

OraQuick Rapid HIV Testing Guidelines

Policies, Procedures and Quality Assurance

Supplement to:

**HIV Counseling and Testing Guidelines,
Policies and Recommendations (1997)**

California Department of Health Services
Office of AIDS



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Introduction

This manual is intended to provide guidance to California Department of Health Services/Office of AIDS (DHS/OA) HIV Counseling and Testing (C&T) sites performing the OraQuick rapid HIV testing procedure. This document outlines policies and procedures for conducting OraQuick Rapid HIV testing, including procedures for provision of counseling and testing services, quality assurance, and safety.

Guidelines in this manual are designed to meet California legal requirements and quality assurance standards for waived HIV-testing in DHS/OA C&T sites; significant deviation from these guidelines could result in violation of federal or state legal requirements. ***A copy of this document should be readily available to all counseling and testing personnel for immediate reference.***

These guidelines are intended to supplement existing policies and procedures outlined in HIV Counseling and Testing Guidelines, Policies and Recommendations (1997). Please refer to the original guidelines for issues not covered in this supplementary document.

How to Use This Document

In addition to guidelines for procedures and quality assurance activities, this document contains an appendix with several useful forms that may be used as-is or modified to meet local needs. Before implementing rapid HIV testing in any setting, the Site Preparation Checklist must be completed and on file with the counseling and testing coordinator. Additionally, each site must have a written quality assurance plan that details a local implementation plan consistent with DHS/OA guidelines. The addendum titled “Site QA Plan” provides a template that, when modified with local information, will satisfy this requirement.

Clinical Laboratory Improvement Amendment

The Clinical Laboratory Improvement Amendment of 1988 (CLIA) is a federal regulation that applies to all clinical laboratory tests, such as tests for HIV antibodies. All tests that are approved by the FDA are assigned a classification under CLIA: high complexity, moderate complexity, or “waived.” This classification determines the level of qualifications required for personnel responsible for conducting and overseeing testing, as well as requirements for training, quality assurance, and proficiency testing. Agencies conducting *any* clinical laboratory test, including CLIA-waived tests, must have the appropriate CLIA certificate to authorize such testing.

The OraQuick Rapid HIV test has been classified as waived under CLIA. All settings intending to use the OraQuick device must obtain a CLIA certificate of waiver authorizing this test to be performed at their physical location. (More advanced certificates such as a CLIA certificate of moderate complexity, or a CLIA certificate of provider-performed microscopy are also acceptable to authorize tests that are CLIA-waived.)

The Limited Public Health Use Exception of CLIA may allow several sites to operate under a single certificate.

[Information and an application for obtaining a certificate of waiver](http://cms.hhs.gov/clia/) are available at <http://cms.hhs.gov/clia/>.

OraQuick Rapid HIV-1 Antibody Test

The OraQuick Rapid HIV-1 test is a simple-to-use device that delivers HIV results in as little as 20 minutes using a single drop of whole blood. It was approved for use in the U.S. by the Food and Drug Administration (FDA) in November 2002, and categorized as “waived” under CLIA in January 2003, resulting in reduced requirements for training and oversight. Additionally, the OraQuick is very accurate, with sensitivity and specificity performance that exceeds the FDA standards for approval.

Although the OraQuick rapid HIV test is accurate and simple to use, great care is required to effectively implement this technology into DHS/OA-funded C&T settings. As with all screening tests for HIV, positive test results require confirmatory testing, and specific procedures and quality assurance measures must be followed to ensure that all clients testing for HIV receive accurate results and effective services.

As of October 2003, the OraQuick device was approved only for HIV-1 testing using finger stick or venipuncture whole blood samples. However, future versions of this device may include oral fluid testing, plasma testing, and testing for HIV1/2. Please read the package insert supplied with the OraQuick device to determine if these or other uses have been approved.

Policies and Procedures

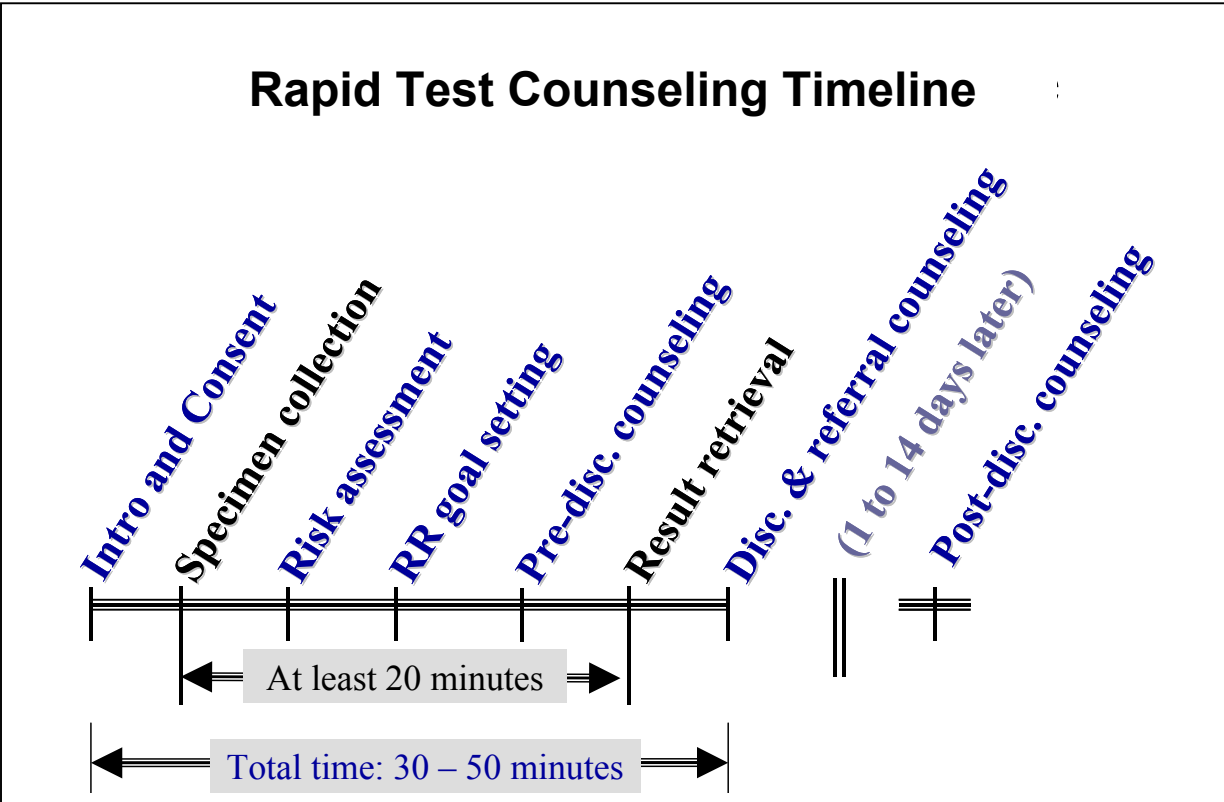
The sections below detail policies and procedures for conducting HIV counseling and testing using the OraQuick rapid HIV test.

Overview of testing process

Because OraQuick test results are available in as little as 20 minutes, this technology provides HIV prevention workers with an unprecedented opportunity to deliver counseling and testing, including result disclosure, within a single session. This has the benefit of ensuring that a substantially greater proportion of clients will receive their test results, along with result-specific counseling and referrals. Challenges include integrating this process into an existing system in ways that 1) minimize disruption, and 2) maximize the effectiveness of the services provided. Policies and procedures outlined in this section represent “best practices” for achieving an optimal balance in meeting these challenges gleaned from OA-supervised piloting experiences.

Clinic Flow Timeline

The timeline depicted below represents the optimal flow of a client through HIV counseling and rapid testing services. Total time required for services provided in a combined risk-assessment-and-disclosure session is approximately equivalent to time required to effectively provide separate risk assessment and disclosure services to a high-risk negative or positive client under standard testing.



Note that the order of the procedure for rapid testing varies slightly from the two-session procedure in that for rapid testing, *sample collection occurs immediately after informed consent is obtained*, so that the test kit can be processing during the 20-minute risk assessment session. Result disclosure may then occur directly after risk assessment and goal setting. This process may also be adapted to settings that integrate other services with HIV C&T, such as STD or HCV testing, provided the client still receives at least 20 minutes of HIV risk assessment counseling, and disclosure of rapid HIV test results occurs within the single session, without the client being sent to a waiting room or other unsupervised setting prior to result disclosure.

Reimbursement rates for risk assessment and disclosure counseling are identical, regardless of whether both components are performed in a single session, as for rapid testing, or whether each component is performed in a separate session, as for standard testing. (Note, however, that because rapid testing procedures virtually ensure that all clients will undergo disclosure counseling, a site using rapid testing will receive more reimbursement than a site seeing an equivalent number of clients under standard testing, because the rapid testing site will perform more disclosures.)

The sections below describe the policies, procedures, and best practices for conducting each service component appearing in the graphic above.

Introduction and Informed Consent

Clients arriving at the testing site must be informed of the options available to them prior to testing for HIV, including standard vs. rapid testing, and anonymous vs. confidential testing, regardless of whether the site offers all of the available services. For example, a site that offers only anonymous testing should also provide a brief explanation of confidential testing and be prepared to provide a referral to a site that offers this type of testing in the event that a client prefers this option.

Choice of Testing

Anonymous vs. confidential: Explain the meaning of anonymous vs. confidential as it pertains to HIV testing, as described in the C&T guidelines. Include an explanation of non-names HIV reporting and its relation to confidential testing.

Rapid vs. standard: Explain that for standard testing, the client must return after a week or two to receive his/her test results. Be sure the client understands that test results from rapid HIV tests are available by the end of the risk assessment session, and that a preliminary positive result requires confirmation.

Sample collection: Be sure to adequately explain sample collection requirements for each type of testing, including confirmatory testing. For instance, if your site offers OraSure standard testing and OraQuick finger stick rapid testing, then the client must understand that if they choose rapid testing, sample collection will entail a finger stick, and if the result is preliminary positive, they will also be required to submit an oral fluid sample prior to leaving the site.

Summarize the Process

Once the client has selected a specific testing option, briefly summarize the process, explaining where the client will go and with whom, what will happen, and approximately how long it will take. Clients who elect OraQuick rapid testing must also be provided with the “Subject Information Pamphlet” that is included with the OraQuick tests, prior to sample collection.

Informed Consent

There are several elements that make up informed consent for any type of HIV testing. Clients must understand the meaning and ramifications of HIV testing, including the fact that no tests are 100% accurate, and that they may test anonymously or confidentially. They must understand that the sample being collected will be tested for HIV, and that positive results (but not names) from confidential tests will be forwarded to the health department.

Rapid testing requires another two elements to which clients must consent prior to being tested: 1) Clients must understand that results will be available during the same session, and 2) Clients must understand that positive rapid test results require confirmatory testing and must consent to submit a second sample in the event of a preliminary positive result.

California law requires HIV positive screening results to be confirmed with a second independent test. A client who does not consent to provide a second sample in the event of a preliminary positive may only be offered standard lab-based testing. With lab-based testing, a single sample may be tested with a screening HIV test (EIA), and subsequently confirmed with a second independent test (Western Blot or IFA), allowing compliance with California law.

A consent form, available in the appendix of this document, has been created to accommodate the additional consent requirements for rapid HIV testing. These forms are available in both English and Spanish.

(Special Note: Sites that have the capacity to conduct counseling for monolingual clients speaking languages other than English or Spanish are encouraged to develop translations of these and other forms, as resources allow. Please provide any translations to the Office of AIDS so that OA may act as a clearinghouse, making these translations available to other sites that may find them useful.)

Specimen Collection and Test Kit Operation

Once consent has been obtained, the counselor (or other qualified personnel) should begin the process of collecting the sample and starting the OraQuick test. Conduct the OraQuick testing process according to the manufacturer's directions found in the test package insert and DHS/OA training and quality assurance guidelines. The manufacturer's package insert is the primary source of instructions for conducting the test and must be followed explicitly. Steps for operating the OraQuick test kit are available in the appendix and may be posted in the testing room near the testing area. As the primary source of directions for performing rapid tests, the manufacturer's test and control package insert instructions must be available at every site where rapid testing is conducted.

Personnel Qualifications

For the OraQuick testing device, specimen collection must be conducted by personnel who are qualified both to collect the specimen and to operate the test kit. To be qualified to collect finger stick blood specimens, California regulation requires that unlicensed personnel be certified as Limited Phlebotomy Technicians.

All personnel operating the OraQuick rapid HIV test kit in DHS/OA C&T programs must successfully complete the DHS/OA OraQuick test kit training and proficiency testing prior to conducting testing on client specimens for OA-funded programs.

Therefore, required training to conduct rapid counseling and testing is as follows:

1. To provide HIV counseling: OA-approved Basic I and Basic II (including single-session counseling component), and current CET
2. To provide specimen collection: Limited Phlebotomy Certification (or more advanced phlebotomy certification, or medical licensure)
3. To conduct OraQuick rapid tests: OA OraQuick test kit training and proficiency testing

Setting

Test kit operation must occur in an appropriate setting away from the counseling area to avoid distracting the client, and to allow the counselor/test kit operator appropriate opportunities to consult with other staff, if necessary, prior to delivering the test result.

Specimen collection may occur either in the testing area, after which the client must be moved to the counseling area to begin risk assessment counseling, or it may occur in the counseling or other intake area, and the reagent vial with the sample must be recapped and transported to the testing area.

Minimum requirements for the testing area are as follows:

1. The area must have sufficient space to store testing materials such as gloves, cotton balls, test kit pouches, etc., as well as sufficient biohazard disposal containers needed for daily clinic operation. (Additional test kit and supplies storage may be located elsewhere.)
2. There must be appropriate disposal for biohazardous materials, including sharps and non-sharps, and non-biohazardous materials.
3. The area must have a secure, flat surface upon which the test kit may develop. This surface should be located/secured to minimize the likelihood of spillage.
4. The area must be clean and well-lit.
5. A clock and a thermometer (preferably digital) for monitoring the time and temperature of developing testing kits must be appropriately located within the testing area. Calibration services for thermometers may be available from local public health laboratory facilities.
6. The areas in which test kits are stored/operated during clinic hours must be temperature controlled/monitored to remain within the appropriate temperature range for test kit storage and operation.
7. The area must be securable against unauthorized access and arranged to ensure that developing test kit result windows are not be visible to unauthorized personnel, including subsequent clients, to maintain confidentiality.
8. The area must be, at a minimum, visually separate from the counseling area, and should require the counselor to exit the counseling area to retrieve the result. This allows the counselor an opportunity to discreetly consult with other staff prior to delivering the test result, and minimizes distraction to the client.
9. The area must be designated off-limits to smoking, eating, drinking, and applying make-up (including chap stick), or any other activities that increase the chance of exposure to hazardous materials.

Safety

All sites conducting specimen collection of hazardous fluids must ensure compliance with OSHA requirements and Blood borne Pathogen guidelines, including requirements for training and posting of procedures and safety precautions. See the Safety section of this document for more information concerning safety issues.

Risk Assessment Counseling

Risk assessment counseling in single-session settings is very similar to standard risk assessment counseling, and includes a thorough assessment of behaviors that may be putting the client at risk for HIV, as well as a client-centered approach to developing a plan for risk reduction. Differences include aspects of the risk-reduction goal setting, and a pre-disclosure component to assess the client's readiness to receive his or her result.

Existing counselors who received Basic I/II training prior to the inclusion of counseling techniques for rapid HIV testing must successfully complete DHS/OA rapid testing counselor update training to be eligible to conduct counseling in a rapid testing setting. This training includes techniques for adapting risk reduction goal setting to single-session settings, assessing client readiness to receive test results, and important elements of delivering preliminary positive test results.

Pre-Disclosure Counseling

Pre-disclosure counseling is a component of the risk assessment session that involves assessing clients' readiness to receive their test results. During the informed consent process, all clients electing rapid testing must acknowledge that they will be receiving test results at the end of the risk assessment session. However, in some cases, issues discussed during risk assessment may result in a client becoming nervous or anxious about receiving his or her result. In this case, it is the counselor's task to assess the client's readiness, and if necessary and appropriate, to attempt to assist the client in becoming ready to receive his or her result. If the client remains unprepared to receive the test result, the counselor may set up a return appointment with the client for result disclosure. It is particularly important for the counselor to evaluate and help the client to eliminate any barriers to returning.

Retrieving Test Results and Result Disclosure

Once the counselor is confident that the client is prepared to receive his or her test result, the counselor will follow site-specific protocols to retrieve the test result. The client should wait in the counseling room while the counselor leaves to retrieve the test result.

Important elements of this process include:

Ensuring that result retrieval does not take an undue amount of time. For most clients, the most anxiety-provoking activity is waiting for test results. While rapid testing reduces this waiting period from a matter of weeks to a matter of minutes, even two minutes of waiting is perceived as an extended period to an anxious client. Be sure that:

1. The room from which test results will be retrieved is relatively near the space(s) used for counseling. If the rooms are more than a minute or so apart, retrieving the test result will take too long.
2. There is a streamlined process for retrieving results. When the counselor arrives at the

room to retrieve the results, he or she should be able to access the results immediately without interrupting another counselor, client, or other staff activity.

Ensuring that the counselor is mentally prepared to deliver results. Most counselors report some anxiety when preparing to retrieve rapid HIV test results to deliver to the client. Because there is no way to know in advance which clients will receive preliminary positive results and require more intensive counseling, it is important to have systems in place to provide support to the counselor during this process. If possible, it would be useful to have additional staff available during this process in order to verify the test result by providing an independent reading of the result, and to provide a brief consultation regarding a client-centered approach to disclosure of the result.

Adequate selection, training and preparation for counselors prior to implementing rapid testing is a critical part of this process. Counselor support and debriefing activities after a difficult disclosure are also important.

Specific instructions for reading OraQuick test kit results are contained in the manufacturer's package insert that is included with each OraQuick purchase. Note that only qualified personnel may read and record the results of the OraQuick rapid HIV test.

Disclosure and Referral Counseling

For rapid testing, result disclosure occurs immediately following risk assessment counseling and goal setting, and must be conducted by the same counselor to maintain continuity of client-counselor rapport. This represents a change from the current standard, in which some counselors "specialize" in positive disclosure counseling. Although this new standard may represent a challenge for some counselors, the end result is an improved counseling session for the client, who benefits from a more immediate result disclosure, improved focus and recollection of issues discussed during the risk assessment session, and a continuity of rapport with the counselor.

There are three possible results that may be given by the OraQuick rapid HIV test: negative, preliminary positive, and invalid. Disclosure procedures for each are delineated below.

Negative Test Result

A negative test result is considered a "confirmed" result disclosure because no further testing is required. Procedures for disclosing a negative rapid test result are identical to procedures for lab-based negative results. A negative test result indicates that no antibodies to HIV were detected. Disclosure should focus on enhancing the client's intentions to initiate/continue risk reduction activities, and ensuring that the client understands the window period, and how it applies to this test result. The window period for OraQuick is identical to that of lab-based testing.

Preliminary Positive Test Result

A preliminary positive result indicates that HIV antibodies were detected; however, all preliminary positive results require confirmation with a second independent test. The counselor rapid testing update training includes training on techniques for delivering preliminary positive results. At a minimum, a preliminary positive disclosure session must include:

1. Delivery of the test result in direct, neutral tone
2. Time for the client to process the meaning of the result and the counselor to explore the

client's understanding of the result

3. Collection of a confirmatory test sample
4. Setting a return appointment for confirmatory disclosure
5. Appropriate referrals

Delivery of test result/Extra time for counseling

The counselor should follow OA counselor training guidelines for delivery of test results. If possible, the counselor should notify the supervisor/clinic manager that a preliminary positive result is being delivered, so that the manager can take action to divert clinic flow to accommodate additional time required for this type of disclosure session. Expect preliminary positive result delivery to take significantly longer than negative disclosures.

Collect confirmatory sample

A confirmatory sample of either venipuncture blood or oral fluid must be collected prior to the client leaving the clinic site. The counselor should follow OA counselor training guidelines to accomplish this in a client-centered manner. For example, most clients need some time to explore the significance of the preliminary positive result before moving on to more pragmatic tasks such as submitting a second sample for confirmatory testing. Currently, some clients retest later after receiving a positive result to rule out the possibility of a laboratory error. The confirmatory process for rapid testing serves to provide similar reassurance to the client that the test result they received is accurate without having to retest later.

Note that confirmatory samples must be collected even from clients who intend to request follow-up testing elsewhere, such as from their medical provider. California law requires that all preliminary positive results be confirmed with a second, independent test.

Transitioning to confidential services for confirmatory testing

Clients who initially elect to test anonymously may wish to transition to confidential services for confirmatory testing in order to ease their entry into care and other support services. In settings that can offer confidential testing, this is easily accomplished by completing a “consent to transition to confidential testing” form (available in the appendix), and filling in the additional information on the lab slip/requisition form. Sites that offer only anonymous testing should be prepared to refer clients to settings that offer confidential services. However, because California law requires confirmatory testing for all preliminary positives, counselors should encourage clients to submit a confirmatory sample prior to leaving the site in order to verify that confirmatory testing was conducted.

Schedule disclosure appointment

Be sure that the client understands the importance of returning for their confirmatory disclosure session. This is the session in which the counselor will disclose confirmatory results, “check-in” with the client regarding their reactions to the result, and provide firm linkages to medical and other services, as appropriate to the client. If the client is tested confidentially, or elects to transition to confidential services for confirmatory testing, it is appropriate to solicit contact information and instructions in order to follow-up with clients who may miss their confirmatory disclosure.

Make appropriate referrals

Appropriate referrals include referrals to mental health services, alcohol/drug programs, Early Intervention Programs (EIP), etc. Medical referrals should be made only upon confirmation of the preliminary result. Ensuring that all high-risk negative and HIV positive clients receive

specific, useful referrals is a principal goal of HIV C&T. It is desirable to introduce the client to staff from the appropriate referral service, where possible.

Other issues that may come up during a preliminary positive result disclosure include:

Reporting results using non-names code

Rapid HIV screening test results are not reportable. Reporting of a positive test result may only be conducted when the result is confirmed under a confidential testing protocol. Wait for confirmation of the test result, and then report according to standard procedures. If a preliminary positive test result is not confirmed, it is not reportable.

Referring to care

Medical care for HIV is not provided prior to confirmatory testing. Medical referrals are more appropriately provided at the confirmatory disclosure session. However, it is acceptable to refer a preliminary positive client to EIP for general support services.

Referring to Early Intervention Program (EIP)

Clients who test preliminary positive may be referred to EIP, if available.

Conducting PCRS

Clients receiving preliminary positive results may have concerns regarding what and how to tell partners about their status. CDC guidelines recommend that these clients be encouraged to avoid behaviors that could transmit the virus. It would be appropriate for counselors to explore issues concerning partners in a client-centered way, helping clients determine whether, how and what to tell partners about their HIV status, as well as to discuss the need for transmission risk-reduction behavior while awaiting confirmation. Clients may also be informed at this time that, upon request, the health department will help them notify partners of their exposure to HIV when the preliminary result is confirmed.

Invalid Test Result

Unlike standard lab-based tests, the OraQuick test does not have a possible “indeterminate” outcome. All valid OraQuick results are either negative or preliminary positive. However, if the internal control line does not appear, or line(s) are not appropriately aligned in the result window, the result is invalid. (See test kit package insert provided with the OraQuick device for details.)

A client who receives an invalid test result may be offered the option of retesting with another rapid test or submitting a sample for lab-based standard testing and returning for the result. If a second rapid test yields an invalid result, the client should be encouraged to submit a lab-based sample, and rapid testing external control units should be used to verify that the test kits are functioning properly. (See QA section of this document under “quality control procedures” for details.)

Post-Disclosure Counseling

Post-disclosure counseling is intended to provide additional support and services to high-risk negative and positive clients. Additionally, post-disclosure sessions are to be used to provide confirmatory test results after the initial disclosure of preliminary positive results for rapid testing clients.

A post-disclosure counseling session must occur on a separate day from the initial disclosure session, and should be used to check in with clients regarding progress towards risk-reduction goals, and/or to provide direct linkages to services. For example, a counselor may schedule a post-disclosure session with a high-risk client who received a negative rapid test result in order to explore progress towards a specific, short-term risk-reduction goal, and to introduce the client to a case management specialist to follow-up on an earlier referral.

A post-disclosure session scheduled to provide confirmatory results for rapid test preliminary positives should also be used to provide direct linkages to services. For example, it would be desirable to have a representative from the local EIP or other referral service on hand to transition the client directly into appropriate services.

Confirmatory Result Disclosure

The confirmatory result for preliminary positives is disclosed to the client at the post-disclosure session. This session will consist of informing the client that the preliminary positive test result was confirmed, checking in with the client about their emotional reactions, needs, and intentions, and following up with appropriate referrals, including medical referrals and referrals to PCRS, if appropriate. If possible, confirmed result disclosure should be conducted by the same counselor that conducted the previous counseling.

On rare occasions, preliminary positive results will NOT be confirmed. Follow confirmatory testing protocols below to determine what recommendations to make to the client. The two most likely reasons that a preliminary positive test result may be followed by a negative confirmatory result are:

1. *The client may be seroconverting.* Because all tests are different, sometimes one test, such as the OraQuick rapid HIV test, may detect HIV before the standard EIA or Western Blot. Follow confirmatory procedures below to re-test this client with a standard blood test, including Western Blot or IFA. Sample collection for the second confirmatory test should be collected at least one week after the original preliminary positive result – typically, when the client returns for the confirmatory result at the post-disclosure session. If the client was in the process of seroconverting, this final confirmatory test result will be positive.
2. *The original result may have been a “false positive.”* That is, something in the client’s specimen that was not HIV may have reacted with the test kit to result in a preliminary positive result. Since everyone’s blood is a little different, this sometimes happens with any kind of laboratory test. This is why confirmatory testing is always done for positive results on screening tests such as the EIA or OraQuick test for HIV. Follow confirmatory procedures below to re-test this client with a standard blood test, including Western Blot or IFA confirmation. If the original result was a false positive, this final confirmatory test result will be negative.

Follow-up must be conducted for any confidentially tested clients who fail to return for confirmed result disclosure. Check the confidential consent form or consent to transition to confidential testing for client contact information and instructions.

Confirmatory Testing Protocols

Prior to implementing rapid testing in local settings, C&T coordinators should ensure that laboratories are familiar with CDC guidelines for confirmatory testing for preliminary positive rapid test results. The CDC recommends:

For confirmatory testing, the current standard testing algorithm should be followed, with the following exceptions:

All OraQuick reactive (preliminary positive) results must be followed up with either a Western blot or immunofluorescent assay (IFA) for confirmation.

Confirmatory testing can be done on blood (plasma, serum or dried blood spots) or oral fluid specimens. Urine testing should not be performed due to its lower sensitivity (i.e., ability to detect positive results).

With blood specimens, enzyme immunoassay (EIA) screening tests prior to the Western blot or IFA confirmatory test are optional. If an EIA is performed, even if it is non-reactive, the specimen must proceed to Western blot or IFA testing (reactive EIA specimens will automatically be tested by Western blot or IFA). For oral fluid testing, both EIA and Western blot testing should be performed to confirm results.

Test requisition slips used for confirmatory testing must inform the laboratory that the sample being submitted is a confirmatory sample for a preliminary positive rapid HIV test.

Note that although oral fluid specimens may be used to conduct confirmatory testing for preliminary positive rapid test results, in settings that have the capability, standard blood testing is preferable. Because oral fluid testing is slightly less sensitive than blood testing, using oral fluid for confirmatory testing may result in a slight increase in discordant results.

Follow up testing for negative or indeterminate confirmatory result

Most confirmatory test results will be positive; however, some may be negative or indeterminate. If the Western blot or IFA test is negative or indeterminate, it is recommended that:

- If the original confirmatory test was done on a blood specimen, another confirmatory test should be conducted with a new specimen to rule out specimen mix up or seroconversion.
- If the original confirmatory test was done on an oral fluid specimen, a repeat confirmatory test with a blood specimen should be done, since the oral fluid test is slightly less sensitive than the blood test.

Settings that offer only oral fluid confirmatory testing

In settings that offer only oral fluid confirmatory testing, a discordant result (i.e., a preliminary positive result followed by a negative or indeterminate confirmatory result) will necessitate referring clients to settings that offer blood specimen confirmatory testing. Agreements should be established with nearby testing sites to facilitate this process. To remove barriers to confirmatory testing and to maintain continuity of service for the client, the ideal procedure would involve referring the client to the secondary setting for blood draw only, while maintaining counseling and record keeping at the original site. The process should include the following steps:

- 1) Inform the client of the necessity to be retested with blood.
- 2) Provide client with a referral or set up an appointment for the client at the most convenient site that offers this service.
- 3) Schedule return appointment for disclosure at original site.
- 4) Inform the secondary setting that the client will be coming in for blood draw only (no counseling). Arrange to receive the test result at original site, and to link this result to original client paperwork.
- 5) Disclose final result to client and provide referrals as necessary; document final result on original CIF and other paperwork.

Recommendations for further follow up testing

There is a small chance that clients who receive a preliminary positive result that is not confirmed by two subsequent tests, but who are still in the window period, may be showing early signs of seroconversion. Clients who are still in the window period and whose preliminary positive result is not confirmed should be encouraged to seek follow-up testing after 30 days in addition to the recommendation to test after the end of the window period to ensure that seroconversion is detected as soon as possible.

Quality Assurance

Quality assurance refers to planned and systematic activities designed to ensure that services are being delivered effectively and that errors or substandard procedures are detected and corrected to avoid adverse outcomes. Quality assurance activities are applied to all aspects of service delivery, including both counseling and testing procedures. An effective quality assurance program is one that is integrated into the policies and procedures performed in a given setting rather than conducted sporadically “as an afterthought.”

Quality assurance guidelines contained in this document focus primarily on quality assurance procedures for OraQuick rapid HIV testing. For guidance regarding quality assurance for other aspects of HIV counseling and testing activities, please see DHS/OA HIV Counseling and Testing Guidelines, Policies and Recommendations (1997).

The basic elements of a QA program must be in place before offering testing. These basic elements, the building blocks of a QA program, are listed below and explained in more detail in the rest of this document.

1. Preparing for Implementation
2. Personnel Requirements
3. Process control
4. Documents and records
5. Troubleshooting and Problem-solving

Preparing for Implementation

Prior to implementing rapid HIV testing, several preparatory steps must be taken. Before offering rapid HIV testing to clients, take the time to:

- Identify the individual(s) who will take lead responsibility for managing the QA program. Likely candidates include the counseling and testing coordinator, the county health officer, the CLIA-waived laboratory director, the clinic manager, or some combination.
- Adapt the guidelines contained in this document to reflect QA protocols specific for your settings. Specifically identify who is responsible for which QA tasks, when, where, and how often they will be performed, and how they will be documented.
- Create mechanisms for communication so that QA issues are brought to the attention of the appropriate individual. For instance, although the site supervisor may be responsible for ensuring that there is adequate lighting in the testing area, it is likely that testing personnel will be the first to notice if a bulb burns out.
- Ensure that testing sites meet all applicable federal, state, and other regulatory requirements, including compliance with CLIA, OSHA, and Blood Borne Pathogen Guidelines.
- Verify the testing process. That is, once protocols are established in writing, verify that the procedures work as expected. Walk through the process in each of the settings of intended use. Make sure that all of the necessary components are in place: staff are trained and competent, test kits are functional, counseling, confirmatory specimen collection, biohazard disposal, and other procedures are functional and efficient.

- Copies of these guidelines and the directions in the manufacturers test and controls package insert must be available at each site where rapid testing is done. The inserts are the primary source of instructions for conducting the tests and must be followed explicitly.

See Site Preparation Checklist in the appendix of this document for a more complete list of preparatory steps.

Personnel Requirements

Having qualified, trained staff who perform and supervise OraQuick testing and the various activities in the QA program is one of the most important factors for ensuring accurate and reliable results. Key aspects of this element are:

- Personnel qualifications & responsibilities
- Training Requirements

Personnel Qualifications and Typical Responsibilities

The table below lists personnel involved in the testing process, and their typical responsibilities for quality assurance. Each local health jurisdiction may adapt the designations below to suit the structure of their organization, provided the qualifications for laboratory director and testing personnel are met.

Personnel	Qualifications	Typical QA Responsibilities
Laboratory Director	MD, or otherwise licensed to direct clinical laboratory	<ul style="list-style-type: none"> • Monitor compliance with regulatory requirements, including CLIA, OSHA, B/BP • Assure competency of supervisory personnel to conduct QA activities • Final review of QA documentation • With C&T coordinator, delegate QA tasks to appropriate personnel • Ultimate responsibility for all aspects of testing.
C&T coordinator/ Site Supervisor	Baccalaureate Degree (17 CCR 1036.3) and OA-rapid test training	<ul style="list-style-type: none"> • With lab director, develop/adapt QA plan for local use • Conduct or assign QA tasks in specific settings, including external control processes, test kit storage, control unit storage • Provide for test kit distribution and inventory processes • Initial review of QA documentation • Oversee testing process and resolve technical problems • Conduct periodic competency evaluation • Ensure personnel are qualified for assigned duties

Personnel	Qualifications	Typical QA Responsibilities
Testing personnel	OA-trained HIV counselor or healthcare personnel providing direct patient care (BPC 1206.5)	<ul style="list-style-type: none"> • Follow manufacturers directions and site QA and safety procedures • Document test-specific QA measures such as time and temperature of test during processing • Bring to attention of supervisor any QA concerns noted

Although there are specific quality assurance duties assigned to various personnel, every person involved in the testing process has the responsibility to both 1) complete the QA duties assigned to them, and 2) to bring any other QA issues noted to the attention of appropriate supervisory personnel. Testing personnel, as the “front line” workers, are likely to be the first to notice changes in testing conditions that may impact quality of testing, including temperature control issues, lighting, safety issues, etc. These personnel should be encouraged to be attentive to all aspects of the testing process, and to discuss with their supervisor any issues that may require attention.

Desirable personnel qualities

In addition to regulatory requirements, it is recommended that certain qualities be considered when selecting personnel to perform the OraQuick test. These include the following:

- *Sincerity and commitment* – A dedication to performing testing according defined procedures, including quality assurance measures.
- *Responsibility and initiative* – A sense of personal responsibility for the entire testing process, and the initiative to notify appropriate supervisory personnel of any quality assurance concerns.
- *Literacy* – The ability to read instructions, record results, and document QA procedures.
- *Organizational skills* – The ability organize and manage several tasks simultaneously, to the extent required by job duties.
- *Decision-making skills* – The ability to interpret results and be able to recognize and handle problems that might arise.

Immediate supervisors should be aware of the skills and abilities of testing personnel, and provide supervision and oversight accordingly.

Testing Personnel Training Requirements

To be eligible to conduct rapid HIV counseling and testing, counselors must have successfully completed OA single-session counseling rapid test training. There are two components to this training: 1) counseling skills update, which focuses on updating counseling skills specifically relevant to single-session counseling used in conjunction with rapid HIV testing; and 2) OraQuick test kit training, which provides instruction and hands-on practice at operating the OraQuick rapid HIV test. This component also includes a proficiency exam, which must be successfully completed prior to conducting testing on client samples.

Successful completion of each component will be assessed independently. Counselors may only provide services corresponding to the training component(s) successfully completed. That is, a counselor who successfully completes the counseling component but not the testing

component may provide counseling in rapid testing settings, but may NOT operate the test kit (and vice versa).

OA will provide documentation of this training, which should be kept on file at the testing site.

Testing personnel must also be qualified to conduct appropriate sample collection for the type(s) of testing offered. For collection of finger stick whole blood samples, unlicensed personnel must obtain Limited Phlebotomy Technician (LPT) certification. For collection of venipuncture blood samples, unlicensed personnel must obtain Certified Phlebotomist Technician 1 (CPT1) certification. Training must be provided by a DHS-approved training program. For [information regarding this training](http://www.dhs.cahwnet.gov/ps/ls/lfsb/html/Phlebotomy.htm), see <http://www.dhs.cahwnet.gov/ps/ls/lfsb/html/Phlebotomy.htm>

or contact:

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Note that certain classifications of health care personnel such as RNs and LVNs are not required to complete this training, and that an experienced or currently working phlebotomist (prior to April 9th, 2003) has until April 9th, 2006 to obtain a state certificate under the grandfathering clause.

Competency Assessment

At periodic intervals after training, competency should be demonstrated and documented. Competency must be demonstrated for all tasks for which an individual is responsible, including both counseling skills and testing responsibilities. The supervisor or trainer should perform the assessment. Ideally, the evaluator would “shadow” the counselor through the entire counseling and testing process, from obtaining informed consent through result disclosure counseling.

Separate checklists have been created to assist with evaluating counseling skills and testing competency. The counseling evaluation form is available in the “Forms” section of the HIV Counseling and Testing Guidelines (1997), along with guidelines for its use. The testing competency checklist is available in the appendix of this document, and includes items for evaluating skills related to successfully performing the OraQuick rapid test, included related quality assurance measures.

Recommendations for test kit competency assessment

Observe and document competency for personnel who have successfully completed the test kit training and proficiency testing by assessing each of the elements of the operation in accordance with the items on the “OraQuick Test Kit Competency Checklist” (available in the appendix). This assessment should be performed:

1. Once in the clinical setting after training and prior to conducting testing on client specimens (using a control unit or proficiency panel specimen);
2. During the first five tests conducted on client specimens;
3. After six months of testing experience; and
4. Subsequently, on an annual basis.

For sites where separate personnel perform counseling duties and testing duties, each should be evaluated independently within their work environment. If testing personnel have the responsibility for running several tests simultaneously, these organizational skills should also be evaluated for compliance with local protocols.

Documentation of competency assessment should be maintained in the personnel file.

An additional resource for proficiency and competency assessment is available through the CDC Model Performance Evaluation Program (MPEP). This program provides specimen panels at no cost to participating laboratories. Participants test the samples and return the results to CDC for analysis to ensure that the laboratory is producing accurate results. This is a useful program, provided free of charge, for external competency assessment.

For more information, go to <http://www.phppo.cdc.gov/mpep> and click on: [2003 Rapid HIV Testing “HIV-1 Rapid”](#)

Process Control

In addition to the procedures for operating OraQuick rapid HIV tests and providing single-session counseling, which are detailed in the “Procedures” section of this document, certain activities must occur before, during, and after testing to ensure that testing procedures are performed correctly, the environment is suitable, and the test kit works as expected to provide accurate results. These procedures are collectively referred to as process control procedures.

Primary vs. Satellite sites

Procedures for managing inventory, monitoring storage, and running external controls may vary depending upon the structure of the local testing system. One way to centralize the responsibilities of process control activities is to designate one or more sites as “primary” sites and other sites as “satellite” sites. In this system, the primary site(s) are responsible for performing many of the tasks related to external control testing, which may save time and money.

An obvious example of a primary/satellite combination would be a mobile testing unit as a satellite of its “home base” site. In this system, test kits and control units would be stored at the primary site, which would then be responsible for the bulk of the process control tasks such as test kit and control unit storage temperature monitoring, and periodic external control testing. The mobile unit, as a “satellite” site, would only take as many tests as needed for a short time period, and would not be required to run periodic external test controls. Note that although the mobile testing unit would not need to run periodic external controls, external controls would be needed for the unit as a “new setting,” and to troubleshoot problems, such as in the event that test kit storage on the van exceeded the recommended range, or in the event of two invalid test results in a row. (See details regarding external control testing for details regarding these requirements.)

This system could be also used in small jurisdictions where the local health department is established as the “primary” site that then distributes inventory periodically to its “satellite” sites. In larger counties there may be several “primary” sites that serve designated satellite sites.

Quality Control Procedures

Prior to conducting tests on client samples, and on an ongoing basis, certain procedures must be performed to ensure that the test kits are operating correctly, the storage areas for the test

kits and control units are acceptable, and the testing area is suitable. These activities include monitoring the temperature in the storage area(s) for the test kits and control units, monitoring inventory, and running external controls.

Monitoring storage area temperature

OraQuick test kits must be stored within the temperature range specified by the manufacturer's test kit package insert (currently 35° – 80° F), and control units must be stored within the temperature range specified by the manufacturer's control unit package insert (currently 35° – 46° F – i.e., under refrigeration). Copies of each of these inserts must be available at every site performing rapid testing. Control units may NOT share a refrigerator with food items. (See control unit package insert for more requirements and restrictions.) Test kits do not require refrigeration, but may be refrigerated if desired. (Please note that test kits must come to room temperature – minimum 59° F – before use. See test kit package insert for more details or updated information.)

To monitor temperature, place a thermometer in each storage area; e.g., on the shelf in the refrigerator or cabinet where the items are stored. Post a temperature control log (available in appendix) on the outside of the cabinet or refrigerator; check and record temperature daily.

For mobile testing units or settings where temperatures may fluctuate over the course of a few hours, monitor temperature in the portable/temporary storage area more frequently, such as hourly. Record time and temperatures on a temperature control log. If testing and/or control units used in the field are to be returned to main stock, use this log to verify that the units were maintained in continuous temperature compliance.

Monitoring inventory

It is important to monitor test kit and control unit inventory in order to avoid 1) running out, and 2) units expiring on the shelves. Test kits and control units have a defined shelf life and MAY NOT be used past their expiration dates, so it is important to put procedures in place that ensure an adequate, but not excessive supply, and to ensure that older test kits/control units are used first.

Additionally, because this test is not available as a “home use” kit, there may be a black market for the devices. As such, it will be important to not only monitor, but also control inventory by using secure storage areas and sufficiently stringent monitoring procedures. Inventory log sheets should account for each test, and indicate whether it was used to test a client sample, to run external controls, for training/practice purposes, or was not used for some reason, such as past expiration date, faulty packaging, storage temperature non-compliance, etc.

External quality controls

Each OraQuick device is equipped with an “internal” control device that consists of a line that appears next to the “C” in the device window when a valid result is obtained. This control verifies that sufficient sample was collected, and that the sample and reagent migrated through the device properly.

In addition to this internal control, external quality controls must also be run periodically to verify that the device is accurately detecting HIV antibodies. An external quality control unit consists of two vials of clear fluid made from human plasma. Each vial contains enough fluid to run approximately 25 OraQuick tests. One vial contains fluid that will test negative; the other vial contains fluid that will test positive.

The external quality control process consists of running two OraQuick tests, one using a drop of fluid from the positive control vial, and one using fluid from the negative control vial, to ensure

that the OraQuick tests are obtaining the proper result. The manufacturer's controls package insert is the primary source of information on how to run controls and should be followed explicitly. *(Please note that the positive control will result in a very light test line. This is known as a "challenge" sample, and is intentionally designed to yield a "weak" positive. A test that is capable of detecting this weak positive is fully functional to detect HIV antibodies in client samples.)*

When to run external controls

External controls are run to verify that the test kits are working as expected, that operators are performing the test properly, and that results are accurate and legible in a given setting. Controls should be run:

- By each new operator prior to performing testing on patient specimens
- In each new setting or whenever conditions in a setting have changed significantly
- When opening a new test kit lot or a new shipment of test kits is received
- If the temperature of the test storage area falls outside of acceptable range
- If the temperature of the testing area falls outside of acceptable range
- At periodic intervals as dictated by the user facility
- Whenever two invalid results in a row are obtained

By each new operator prior to performing testing on patient specimens

This is to verify that new operators are able to run the test properly. Operators who have completed the OA training have already satisfied this requirement. However, each new operator, as part of the competency assessment, should complete at least one test in the clinical setting prior to testing client samples. Control unit or proficiency panel samples may be used for this.

In each new setting or when conditions in a setting have changed significantly

Controls should be run in each new setting to verify that all of the elements of the setting (e.g., lighting, temperature, level surface, etc.) are sufficient to yield the correct result. If conditions in an existing setting conditions change significantly, controls should be run again.

When opening a new test kit lot/whenever a new shipment of test kits is received

A "lot" consists of about 1000 tests kits which were manufactured together, and which will all bear the same lot number on the outside of the test kit package. A "shipment" is the quantity of test kits that arrive in a single delivery. External control testing will verify that the lot/shipment is functioning properly after the shipping process.

If a shipment contains units from a single lot, one set of controls on that shipment will verify the functionality of both the lot and the shipment. If the shipment contains units from more than one lot (i.e., contains more than one lot number), external controls must be run on each lot.

If the temperature of the test storage area falls outside of acceptable range

If the test kit storage area in either a primary or satellite/temporary location is suspected to have fallen outside the acceptable temperature range as specified in the manufacturer's package insert, external controls must be run to verify that the test kits are still functioning properly PRIOR to resuming use of the kits to test client specimens.

If test kits from a satellite/temporary storage area are to be re-integrated into primary stock, it must be verified that they have been maintained in continuous temperature compliance, OR

external controls must be run to verify that the test kits are still functioning properly before they are re-integrated.

If the temperature of the testing area falls outside of acceptable range

If the temperature of the area where test kits are operating falls outside the recommended range as specified in the manufacturer’s package insert, external controls may be run to verify that the test kits are functioning properly in this environment. However, OA recommends that testing be suspended until the temperature in the testing area can be adjusted to within the acceptable range.

At periodic intervals as dictated by the user facility.

External controls must be run periodically, to verify that existing stock continues to function properly. Testing sites should determine the optimal frequency for running controls based on test site volume and type of testing done – confidential vs. anonymous. Consider that if controls fail (i.e., either the positive or negative control vial yields an incorrect result, and it is determined that it was not a result of bad controls), all of the tests run since the last successful control test are called into question. In that event, sites would need to contact the clients who tested (for confidential settings) or publicize the testing failure (for anonymous settings) asking clients to return for re-testing.

Suggested intervals for conducting external quality controls are in the table below.

Site volume	Tests per month	Run controls
Low	Less than 25	Every 2-4 weeks
Intermediate	Between 25 – 500	Every 25- 50 tests
High	Greater than 500	Daily

For ease of implementation, it is better to determine specific times to run controls (e.g., in a setting that averages 50 tests per week, run controls every Monday and Thursday morning before clinic hours) rather than electing to run controls every 25 tests, as this may inconveniently fall in the middle of clinic hours, disrupting clinic flow.

Whenever two invalid results in a row are obtained

If two invalid results in a row are obtained, running controls will help determine if repeated invalid results are due to the test device or the specimen. If the same test kit lot gives repeated invalid results, the test kits may have gone bad. If controls are successful, invalid results may be due to the client specimen. In that case, the client should then be offered standard testing.

If an excessive number of test devices produce invalid results, or if there is any other reason to suspect that the test kits are not functioning as expected, external controls should be run. If external controls are successful, troubleshooting procedures should attempt to determine if the problem lies with the test operator, the environment, etc. in order to determine the necessary corrective action.

Documents and Records

One of the characteristics of an effective quality assurance program is comprehensive documentation. Documentation serves the dual purposes of providing structure to ensure that necessary QA activities take place, and providing evidence that all measures were successfully completed. Periodic supervisory review of QA documentation is essential. Like other

documentation, QA documents should be stored for three years past the end of the contract period.

In addition to the documentation already in place for conducting standard (laboratory-based) HIV testing, use of the OraQuick testing device requires some additional documentation, including:

- Documentation of additional training (e.g., phlebotomy, test kit operation, rapid test counseling skills, etc.)
- Documentation of External Quality Control for OraQuick tests
- Documentation of appropriate test kit and control unit storage
- Documentation of appropriate test kit operation

Documents have been created to meet each of these needs. The documents and detailed instructions for completing them appear in the appendix. Below is a brief description of each one.

Training documentation

Documentation for all required training should be on file. Such documentation may consist of letters of successful completion, certificates of attendance, certification documents, etc., as appropriate. A summary of training for personnel performing counseling and testing services is available in report form from the Counseling Information System

External quality control log

A log documenting external quality control procedures appears in the appendix, and includes the date and time of QC testing, lot number and expiration of the test kit, lot number and expiration date of the controls, control results, etc. This document should be used anytime external quality control tests are conducted. Data from this log may be compared to existing testing logs and/or information contained in the testing database to verify that control testing is done at appropriate intervals, and to identify which tests may be called into question in the event of a QC failure. A summary of this information is available from the Counseling Information System.

Test kit storage temperature log

A log documenting storage temperature for test kits appears in the appendix. This log may be used to document storage temperatures either in a primary storage site or in a temporary storage site such as a mobile testing unit. Temperature should be recorded periodically according to site protocols – typically daily, but more frequently for less temperature-stable settings such as mobile units.

Control unit storage temperature log

A log documenting storage temperature for control units also appears in the appendix. This log is used to document storage temperatures of the refrigerated space where control units are stored. Temperature should be recorded periodically according to site protocols – usually daily.

HIV antibody test requisition form

The test requisition form has been redesigned to accommodate quality assurance elements related to rapid HIV test kit operation. The section of the document related to rapid testing includes space to report test kit lot number, date, operating time and temperature, etc. It also

includes space for the testing personnel's identifying information, which indicates that the operator attests that all elements of the testing process were performed correctly.

Rapid test inventory log

Inventory control procedures should include a method for logging information regarding date and quantity of test kits received, lot number(s), expiration date(s), number of test kits used for each purpose (e.g., control testing, client testing, unusable tests [including reasons – expired, stored out of range, spilled, etc.]) number of kits remaining, etc. An example inventory log is included in the appendix. Inventory procedures will ultimately be integrated into existing data systems.

Expired test kits should be returned to Office of AIDS, unless other arrangements have been made with OA for disposal.

Troubleshooting log

A troubleshooting log for documenting problems or unusual occurrences can be invaluable for detecting patterns, for after-the-fact investigation when something fails, and a basis for discussion regarding ways to improve the process. No formal log sheet has been developed for this topic, but the ideal would be to designate a notebook as the troubleshooting log. Each entry should include:

1. Date
2. Person making the entry
3. A description of the problem or event
4. The action(s) taken to resolve the problem or deal with the event
5. The outcome of that action (e.g., whether the problem was resolved, etc.)

Space to suggest alternative actions, write down questions, etc. may also be useful.

Errors

If you happen to accidentally enter incorrect information or enter information in the wrong blank, draw a single line through the mistake(s) and initial the line in the margin. Do not use white out or otherwise obliterate errors.

Review of QA documentation

The C&T Coordinator, in conjunction with the Laboratory Director, should determine an appropriate process for reviewing all QA documentation on at least a monthly basis. The Lab Director is responsible for the final review of all quality assurance documentation. (Site supervisors should monitor QA and QA documentation on an ongoing basis.) Documentation for review must at a minimum include 1) analytic process information recorded on the laboratory slip (e.g., test kit expiration date, time and temperature of test kit operation, etc.); 2) External Quality Control log information; 3) test kit and control unit storage temperature logs; and 4) training documentation. Most of this information is available in report form from the HIV Counseling Information System (version HIV6 or later).

If the review results in questions or issues concerning the adequacy of QA procedures, the Lab Director and/or C&T coordinator should initiate immediate corrective action. If there are any issues that call into question the accurate functioning of the rapid test kits, rapid testing should be suspended until accurate functioning is verified by external control processes.

The review process should occur during the first two weeks of each month for the previous month.

Additionally, an annual review should be conducted to monitor personnel qualifications, including continuing education requirements, competency assessments, and qualifications of new personnel.

Troubleshooting and Problem Solving

Each site should have a method to detect and document problems that occur at any point in the testing process, especially those that may affect the accuracy of test results. Significant problems should be immediately reported to the appropriate supervisory personnel. Problems and unusual events should be documented in a troubleshooting log that contains fields to describe the problem and actions taken to resolve the problem.

At a minimum, testing personnel should be aware of troubleshooting procedures and events which require the notification of supervisory personnel, including all of the events listed in the troubleshooting table below. Additionally, testing personnel should be specifically trained regarding:

- What to do (whom to report to) when QA requirements need correction (light bulb is out, temperatures out of range, thermometer/clock missing, etc.)
- When to discontinue testing (external controls fail, or two invalids in a row, and external controls not available on site, etc.)
- How to document problems/action taken – e.g., a troubleshooting log book to document problems and actions taken to resolve problems, including guidance regarding what is appropriate to enter in the log book, such as any invalid test results, any out of range temperatures, forgot to check temperatures at right time, unusual client reactions, etc.

Problem	Action
Control testing fails to yield accurate results	Retest with a new control unit to determine whether failure was a result of test kits or control units. (Do not test client specimens until proper functioning of the test kits has been verified.)
Second attempt at control testing fails with new control unit	Do not test client specimens until problem is resolved. Notify Supervisor; notify OA and manufacturer. Consult troubleshooting log to identify possible reasons for failure. Begin preparations to notify clients who tested since last successful external control test that previous HIV test result may not be reliable. If other stock/lots of rapid HIV tests are available, client rapid testing may be resumed after proper test functioning of this stock/lot has been verified by external control testing. Otherwise offer only standard testing.
Invalid test result occurs while testing a client specimen	Offer the client the option of retesting with a rapid test or with a standard lab-based test.
Two invalid test results occur in a row while testing client specimens	Offer clients standard testing. Do not test further client specimens until problem is resolved. Run controls to determine if invalid results are due to client sample or test kits. If controls fail,

Problem	Action
	see above.
Test kit storage area temperature exceeds recommended range.	Run external controls to verify test kits continue to function properly.

Counseling

In addition to quality assurance procedures designed to ensure effective testing procedures, quality assurance practices surrounding counseling must continue to occur, as well. Some new areas of quality assurance related to rapid test counseling include ensuring that counselors selected to conduct rapid testing have adequate skills for the necessary tasks, and evaluating and supporting counselors in the performance of these tasks.

Selection of Counselors for Rapid Testing

Counselors selected to perform rapid test counseling must, at a minimum, 1) be capable of engaging the client around HIV risk behaviors for at least the 20 minute period during which the test processes, and 2) be willing and able to conduct an effective preliminary positive disclosure session.

Counselors operating rapid test kits must also be capable of collecting the specimen, observing all QA and safety requirements, and accurately reading the result.

Evaluating Counseling Skills

Current guidelines require that counseling skills be evaluated at least annually by a supervisor and/or senior counselor. During the initial implementation phase of rapid testing, counseling skills, especially those related to rapid testing, should be initially evaluated within a few weeks of beginning rapid testing, and then again within the first year. Existing counselor evaluation forms may be adapted to include issues of specific concern to rapid testing. Remedial training, group discussion, peer “shadowing,” or other activities should be implemented to improve any weak areas.

Supporting Counselors

HIV risk-reduction counseling is a challenging and emotionally taxing vocation. Counselors providing services in the context of rapid testing and single-session counseling are additionally challenged by new testing responsibilities and unique counseling situations, such as delivering preliminary positive results with little notice. Counselors currently conducting single-session counseling report that, although challenging, this format typically results in a more intense rapport with the client, and is generally preferred to standard testing by counselors and clients alike.

Because of the additional challenges associated with rapid testing, it is even more important to provide support to counselors. Specific areas of necessary support vary somewhat by venue and personnel requirements and capacities, but may include:

“Back-up” result reading. It may be useful in some settings to have a second counselor or supervisor do a “back-up” reading of each test result, to verify that the result is as recorded. An

alternative would be to establish a procedure that would allow counselors to call for a “back-up” reading of a particular result, if they felt for any reason that this was necessary. Either of these procedures may relieve some of the stress associated with the new responsibility of reading HIV test results.

Result delivery consultation. Prior to delivering a preliminary positive result, counselors may benefit from briefly consulting with a senior counselor or supervisor to establish a strategy for client-centered result disclosure. Especially because the “preliminary” positive result is a new concept in HIV testing, and also because many counselors who have not previously delivered positive results may be called upon to do so, this practice may be helpful.

Post-disclosure debriefing. Especially after delivering a preliminary positive, but also after some negative disclosures, a debriefing session with a supervisor and/or other counselors may be useful for defusing tensions and for discussing concerns and suggestions for dealing with difficult counseling elements. If testing duties are performed by non-counselors, it may be useful to include them in the debriefing, as well, since they also interact with clients. If possible, it may be useful to have a “pinch hitter” counselor to relieve a counselor who has just had a particularly taxing session.

Emotional/stress release. Other emotion/stress release tactics may also be called for, such as professional counseling, counselor support groups, etc.

Safety

Occupational Safety and Health Administration Standards

Sites offering rapid HIV testing must meet the United States Department of Labor Occupational Safety and Health Administration (OSHA) standards for blood-borne pathogens. Each site must:

- Provide training for all employees with occupational exposure
- Have a written Exposure Control Plan
- Provide personnel with protective equipment, such as gloves and laboratory coats
- Make the hepatitis B vaccination series available to all employees who have the potential for occupational exposure
- Provide post-exposure evaluation and follow-up to all employees who have had an exposure incident
- Contain and dispose of biohazardous waste in accordance with applicable regulations

More detailed information is available at the United States Department of Labor Occupational Safety and Health Administration [website](http://www.osha.gov/): <http://www.osha.gov/> and the California [Department of Industrial Relations website](http://www.dir.ca.gov/occupational_safety.html), Division of Occupational Health and Safety: http://www.dir.ca.gov/occupational_safety.html

Universal Precautions

Sites must also observe universal precautions, as outlined by the CDC: CDC. Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other blood borne pathogens in health-care settings. *MMWR* 1988; 37(24):377-388.

Appendix A: OraQuick Results – Example Sheet

OraQuick Results

Non-Reactive – Negative



Reactive – Preliminary Positive



Invalid



Appendix B: Test Kit Steps

Test Kits Steps for OraQuick Test Procedure

In all cases, the manufacturer's package inserts must be followed explicitly in conducting these tests. The points below supplement those instructions.

1. Gather materials
2. Examine test kit pouch (unopened, room temperature, absorbent pack)
3. Record lot number
4. Record expiration date
5. Record initials
6. Open pouch, remove vial
7. Affix client number to vial
8. Affix client number to CIF/lab slip
9. Open vial and put in stand
10. **Put on gloves**
11. Collect sample
12. Visually examine loop
13. Stir in sample, loop to biohazard
14. Examine vial – fluid pink?
15. Insert test kit
16. Record start time
17. Record temperature

Notes:

Appendix C: Detailed Test Kit Steps

Detailed Test Kit Steps for OraQuick Test Procedure

The manufacturer's test package insert is the primary source of directions on how to conduct the test and must be followed explicitly. Each site that provides rapid tests must have a copy of it and the insert for external controls. The following supplements those instructions.

1. Gather materials

- *Test kit materials:* an unopened test kit pouch, test kit stand, specimen collection loop, lab slip/CIF, client number stickers, gloves, workspace cover, laboratory insert instructions
- *Fingerstick materials:* puncture device, alcohol wipe, sterile gauze or cotton balls, bandage
- *Testing space items:* biohazard container, thermometer, clock/timer, good lighting

2. Examine test kit pouch

- Test pouch must be unopened, to protect absorbency of test kit pad
- Test pouch should be at "room temperature" – between 59° and 80° F. If test kits are stored refrigerated, allow to come to room temperature before operating.
- Side of pouch with test kit in it must contain an absorbent packet. If not, dispose of entire pouch and use a new one.

3. Record lot number

- Lot number is stamped on bottom right of package; record this number on lab slip

4. Record expiration date

- Expiration month and year is stamped below lot number. Kit expires at the end of the month and year stamped. Discard kit if expired. (Remember to document expired kits on inventory log.)

5. Record initials

- Record initials of counselor operating the test kit and reading the results on the lab slip.

6. Open pouch, remove vial

- Feel the pouch to determine which side contains the vial of reagent. Open only that side of the pouch. Remove vial and set pouch aside.

7. Affix client number to vial

- Affix client number to back of vial vertically, so the number will be visible when the vial is inserted into test kit stand.

8. Affix client number to CIF/lab slip

From the same sheet of numbers, affix a sticker to the CIF, lab slip, and any other paperwork which must be linked. (e.g., consent form, etc.)

9. Open vial and put in stand

Open the vial by gently rocking the lid back and forth. Insert into the stand by sliding the vial in from the top. Ensure that the vial is seated fully in the stand, and that the client number is visible.

10. Put on gloves

- Universal precautions require that all health care providers use gloves when dealing with potentially infectious fluids. Use gloves to collect fingerstick blood samples, and when handling used test kits and vials, or any other materials that have come into contact with potentially infectious fluids.

11. Collect sample

- Follow all directions according to your fingerstick device and phlebotomy training to puncture finger; touch the “loop” to the drop of fingerstick blood until blood fills loop.

12. Visually examine loop

- Examine loop carefully to ensure that the entire loop is filled with blood.

13. Stir in sample, loop to biohazard

- Use the loop to stir the sample into the vial of reagent. Discard the loop into a biohazard container when finished. Discard any other materials that have contacted potentially infectious agents in biohazard containers according to site guidelines.

14. Examine vial – fluid pink?

- Carefully examine vial to ensure that the fluid in the vial appears pink. If not, discard and start over.

15. Insert test kit

- Open the other side of the pouch, and remove the test kit without touching the absorbent pad. Carefully insert the test kit into the vial. Ensure that the pad is touching the bottom of the vial and the test kit window is facing forward.

16. Record start time

- Record the time on the lab slip in the space labeled “Begin Test - Time.”

17. Record temperature

- Record the temperature on the lab slip in the space labeled “Begin Test - Temperature.”

Notes:

Appendix D: HIV Antibody Test Laboratory Requisition Form

HIV ANTIBODY TEST

CALIFORNIA STATE DEPARTMENT
OF HEALTH SERVICES

LOCAL LABORATORY NUMBER

Unique Office
of AIDS Client
Number

999-9999-9



LABORATORY NAME & ADDRESS:

CLINIC/SITE NAME, ADDRESS, & PHONE:

ATTACH LABEL TO REPORT
FORM AND BLOOD SPECIMEN

999-9999-9

999-9999-9

999-9999-9

999-9999-9

999-9999-9

999-9999-9

999-9999-9

999-9999-9

SEND REMAINING LABELS WITH
COPIES 1, 2, & 3 OF FORM TO
THE LABORATORY

SPECIMEN DATE:
(m/d/yyyy)
RETURN APPOINTMENT DATE:
(m/d/yyyy)
GENDER: (1) MALE (2) FEMALE (3) M-F (4) F-M
DATE OF BIRTH:
(m/d/yyyy)
RESIDENCE COUNTY: _____
RESIDENCE ZIP CODE:

CONFIDENTIAL TESTING USE ONLY

LAST NAME: _____
SSN: (last 4 digits, 0000 if unknown)
SOUND EX CODE:

RAPID TEST USE ONLY

LOT NUMBER:
EXPIRATION DATE: (m/d/yyyy)
COUNSELOR/TECH INITIALS:
SPECIMEN: (1) ORAL (2) FINGER STICK (3) VENIPUNCTURE

BEGIN TEST		END TEST	
TIME	TEMPERATURE	TIME	TEMPERATURE
<input type="checkbox"/> AM <input type="checkbox"/> PM	° F	<input type="checkbox"/> AM <input type="checkbox"/> PM	° F

RESULT: (1) PRELIMINARY POSITIVE (indicate confirmatory specimen)
 (2) NEGATIVE
 (3) INVALID ID, reason: _____

CONFIRMATORY SPECIMEN GIVEN: (1) YES (2) NO
LAB SPECIMEN
SPECIMEN: (1) ORAL (2) FINGER STICK (3) VENIPUNCTURE

LABORATORY USE ONLY

ELISA: (1) REACTIVE (2) NON-REACTIVE
SUPPLEMENTAL TEST PERFORMED:
 (1) IFA (1) WESTERN BLOT
 (1) REACTIVE (1) REACTIVE
 (2) NON-REACTIVE (2) NON-REACTIVE
 (3) NONSPECIFIC/ UNSATISFACTORY (3) INDETERMINATE

SUMMARY INTERPRETATION:


(1) HIV ANTIBODY DETECTED
 (2) NO HIV ANTIBODY DETECTED
 (3) INCONCLUSIVE - SUBMIT ANOTHER SPECIMEN
 SEE ENCLOSED NOTE

NOTE: _____


DATE RECEIVED BY LAB: (m/d/yyyy) _____
DATE REPORTED: (m/d/yyyy) _____

DHS 8257 (9/03)


LABORATORY COPY

HIV ANTIBODY TEST		Unique Office of AIDS Client Number	 999-9999-9																
CALIFORNIA STATE DEPARTMENT OF HEALTH SERVICES		LOCAL LABORATORY NUMBER																	
SPECIMEN DATE: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (mm/dd/yy) RETURN APPOINTMENT DATE: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (mm/dd/yy) GENDER: <input type="checkbox"/> (1) MALE <input type="checkbox"/> (2) FEMALE <input type="checkbox"/> (3) M-F <input type="checkbox"/> (4) F-M DATE OF BIRTH: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (mm/dd/yyyy) RESIDENCE COUNTY: _____ RESIDENCE ZIP CODE: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		LABORATORY NAME & ADDRESS: _____ _____ _____ CLINIC/SITE NAME, ADDRESS, & PHONE: _____ _____ _____																	
CONFIDENTIAL TESTING USE ONLY		LABORATORY USE ONLY																	
LAST NAME: _____ SSN: (last 4 digits, 0000 if unknown) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> SOUNDEX CODE: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		ELISA: <input type="checkbox"/> (1) REACTIVE <input type="checkbox"/> (2) NON-REACTIVE SUPPLEMENTAL TEST PERFORMED: <input type="checkbox"/> (1) IFA <input type="checkbox"/> (1) WESTERN BLOT <input type="checkbox"/> (1) REACTIVE <input type="checkbox"/> (1) REACTIVE <input type="checkbox"/> (2) NON-REACTIVE <input type="checkbox"/> (2) NON-REACTIVE <input type="checkbox"/> (3) NONSPECIFIC/ UNSATISFACTORY <input type="checkbox"/> (3) INDETERMINATE																	
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SPECIMEN: <input type="checkbox"/> (1) ORAL <input type="checkbox"/> (2) FINGER STICK <input type="checkbox"/> (3) VENIPUNCTURE																			

 RETURN THIS COPY TO TEST SITE
 DHS 8257 (9/03)


HIV ANTIBODY TEST		Unique Office of AIDS Client Number	 999-9999-9																
CALIFORNIA STATE DEPARTMENT OF HEALTH SERVICES																			
SPECIMEN DATE: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (mm/dd/yy) RETURN APPOINTMENT DATE: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (mm/dd/yy)																			
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 RETURN THIS COPY TO TEST SITE (data entry copy)
 DHS 8257 (9/03)

HIV ANTIBODY TEST	Unique Office of AIDS Client Number	 999-9999-9																	
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TEST SITE COPY

DHS 8257 (9/03)

CALIFORNIA STATE DEPARTMENT OF HEALTH SERVICES	Unique Client Number	 999-9999-9
SPECIMEN DATE: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>(mm/dd/yy)</i> RETURN APPOINTMENT DATE: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>(mm/dd/yy)</i>	YOU MUST BRING THIS SLIP WITH YOU ON YOUR RETURN APPOINTMENT DATE CLINIC/SITE NAME, ADDRESS, & PHONE: _____ _____ _____	

CLIENT COPY

DHS 8257 (9/03)

Appendix E: HIV Antibody Test Laboratory Requisition Form Guide

Guidance for Completing the HIV Antibody Test Laboratory Requisition Form

This document provides health care providers and laboratory clinicians a description of the California Department of Health Services (DHS), Office of AIDS (OA), *HIV Antibody Test Laboratory Requisition Form* (LRF), describes form elements, and result recording procedures. Reliance on this guidance will minimize confusion. Refer to the *OraQuick Rapid HIV Testing in Counseling and Testing Settings: Supplement to HIV Counseling and Testing Guidelines, Policies, and Recommendations (1997)* for more detailed information for performing the OraQuick rapid HIV testing procedure. Whenever questions are unresolved by this document contact David Webb at the State OA at (916) 449-5826. To order additional LRFs contact Denise Humenik at (916) 449-5822. For information regarding OraQuick rapid testing procedures contact Sandy Simms at (916) 449-5797.

The LRF is used by anonymous and confidential publicly-funded counseling and testing (C&T) programs and other programs for both rapid and standard HIV antibody tests. The LRF is a professional tool to be used **ONLY** by HIV counselors who have completed the State-sponsored training and laboratory clinicians. Supervised use by new counselors is permitted as part of their training (this does not apply to performing rapid tests). Only qualified personnel who have completed DHS/OA OraQuick test kit training and proficiency testing may conduct, read and record the results of a rapid HIV test. Untrained staff should **NEVER** perform client testing or interpret results. Information is appropriately discussed with clients by trained staff in the context of providing HIV counseling services. This information is critical to the continuous improvement of primary HIV prevention in California. Incomplete or inaccurate recording of this information diminishes the impact of HIV counseling, violates contractual obligations and risks support for effective prevention services. The LRF must be available during counseling sessions when test results are given to clients.

The LRF is comprised of five copies. The **LABORATORY COPY** (copy #1), **RETURN THIS COPY TO TEST SITE** (copy #2), and **RETURN THIS COPY TO TEST SITE (data entry copy)** (copy #3) is sent to a clinical laboratory. The **RETURN THIS COPY TO TEST SITE** (copy #2) and **RETURN THIS COPY TO TEST SITE (data entry copy)** (copy #3) are stapled together and sent back to the clinic/site from the laboratory. The **RETURN THIS COPY TO TEST SITE** (copy #2) contains sensitive information and may be filed separately from the Counseling Information Form (CIF). The **RETURN THIS COPY TO TEST SITE (data entry copy)** (copy #3) is double stapled to the CIF for entry into the Counseling Information System (CIS). The **TEST SITE COPY** (copy #4) is retained by the testing clinic/site. The **CLIENT COPY** (copy #5) is given to the client who must bring the slip to the test result disclosure session.

The LRF is organized into seven different areas. Data in the first area is collected for all clients and includes the date of the specimen, return appointment date (if applicable) and client demographics. The **CONFIDENTIAL TESTING USE ONLY** area is only for clients who elect to test confidentially. Rapid test specimen, quality control measures, and rapid test result information are recorded in the **RAPID TEST USE ONLY** area. The **LAB SPECIMEN** area is recorded for all standard HIV tests and rapid confirmatory tests. The **LABORATORY NAME & ADDRESS** and **CLINIC/SITE NAME, ADDRESS, & PHONE** are recorded in the area provide. The **LOCAL LABORATORY NUMBER** area and **LABORATORY USE ONLY** areas are for laboratory use only for tracking and recording tests conducted by clinical laboratories.

GENDER, DATE OF BIRTH, RESIDENCE COUNTY, and **RESIDENCE ZIP CODE** must match what is recorded on the CIF. **GENDER, DATE OF BIRTH, SOUNDEX CODE** (created from an algorithm of the **LAST NAME**), and **SSN** together create a Non-Name Code recorded in California's HIV Reporting System for confidential positive test results. Note: **LAST NAME, SSN, SOUNDEX CODE, NOTE, DATE RECEIVED BY LAB, DATE REPORTED,** and **LOCAL LABORATORY NUMBER** are not entered into the CIS database.

Form Elements

All information should be completely recorded for each testing procedure. Blanks represent incomplete data and can affect the level of payment for counseling and testing services and reflect the adequacy of the service provided. In this guidance, major headings are the same as the form's label for each area. Topic labels are in bold print. Literal content of an item on the form is presented in italics.

LOCAL LABORATORY NUMBER

The *LOCAL LABORATORY NUMBER* is reserved for a specimen tracking number used by the laboratory to identify the laboratory where services are provided and to track specimens.

Unique Office of AIDS Client Number

This *Unique Office of AIDS Client Number* is used to ensure client confidentiality and, in the event of a confirmed positive test, assist in matching/unduplicating reported HIV cases. This number is used along with the labels to track the specimen and HIV antibody test, HIV counselor assessment, appointment log, and other record keeping.

SPECIMEN DATE

The *SPECIMEN DATE* identifies when the specimen was taken and is used to track the volume of testing at each laboratory site.

RETURN APPOINTMENT DATE

Indicate the date the client should return for their test results for standard test results, confirmatory results for preliminary positive rapid tests, and clients unprepared to receive a rapid test result the same day it was performed. The *RETURN APPOINTMENT DATE* helps labs to schedule procedures in a timely manner so test results can be sent to testing sites prior to the clients return for their results.

GENDER

Indicate the client's *GENDER* as (1) *MALE*, (2) *FEMALE*, (3) *M-F* (transgender male-to-female) or (4) *F-M* (transgender female-to-male).

DATE OF BIRTH

Record the client's complete *DATE OF BIRTH*: two-digit month, two-digit day and four-digit year (e.g., 03/06/1963 for March 6, 1963).

RESIDENCE COUNTY

Indicate the county where the client has his/her primary residence.

RESIDENCE ZIP CODE

Indicate the ZIP code of the client's residence or hang out ZIP code if client is homeless.

CONFIDENTIAL TESTING USE ONLY

This area is reserved for confidential testing use ONLY. This information must NEVER be collected for clients electing to test anonymously.

LAST NAME

Record the clients *LAST NAME* (surname). Some clients may use two last names or hyphenated names. If this is the case, please enter both last names as one word in this area omitting hyphens (e.g., Jones-Smith is entered as JonesSmith). A Soundex code is created from the last name. We can only be sure of unduplicated reports of HIV cases if the names are recorded consistently and accurately.

SSN

Record the last four digits of the client's Social Security Number (*SSN*). If the *SSN* is not available, enter four zeroes (0000) instead. Every effort should be made to obtain the last four digits of the clients *SSN*. Clients should be reminded that these four digits cannot be linked to their identity.

SOUNDEX CODE

The laboratory generates the *SOUNDEX CODE*. Soundex is a four-digit algorithm produced from the first letter and subsequent consonants of a person's last name, consisting of one letter and three numbers. Once it is generated, It is highly unlikely that the soundex code can be reversed (or decoded) to reveal a person's last name.

RAPID TEST USE ONLY

This area is for recording rapid test kit information, quality assurance measures, and results.

LOT NUMBER

Record the eight-digit *LOT NUMBER* stamped on the bottom right of the Oraquick rapid test kit packaging.

EXPIRATION DATE

EXPIRATION DATE month and year (*mm/yy*) is stamped below the lot number on the OraQuick rapid test kit packaging. Kit expires at the end of the month and year stamped. Expired tests must be returned to the OA.

COUNSELOR/TECH INITIALS

Enter the initials of the counselor or technician operating the test kit.

SPECIMEN

Indicated the type of *SPECIMEN* collected for the rapid test. Mark (1) *ORAL* for oral fluid specimens, (2) *FINGER STICK* for blood fingerstick specimens, or (3) *VENIPUNCTURE* for blood specimens collected through venipuncture. Note: OraQuick has not been approved by the Food and Drug Administration (FDA) for oral fluid testing as of September 2003.

BEGIN TEST

BEGIN TEST is when the absorbent pad is inserted into the vial containing the sample.

TIME: Record the starting time (e.g., 1:30 for one thirty) and indicate whether it is AM or PM.

TEMPERATURE: Record the current temperature in the testing room in degrees Fahrenheit.

END TEST

END TEST is when the test result is read.

TIME: Record the ending time (e.g., 1:50 for one fifty) and indicate whether it is AM or PM.

TEMPERATURE: Record the current temperature in degrees Fahrenheit.

RESULT

Record the *RESULT* of the rapid test. Mark either (1) *PRELIMINARY POSITIVE*, (2) *NEGATIVE*, or (3) *INVALID*. If the result is *PRELIMINARY POSITIVE* then indicate whether or not the client gave a confirmatory specimen. If the result is *INVALID* then briefly describe the reason you think the result is invalid (e.g., spilled vial, temperature out of range, unknown, etc.).

Offer the client the option of retesting with a rapid test or with a standard lab-based test if the result is *INVALID*. If two invalid test results occur in a row offer clients standard testing. See **Recording Multiple Tests** below for recording procedures for multiple tests.

CONFIRMATORY SPECIMEN GIVEN

Indicated whether or not a confirmatory specimen was collected for clients with *PRELIMINARY POSITIVE* results. Indicate the specimen type of the confirmatory specimen in the **LAB SPECIMEN** area.

LAB SPECIMEN

This area is for recording the *LAB SPECIMEN* for standard tests or confirmatory tests for rapid tests.

SPECIMEN

Indicate the type of *SPECIMEN* collected. Mark (1) *ORAL* for oral fluid specimens, (2) *FINGER STICK* for blood fingerstick specimens, or (3) *VENIPUNCTURE* for blood specimens collected through venipuncture.

LABORATORY NAME & ADDRESS

List the name, address, and phone number of the clinical laboratory that will receive the specimen and perform the test.

CLINIC/SITE NAME, ADDRESS, & PHONE

Indicate the name, address, and telephone number of the clinic or site where the specimen was obtained. Clinic/site information allows laboratories to identify where test results are to be sent.

LABORATORY USE ONLY

This area is reserved for the clinical laboratory.

ELISA

The enzyme-linked immunosorbent assay (*ELISA*) is a test used to check for the presence of antibodies to HIV in blood samples. (1) *REACTIVE* results of ELISA indicate the presence of HIV antibodies in the blood and require a supplemental test to confirm results. (2) *NON-REACTIVE* results indicate that no HIV antibodies were found. The results of the *ELISA* test are used in the disclosure session to explain test results to testers, HIV surveillance, and data analysis.

SUPPLEMENTAL TEST PERFORMED

A *WESTERN BLOT* or an immunofluorescent assay (*IFA*) test is used to confirm reactive ELISA test results and preliminary positive rapid test results. Both tests check for the presence of antibodies to HIV in oral/blood samples and are used in the disclosure session to explain test results to clients and for HIV surveillance and data analysis. Indicate whether an (1) *IFA* or (1) *WESTERN BLOT* was performed.

IFA

(1) *REACTIVE* indicates that HIV antibodies were found; (2) *NON-REACTIVE* indicates that no antibodies were found; (3) *NONSPECIFIC/UNSATISFACTORY* indicates that the results could not be interpreted as reactive or non-reactive.

WESTERN BLOT

(1) *REACTIVE* indicates the presence of HIV antibodies; (2) *NON-REACTIVE* indicates the results were negative; (3) *INDETERMINATE* indicates that the results were inconclusive.

SUMMARY INTERPRETATION

SUMMARY INTERPRETATION provides an additional confirmation of tests by providing a summary of test results and assists the disclosure counselor during the disclosure session in explaining results to clients. (1) *HIV ANTIBODY DETECTED* indicates that

the test result is positive; (2) *NO HIV ANTIBODY DETECTED* indicates a negative result; and (3) *INCONCLUSIVE-SUBMIT ANOTHER SPECIMEN* indicates the test was indeterminate and another specimen is needed for testing. See **Recording Multiple Tests** below for recording procedures for multiple tests.

SEE ENCLOSED NOTE: This informs the disclosure counselor that additional notes on the results of the test result are include with the form.

NOTE

This area is for laboratory notes to the clinic/site regarding the summary interpretation.

DATE RECEIVED BY LAB

Used by the clinical laboratory to record when the laboratory received the specimen. The date the specimen was received by the lab assists in the scheduling of laboratory procedures.

DATE REPORTED

Indicates the date the laboratory reported the results to the service provider. The date the lab reported the results confirms that results have been sent to the testing site for the disclosure session.

Recording Multiple Tests

There are rare circumstances in which an invalid rapid test, a discordant rapid test, and standard inconclusive tests required additional testing and a new LRF. The *Unique Office of AIDS Client Number* on the CIF must match the *Unique Office of AIDS Client Number* printed on LRF with the final test results. These multiple tests are entered into the CIS.

The circumstances that require the recording of multiple tests are:

Invalid rapid test: Client elects to retest with another rapid test during the risk assessment after receiving an invalid rapid test. Note: If client elects to retest by submitting a sample for a lab-based standard test during the risk assessment then it is not necessary fill out a new LRF.

Discordant confirmatory test: Client elects to retest during the disclosure session after receiving a negative or inconclusive confirmatory test after a preliminary positive rapid test.

Standard inconclusive test: Client elects to retest during the disclosure session after receiving an inconclusive result on a standard lab-based HIV test.

Follow these procedures below so the correct *Unique Office of AIDS Client Number* is recorded correctly. The final result *Unique Office of AIDS Client Number* must match the *Unique Office of AIDS Client Number* on the CIF.

1. Fill out a new LRF for the second test.
2. Place a *Unique Office of AIDS Client Number* label from the new LRF over the client number label of the first test on the CIF.
3. Record the number of the first LRF on the new LRF.
4. Double staple the **RETURN THIS COPY TO TEST SITE (data entry copy)** copy of the first test to the CIF.
5. Double staple the new **RETURN THIS COPY TO TEST SITE (data entry copy)** copy to the CIF when you receive the final result.

There may be as many as three LRF stapled to the CIF in extremely rare cases where there was an invalid rapid test and a discordant confirmatory test.

Appendix F: Anonymous Consent Form

Consent to Test for HIV – Anonymous

Anonymous consent form to be completed by COUNSELOR to verify verbal consent given by client. No client identifying information should appear on this form.

Counselor initials

Client has been informed of the differences between anonymous and confidential HIV testing. Client understands that confidential reactive HIV test results will be forwarded using a non-names code to the California Department of Health for record-keeping purposes.

Client has been informed about the limitations and implications of HIV tests. Client understands that HIV tests' accuracy and reliability are not 100% certain.

Counselor initials

Rapid Testing Only

Client has been informed that s/he will receive his/her initial HIV test result before leaving today. Client understands that a negative test result does not require confirmation.

Client has been informed that a reactive rapid HIV test result must be confirmed by a laboratory based test. Client consents to give a blood or oral fluid sample for this confirmatory test if his/her initial test result is reactive.

Counselor: By my signature below, I affirm that I have provided information to the client concerning the benefits and risks of HIV testing, and that she/he has had a chance to ask questions which were answered to his/her satisfaction. I affirm that the client has given verbal consent to each of the points initialed above, and does consent to submit a blood or oral fluid sample to be tested for HIV.

_____ Date

_____ Counselor Signature

_____ Counselor Printed Name

Appendix G: Anonymous Consent Form – Spanish

Consentimiento para Hacer la Prueba de VIH – Anónimo

Forma de consentimiento será completado por un/a CONSEJERO/A para verificar que consentimiento verbal fue proveido por el cliente. Ninguna información que identifique el cliente debería de aparecer en esta forma.

Iniciales del
consejero/a

El cliente ha sido informado acerca de las diferencias entre las pruebas anónima y confidencial del VIH. El cliente comprende que los resultados confidenciales y reactivos de la prueba de VIH serán mandado utilizando un código sin nombre al Departamento de Salud de California para recordar datos.

El cliente has sido informado sobre las limitaciones e implicaciones de las pruebas de VIH. El cliente comprende que la exactitud y veracidad de las pruebas de VIH no son 100% seguro.

Iniciales del
consejero/a

La Prueba Rápida Solamente

El cliente ha sido informado que hoy, antes de salir, recibirá el resultado inicial de su prueba de VIH. El cliente comprende que un resultado negativo no requiere confirmación.

El cliente ha sido informado que un resultado positivo de la prueba rápida de VIH tiene que ser confirmado por una prueba del laboratorio. Consiente dar una muestra de sangre o fluido oral para esta prueba confirmatoria si su prueba inicial sale positiva.

Consejero/a: Con mi firma que sigue, afirmo que he proveido información al cliente que explica los beneficios y riesgos de las pruebas de VIH, y el cliente tuvo la oportunidad de hacer preguntas que fueron contestadas de manera satisfactoria. Afirmo que el cliente ha dado consentimiento verbal para cada punto inicializado arriba, y consiente someter una muestra de sangre o fluido oral para recibir la prueba de VIH.

Fecha

Firma del Consejero/a

Nombre en Letras Molde del Consejero/a

Appendix H: Confidential Consent Form

Consent to Test for HIV – Confidential

Client initials

I have been informed of the differences between anonymous and confidential HIV testing. I understand that reactive HIV test results will be forwarded using a non-names code to the California Department of Health for record-keeping purposes.

I have been informed about the limitations and implications of HIV tests. I understand that HIV tests' accuracy and reliability are not 100% certain.

Client initials

Rapid Testing Only

I have been informed that I will receive my initial HIV test result before I leave today. I understand that a negative test result does not require confirmation.

I have been informed that a reactive rapid HIV test result must be confirmed by a laboratory based test. I consent to give a blood or oral fluid sample for this confirmatory test if my initial test result is reactive.

By my signature below, I acknowledge that I have been given information concerning the benefits and risks of HIV testing, and have had a chance to ask questions which were answered to my satisfaction. I consent to submit a blood or oral fluid sample to be tested for HIV.

Date

Signature

Last 4 digits SS #

Printed Name

Client initials

Contact Information

In the event that I miss my follow-up appointment, I consent to be contacted by _____ to reschedule my missed appointment.

(agency representative)

Address

City

State

ZIP Code

Home phone

Alternate phone

Additional contact instructions: _____

Appendix I: Confidential Consent Form – Spanish

Consentimiento para Hacer la Prueba de VIH – Confidencial

Iniciales del
Cliente

_____ He sido informado sobre las diferencias entre las pruebas anónima y confidencial de VIH. Comprendo que los resultados de la prueba reactiva de VIH serán reportado al Departamento de Salud de California para archivar los datos utilizando un código sin nombre.

_____ He sido informado sobre las diferencias entre las pruebas anónima y confidencial de VIH. Comprendo que los resultados de la prueba reactiva de VIH serán reportado al Departamento de Salud de California para archivar los datos utilizando un código sin nombre.

Iniciales del
Cliente

La Prueba Rápida Solamente

_____ He sido informado que hoy recibiré el resultado inicial de mi prueba de VIH antes de salir. Comprendo que un resultado negativo no requiere confirmación.

_____ He sido informado que un resultado positivo de la prueba rápida de VIH tiene que ser confirmado por una prueba del laboratorio. Consiento dar una muestra de sangre o fluido oral para esta prueba confirmatoria si mi prueba inicial sale positiva.

Con mi firma que sigue, confirmo que he recibido información que explica los beneficios y riesgos de las pruebas de VIH, y tuve la oportunidad de hacer preguntas que fueron contestadas de manera satisfactoria. Consiento someter una muestra de sangre o fluido oral para recibir la prueba de VIH.

_____ Fecha

_____ Firma

_____ Los últimos cuatro números
de su seguro social

_____ Nombre en Letras de Molde

Iniciales del
Cliente

Información de Contacto

_____ Si faltó a mi cita de seguimiento, consiento ser contactado por _____ para hacer una cita nueva.
(representante de agencia)

Dirección		
Ciudad	Estado	Código Postal
Teléfono de casa	Teléfono alternativo	
Instrucciones adicionales para contactarme: _____		

Appendix J: Consent to Transition to Confidential Testing

Consent to Transition to Confidential Testing

Client initials

I have been informed of the differences between anonymous and confidential HIV testing. I understand that reactive HIV test results will be forwarded using a non-names code to the California Department of Health for record-keeping purposes.

I hereby give my permission to transition my testing status from anonymous to confidential.

By my signature below, I acknowledge that I have been given information concerning anonymous vs. confidential testing, and have had a chance to ask questions which were answered to my satisfaction.

Date

Signature

Last 4 digits SS #

Printed Name

Client initials

Contact Information

In the event that I miss my follow-up appointment, I consent to be contacted by _____ to reschedule my missed appointment.

(agency representative)

Address		

City	State	ZIP Code
_____	_____	_____
Home phone	Alternate phone	
_____	_____	
Additional contact instructions: _____		

[Note to counselor: attach this form to the anonymous consent form completed previously and link using the Unique Office of AIDS Client Number.]

Appendix K: Temperature Logs

Appendix L: External Quality Control Log

Problem Documentation

Page ___ of ___

Date	CIF	Initials	Lot #	Exp date	Problem	Corrective Action Taken

Initial Review _____ signature _____ / / date _____ Final Review _____ signature _____ / / date _____

Appendix M: External Quality Control Log Instructions

External Quality Control Log Instructions

Use this external quality control (EQC) log to document the process each time external controls are run. External controls should be run periodically and after certain triggering events to establish that the OraQuick test kits are functioning properly. See the OA rapid testing guidance for more information.

This log consists of two sides or pages. The “front” side is labeled “External Quality Control Log for (month)/(year).” The “back” side is for problem documentation related to EQC procedures.

Front Side

To run EQC, two tests kits are used. One test kit is used to process the negative sample, and one to process the positive sample. The information and outcome for both tests are recorded across a single line of the EQC log.

Date

Date the controls are run

Site

Identifying code for the site at which these controls are run. Should be consistent with information used in HIV Counseling Information System.

Initials

Initials or numeric code of counselor or technician conducting controls. Should be consistent with information entered into HIV Counseling Information System.

QC code

Reason or triggering event for running controls. See codes listed on bottom of front side.

Test kit – Lot #

Lot number listed on outside pouch of the test kits used. Both test kits must have the same lot number and expiration date. If testing more than one lot, run a positive and negative control for each lot.

Test kit – Exp date

Expiration date listed on outside pouch of the test kits used.

Control Kit – Lot #

The lot number listed on the outside of the control unit box.

Control Kit – Closed vial exp

The expiration date printed by the manufacturer on the outside of the control unit box.

Control Kit – Open vial exp

Control units expire after a specified period of time has passed since opening. (See control unit package insert for time period specified by manufacturer. As of this writing [Sep 03], the package insert indicates that control units expire three weeks after opening.) Both the date the vials were opened and the date the controls expire must be handwritten on the control unit box when opened.

Negative (Positive) Control – Start time/temp

The time and temperature in the testing area when the test kit processing the negative (positive) control was inserted into the vial of reagent.

Negative (Positive) Control – End time/temp

The time and temperature in the testing area when the test kit processing the negative (positive) control was read; must be within the time period specified by the manufacturer.

Negative (Positive) Control – Result

Circle “P” if the result was positive or reactive; N if the result was negative or non-reactive; or “I” if an invalid result was obtained.

Result Acceptable?

Circle “Yes” if the positive control yielded a positive result and the negative control yielded a negative result. For any other combination of results, including invalid, circle “No.” If the result of the EQC process is unacceptable, document the problem on the back of the EQC log and take proper steps to remedy the problem, according to OA guidelines and site-specific QA procedures. Client testing using the OraQuick device must be halted until the problem can be resolved and proper functioning of the test kits is verified.

Back Side

Entries should be made on the back side of the EQC log in two general cases:

1. If controls are required for an unusual reason
2. If controls fail

If controls are required for an unusual reason

If it is necessary to run controls for a reason not listed on the front of the log under “QC code,” document the reason for running controls on the backside of the log. Some possible reasons could be: two invalid test results in a row, an unusual number of positive results given local prevalence, or any other event that calls into question the functioning of the test kits.

If this occurs, document the date of the event, the Unique OA Number(s) from the CIF if the event is related to a specific client test, the initials of the technician running the controls, the lot number and expiration date of the test kit, the problem, and the corrective action taken.

If controls fail

If controls being run for any reason fail, document this event on the back of the EQC log. Include the date, [skip the box labeled “CIF”], the initials of the technician running the controls, the lot number and expiration date of the test kit, the problem, and the corrective action taken.

Under “problem,” list “failed controls” along with an explanation, if known. (For instance, controls may fail because the technician neglected to insert the sample, or the test kit was knocked over while in process. If this is known to be the case, document that here.)

Under “corrective action taken,” document what steps were taken to resolve the problem, such as re-running controls, re-running controls with a new control unit, notifying the manufacturer, etc.

Appendix N: Rapid Test Inventory Log

Rapid Test Inventory Log

LHD/ Agency Number:

--	--	--	--

Primary Site Number:

--	--	--	--

For OraQuick rapid test shipment received enter the date received, lot numbers, lot number expiration date, and number of tests received below.

Date Received:

--	--	--	--	--	--

(mm/dd/yy)

Lot Number(s):

Expiration Date(s):

(mm/yy)

Number Tests Received:

--	--	--	--	--

For inventory control, indicate below the number of damaged tests received, used tests, or unusable tests for the shipment above. Damaged tests should be claimed to the shipper and expired tests should be returned to the Office of AIDS. For unusable tests, indicated the reason (i.e., stored out of range, spilled, damaged in the field, etc.).

Testing Usage Log:

Damaged Tests Received					
Clients Tested					
Counselor Competency					
Control Tests					
Expired Tests					
Unusable Tests <i>(damaged, stored out of range, spilled, etc.)</i>					
Tests Unaccounted For					
Total Tests <i>(should equal Tests Received)</i>					

Damages claimed? ⁽¹⁾ Yes ⁽⁰⁾ No

Date tests sent to OA: ____ / ____ / ____.

Reasons for unusable tests: *(mark all that apply)*

- ⁽¹⁾ *stored out of range*
- ⁽¹⁾ *spilled*
- ⁽¹⁾ *damaged in field*
- ⁽¹⁾ *other reason, specify below:*

Appendix O: HIV Counseling Information Form

HIV COUNSELING INFORMATION FORM

Unique Office of AIDS Client Number

Administrative Information

Agency/ LHD no.:

Site no.:

Clinic type: (mark one)

(1) Alternative test site (8) Street outreach
 (2) Family planning (9) Mobile van
 (3) STD clinic (10) TB clinic
 (4) Alc./drug treatment (11) Youth drop in
 (5) Detention facility (12) Other health department
 (6) Primary care/CHC (13) Other, specify: _____
 (7) HIV test

Client's test election: (mark one)

(1) Tested anonymously
 (2) Tested confidentially
 (3) Declined testing/not tested

Counseling Dates

(date and initial) Service Date (mm/dd/yy) Initials (print)

Risk assessment:

Follow-up contact:

(to reset missed disclosure/post disclosure sessions by confidential clients)

Disclosure session:

(this may be the same date as risk assessment for rapid test results)
 (carefully verify anonymous clients using Client Information)

(1) Mark if post disclosure counseling scheduled.

Post disclosure session:

(for rapid test positive confirmatory disclosures and post disclosure)
 (carefully verify anonymous clients using Client Information)

First letter of last name:

Enter first letter of last name.
 Mark "*" if declined/refused.

Alternative billing:
 (mark all that apply)

(1) No billing to OA
 (1) Risk Assessment
 (1) Disclosure
 (1) Post Disclosure
 (1) Laboratory Work

Detuned: (studies only)

(1) DTR (recent)
 (2) DTL (long standing)
 (3) DTNT (not tested)

Client Information

Race/ethnicity: (mark one or two)

1st 2nd

(1) (1) African American (not Hispanic)
 (2) (2) American Indian/Alaskan Native
 (3) (3) Asian/Pacific Islander
 (4) (4) Hispanic/Latino(a)
 (5) (5) White (not Hispanic)
 (6) (6) Other, specify: _____

Date of birth: (mm/dd/yy)

Gender and pregnancy: (mark one)

(1) Male
 (2) Female
 (3) Pregnant female
 (4) Transgendered: male to female
 (5) Transgendered: female to male
 (6) Other, specify: _____

Sexual orientation: (mark one)

(1) Heterosexual (straight)
 (2) Bisexual
 (3) Gay, lesbian, queer, or homosexual
 (4) Other, specify: _____
 (5) Client doesn't know

Residence county:

Residence zip code:

(1) Mark if client is homeless.

Client was referred by: (mark one)

(1) HIV+ partner
 (2) PCRS/partner notification
 (3) OA NIGHT outreach (incentive/referral)
 (4) Other outreach worker
 (5) HIV education program
 (6) AIDS telephone hotline
 (7) Other AIDS agency
 (8) Alcohol/drug treatment program
 (9) M.D./health clinic
 (10) Friend/relative
 (11) Media (TV, radio, print)
 (12) Internet
 (13) No identifiable referral source

Client's reason for testing: (mark one)

(1) Reconfirming HIV+ result
 (2) Reports AIDS-like symptoms
 (3) Has current HIV+ partner
 (4) Had past HIV+ partner
 (5) TB diagnosis
 (6) STD related
 (7) Hepatitis diagnosis
 (8) Pregnancy
 (9) Risky behavior
 (10) Starting a new relationship
 (11) Partner request
 (12) Rape/assault
 (13) Exposure to blood
 (14) Immigration
 (15) Other, specify: _____

HIV Testing History

Number of prior HIV tests: (circle one)

(0) (1) (2) (3) (4) (5) (6) (7) (8) (9+)

Date of last test result: (mm/yy)

Last test result: (mark one)

(1) Positive
 (2) Negative
 (3) Inconclusive
 (4) Did not return for results

Risk Reduction Steps

Risk assessment stage of change: (mark one)

(1) Not thinking about it (Precontemplation)
 (2) Thinking about it (Contemplation)
 (3) Ready for action (Preparation)
 (4) Action
 (5) Maintenance

Immediate risk reduction step:
 (to be accomplished by client before disclosure)

At disclosure: risk reduction step(s): (mark one)

(1) No step established at risk assessment
 (2) Client made no effort
 (3) Step attempted
 (4) Step achieved

Post disclosure/short-term risk reduction step(s):

Long-term risk reduction step(s):

Referrals

Client referrals:
 Record at risk assessment (RA), disclosure (D) and post disclosure (PD). Order by marking 1 for your primary referral. Other referrals should be numbered 2 and 3.

	RA	D	PD
(1) NONE			
(2) Referral list only			
(3) Other HIV testing			
Risk/harm reduction			
(4) Prevention case management (PCM)			
(5) HIV education & prevention services			
(6) Follow-up HIV counseling			
(7) Prevention skill development			
(8) Prevention support group			
(9) Individual psychotherapy/counseling			
Substance use services			
(10) Alcohol/drug treatment			
(11) Twelve step program			
(12) Needle exchange program			
HIV positive referrals			
(13) Early intervention program (EIP)			
(14) HIV case management			
(15) HIV medical care/evaluation/treatment			
(16) PCRS/partner notification			
Other referrals			
(17) Post-exposure prophylaxis (PEP)			
(18) Hepatitis testing/vaccination			
(19) STD clinic			
(20) Reproductive health services			
(21) Other Non-HIV medical services			
(22) Social services			
(23) Other, specify: _____			

Counselor: Review/Assess Introductory Issues

Anonymity/confidentiality/non-names testing.
 Risk assessment process and purpose of form.
 What the HIV test measures.
 Meaning/accuracy of test results
 (preliminary positive, positive, negative, inconclusive).
 Impact of HIV on the immune system.

Counselor: Review/Assess Testing Issues

Window period/date of any follow-up test.
 Process of testing.
 Coping with waiting for test results.
 Client's readiness to be tested.
 Offer testing, if appropriate.
 Encourage the client to return for results.

Counselor Notes:

Discuss and record the client's behavior during the **last two years** unless otherwise indicated. If client has received an HIV test result during the last two years then discuss and record the client's behavior since the date of the client's last test result.
Date of last test result: (if within last 2 years) ____ / ____ (mm/yy) (from HIV Testing History on front of form)

Sexual Risk History (last 2 years/last result)

Total number of sex partners: (last 2 years/last result) (000-999) <input type="text"/>			
Male sex partner(s).			
Partner(s): (mark one <input checked="" type="checkbox"/> <input type="checkbox"/> (0) no partners <input type="checkbox"/> (1) one or more <input type="checkbox"/> (*) declined/refused	Sexual activity:		Frequency of barrier use:
	Oral	Yes <input type="checkbox"/> No <input type="checkbox"/>	Never Sometimes Always <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Vaginal	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal insertive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal receptive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
Female sex partner(s).			
Partner(s): (mark one <input checked="" type="checkbox"/> <input type="checkbox"/> (0) no partners <input type="checkbox"/> (1) one or more <input type="checkbox"/> (*) declined/refused	Sexual activity:		Frequency of barrier use:
	Oral	Yes <input type="checkbox"/> No <input type="checkbox"/>	Never Sometimes Always <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Vaginal	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal insertive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal receptive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
Transgendered partner(s).			
Partner(s): (mark one <input checked="" type="checkbox"/> <input type="checkbox"/> (0) no partners <input type="checkbox"/> (1) one or more <input type="checkbox"/> (*) declined/refused	Sexual activity:		Frequency of barrier use:
	Oral	Yes <input type="checkbox"/> No <input type="checkbox"/>	Never Sometimes Always <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Vaginal	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal insertive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal receptive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
Sex with sex worker(s)/prostitute(s).			
Partner(s): (mark one <input checked="" type="checkbox"/> <input type="checkbox"/> (0) no partners <input type="checkbox"/> (1) one or more <input type="checkbox"/> (*) declined/refused	Sexual activity:		Frequency of barrier use:
	Oral	Yes <input type="checkbox"/> No <input type="checkbox"/>	Never Sometimes Always <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Vaginal	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal insertive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal receptive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
Sex partner(s) who injected drugs or other substances.			
Partner(s): (mark one <input checked="" type="checkbox"/> <input type="checkbox"/> (0) no partners <input type="checkbox"/> (1) one or more <input type="checkbox"/> (*) declined/refused	Sexual activity:		Frequency of barrier use:
	Oral	Yes <input type="checkbox"/> No <input type="checkbox"/>	Never Sometimes Always <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Vaginal	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal insertive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal receptive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
HIV-infected sex partner(s).			
Partner(s): (mark one <input checked="" type="checkbox"/> <input type="checkbox"/> (0) no partners <input type="checkbox"/> (1) one or more <input type="checkbox"/> (*) declined/refused	Sexual activity:		Frequency of barrier use:
	Oral	Yes <input type="checkbox"/> No <input type="checkbox"/>	Never Sometimes Always <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Vaginal	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal insertive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal receptive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
Did client know partner's HIV-positive status prior to sexual contact? <input type="checkbox"/> (1) <input type="checkbox"/> (0) <input type="checkbox"/> (*)			
(Females Only) Male partner(s) who has had sex with a male.			
Partner(s): (mark one <input checked="" type="checkbox"/> <input type="checkbox"/> (0) no partners <input type="checkbox"/> (1) one or more <input type="checkbox"/> (*) declined/refused	Sexual activity:		Frequency of barrier use:
	Oral	Yes <input type="checkbox"/> No <input type="checkbox"/>	Never Sometimes Always <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Vaginal	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)
	Anal receptive	<input type="checkbox"/> (1) <input type="checkbox"/> (0)	<input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)

Optional Data

Item 1:	Item 3:
Item 2:	Item 4:

Substance Use History (last 2 years/last result) (*) declined/refused

Substance use: (mark all that apply <input checked="" type="checkbox"/> <input type="checkbox"/> (1) no alcohol or drug use	TFC	Injected:		Frequency used with sex:			
		Yes	No	Never	Rarely	Sometimes	Usually
<input type="checkbox"/> (1) alcohol		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) marijuana (pot, grass, weed, hash)				<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) heroin, etc. (junk, skag, smack, H)		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) barbiturate/tranquilizers		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) crack (rock)		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) amphetamine (crank, crystal, tina)		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) cocaine (powder)		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) nitrate/nitrite (poppers, rush)				<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) ecstasy (MDMA, Adam, E, X)		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) GHB (liquid ecstasy, gina, G)		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) ketamine (special K, K)		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) Viagra (Cialis, Levitra, Metabs, Caverta, Generac - Viagra, Cialis, & Levitra)				<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) hallucinogens (LSD, acid, psilocybin, peyote, mescaline, PCP)		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
<input type="checkbox"/> (1) other, specify: _____		<input type="checkbox"/> (1)	<input type="checkbox"/> (0)	<input type="checkbox"/> (1)	<input type="checkbox"/> (2)	<input type="checkbox"/> (3)	<input type="checkbox"/> (4)
Injection behaviors: (complete if injected)							
Never Sometimes Always TFC				Yes No			
Shared needles <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)				Shared with a known HIV+ partner? <input type="checkbox"/> (1) <input type="checkbox"/> (0)			
Cleaned works <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)							
Needle exchange <input type="checkbox"/> (1) <input type="checkbox"/> (2) <input type="checkbox"/> (3)				Is NE available in client's area? <input type="checkbox"/> (1) <input type="checkbox"/> (0)			
Needle/syringe sources: (mark all that apply <input checked="" type="checkbox"/> <input type="checkbox"/> (1) needle exchange program <input type="checkbox"/> (1) needle dealer/seller <input type="checkbox"/> (1) close friend <input type="checkbox"/> (1) secondary exchange <input type="checkbox"/> (1) shooting gallery <input type="checkbox"/> (1) sexual partner <input type="checkbox"/> (1) pharmacy/drug store <input type="checkbox"/> (1) diabetic <input type="checkbox"/> (1) other source							
IDU treatment history	Never <input type="checkbox"/> (1)	Currently in treatment <input type="checkbox"/> (2)	Within last 2 yrs/last result <input type="checkbox"/> (3)	Prior to last 2 yrs/last result <input type="checkbox"/> (4)	TFC		

Other Risk History

STDs/hepatitis (last 2 years/last result): (mark all that apply <input checked="" type="checkbox"/> <input type="checkbox"/> (*) declined/refused			
<input type="checkbox"/> (1) no STDs/hepatitis	<input type="checkbox"/> (1) genital/anal warts (HPV)	<input type="checkbox"/> (1) syphilis (syph, the pox, lues)	<input type="checkbox"/> (1) genital herpes (HSV)
<input type="checkbox"/> (1) gonorrhea urethral (GC, clap, drip)	<input type="checkbox"/> (1) hepatitis A (HAV)	<input type="checkbox"/> (1) gonorrhea oral (GC, clap, drip)	<input type="checkbox"/> (1) hepatitis B (HBV)
<input type="checkbox"/> (1) gonorrhea anal/rectal (GC, clap, drip)	<input type="checkbox"/> (1) hepatitis C (HCV)	<input type="checkbox"/> (1) chlamydia	<input type="checkbox"/> (1) other, specify: _____
<input type="checkbox"/> (1) trichomoniasis (trich)			
Viral STDs/hepatitis (lifetime history): (mark all that apply <input checked="" type="checkbox"/> <input type="checkbox"/> (*) declined/refused			
<input type="checkbox"/> (1) no lifetime viral STDs/hepatitis	<input type="checkbox"/> (1) hepatitis A (HAV)	<input type="checkbox"/> (1) genital/anal warts (HPV)	<input type="checkbox"/> (1) hepatitis B (HBV)
<input type="checkbox"/> (1) genital herpes (HSV)	<input type="checkbox"/> (1) hepatitis C (HCV)		
Hepatitis vaccination (lifetime history): (mark one each <input checked="" type="checkbox"/> <input type="checkbox"/> (*) declined/refused			
Completed vaccination series for hepatitis A (HAV)?			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)
Completed vaccination series for hepatitis B (HBV)?			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)
Other risk factors (last 2 years/last result): (mark one each <input checked="" type="checkbox"/> <input type="checkbox"/> (*) declined/refused			
Received money/other items or services for sex.			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)
Received drugs for sex.			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)
Behavior resulting in other blood-to-blood contact (SM, tattooing, piercing, cuts, etc.) or that allows blood contact with mouth, vagina or anus.			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)
Shared objects/fingers inserted in mouth, vagina or anus.			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)
Blood-to-blood exposure on the job.			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)
Job exposure blood known to be HIV+.			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)
Blood/blood product transfusion before 1985 (or in a country where blood is/was not tested for HIV).			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)
Child born of an HIV-infected woman.			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)
Other behavior, specify: _____			Yes <input type="checkbox"/> (1) No <input type="checkbox"/> (0) <input type="checkbox"/> (*)

Counselor: Review/Assess Basic Issues

<input type="checkbox"/> Discuss safer sex guidelines.	<input type="checkbox"/> Demonstrate proper condom/barrier use.
<input type="checkbox"/> Role-play with client to build needed skills.	<input type="checkbox"/> Discuss obstacles to condom/barrier use
<input type="checkbox"/> Partner risks as they relate to client risk.	<input type="checkbox"/> Cultural/peer influences.
<input type="checkbox"/> Risk reduction communication with partner.	<input type="checkbox"/> Domestic violence/sexual assault.
<input type="checkbox"/> Integration of birth control & risk reduction.	<input type="checkbox"/> Voluntary PCRS/partner notification.
<input type="checkbox"/> Pregnancy/maternal transmission (uterus, birth, breastfeed).	

Counselor: Review/Assess Drug and STD Issues

<input type="checkbox"/> Prevention/harm reduction/safer sex with IDUs.	<input type="checkbox"/> Demonstrate proper needle cleaning.
<input type="checkbox"/> Explore alcohol & drug treatment/recovery.	<input type="checkbox"/> Drugs with sex as co-factor for HIV risk.
<input type="checkbox"/> Behaviors affecting other STDs (eg. rimming).	<input type="checkbox"/> STDs as a co-factor for HIV risk.
<input type="checkbox"/> Health effects of concurrent STD/HIV (e.g. pelvic inflammatory disease).	

Time Frame Code (TFC): (studies only) 6 = within past 6 months 1 = within past 12 months
 2 = within past 2 years + = greater than 2 yrs 9 = unknown * = declined/refused

Appendix P: HIV Counseling Information Form Guide

Guidance for Completing the HIV Counseling Information Form (HIV6)

This document was developed to: provide HIV counselors a better understanding of the California Department of Health Services, Office of AIDS (OA), *HIV Counseling Information Form* (CIF); describe the CIF's role in HIV counseling; and insure consistent recording of client information. Most items are open to interpretation. This guidance provides a detailed explanation of each item on the form. Reliance on this guidance will minimize confusion of meaning. Whenever questions are unresolved by this document or suggestions for better HIV counseling contact David Webb at the State OA, (916) 449-5826. To order additional CIFs contact Denise Humenik at (916) 449-5822.

The CIF is a professional tool to be used ONLY by HIV counselors who have completed the State-sponsored training. Supervised use by new counselors is permitted as part of their training. The CIF reflects and records key aspects of the HIV counseling content and is designed to assist with the counseling process. This information is appropriately discussed with clients and recorded only by trained staff in the context of providing HIV counseling services. With the exception of a few administrative items, the content of this form is essential for adequate client-centered HIV counseling. HIV counseling cannot be client centered unless the counselor has a complete understanding of the client's risks and current issues. The CIF has been designed in intensive collaboration with the HIV counselor training curriculum development staff, HIV counselor trainers and senior counselors. The information is recorded to insure that it is obtained and available for reference during HIV risk assessment, disclosure and post disclosure HIV counseling sessions. It is the basis for service documentation and reimbursement. It also provides program planners with information about the HIV counseling process and our clients. This information is critical to the continuous improvement of primary HIV prevention in California. This information should NEVER be collected by untrained staff, by clients, or outside the counseling context. Incomplete or inaccurate recording of this information diminishes the impact of HIV counseling, violates contractual obligations and risks support for effective prevention services.

The CIF is organized into five different types of blocks. Heavy-bordered grey blocks contain information that must be completed for services to be reimbursed by the State. Two light-bordered boxes are for studies using detuned HIV enzyme-linked immunoabsorbent assay (ELISA) or enzyme immunoassays (EIA). Two heavy-bordered white boxes contain the first letter of the client's last name and alternative billing. Rounded blocks provide lists of potential topics that HIV counselors should consider discussing with each client. Some must be discussed with every client but few clients will require the discussion of every issue. A check off box for each topic provides a handy means of noting what was covered with the client in the counseling session, important information for disclosure sessions. Using these boxes provides prompts, notes coverage of topics and provides communication to disclosure counselors. Double-bordered white blocks summarize information about the client and the client's risk reduction plan obtained during the risk assessment process. The CIF is organized to reflect the HIV counseling process. While strict reliance on the CIF results in poor counseling, many counselors glance at it occasionally for support, prompts and recording information at convenient points during the interview. The front side of the form covers the introductory portion of the risk assessment session. The core risk assessment is found on the back side and later issues such as referrals and setting a risk reduction plan late in the session are again found on the front. This is a general organizational theme and will not apply to every HIV counselor's style or client session. The CIF must be available during disclosure counseling to support the counseling process, to assess immediate risk reduction goal attainment, to correct and update initial information, and to add final referrals.

All information should be completely recorded for each client, except for those clients who decline to provide the information. In the risk history sections, the HIV counselor must check the declined/refused box for that section when the client declines to provide the risk information addressed. Blanks represent incomplete risk assessments and can affect the level of payment for counseling and testing services and reflect the adequacy of the service provided.

In this guidance, major headings are the same as the form's label for each block. Topic labels are in bold print. Literal content of an item on the form is presented in italics.

Unique Office of AIDS Client Number

A unique OA client number is required for data reporting and payment for services provided. Never use the same number on two different CIFs.

Risk assessment counseling only

When testing does NOT follow risk assessment counseling, a number from the OA supplied inexpensive **white** single numbered labels should be used on each form.

Testing with the OA laboratory slip with purple labels

OA numbers for clients who test are obtained from the **purple** labels on the OA laboratory slips.

Non-OA laboratory slips

If laboratory slips other than OA's purple ones are used, the OA can supply a **yellow** number sticker sets to use with alternate laboratory slips for marking the CIF form, specimen container, etc. The yellow number is used for data entry into the HIV Counseling Information System computer program. (If alternate laboratory slips have a sufficient number of labels, the single white OA number can be placed on the CIF form along with a number from the laboratory slip, tying the two numbers together.)

Administrative Information

Agency/LHD no.

The code number assigned to the local health department (LHD) or other contracting agency by the OA.

Site no.

The number assigned by the LHD or agency to the site where the services were provided. This number should be used to identify physical addresses where C&T services are regularly provided. They should not be assigned, for instance, to every street corner stop of a mobile van route.

Clinic type

Clinic Type provides a list of all the main types of venues where publicly funded counseling and testing is provided. The HIV counselor should select a clinic type that most closely matches the clinic where the HIV service was provided. When none of the defined choices apply, use (12) *Other health department*, if the HIV service is being provide by a public health department and (13) *Other,specify*, for all other possibilities.

1. *Alternative test site*: Local health department Alternative Test Site (ATS) where, by State statute, only free and anonymous testing is conducted. The name cannot be used by other anonymous clinics.
2. *Family planning*: A clinic scheduled solely or primarily to provide family planning services.
3. *STD clinic*: A clinic providing solely or primarily sexually transmitted disease services.
4. *Alc./drug treatment*: Any clinic or site where alcohol or drug treatment services are provided.
5. *Detention facility*: Any juvenile hall, jail or prison.
6. *Primary care/CHC*: A facility or community health clinic (CHC) offering a variety of medical services as needed.
7. *HIV test*: A clinic scheduled to provide confidential or anonymous HIV counseling and testing only, not in conjunction with other services and **NOT an ATS**.
8. *Street outreach*: Street outreach provides education, counseling, HIV testing, referrals, and follow-up services in venues where high-risk populations congregate.
9. *Mobile van*: Testing provided in a vehicle or testing done in the field at no established location. This does NOT include testing done at a given site by a mobile team, if testing is regularly offered at this location.
10. *TB clinic*: A clinic scheduled to provide tuberculosis (TB) diagnosis and/or treatment.
11. *Youth drop in*: A drop in center is a small, store-front-style building located on an active pedestrian thoroughfare, near public transportation. Its purpose is to provide prevention services in a private and comfortable manner to low-income youth at high risk for HIV infection.
12. *Other health department*: HIV testing at a public health department activity not described by the other choices (e.g., immunization clinic, Supplemental Nutrition Program for Women, Infants and Children (WIC) clinic). This includes clinics conducted by LHD contractors that are NOT defined above.
13. *Other, specify*: Any other clinic offered by an organization other than a public health department and not described by the other categories.

Client's test election

This category indicates the client's informed decision whether or not to test. If a client tests, the HIV counselor must specify which OA counseling and testing (C&T) protocol (anonymous vs. confidential) was followed. If the client declined to be tested or the client chooses not to be tested after talking to the counselor the HIV counselor must indicate the client declined to be tested.

1. *Tested anonymously:* Client chose to test and was tested under the anonymous protocol (ATS, or other, non-ATS anonymous testing site).
2. *Tested confidentially:* Client chose to test and was tested under the confidential protocol where name and locating information were taken.
3. *Declined testing/not tested:* The outcome of the risk assessment session was the mutual recognition that the client had no known risk of having been exposed to HIV, had tested recently with a lack of high-risk behavior since the last test, or came to test immediately after a risky event and testing may not provide an accurate result (within the 6 month window period). Some clients do not fully understand how often testing is needed and/or use testing to reassure themselves (e.g. feeling that testing is somehow prophylactic). Clients should be helped to pay more attention to real prevention strategies and less to very frequent testing.

Clients may decline testing because they may not be convinced that anonymity/confidentiality will be maintained. A number of clients have unreasoned fears that their HIV results will be disclosed. Some client needs are better served by referring them from a confidential setting to an anonymous setting. Some clients, usually in small rural settings, have the more reasonable fear that complete anonymity is sometimes hard to maintain in some settings. These clients may benefit from being referred to sites where their anonymity will be assured. These clients should be reassured that information is well protected at the testing site and no identifying information is reported to the county or state.

For some people the fear of being HIV-infected results in an effort to avoid the potential knowledge. While one counseling task is to help clients confront their fears and take constructive action, it is not always accomplished in one session. A client should never be pressured to take a test. Discuss concerns and invite client to return for testing later.

There may be circumstances that prompted the HIV counselor NOT to offer a test to the client. One obvious example occurs when an intoxicated client is unable to provide informed consent. Belligerent clients may also present grounds for discontinuing services.

Counseling Dates

Record the date of the service and the initials of the HIV counselor providing the service. Counselors must use initials consistently. These initials verify the successful completion of a contractual obligation. Initials for each counseling service on each CIF are checked against the computerized roster of active HIV counselors when entered. Billing is done on the basis of these fields and accuracy is essential. **Illegible information will prevent services from being reimbursed.** Dates are entered as Month/Day/Year (e.g., 08/29/03). All counselors must have current HIV counselor training to be reimbursed for services rendered, unless a counselor is new, in which case may be reimbursed for up to three months (under supervision) prior to taking a training (this does not apply to performing rapid testing). Only qualified personnel may conduct, read and record the results of a rapid HIV test.

Risk assessment:

Risk assessment counseling was completed for this client. Provide date of the session and initials of risk assessment counselor in the boxes.

Follow-up contact

Follow-up contact with confidential client who missed scheduled disclosure session or a post disclosure rapid test positive confirmatory disclosure session to reset appointment for disclosure/post-disclosure session. Provide date of contact and initials of follow-up person in the boxes. For this service only, follow-up contacts may be made by staff other than counselors. Contact can be in the form of a phone call, letter, or through street outreach connections.

Disclosure counseling

Disclosure and referral counseling was conducted with this client. Provide date of session and initials of disclosure counselor in the boxes. Disclosure provided on the same day as the test for rapid HIV testing should be indicated in this area.

(carefully verify anonymous client using form information): When disclosing standard testing results, especially anonymously, use the descriptive information provided on the CIF form to insure that the person presenting for the disclosure session is the same as the client tested.

Mark if post disclosure counseling scheduled.

Check this box when a post disclosure counseling session is scheduled for the client. **IMPORTANT:** Checking this box tells the data system to hold the client record until the post disclosure session date is recorded or for 60 days, which ever comes first. If this box is not marked the data system will consider the client record complete and ready for invoicing once the client returns for his/her test result and the disclosure session is recorded.

Post disclosure counseling

Positive confirmatory rapid testing disclosure or post disclosure counseling session was conducted with this client. Provide date of session and initials of post disclosure counselor in blanks. Post-disclosure clients can not be counseled on the same day as the disclosure session or more than 60 days after the risk assessment session.

First letter of last name

Enter the client's first letter of their last name in the box. Input an asterisk (*) if the client declines/refuses to provide information. A matching criterion is made up of the first letter of the client's last name, date of birth, race, gender and resident county. The purpose of the matching criteria is to anonymously track successful referrals to and from HIV C&T services to maximize client access to HIV primary prevention services. These few data items will allow a high accuracy of knowing if an outreach client was successfully linked to testing services. Anonymity and confidentiality remain unchanged and are assured by the use of this very limited information.

Alternate billing

Ordinarily, the services recorded on the CIF form are billed to the OA when entered into the HIV Counseling Information System computer program. This block is normally left blank but when marked allows the billing of none or only a portion of these services. If none of the services are to be billed to the OA, mark *No billing to OA*. Some testing is not billed to the OA such as tests done under court order (sex workers, sex offenders and others) or when paid for by other sources of funding like: CDC, county public health money, other grant/funds, state-mandated claims fund, or the client. In most cases it is still desirable to record all HIV services in the same database.

When one or two of the reimbursable services is billed to another source, the remaining one or two services can be billed to the OA, if appropriate, by marking the one(s) to bill to OA. For example, the OA will pay for a risk assessment counseling session for a client seeking an HIV test needed to apply for immigration but it will not pay for the test. In this case, *Risk assessment* can be marked for OA billing. Only alternative billing items that are marked will be billed to OA.

Detuned

This area is used for areas that have internal review board (IRB) approval for detuned HIV enzyme-linked immunoabsorbent assay (ELISA) or enzyme immunoassays (EIA). The standard HIV ELISA can detect relatively low levels of antibodies. The detuned assay is a less sensitive test that can only detect antibodies at higher levels achieved during the period six months or more after infection. If the standard ELISA detects HIV antibodies then a detuned or weaker version of the ELISA is used to determine whether a person was infected within six months of taking an HIV antibody test or prior to the six-month period. Using a combination of both tests, a positive/negative result indicates a recent HIV infection and a double positive means a long-standing infection. Leave this area blank if detuned testing is not being performed at your testing location.

Researchers can use this testing strategy to learn more about persons seeking HIV testing at publicly funded testing sites. Epidemiologists can use this tool to track new infections in high-risk populations and investigate where prevention efforts may need to be directed. It may also be useful in partner counseling and referral services (PCRS) in determining when infection may have occurred.

Client Information

Race/ethnicity

The purpose of race/ethnicity is to identify cultural issues that may be appropriate for the counselor to address. It provides program planners the race/ethnic proportions of clients needing services. The five "standard" census groups are used. Encourage the client to identify the one group of closest identification, and record it under *1st*. Ask clients if there is a second group with which they identify and record it under *2nd*. The benefit of this approach is that it provides both a "simple" description and a more precise definition of clients of mixed race. This level of detail may help counselors understand cultural issues important to the client's HIV risk reduction.

Date of birth

Record the client's date of birth by reporting the month, day and last two digits of the birth year in the boxes (e.g., 04/25/80). If the client only gives you their age then enter 0 for month and day followed by the year of birth (e.g., 00/00/80).

Gender and pregnancy

Enter the client's self-identified gender. *Female* and *Pregnant female* alternatives are listed here to simplify the form. Don't forget to ask about pregnancy and mark (3) *Pregnant Female* if the client is sure she is pregnant. Mark (2) *Female* if client acknowledges that she might be pregnant, but does not know or client knows she is not pregnant. Transgendered clients may be pre or post operative. If a transgendered client was biologically male at birth then indicate (4) *Transgendered: male to female*. If a transgendered client was biologically female at birth then mark (5) *Transgendered: female to male*. (6) *Other, specify* is for any other self-identified gender, such as intersex or hermaphrodite (both genitalia).

Sexual orientation

Enter the client's self-reported sexual orientation regardless of their sexual behavior. There are many different definitions and conceptions of sexual orientation - including sexual attraction, identity, lifestyle, partnership and community. Sexual orientation may be fluid, changing within an individual over time, and felt differently by different individuals. Instead of imposing one definition of sexual orientation, the client should use their own definition of sexual orientation when answering this question.

Mark (1) *Heterosexual (straight)* if client self-identifies as being heterosexual or straight or attracted solely to members of the opposite gender. Mark (2) *Bisexual* if client self-identifies as being bisexual or attracted to persons of both genders (not necessarily to an equal degree). If client identifies as gay, lesbian, queer, homosexual, "same gender loving", or attracted solely to members of the same gender mark (3) *Gay, lesbian, queer, or homosexual*. If clients specify another sexual orientation then mark (4) *Other, specify*. If client is undecided about their sexual orientation mark (5) *Client doesn't know*. If client declines or refuses to indicate a sexual orientation then do not mark any of the boxes.

Residence county

Record the county of the client's primary residence. For transients, record the county in California where the client most often resides. Out-of-state clients are marked as 99.

Residence zip code

Enter the zip code where the client's residence is located. For transients, enter the zip code where the client most often resides. Out-of-state clients are marked as 99999. These two geographic questions help localize the client for appropriate referral service sites and identify areas of higher concentration of high-risk clients and HIV infected persons for program planning.

Mark if client is homeless.

Mark box if client is homeless. Knowledge of this is particularly important for scheduling disclosure sessions, as it may be impossible to contact these clients.

Client was referred by

Referral sources are ordered to simplify recording. Please mark the lowest numbered referral source that the client reports and enter this number into the data system. For example, if the client says they heard about the clinic's HIV testing by calling the *AIDS telephone hotline* number (6) and that they have seen advertisements for testing on the *Internet* number (12), mark number (6) only. (Others can be checked for use in counseling.)

1. *HIV+ partner*: The client has/had an HIV-infected sex or needle-sharing partner who told the client they are HIV-positive and that the client should get tested.
2. *PCRS/partner notification*: Client was notified by a health care worker that the client had a sex and/or needle-sharing partner who was HIV-positive (PCRS = partner counseling and referral services).
3. *OA NIGHT outreach (incentive/referral)*: This is only for those clients contacted by the OA funded Neighborhood Intervention Geared to High-risk Testing (NIGHT) Outreach Program. If unsure, do NOT mark it.
4. *Other outreach worker*: Client was referred by a health worker providing street outreach services (other than 3 above).
- 5.-12. As indicated.
13. *No identifiable referral source*: Use this field when the client was referred by an individual or organization other than those identified in 1 through 12. Mark if the client does not give a source or client was not referred for testing at all but is being counseled while attending the clinic for another reason.

Client's reason for testing

The choices provided are ordered. Mark one choice. It should be the lowest numbered reason that the client reports. If the client says they are *Reconfirming an HIV+ result* and also had a prior *HIV+ partner* only enter (1) *HIV+ partner* into the data system. (Other reasons can be marked for counseling purposes.)

1. *Reconfirming HIV+ result*: The client has already tested HIV-positive and is returning for more HIV counseling/testing.
2. *Reports AIDS-like symptoms*: Client complains of symptoms that the HIV counselor can reasonably interpret as being associated with AIDS. This is not a diagnosis, just a reasonable interpretation. If the client complains about symptoms that are rarely or never associated with AIDS, do not mark 2. (Physical symptoms as a motivation for testing may be an important counseling issue, whether they are associated with AIDS or not.)
3. *Has current HIV+ partner*: Client has a **current** sex or needle-sharing partner who is HIV-infected.
4. *Had past HIV+ partner*: Client has a **past** sex or needle-sharing partner who is HIV-infected.
5. *TB diagnosis*: Client has been diagnosed with tuberculosis (TB).
6. *STD related*: Client is testing for HIV because they have been diagnosed with a sexually transmitted disease (STD).
7. *Hepatitis diagnosis*: Client is testing for HIV because of a hepatitis diagnosis.
8. *Pregnancy*: Client is pregnant and is testing to protect the baby from the risk of maternal transmission.
9. *Risky behavior*: Client says they are testing because of risky behavior.
10. *Starting a new relationship*: Client is starting a new sexual relationship.
11. *Partner request*: Client indicates that a sexual or needle sharing partner asked them to be tested.
12. *Rape/assault*: Client states they are testing because they have been sexually assaulted.
13. *Exposure to blood*: Client indicates that they have been exposed to blood on the job.
14. *Immigration*: Client says they are testing because of immigration.
15. *Other, specify*: Client had a reason for testing that was not similar to the listed reasons.

HIV Testing History

Number of prior HIV tests

Circle the number of HIV tests the client has had before the current test. Zero (0) is important to circle for all clients who have NOT had a prior test. It is important for the counselors and program people to know who is testing for the first time. Marking no number means the HIV counselor did not ask or client refused to say. *(This information is important, but we do not intend to suggest that the HIV counselor debate with the client whether he/she has had 5 or 6 prior tests or whether the last test was May or June of 1995. Do not get bogged down.)*

Date of last test result

Enter the month and year of the client's last test result in the boxes. Ask the client to guess if they do not remember the month. Counselors need to know recent testing intervals and planners need to know more than the year even for old testing, so please approximate the month if necessary. Prompt client for seasons or holidays if necessary (e.g. "Was it in the winter?").

Last test result

Mark last test result (1-3), as appropriate, or 4 if client tested but did not return for results.

Risk Reduction Steps

Risk assessment stage of change

Clients are often in different stages of readiness to change. Interventions need to be matched with the client's current stage or readiness to change to be most effective. Indicate the behavior that you are assessing and discussing with the client and mark the appropriate client's stage of change for intervention/prevention plan. Mark (1) *Not thinking about it (Precontemplation)* if the client has no intentions to change their behavior. Mark (2) *Thinking about it (Contemplation)* if client has formed intention to change, but has no specific plans to change in the near future. Mark (3) *Ready for action (Preparation)* if client has plans to change behavior in the immediate future and may have taken some initial actions. Mark (4) *Action* if client has begun changing behavior, but the behavior change is relatively recent. Mark (5) *Maintenance* if client has maintained consistent behavior change for an extended period of time and the newly acquired behavior has become a part of everyday life. It is important to remember that these stages of change are not linear. Clients will tend to move fluidly back and forth between stages and relapse to an earlier stage is always possible.

Immediate risk reduction step

Behavior change is often incremental. The interval between counseling sessions is an excellent opportunity to set a manageable risk/harm reduction step with the client. Motivation is highest during this period and there is an opportunity during the disclosure or post disclosure session to discuss the client's efforts, to support and build on them, or to process alternatives.

In this block summarize a concrete, step that the client believes they can accomplish before the disclosure session. Write sufficient detail so that it can be discussed in the disclosure session. Always try to select with the client an attainable step so that you can build upon success.

At disclosure, risk reduction step(s)

During the disclosure session for standard tests or the post disclosure session for rapid tests, the HIV counselor can discuss the step and evaluate the degree to which the client was able to accomplish it. Mark (1) *No step established at risk assessment* if no step was written in the block (this may be because the client refused or declined). Mark (2) *Client made no effort* if the client did not think about it or undertake it in any way (e.g. “Oh yeah, I forgot about that”). (3) *Step attempted* should be used to indicate the client actively pursued the step, even if it was only to think hard about doing it and then giving up. (4) *Step achieved* should be reserved for situations when it is clear the client was able to come to grips with the issue and achieve the stated step. If the client describes an appropriate behavior substituted for the original goal behavior, the new behavior should be evaluated for degree of achievement. This area is left blank for negative rapid tests unless a high-risk negative client returns for a post disclosure session.

The examination of this step is very important to the risk reduction process. It may be the first of many successful risk reduction steps for the client or a major signal to the HIV counselor that another risk reduction strategy is necessary. This data is also collected in the hope that examined in the aggregate; we will be able to find client patterns, which can aid the HIV counseling risk reduction process.

Post disclosure/short-term risk reduction step(s)

The post disclosure session is for HIV-positive confirmatory rapid test disclosures or can be arranged for any high-risk or HIV-positive or HIV-inconclusive client. It is an opportunity to follow up with additional counseling and referrals. Ideally, the post disclosure session can be used as an opportunity to connect a client with a specific referral source by having an individual from the referral source attend the post disclosure session as well. A concrete short-term risk reduction plan is extremely important for the client during both the initial disclosure session and the post disclosure session. These short-term steps should be designed to help the client make incremental changes. Summarize what clients can do immediately and what precautions can be taken in the short term after each session. Briefly summarize them in this block. Additional notes may be made in the **Counselor Notes** area.

Long-term risk reduction step(s)

A concrete risk reduction plan should always be a part of HIV counseling. Risk reduction does not occur in the abstract. It is also important to discuss it in steps: what can be done immediately; what can be undertaken in the short term; and what are the behaviors to be worked toward in the long run? Briefly summarize them in this block. They must be reviewed in the disclosure and post disclosure sessions and they may be altered or elaborated, especially in light of the outcome of the immediate risk reduction effort.

Referrals

Providing referrals to high-risk clients is an essential task of HIV counseling. Our limited services must be followed up by additional behavior change interventions or other supportive services for high-risk clients. Choose a primary referral with the client, the one that is most essential for risk reduction. Mark a “1” to indicate that the client was referred to that service. If a second referral is appropriate, mark a “2” next to it and “3” for the third referral. Only three referrals are recorded into the data system. If no referral is made mark a “1” next to (1) *NONE*. Complete this process at the risk assessment (RA), after test results are given during disclosure (D) counseling and

again at the post disclosure (PD) counseling session. Risk assessment, disclosure, and post disclosure referrals may be identical or they may differ. All three should be marked for high-risk clients. Lower risk HIV-negative clients will have all referrals listed under *RA* counseling only. To receive the additional referral reimbursement, a referral numbered 3 to 22 must be marked in the disclosure column for high-risk, HIV-positive and HIV-inconclusive clients only.

Counselor: Review/Assess Introductory Issues

This section is for counselors to review and assess introductory issues that must be covered with the client in the initial stages of the counseling session. Reviewing these issues will not only help the counselor develop rapport with the client, but also help the counselor assess the goals and needs of the client. This is also a good time to clarify any questions that the client has regarding HIV and HIV related issues. Review and mark any issues discussed during the session. These items are not recorded in the data system.

Counselor: Review/Assess Testing Issues

This section is provided for the counselor to review and assess testing issues with the client to help the client better understand the testing process. The counselor will need to review these testing issues and clarify any important points that were missed or that needed to be restated for the client to make an informed decision to test. It is also a good time to highlight the importance of the client to come back for the result. Review and mark any issues discussed during the session. These items are not recorded in the data system.

Counselor Notes

This section is for free form notes of relevance to the counseling session. These are particularly useful to communicate impressions or significant issues to the disclosure counselor, especially in those settings where there is usually a different counselor.

Sexual Risk History

When examined collectively, these items provide a complete risk history of the client's potential for sexual HIV transmission as well as some idea of the probability of HIV exposure. This assessment will allow the counselor to center the discussion of HIV risk reduction on the client's risk issues.

Sexual activity is organized by the types of partners a client may have. Types of partners tend to indicate the risk of exposure. The sexual activities in conjunction with barriers used indicate the risk of transmission with each type of partner. Counselors should explore the types of sexual activity the client acknowledges. For example, counseling will be affected by whether the oral sex is fellatio or rimming.

Identifying higher risk clients for enhanced counseling with greater reimbursement is achieved by this risk assessment. Any risk indicator that is associated with an increase in the chance of being HIV infected has been identified from HIV client data. Clients currently receiving disclosure counseling include:

Test Result

- All HIV-positives and HIV-inconclusives

Risk Behaviors

- Men who have sex with men (MSM)
- Transgendered
- Injection drug users (IDUs)
- Sex workers (drugs or money)
- Clients with partners they know to be:
 - HIV-positive
 - IDUs
 - Sex workers
 - Bisexuals
- Occupational HIV+ exposure
- Child with maternal HIV exposure
- Women who practice receptive anal sex
- Stimulant users (crack, amphetamines, cocaine, nitrates/ites & ecstasy)

These indicators will be revised as the correlates of elevated risk change. These categories identify higher reimbursements for counseling and are associated with HIV risk BUT they are not a definition of risk. That can only be determined by each individual risk assessment.

For the risk assessment to work properly, **a response must be recorded for each item.** Discuss and record the client's behavior during the **last two years** unless otherwise indicated.

Date of last test result

If the client has received an HIV test result within the last two years then discuss and record the client's behavior since the date of the client's last test result in the blank (mm/yy). This will be the same date provided in the **HIV Testing History** on the front of the form. This time period is the one most relevant to assess for planning the client's risk reduction strategy.

Time Frame Code (TFC)

The shaded areas marked *TFC* for Time Frame Code are used in areas collecting more detailed time frames for specific behaviors and areas utilizing detuned assays. If directed to use this area, use the **Time Frame Code** box in the lower right hand corner of the page as a guide for completing this area. If a client has difficulty remembering the last time they performed a particular activity prompt client for an approximate time of the activity (e.g., Was it in the summer?, Near a holiday?). Try not to get bogged down and enter the *TFC* that comes closest. If a client does not recall the last time they engaged in a particular activity enter a "9" in the TFC box. If a client declines or refuses to provide information then enter an asterisk (*).

If Yes, is marked under a **Sexual activity** then indicate the correct *TFC* and then ask client about their **Frequency of barrier use**. If a **Substance use** box is marked (other than *no alcohol or drug use*) then indicate the *TFC* when they last used that substance. If a client is an injection drug user and has indicated that they *Sometimes* or *Always* shared needles then indicate the *TFC* they last

shared needles. If the client says they *Sometimes* or *Always* clean their injection equipment then record the *TFC* of the last time they cleaned their works. If client accesses needle exchange sites *Sometime* or *Always* then record the *TFC* they last accessed a needle exchange site. If client indicated they are currently or have been in treatment in the past then indicate the appropriate *TFC*.

Total number of sex partners

Indicate the total number of sex partners the client has had during the last 2 years or since their last test result. Enter 000 if client has had no sex partners during that time.

Partner(s)

Mark (0) *no partners* to indicate that the client does NOT know of having had this particular type of partner in the assessment period.

or

Mark (1) *one or more* to indicate if client had one or more of this type of partner during the *last two years or since the last result*.

or

Mark (*) *decline/refused* to indicate if client declines/refuses to provide this information.

Blank indicates that the HIV counselor did not perform a complete risk assessment.

Sexual activity and Frequency of barrier use

Mark (1) *Yes* or (0) *No* box for any/all sexual activities listed that the client has participated in. Lack of a response indicates the counselor did not ask the client. For each sexual activity client indicated as *Yes*, mark the frequency of barrier use for that sexual activity. If a client acknowledges a particular type of sex but is unclear about barrier protection, mark (1) *Never*. For many clients barrier use is *Sometimes* and marking (2) is appropriate. However, for some there is a consistent pattern of condom use especially with certain partners. These should be marked (3) *Always*. Barrier protection items should be left blank when **Partner(s)** is marked (0) *no partners* or the client does not participate in that sexual activity with that type of partner. This system cannot wholly describe “reality.” It should be marked to best reflect the client’s risks of HIV exposure and transmission. When recording activities remain focused on the sexual activity the client performs. It is easy to start thinking about the partner’s activity instead.

Did client know partner’s HIV-positive status prior to sexual contact?

Answer (1) *Yes* if client indicates they have had a HIV infected sex partner(s) and knew that one (or more) the sex partner(s) were HIV-positive before having sex. Mark (0) *No* if client did not know their partner(s) status until after they had sex.

Optional Data

These fields are for other data that are specific to agencies that are not on the CIF. If you have question regarding these fields, ask your HIV counseling supervisor.

Substance Use History

Substances use

Mark the (*) *declined/refused* box if the client declined or refused to give a history of their alcohol and drug use. Leaving the **Substances Use History** boxes blank and NOT marking the (*) *declined/refused* box indicates HIV counselor did not perform a complete drug assessment. If client indicates that they have not used any alcohol or drugs, mark *no alcohol or drug use*. Make a check mark in the box next to alcohol or any of the specific drugs used. Note that the drugs listed are loosely organized into depressants, stimulants, hallucinogens, and erectile dysfunction prescription drugs. (Do NOT include psychotropic drugs prescribed by a psychiatrist.) Specify drugs not listed by marking *other, specify* and naming it in the blank space provided. Learn the current street names for each drug listed. The issue here is cofactors affecting safer sex decisions and injection risks. Drugs used with sex may affect judgment leading to unsafe sexual practices. Drugs may stimulate sexual behavior. Sex may be part of drug transactions.

In the **Injected** box in the second column, mark (1) *Yes* if the client injected the substance and (0) *No* if they have not injected the substance. Blank indicates that the HIV counselor did not perform a complete risk assessment. Other substances injected such as vitamins or steroids should be indicated by marking the *other, specify* box and also by checking the **Injected** box.

For alcohol or any drug marked, indicate the **Frequency used with sex**. Mark (1) *Never* if the client is always drug free during sex.

Injection behaviors

For clients who have injected substances, issues of shared needles, needle exchange programs, cleaning works, syringe sources and IDU treatment history are important in the client risk assessment and intervention plans. (Note: a client will be categorized as high risk if injection drug use is indicated in the preceding alcohol and drug use section.) Leave all items in these section blank for non-IDU clients.

Shared needles: Has the client shared needles with another person? Mark (1) for *Never*, mark (2) for *Sometimes* or mark (3) if the client *Always* shares needles with another person.

Shared with a known HIV+ partner? Mark (1) *Yes* if shared needles with a known HIV-positive partner. Mark (0) *No* if client has not shared needles or has not shared needles with a known HIV-positive injection partner.

Cleaned works: Does the client clean the injection equipment? Mark (1) for *Never*, mark (2) for *Sometimes* or mark (3) if the client *Always* cleans his/her injection equipment.

Needle exchange: Has the client ever accessed a needle exchange program? Mark (1) for *Never*, mark (2) for *Sometimes* or mark (3) if the client *Always* accesses needle exchange programs.

Is NE available in client's area? Mark (1) *Yes* if needle exchange (NE) is available in client's area or (2) *No* if it is not available regardless if client uses needle exchange or not. Clients may use other sources for needles/syringes or may use needle exchange outside of the their area (i.e., different city or county).

Needle/syringe sources: Mark all needle/syringe sources.

needle exchange program: Has the client obtained needles/syringes from a needle exchange program (NEP)?

secondary exchange: Has the client received syringes from other individuals who access the NEP? Some IDUs do not feel comfortable attending a NEP (e.g., they do not want neighbors or friends to know they are an injector; they fear being stigmatized.). Nevertheless, some IDUs are beneficiaries of the NEP through peers who take their used syringes, exchange them at the NEP for new syringes, and return the new syringes to the peer who originally gave them the old syringes.

pharmacy/drug store: Has the client obtained syringes at a pharmacy or drug store? This response applies to clients who access syringes at pharmacies in California and across the border in states (e.g., Oregon) or countries (e.g., Mexico) that legally sell syringes over-the-counter. (This response may be more relevant when California legislation is in place that allows pharmacies to sell syringes over-the-counter, without a doctor's prescription.)

needle dealer/seller: Has the client bought (or received for free) a needle/syringe from an individual who regularly sells needles/syringes on the street?

shooting gallery: Has the client obtained a needle/syringe (new or used) in a shooting gallery (i.e., a location where IDUs typically inject: usually someone else's home, an apartment, an abandoned building, a park, a street, an alley).

diabetic: Has the client received a needle/syringe (free or for a fee) from an individual who is an insulin injecting diabetic and who obtains syringes by prescription from the pharmacy?

close friend: Has the client received/borrowed a needle/syringe from a close friend (e.g., peer, running buddy, associate)?

sexual partner: Has the client received/borrowed a needle/syringe from a person with whom they have had sex (e.g., spouse, partner, girlfriend/boyfriend, date)?

other source: Has the client obtained a syringe from any source other than those listed above?

IDU treatment history: Is the client currently in treatment? Has the injecting client ever been in treatment? Mark (1) for clients who have *Never* accessed treatment programs, mark (2) for client who are currently in treatment, mark (3) for clients who have accessed treatment programs within last 2 years or since last result or mark (4) if client accessed treatment prior to last years or since last test result.

The answers to each of these questions are critical to successful risk reduction for injectors.

Other Risk History

STDs/hepatitis

Obtain hepatitis and sexual transmitted disease (STD) history for clients from the last two years or since the last test result. Mark the appropriate boxes based on what the client reports. Make appropriate referrals based on client needs. If client indicates that they have not had a STD or hepatitis diagnosis in the last 2 years or since the last test mark *no STDs/hepatitis* and ask about lifetime history of viral STDs/hepatitis. Mark the (*) *declined/refused* box if the client is unwilling to provide a hepatitis and STD history. Many or frequent STDs may suggest high transmission risk that should be reduced. Indications of exposure to high-risk partners as well may indicate very high risk of infection.

Viral STDs/hepatitis

Mark if client states they have had Hepatitis (HAV, HBV, HCV) or viral STDs (HPV, HSV) during their lifetime (this maybe the same as the previous question). Mark the appropriate boxes based on what the client reports. Make appropriate referrals based on client needs. If client indicates that they have not had a viral STD or hepatitis diagnosis during their lifetime mark *no lifetime viral STDs/hepatitis*.

Hepatitis vaccination

Hepatitis A virus (HAV) and hepatitis B virus (HBV) vaccinations require a two or three shot series. Two HAV vaccines are currently approved for use in the U.S. for persons over 2 years old and both require two doses (shots) taken about 6 to 18 months apart. Two HBV vaccines are available for all persons and are usually given in three doses (shots) over a 6-month period. A 2-dose regimen (the second dose is given 4-6 months after the first) for one of the vaccines has been approved for use in persons 11-15 years old. A combined HAV and HBV vaccine is available for persons 18 and older and is given in 3 doses over a 6-month period. Mark (1) *yes* if the client states they have completed a series of vaccinations. Mark (2) *no* if client indicates that they have not been vaccinated, have not completed the series, or does not know whether or not they have had a complete series of vaccinations. Mark the (*) *declined/refused* box if client refuses or declines to answer.

Men who have sex with men, injection and non-injection drug users, and persons who live in communities with high rates of hepatitis are at highest risk for HAV. HAV is found in the stool of persons with hepatitis A. HAV is spread by anilingus (i.e., rimming), close personal contact, and eating food or drinking water containing HAV. HAV can cause a mild “flu-like” illness, jaundice (yellow skin or eyes), and severe stomach pains and diarrhea. In very rare cases, HAV can cause death. People who have been infected with HAV develop a protective immunity and cannot get hepatitis A again and are no longer infectious to others.

High rates of HBV occur among injection drug users, men who have sex with men, people who have multiple sex partners, and people in contact with people with chronic HBV or with jobs involving contact with blood. HBV is transmitted through the sharing of blood and body fluids with an infected person. HBV can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death.

Discuss with clients who are at high risk for hepatitis about vaccinations for HAV and/or HBV. Clients who are unsure about whether or not they have been vaccinated can talk to their medical provider about seeing if they have antibodies for HAV and/or HBV. It is recommended for people who are HIV-positive to be vaccinated for both HAV and HBV.

Other risk factors

Record other risk factors that a client has been exposed to in the last two years or since last test result. Mark (1) Yes if client indicates the risk factor, (2) No if client indicates not having that risk factor, or (*) declined/refused if client does not want to disclose information. Leaving all boxes blank indicates that counselor did not ask client about additional risk factors.

Received money/other items or services for sex. This includes any commercial transaction in which the client provides sex, excluding drugs.

Received drugs for sex.

Behavior resulting in other blood-to-blood contact (SM, tattooing, piercing, cuts, etc.) or that allows blood contact with mouth, vagina or anus. This is a catch-all category. More specific risks should be recorded elsewhere. This is specifically for other ways that blood to blood contact is clearly indicated. (SM = sadomasochism)

Shared objects/fingers inserted in mouth, vagina or anus. This is a catch-all category. More specific risks should be recorded elsewhere. This is specifically for other ways that could pose a risk of transferring bodily fluids but where no obvious blood-to-blood contact is indicated.

Blood-to-blood exposure on the job.

Job exposure blood known to be HIV+. This risk factor cannot be checked if *Blood-to-blood exposure on the job* is not checked.

Blood/blood product transfusion before 1985 (or in a country where blood is/was not tested for HIV).

Child born of an HIV-infected woman.

Other behavior, specify. This risk factor is for any other relevant behavior not specifically descriptive of risk. Record sexual assault here in this blank. Be sure to assess the specific risks involved and record along with other risk behavior.

Counselor: Review/Assess Drug and STD Issues

This section is for counselors to review and assess drug and STD issues that must be covered with the client in the initial stages of the counseling session. Reviewing these issues will not only help the counselor develop rapport with the client, but also help the counselor assess the goals and needs of the client. Review and mark any issues discussed during the session. These items are not recorded in the data system.

Counselor: Review/Assess Basic Issues

This section is for counselors to review and assess basic issues related to HIV prevention that must be covered with the client in the initial stages of the counseling session. Reviewing these issues will not only help the counselor develop rapport with the client, but also help the counselor assess the goals and needs of the client. Review and mark any issues discussed during the session. These items are not recorded in the data system.

Appendix Q: OraQuick Test Kit Competency Checklist

OraQuick Test Kit Competency Checklist

Date: _____ Site: _____ Name: _____

- Gathers/arranges all materials
- Examines test kit pouch (unopened, room temperature, absorbent packet)
- Records lot number
- Records expiration date
- Records initials
- Affixes client number to back of vial
- Affixes client number to CIF/lab slip
- Successfully opens and positions vial in stand (no spillage, vial to bottom of stand)
- Wears gloves for all subsequent steps**
- Visually examines loop to ensure it is full of sample
- Stirs in sample, loop to biohazard
- Examines vial for pink fluid
- Successfully inserts test kit (no spillage, window forward, pad touching bottom of vial)
- Did NOT remove test kit until ready to insert*
- Did NOT touch flat pad when inserting test kit*
- Records start time and temperature on lab slip
- Successfully completes all steps (if not, note what was missing/incorrect below):

Notes:

Evaluator Name: _____ **Evaluator Signature:** _____

Appendix R: Site Preparation Checklist

Site Preparation Checklist

Counseling and Testing Coordinators must complete this checklist for each site conducting rapid HIV testing prior to beginning testing. A copy of this document should remain on file for each site. Unless otherwise noted, page numbers referenced refer to Rapid HIV Testing Guidelines. See guidelines for additional details and resources.

Site name _____
Site address _____
(physical location) _____
Street _____
City _____ State _____ ZIP Code _____

Site manager _____
Phone number _____

Legal/Administrative (pp. 4 - 5)

CLIA certification (Certificate # _____)

Safety: (p. 31)

Notes:

OSHA/ Blood-borne Pathogen Compliance _____

Personnel Qualifications & Training (pp. 18 -21)

Single-session counseling training (documentation on file) _____
 Rapid HIV test kit training (documentation on file) _____
 Phlebotomy certification (documentation on file) _____

Test Kit Storage (pp. 23, 27)

Area secured against unauthorized access _____
 Temperature controlled/acceptable _____
 Thermometer located in storage area _____
 Temperature control log sheet posted _____
 Inventory procedures established _____

Control Unit Storage (pp. 23, 27)

Non-food refrigerator _____
 Thermometer located on refrigerator shelf _____
 Temperature control log posted _____

Testing Area (pp. 8 - 9)

Notes:

- Separate from counseling area
- Secured against unauthorized access
- Confidentiality measures in place
- Thermometer near testing area
- Clock near testing area
- Testing area clean & well-lit
- Flat surface for undisturbed test kit processing
- Biohazard disposal (sharps and non-sharps)
- Step-by-step instructions posted (optional)
- Result pictures posted (optional)
- Universal Precautions posted (optional)

Materials

- Testing materials (Test kits, loops, stands, etc.)
- Phlebotomy materials (finger stick devices, bandages, etc.)
- Forms & Documents (CIF, lab slip, etc.)
- Protective gear (gloves, lab coats, etc.)
- Test kit and control unit package inserts
- Other: _____

Testing Process Verified

- Complete testing process “dry run” successful (p. 17)
- Personnel proficient with process, paperwork (appendices)
- Personnel familiar with confirmatory guidelines (pp. 15 - 16)
- Personnel aware of emergency procedures (Local guidance)
- Competency assessment completed (on file) (pp. 21 – 22)
- External control testing successfully completed (pp. 23 - 25)

Quality Assurance Plan (p. 4)

- Written QA plan completed (on file)

Notes:
