22.2 percent reported alcohol use in the last 30 days.
- 14.1 percent reported having sex while under the influence of drugs and/or alcohol in the last 30 days.

few weeks later to receive the results. Thirty to 40 percent of those tested with the traditional HIV test do not return to receive their test results.⁶ Often, those who do not return are those at high risk of HIV infection.⁷ Because RHT provides negative and preliminary positive results on the same day, more people receive their test results than if tested using the traditional method. Fewer people are lost to HIV testing followup, even if they drop out of SUD treatment. In a comparison of clients who were tested using traditional tests with clients who were tested using RHT devices, a meta-analysis found that those tested with RHT were 1.5 to 2.2 times more likely to receive their HIV test results.⁸ Therefore, RHT may increase the number of individuals who become aware of their HIV status and receive HIV counseling, education, and medical care.^{6,9}

Prevention of late diagnosis of HIV

An HIV diagnosis is considered late if a person is diagnosed with AIDS less than 1 year after the date of the HIV diagnosis.¹⁰ Between 2004 and 2006, approximately 40 percent of people who injected drugs and who were also unknowingly infected with HIV received late diagnoses.¹⁰ AIDS is a consequence of HIV infection and represents a late stage of disease progression. Consequently, late diagnoses delay and complicate medical treatment and result in worse treatment outcomes, including a reduction in life expectancy.¹⁰

HIV infection disproportionately affects different ethnic and racial populations in the United States. Among the estimated number of people with HIV infections, African Americans,

Hispanic Americans, and American Indians/Alaska Natives had higher rates of infection in 2006 than Caucasian or Asian/Pacific Islander Americans.¹ In addition, people receiving late diagnoses were also disproportionately from these minority groups.¹¹ These populations traditionally have less access to medical and preventive care, including HIV testing. RHT may increase access to HIV treatment by increasing the number of people who can determine their HIV status. RHT can be easily offered in nontraditional settings (e.g., SUD treatment and outreach clinics) and offer more opportunities for testing to people who are underserved medically.¹¹

Improved SUD treatment outcomes

Determining a client's HIV status while the person is in SUD treatment may have several benefits. Clients will be informed about their preliminary HIV status and, if needed, offered additional testing, counseling, and treatment. Such treatment could be enhanced and made more effective by taking into account the client's HIV status and tailoring SUD treatment for those who are receiving HIV-treatment medications.

Prevention of adverse medication interactions

Some clients entering SUD treatment do not reveal that they are receiving treatment for HIV/AIDS, possibly because of the fear of a negative reaction. However, this information helps the healthcare provider choose appropriate SUD medication and dosages that may help a client avoid adverse interactions between HIV and SUD medications (e.g., methadone).^{12,13}

Improved satisfaction with the HIV testing process

RHT has been shown to be acceptable to clients and counselors. In a study of 1,610 clients at a community-based clinic that offered RHT and traditional HIV testing, 91 percent of the clients chose RHT. Both counselors and clients were more satisfied with the RHT experience than the traditional testing experience.¹⁴ Other studies have found similar levels of acceptance for RHT.^{15,16} The anxiety experienced by clients while waiting several days for traditional HIV test results is also lessened.

Improved HIV treatment outcomes

Without antiretroviral medications for HIV, most people infected with the virus will progress to AIDS in approximately 10 years.⁹ RHT can help determine the presence of antibodies after infection and before the development of AIDS and can facilitate early referral for diagnosis and medical care, preventing unnecessary morbidity and mortality.

Improved HIV/AIDS prevention

Because RHT can increase the number of people who know their HIV status, it can help reduce HIV transmission. There is some evidence that knowing one's HIV status results in a decrease in risky behaviors.¹⁷ One study found that behavior change was motivated by concerns about infecting others and that the initial diagnosis of HIV promoted behaviors that reduced the risk of infecting others, at least in the early stage of the infection.¹⁸ For pregnant women in SUD treatment who have not received routine prenatal care, screening for and identifying and treating HIV infection can help prevent perinatal transmission.³ Once a person is diagnosed and receiving antiretroviral therapy, the risk of HIV transmission is lessened.¹⁹

What Regulations Exist About RHT?

The FDA has approved seven RHT devices to date (Exhibit 1). RHTs are considered point-of-care tests (POCTs) because the sample is collected from the client and the test is performed at the same location. The sample does not need to be sent for testing at another facility, such as a laboratory.

To use POCTs legally in settings without a certified laboratory, treatment programs need to use tests that have

Exhibit 1. Information Sources: FDA-Approved RHT Devices

FDA-Approved Rapid HIV Antibody Screening Tests (comparison chart)

<http://www.cdc.gov/hiv/topics/testing/rapid/rt-comparison.htm>

FDA-Approved Rapid HIV Antibody Screening Tests—Purchasing Details

<http://www.cdc.gov/hiv/topics/testing/rapid/rt-purchasing.htm>

Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays

<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/UCM080466.htm>

been granted a Certificate of Waiver under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. CLIA classifies tests according to accuracy and reliability, and complexity of performing the test. To receive a CLIA waiver, a test must:

- Use direct, unprocessed specimens (e.g., urine, whole blood, oral fluid).
- Be easy to perform.
- Have a small chance of error.

People who do not have formal laboratory technology training can use CLIA-waived testing devices. Not all FDA-approved RHT devices have received CLIA waivers, however. Exhibit 2 provides information sources about CLIA waivers.

To administer POCTs, facilities must register with the Centers for Medicare & Medicaid Services (CMS) and become CLIA-certified. To use RHT devices, facilities must also comply with basic fundamentals of HIV/AIDS training as mandated by individual States and with State regulations for HIV counseling, testing, and referrals. State laws differ

Exhibit 2. Information Sources: CLIA Waivers

CLIA Certificate of Waiver Fact Sheet

<http://www.cdc.gov/hiv/topics/testing/resources/factsheets/roltCLIA.htm>

How to Obtain a CLIA Certificate of Waiver

<https://www.cms.gov/CLIA/downloads/HowObtainCertificateofWaiver.pdf>

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regarding who may perform these services and who may disclose an individual's HIV status to others. Trained service providers need to maintain a copy of their State's compliance documentation on RHT. The National HIV/AIDS Clinicians' Consultation Center provides information on each State's HIV testing laws and policies in its 2011 Compendium of State HIV Testing Laws (http://www.nccc.ucsf.edu/consultation_library/state_hiv_testing_laws).

How Is Testing Done With RHT Devices?

RHT kits include all of the necessary items to perform the test, including the testing device, reagents, specimen-collection device, step-by-step instructions for performing the test, and an information sheet for clients. In some kits, the specimen-collection device is also the testing device. Broadly speaking, if present in the specimen, anti-HIV antibodies produced by the body's immune system in response to the presence of HIV infection will cause a color change on the device. This change in color on the testing device indicates whether the test is reactive to antibodies (preliminary positive) or is nonreactive (negative). The testing device must be read within a strict timeframe to be accurate. The timeframe is different for each device, and the information is included in the kit.²⁰ For more specific information on performing the test and result interpretation, the package insert specific to each test must be consulted closely. If the result is reactive, or a preliminary positive, the rapid test must be followed by a confirmatory test (see Confirmatory testing of a positive RHT result).

When choosing an RHT device, each facility should decide which device best fits its program. CMS provides information on CLIA-waived testing devices (see Exhibit 2). RHT devices that are currently waived by CLIA use oral fluid or whole blood as the testing sample. Oral fluid is collected from the gums; the procedure for taking blood samples varies. The specimen is then placed into the designated area in the testing device.^{20,21} The person administering the test must follow infectious-disease precautions (e.g., wearing gloves) and dispose of biohazardous materials properly. The National Institute for Occupational Safety and Health provides information on

biohazardous waste disposal and ensuring safety of staff at <http://www.cdc.gov/niosh/docs/88-119/waste.html>.

Medical personnel can perform specimen collection and testing, as well as provide HIV counseling, if they are on staff at the treatment facility. However, counselors and paraprofessionals without medical background, but who receive training, can collect specimens, administer and read tests, provide pretest and posttest counseling, and document test results. Training must include specimen collection, test administration, reading of results, documentation, quality control procedures, client interactions, and HIV-test counseling procedures. Knapp and colleagues²² developed a training program for paraprofessionals to perform RHT in nonclinical settings and found that testing by paraprofessionals was cost-effective and freed highly trained healthcare staff to work with clients already identified as HIV positive. In another study, AIDS counselors successfully performed RHT and counseling services after receiving appropriate training.²³ When implementing an RHT program, a facility can decide which staff members will administer the test and counsel clients according to the program's needs and staffing patterns.

Confirmatory testing of a positive RHT result

A preliminary positive RHT result must be followed up soon with a laboratory confirmatory test that is performed by highly trained personnel.²¹ Confirmatory testing can be done on blood or oral fluid specimens, although blood specimens have higher accuracy than oral fluid specimens.²¹ The client is told that the positive result is preliminary and that additional laboratory testing is needed. The client must understand that the result is the initial screening result and is not definite. If possible, a vial of blood is drawn from the client at the facility and sent to a laboratory. If the facility does not have medical personnel to draw a blood specimen, the client needs to be referred elsewhere for confirmatory testing. Having the ability to collect specimens for confirmatory testing at the treatment facility may improve followup because some clients may not go for confirmatory testing as asked. Client refusal of confirmatory testing should be documented. In traditional HIV testing, the sample that initially tests HIV positive is retested using different types of tests to confirm the findings. Thus, RHT provides a preliminary positive

result, while traditional testing represents a sequence of tests that provides the final result. Due to these testing procedures and other considerations, obtaining results from traditional HIV testing takes longer (1 to 2 weeks) compared with RHT.

If the test result is positive, the person is considered to be infected with HIV, but it does not necessarily mean the person has AIDS. A diagnosis of AIDS is not based only on the detection of HIV infection, but on several other factors as well, such as blood counts and the presence of HIV-related illnesses.

Discordant test results

If the laboratory confirmatory test result of a positive RHT is negative or indeterminate, it is considered a discordant test result—that is, one that does not agree with the RHT result. Another laboratory test needs to be performed using a new specimen to determine the person's HIV status. However, in one large study of people with discordant HIV test results, only one-half followed through with the repeat testing. Of those who did, nearly one in five was infected with HIV.²⁴

What Procedures Are Needed to Implement RHT?

The SUD treatment facility needs to develop policies and procedures for conducting RHT. These policies need to include mechanisms to ensure that the facility meets all applicable Federal, State, and other regulatory requirements.

Quality assurance plan

To conduct RHT, a facility must develop a quality assurance (QA) plan²¹ (Exhibit 3). The QA plan should address records management, self-monitoring protocols, and test reliability and validity. The plan should identify QA monitors (e.g., senior staff members, consultants, supervisors) who identify breaches in procedures, ensure that testing mistakes are followed by appropriate corrective actions, and ensure that external controls are performed (see External control testing). Once the QA plan is in place, all appropriate staff members need to be trained and evaluated in adhering to procedures. Communication mechanisms are needed for reporting QA issues so that they can be rectified. If more than one staff member makes

Exhibit 3. Information Sources: Quality Assurance

Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988

http://www.cdc.gov/hiv/topics/testing/resources/guidelines/pdf/qa_guidelines.pdf

Provisional Procedural Guidance for Community Based Organizations

http://www.cdc.gov/hiv/topics/prev_prog/ahp/resources/guidelines/pro_guidance/index.htm

a particular error there may be a need for retraining or changes in training.²⁵

According to the CDC²¹ if confirmatory specimens are collected onsite, the facility needs to establish procedures for:

- Collecting, labeling, processing, storing, and documenting specimen transfer. The referral laboratory test requisition should note that the specimen is from a person who has had a preliminary positive rapid test result.
- Transporting the confirmatory test specimens to the laboratory.
- Obtaining confirmatory results from the laboratory.
- Informing the client of the confirmatory test result.
- Reporting confirmed positive HIV test results to the State health department, as required.

External control testing

All RHT programs require periodic external control testing to ensure that tests are being administered correctly. External control testing kits are available from the manufacturer of the RHT kit chosen by the facility. The kits include known reactive and nonreactive liquid samples (controls); these control samples are surrogate samples used to evaluate the integrity of the test system and whether the person administers the test correctly.²¹

A staff member very familiar with testing procedures performs external control testing. This testing is done^{20,21}

- When a staff person is being newly trained to administer the tests.
- On receipt of a new shipment of test kits to determine whether the devices are working correctly.

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- When a new lot of test kits is opened to determine whether the devices are working properly.
- When the temperature of the storage or testing area falls outside the recommended range to determine whether the devices are still working properly.
- At periodic intervals determined by the testing facility, usually based on the volume of testing.

Client information and linkages to care

FDA requires that people who undergo RHT receive an information sheet, which is included in the test kits. The sheet includes basic information about HIV/AIDS, how the test works, and the meaning of the results; it also emphasizes that a preliminary positive result needs to be confirmed by a standard laboratory test.²⁰

Unless HIV treatment is provided at the SUD treatment facility, memoranda of understanding between the treatment facility and local HIV treatment and other providers are needed so that clients needing medical care can be referred. Possible referral sites include local health departments, AIDS service organizations, HIV/AIDS behavioral health care services, HIV/AIDS medical clinics, and support services (e.g., housing, food, transportation). Case managers may be needed to ensure that clients receive necessary information to access those referrals and other linkages to care.

What Kind of Counseling Do Clients Need?

To maintain confidentiality, a private environment is needed for pretest and posttest counseling and for specimen collection. According to the CDC²⁶, HIV counseling for RHT consists of two parts: (1) providing information to the client about testing, and (2) HIV prevention counseling. All clients must receive information about the test and the voluntary nature of consenting to testing. Clients need to give informed consent for testing (whether the consent is separate or part of a general consent for treatment). HIV prevention counseling addresses prevention of transmission of HIV by emphasizing that the client change his or her behavior to reduce risk factors for transmission of HIV infection.

People providing counseling should stress that positive test results are preliminary.²⁶ The manner in which test results

are delivered can affect the client's reaction and actions afterward (e.g., seeking a confirmatory test for a positive RHT result, seeking treatment, changing risky behaviors). Delivering and receiving results can be stressful, and those providing counseling should be carefully prepared for the task. Clients with negative results should receive HIV prevention messages to avoid infection. Clients with preliminary positive results need counseling on the importance of obtaining confirmatory test results and reassurance that medical treatment and other services are available. This is a stressful time for clients, particularly the waiting time between the preliminary positive HIV test result and when the findings from the confirmatory test are determined. Therefore, a referral for mental health counseling may be appropriate to supplement the SUD treatment the client is receiving.

If the confirmatory test result is positive, the client needs to be provided linkages to facilities that offer medical evaluation and treatment. The client needs to be told about the importance of staying in SUD treatment, achieving a healthful lifestyle, methods to prevent infecting others, and how HIV/AIDS and the anti-HIV medications may affect other medical problems. Substantive and detailed information about counseling is critical, but a thorough description is beyond the scope of this document. Exhibit 4 includes sources of information about HIV counseling and HIV prevention.

Exhibit 4. Information Sources: HIV Counseling and Prevention

HIV Counseling With Rapid Tests

http://www.cdc.gov/hiv/topics/testing/resources/factsheets/rt_counseling.htm

Comprehensive Risk Counseling and Services Implementation Manual

http://www.cdc.gov/hiv/topics/prev_prog/CRCS/resources/CRCS_Manual/pdf/CRCS-Impl-Manual.pdf

CDC's RESPECT-2 Counseling Web Site

<http://www.cdc.gov/hiv/topics/research/respect-2/counseling/index.htm>

2009 Compendium of Evidence-Based HIV Prevention Interventions

<http://www.cdc.gov/hiv/topics/research/prs/evidence-based-interventions.htm>

Treatment Improvement Protocol (TIP) 37: *Substance Abuse Treatment for Persons With HIV/AIDS*

<http://www.ncbi.nlm.nih.gov/books/NBK14660>

Resources

Centers for Disease Control and Prevention, National AIDS Hotline

1-800-CDC-INFO (1-800-232-4636) (English and Español)
TTY: 1-888-232-6348

Centers for Disease Control and Prevention, Rapid HIV Testing

<http://www.cdc.gov/hiv/topics/testing/rapid>

Health Resources and Services Administration, HIV/AIDS Programs

<http://hab.hrsa.gov>

National AIDS Treatment Advocacy Project

<http://www.natap.org>

National Alliance of State and Territorial AIDS Directors

<http://www.nastad.org>

National Association of People With AIDS

<http://www.napwa.org>

National Association of State Alcohol/Drug Abuse Directors

<http://nasadad.org>

National Association of State Mental Health Program Directors

<http://www.nasmhpd.org>

National HIV/AIDS Clinicians' Consultation Center

<http://www.nccc.ucsf.edu/home>

National Institute of Allergy and Infectious Diseases

<http://www.niaid.nih.gov/topics/hivAIDS/understanding/Pages/Default.aspx>

National Institute on Alcohol Abuse and Alcoholism

<http://www.niaaa.nih.gov>

National Institute on Drug Abuse

<http://hiv.drugabuse.gov>

Office of Minority Health

<http://minorityhealth.hhs.gov>

Substance Abuse and Mental Health Services Administration Publications

<http://store.samhsa.gov/facet/issues-conditions-disorders/term/HIV-AIDS>

Substance Abuse and Mental Health Services Administration, Rapid HIV Testing Initiative

http://www.samhsa.gov/hivhep/rhti_factsheet02.aspx

Notes

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