January 1, 2010

HIV Counseling, Testing, and Linkages Protocols, Procedures, and Continuous Quality Improvement Plan

TEMPLATE

San Francisco Department of Public Health
HIV Prevention Section
HIV CTL Network

Special thanks to Shelley Facente, MPH and Vanessa Lee, MPH for the development and design of this template. Also thanks to the Native American Health Center for agreeing to share their policies, procedures, and QA plan, and to the Asian & Pacific Islander Wellness Center and Forensic AIDS Project, who assisted them in development of their document. Thanks to those at Glide who developed the first policies & procedures for rapid testing in San Francisco.
All of their efforts have contributed greatly to the creation of this template.

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INTRODUCTION TO HIV CTL

HIV Counseling, Testing & Linkages (CTL) is an intervention for persons at risk for HIV designed to offer in-depth, one-on-one information, education, referrals, prevention counseling and HIV antibody testing to clients who have not previously tested positive for HIV.

The primary goals are to:
Provide HIV information and HIV education in a client-centered manner, based on a harm reduction model.
Help clients identify risk behaviors, their HIV serostatus, and an HIV prevention or risk reduction plan.
Provide appropriate referrals, linkage to services, and support to maintain a risk reduction plan

HIV CTL has 8 core elements:[1]

1. It is completely voluntary and can only be delivered after informed consent is obtained
2. Information and education are provided regarding: HIV transmission risk, prevention, the testing mechanism, test results, the window period, and where to obtain more information or supportive services
3. Client-centered counseling as a guideline for assessing client's readiness for change, self efficacy and other needs
4. Unambiguous and easily implemented standards for sobriety and assessment of competency to provide informed consent
5. An FDA approved testing technology: rapid testing; conventional testing: OraSure or venipuncture
6. Results are delivered in a supportive fashion and in a way that is understandable to the client
7. Referrals are appropriate and clients are provided with assistance in making linkages, and
8. Referrals and linkages are tracked.

Only counselors or technicians who are trained and certified through a State-sanctioned training program can provide CTL services in San Francisco. Currently, counselor and technician training are provided through AIDS Health Project. The course of training adheres to a state approved curriculum to ensure consistent, up-to-date and accurate information is available to all clients. Furthermore, all counselors employing rapid testing (RT) in their counseling sessions are trained and certified for single-session counseling, as required by the State Office of AIDS.

This document outlines site-specific guidelines and Continuous Quality Improvement measures for conducting HIV CTL, and serves as a supplement to the California DHS/OA HIV Counseling and Testing Guidelines, as well as the DHS/OA guidelines for Rapid HIV Testing in Counseling and Testing Settings (October 2003), in addition to the other requirements and standards that come with participation in the San Francisco HIV CTL Network.

Continuous Quality Improvement (CQI) refers to planned and systematic activities designed to ensure that services are being delivered effectively and that errors are detected and corrected to avoid adverse outcomes. Continuous Quality Improvement activities are applied to all aspects of service delivery, including both counseling and testing procedures.

Continuous Quality Improvement guidelines contained in this document are specific to the site named, and focus primarily on Continuous Quality Improvement procedures for OraQuick Advance rapid HIV testing, as well as any conventional testing available on-site. Guidance regarding Continuous Quality Improvement for other aspects of HIV counseling and testing activities is available in DHS/OA HIV Counseling and Testing Guidelines (1997).

[1] CDC Fact Sheet (2004). *Counseling, Testing, and Referral: An Intervention for Persons at High Risk for HIV*.

INTRODUCTION TO THIS DOCUMENT

This plan is intended to be a living document. The original template is provided to the HIV Prevention Section and should be tailored to specific sites and updated annually and/or as needed. HIV testing is a dynamic and constantly changing field, and as new technologies, improved procedures, or more developed policies are incorporated into the CTL program at [*Site*], this plan will be altered to reflect that. All HIV testing sites that are part of the San Francisco HIV CTL Network have similar plans, helping to ensure an excellent and comparable standard of care no matter where an individual seeks an HIV test in San Francisco.
As a part of the San Francisco Dept. of Public Health, HIV Prevention Section, HIV CTL Network, [*Site*] is required to follow all local, state, and CDC guidelines for HIV CTL, including but not limited to:

1. CDC Revised Guidelines for Counseling, Testing, and Referral Standards and Guidelines (2001)
2. California Department of Health Services, Office of AIDS, HIV Counseling and Testing Guidelines (1997)
3. HIV Prevention Section, HIV Counseling, Testing and Referral Policies and Procedures
4. CDC's Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test (2003)
5. California Department of Health Services, Office of AIDS, Supplement to the HIV counseling and Testing Guidelines (2004) – OraQuick Rapid HIV Testing Guidelines: Policies, Procedures and Quality Assurance

This document offers a comprehensive and detailed explanation of HIV CTL as it exists currently. It is intended to combine the myriad of guidelines and requirements normally found in many different locations. Someone new to the CTL program at [*Site*] should be able to read this plan and understand the ins-and-outs of HIV testing here. However, it also is intended to function as a reference for more experienced testers and counselors, when special circumstances or questions arise.

First, there is an explanation of the fundamentals of the HIV CTL program at [*Site*]. Following that is more detailed descriptions of the types of HIV testing currently available. Next is an account of the intended clinic flow of this site – how clients should experience the services once they arrive.

The next section details HIV CTL procedures. There are two parts, one for rapid testing and one for conventional testing.

The third section describes laboratory requirements and services as they apply to HIV testing at [*Site*], and some information about laboratory safety.

Finally, there is an extensive section on Continuous Quality Improvement, or CQI (sometimes referred to as Quality Assurance or QA). This document details at length who at [*Site*] is responsible for each element of the HIV testing program here, and provides a series of corrective actions that may be taken if needed at any time.

This document should be reviewed periodically to ensure that it is kept up to date and that the program is continuing to align with the plan, which has been carefully thought out and should be followed closely.

HIV Prevention Section staff is available to provide technical assistance at any time. Their contact information, as well as key emergency contacts, can be found on the following page and should be utilized whenever necessary, to ensure that the HIV CTL program at [*Site*] continues to run smoothly and with the highest quality.

EMERGENCY CONTACTS

Position	Name	Phone Number
Medical Director	[*Enter name and/or position here*]	[*Enter contact here*]
CTL Coordinator	[*Enter name and/or position here*]	[*Enter contact here*]
Lab Manager	[*Enter name and/or position here*]	[*Enter contact here*]
CQI/QA lead	[*Enter name and/or position here*]	[*Enter contact here*]
Fire emergency	[*Enter name and/or position here*]	[*Enter contact here*]
Medical emergency	[*Enter name and/or position here*]	[*Enter contact here*]
Biohazard exposure	SFDPH Occupational Infectious Diseases Program	24-hour Needlestick Hotline 415-429-4411

HIV PREVENTION SECTION CONTACTS

Position	Name	Phone Number
Director, HIV Counseling/Testing/Linkage	Teri Dowling	415-554-9167
CTL Data Manager	Nayla Raad	415-554-9039
PalmIt /Medical Data Coordinator	Noah Carraher	415-703-7274
Supplies Coordinator	Alice Heimsoth	415-554-9033
Coordinator Linkage/Partner Services	Nyisha Underwood	415-703-7280
Hepatitis C Testing Coordinator	Alla Rivas	415-554-8450
Technical Assistant Leads	Emalie Huriaux Thomas Knoble Alla Rivas Sonia Bailey	415-437-4694 415-703-7279 415-554-8450 415-554-8451
Coordinator for QA and Training	Sonia Bailey	415-554-8451

HIV Prevention Section fax number (please include a cover sheet): 415-934-4868

FUNDAMENTALS OF HIV CTL AT [*Site*]

[*Site*] provides [*confidential/anonymous*] HIV Counseling, Testing & Linkages [*insert schedule/location here*].

Procedure

[*Briefly describe here the staffing pattern, hours of testing, and target population for HIV CTL services at your site. Who will be offered testing? What priority will be given? Will it be drop-in or by appointment? Will donations be requested? etc.*]

Confidential CTL

Confidential testing refers to HIV antibody testing services in which personal identifiers are known to persons providing the services, and positive results are reported to the San Francisco Department of Public Health in accordance with state reporting requirements. To ensure confidentiality, HIV CTL forms and results are always kept in a locked file.

[*Add information here about your site-specific procedures relating to confidential testing, if you will be offering it. If you will not, include information about how you will refer someone to a confidential test site should they desire this type of test.*]

Anonymous CTL

Anonymous testing refers to HIV antibody testing services in which personal identifiers are not recorded nor associated with the counseling or test results. Written results cannot be provided under any circumstances. Positive results are not reported to the health department.

[*Add information here about your site-specific procedures relating to anonymous testing, if you will be offering it. If you will not, include information about how you will refer someone to an anonymous test site should they desire this type of test.*]

Voluntary CTL

All HIV CTL will be completely voluntary and clients have the right to decline HIV CTL at anytime during the process, or any part of the process, including during initiation of HIV test, risk assessment, testing/specimen collection, disclosure counseling, or referral services. A test will not be provided if the counselor determines that the client is not there for testing under his/her own free will.

Culturally Appropriate CTL

All HIV CTL services will be culturally appropriate to the population being served. This includes sensitivity to ethnicity, gender, sexuality, age, literacy, language, cognitive levels, and other similar factors that affect the experience of the target population. All written client materials with reference to CTL must meet these standards of cultural appropriateness and be provided in [*insert languages as appropriate to your site's client populations*]. In the event that services and materials cannot be provided in the primary language of a client, [*insert here your site's plan for interpreter services so that the needs of these clients can be met*]. In the event that a client is illiterate, [*insert here your site's plan for providing information and services to illiterate clients*].

Sobriety Standards for HIV CTL

[*Include detailed information here about the policies for your site regarding clients who appear to be under the influence of alcohol or drugs at the time of testing. What criteria should a counselor use to determine whether the client is able to provide informed consent (and therefore whether they should provide services)? What*

should the counselor do if someone comes for a test and is unable to provide informed consent due to lack of sobriety? What action should they take if the person becomes belligerent or violent?]

Ability to Provide Informed Consent for HIV CTL

In addition to meeting [*Site's*] standards for sobriety, there are other important considerations to determine whether a client is able to provide informed consent. These include whether they are being coerced to test against their will, whether they are coherent and appear mentally stable, and whether they are capable of understanding the vital details of HIV testing before agreeing to participate, for example. [*Include detailed information here about the other client circumstances that could inhibit a client's ability to provide informed consent at your site. What should counselors do if they encounter someone who they believe cannot provide informed consent?*]

Other Limitations to Provision of HIV CTL

[*Include detailed information here about the other circumstances under which HIV CTL should not be provided or should be discontinued for a client at your site (i.e. aggressive behavior). What should the counselor do if one of these situations arises?*]

HIPAA Standards / Release of Information

[*Although collection of information via the SFCIF forms does not constitute a medical record and require HIPAA release forms to be signed, circumstances at your site may make HIPAA extremely relevant. Include here any site-specific information about HIPAA and release of information as needed.*]

TYPES OF HIV TESTING

Currently, there are **six** possible ways that a person in San Francisco can test for HIV antibodies. [*Site*] will provide [*enter options available here*] and will make referrals to other sites if [*enter remaining options*] are desired.

OraQuick-oral fluid/Stat-Pak Rapid Test Algorithm

The OraQuick/Stat-Pak Algorithm involves an initial test with the OraQuick Advance Rapid HIV-1/2 Antibody Test using oral fluid. Test results are available within 20 minutes (but not more than 40 minutes) of specimen collection. If the OraQuick rapid test is reactive for HIV antibodies, it is disclosed to the client and then a blood draw is collected in order to run more tests. The whole blood from the vacutainer is used to immediately begin the Stat-Pak HIV test, which takes 15 minutes to provide a result. If that result is reactive, the HIV-positive result is disclosed to the client. The blood (already drawn) is sent to the lab for confirmation, the client is welcomed to make an appointment to come back to receive the confirmatory results in a week or sign a medical consent to have the results sent to their medical provider. However, a return appt. for confirmatory disclosure is optional for the client; the importance here is getting the client linked to medical care for further testing. If the result of the Stat-Pak rapid test is non-reactive, then blood is again taken from the vacutainer tube, and used to run the OraQuick Advance Rapid HIV-1/2 Antibody Test which takes 20 minutes. If the OraQuick Advance Rapid HIV-1/2 is reactive, the client is informed that we can't be sure of their HIV status, we are sending their blood to an off-site lab for confirmation and they are welcome to come back to get their results in a week or sign a medical consent to have the results sent to their medical provider. However, a return appt. for confirmatory disclosure is optional for the client; the importance here is getting the client linked to medical care for further testing. If the OraQuick Advance Rapid HIV-1/2 Antibody Test is non-reactive, the result is disclosed to the client as HIV-negative. Either way, the blood (already drawn) is sent to the lab for confirmation, for purposes of the study. However, a return appt. for confirmatory disclosure is optional for the client; and the client is informed that if the off-site lab finds different results, the client will be contacted. [*specify the laboratory your site uses for confirmation on all reactive OraQuick Advance-1/2 finger stick 1st tests in this algorithm*]

OraQuick-finger-stick/Stat-Pak Rapid Test Algorithm

The OraQuick/Stat-Pak Algorithm involves an initial test with the OraQuick Advance Rapid HIV-1/2 Antibody Test using blood from a finger stick. Test results are available within 20 minutes (but not more than 40 minutes) of specimen collection. If the OraQuick rapid test is reactive for HIV antibodies, it is disclosed to the client and then a blood draw is collected in order to run more tests. The whole blood from the vacutainer is used to immediately begin the Stat-Pak HIV test, which takes 15 minutes to provide a result. If that result is reactive, the HIV-positive result is disclosed to the client. The blood (already drawn) is sent to the lab for confirmation, the client is welcomed to make an appointment to come back to receive the confirmatory results in a week or sign a medical consent to have the results sent to their medical provider. However, a return appt. for confirmatory disclosure is optional for the client; the importance here is getting the client linked to medical care for further testing. If the result of the Stat-Pak rapid test is non-reactive, the client is informed that we can't be sure of their HIV status, we are sending their blood to an off-site lab for confirmation and they are welcomed to return in a week for their results (we will run a confirmatory and an RNA test) or they can sign a medical consent to have the results sent to their medical provider. However, a return appt. for confirmatory disclosure is optional for the client; the importance here is getting the client linked to medical care for further testing. Either way, the blood (already drawn) is sent to the lab for confirmation. However, a return appt. for confirmatory disclosure is optional for the client; and the client is informed that if the off-site lab finds different results, the client will be contacted. [*specify the laboratory your site uses for confirmation on all reactive OraQuick Advance-1/2 finger stick 1st tests in this algorithm*]

OraQuick Rapid Test Algorithm, with an oral fluid specimen 1st test

"Oral rapid testing" refers to the OraQuick Advance Rapid HIV-1 / 2 Antibody Test, in which the test kit is used to collect a specimen of oral mucosal transudate (OMT). Test results are available within 20 minutes (but not more than 40 minutes) of specimen collection. If an OraQuick rapid test is reactive for HIV antibodies, it is considered a preliminary positive result, and must be followed immediately with another OraQuick Advance Rapid HIV-1/2 rapid test using a fingerstick whole blood sample. Regardless of the results of that fingerstick test, a venipuncture confirmatory sample must be collected and sent to [*specify the laboratory your site uses for confirmation*] for confirmation. [*If your site does not offer this type of testing, include information about the referral site you use for this service, instead of information about your own site's processes*].

OraQuick Advance Rapid Testing, with a fingerstick whole blood sample

"Fingerstick rapid testing" refers to the OraQuick Advance Rapid HIV-1 / 2 Antibody Test, in which a lancet is used to collect a drop of blood from the finger, which is then tested. As with the oral sample, test results are available within 20 minutes (but not more than 40 minutes) of specimen collection. If an OraQuick rapid test is reactive for HIV antibodies, it is considered a preliminary positive result, and a confirmatory sample (usually venipuncture, with OraSure as a less preferred backup) must be collected and sent to [*specify the laboratory your site uses for confirmation*] for confirmation. [*If your site does not offer this type of testing, include information about the referral site you use for this service, instead of information about your own site's processes*].

OraSure Conventional HIV Test

OraSure refers to the oral specimen collection device used for conventional testing in San Francisco. Samples are sent to [*specify the laboratory your site uses*] and tested for HIV-1 antibodies using an ELISA and Western Blot or Immunofluorescent Assay (IFA) for confirmation of positive results. Results from this test are usually available [*specify length of time it normally takes to get results at your site*]. [*If your site does not offer this type of testing, include information about the referral site you use for this service, instead of information about your own site's processes*].

Venipuncture Conventional HIV Test

Venipuncture refers to the collection of a vial of blood by a State-certified phlebotomist, which is then sent to [*specify the laboratory your site uses*] and tested for HIV-1 antibodies using an ELISA and Western Blot or Immunofluorescent Assay (IFA) for confirmation of positive results. Results from this test are usually available [*specify length of time it normally takes to get results at your site*]. [*If your site does not offer this type of testing, include information about the referral site you use for this service, instead of information about your own site's processes*].

CLINIC FLOW

Initiation of Services

[*Describe here how you will obtain clients for HIV CTL. Will it be drop-in? By appointment? How will this be handled at your site? When the client arrives for a test, who is the first person they will see? How will the counselor be alerted that someone is there to test? Where will they go to begin obtaining informed consent?*]

Conventional Test Specimen Collection

[Describe here the process you will use to collect either oral fluid or venipuncture whole blood from the client. Does the client collect the oral fluid specimen or does the counselor? How do you arrange for a phlebotomist to be available to collect the venipuncture whole blood? How do you arrange for the specimen to go to an off-site lab and how do you collect the results?

Rapid Test Specimen Collection

In the event that a client is being seen for a rapid test, [*describe here the way that the specimen will be collected after informed consent is obtained. Will the first test be done in the counseling room by the counselor (who must also be a trained technician in this case) and then walked to the lab area? Or will all rapid testing clients be walked to the lab area to have the sample collected by a trained technician? If so, will the counselor stay with the client for the time they are in the lab, or wait outside? Who is responsible for running the test and reading the result within the 20-40 minute window? What is the process that will be followed if the OraQuick is reactive and more specimens need to be collected? etc.*]

Initial Rapid Disclosure

[*Describe here how the initial results will be obtained by the counselor.*] If the OraQuick result is negative, refer to the "Final Disclosure and End of Session" section below for information on how to close the session, as a negative OraQuick is a final result. [*Describe here if there are any site-specific procedures counselors should follow regarding negative OraQuick disclosures.*] If the OraQuick result is reactive, and there are secondary tests that will be run [*describe here how that result will be disclosed and what the counselor should do to prepare the client for secondary specimen collection.*]. If the OraQuick finger stick is reactive/preliminary positive and there are no secondary rapid tests run [describe here how the results will be disclosed and how the counselor will prepare the client for the blood draw for the confirmatory test and the client returning for confirmatory disclosure].

Secondary Specimen Collection (if applicable)

[*Describe here the way that the secondary specimens will be collected following a reactive OraQuick test. How will the client arrive in the lab area? Who will do the finger stick and/ or collect the blood draw? Will the counselor (if different) stay with the client while they are in the lab, or wait outside? Who is responsible for running the second and, if applicable, third rapid tests and reading the results within the appropriate time window (must be different from the original counselor, who will be with the client while results are being read)?*]

Wait for Results when more rapid tests will be run

[*If the OraQuick result was reactive and there are one or more rapid tests that need to be run, what will happen during the 15 – 30 minute wait for the results of the second (and possibly third) test(s)? Will the counselor sit with the client in the original testing area? Is there another place they would go? Will the way this time is used be left entirely up to the client? How will the counselor be notified when final results are ready (could be 15 minutes or 25-30 minutes, depending on the results of the second test)? What other site-specific procedures fit here?*]

Disclosure, Linkage to Care and Partner Services (if applicable) and End of Session

[*Describe here how the final, confirmed, results will be provided. For rapid testing include how the results of the rapid test (s) will be obtained by the counselor, how linkages to medical care will be made if applicable, partner services will be offered and how the session will end. Note how the counselor should determine that the client is ready and willing to receive their final result, and that they do not have any more questions. Are there any final items the counselor should be providing to the clients at your site? Will the client be escorted back to a main area, or will they leave on their own? Will the counselor complete testing paperwork at that time, before seeing the next client, or will they have another client right away? If the latter, when will they complete all the paperwork from that day? etc.*]

HIV CTL PROCEDURES

RAPID TESTING

Risk Assessment

Information Addressed Prior to Informed Consent

All clients requesting rapid HIV CTL will be counseled individually in a private, confidential counseling room. In order to obtain informed consent, the counselor must ensure that the client has a full and accurate understanding of the following:

- The purpose of HIV antibody testing
- The difference between anonymous and confidential testing in the State of California, especially as this relates to current HIV reporting laws
- The forms that will be completed in the course of their HIV test, and why
- The risks and benefits of HIV antibody testing
- Information regarding different HIV testing options e.g., standard vs. rapid testing
- The manner in which specimen is collected
- The timeframe of obtaining test results
- The importance of obtaining test results
- The importance of providing good contact information in case follow-up is needed.
- That all preliminary positive/reactive oral rapid tests will be immediately followed with up to two more rapid tests and may take up to a half hour.
- What preliminary positive results indicate, and that a confirmatory specimen must be collected in that case
- What negative results indicate (taking special note of the window period)
- The accuracy of rapid HIV antibody testing (especially related to use of more than one rapid test if the first test is reactive/preliminary positive.

Once all aspects of the testing process have been discussed, the client will then be able to provide written informed consent [*unless your site has anonymous testing - adjust as applicable*]. Client must then receive the "Subject Information Pamphlet" provided for clients by the test manufacturer.

Client-Centered Counseling

Once a client has provided informed consent, s/he shall receive individualized counseling to assist her/him in determining risk factors and behavior modification goals. The majority of the risk assessment will happen after specimen collection, during the 20 minute wait for OraQuick results.

Risk Assessment client-centered counseling shall include:

- A neutral stance on the part of the counselor, and flexibility in counseling approach
- Respect for the choices a client has made and will make
- Evidence of the counselor's ability to actively listen to what the client is saying
- Evidence of the counselor's comfort with discussing explicit risk behaviors in the terminology most desirable for the client
- Evidence of the counselor's understanding of harm reduction, stages of change and the continuum of risk
- Exploration of the context of risk behaviors, such as with regard to use of substances or domestic violence

- Clarification of misconceptions about HIV transmission
- Discussion of STDs when relevant to the client's risk
- Discussion of the client's readiness for testing and receipt of results
- Discussion of client's support system after receiving the test results
- Identification of barriers and supports to behavior change
- Provision of opportunity for building skills related to risk reduction for self and others
- No unnecessary information (i.e. health education that is irrelevant to the risks of the client)
- Focus on the counseling rather than data collection, with the recognition that complete and accurate data collection is a vital part of program planning and evaluation of CTL services.
- An individualized risk assessment to develop:
    - An accurate self-perception of risk
    - Acknowledgement and understanding of the details and context of client's risk, including all relevant co-factors for HIV risk, such as psychosocial, socioeconomic, substance use, and relationship considerations
    - Provision of support by the counselor for positive steps that the client has made toward reducing risk
    - Concrete, acceptable and realistic protective measures to reduce personal HIV risk
    - Development of a concrete and achievable behavior-change step that will reduce HIV risk and is acceptable and appropriate to the client's situation
    - Referrals and linkages to services as needed that meet the client's needs in the most competent and appropriate manner based on the context of their risk

More detail about client-centered counseling can be found in the Basic I and Basic II manuals provided by AIDS Health Project to every counselor who completes their training to become certified.

Post-Exposure Prophylaxis (PEP)

If a client comes in for an HIV test and believes s/he was exposed to HIV within the last 72 hours, counselors should provide information and referrals to a Post-Exposure Prophylaxis (PEP) program. PEP is a 28-day regimen of taking anti-viral medications as soon as possible after exposure to HIV to lower the chances of HIV infection. Ideally, it will be started as soon as 4 hours after infection, but cannot be provided after 72 hours from infection. PEP medications are only available with a prescription. PEP is not usually provided to people who may have been exposed through oral sex, while all other exposures are assessed on a case-by-case basis. Individuals who have had unprotected anal sex or shared syringes are highly recommended to take PEP.

Clients can receive PEP at City Clinic and San Francisco General Hospital. For City Clinic, counselors or clients can call 415-487-5538 to discuss the situation with a counselor before going to the clinic. City Clinic will provide a two-day starter pack, and then a prescription for the remainder of the regimen. This can be filled at any pharmacy, using insurance, paying out-of-pocket (this costs an average of $650, depending on the pharmacy) or registering at San Francisco General Hospital for a sliding scale Community Health Network prescription card (with proof of San Francisco residence and income).

If City Clinic is closed, clients should go to Urgent Care at San Francisco General Hospital. Urgent Care is located at the main campus building (1001 Potrero Avenue) in room 4J. Urgent Care can be contacted by phone at 415-206-8052. Hours PEP is offered at Urgent Care are 5pm – 9pm Monday – Friday and 10am – 5pm Saturdays and Sundays (when City Clinic is closed). If Urgent Care is also closed, clients should go to the SFGH Emergency Room to access PEP as soon as possible after exposure.

[*Include here any site-specific information about PEP. What would you like your counselors to tell clients, and under what conditions should they offer PEP to clients? What else would you like them to know about PEP?*]

Specimen Collection & Testing

Phlebotomy on-site

At all times that rapid testing occurs at [*Site*], someone must be on-site who is legally able to perform fingersticks and blood draws in the State of California. [*Include information here about who this will be for your site. Is it a nurse or doctor who is readily available? Is it a CA state-certified phlebotomist who will be scheduled for each rapid testing shift? etc.*]

Laboratory Specifications

[*Include information here about your site-specific procedures for collecting the specimen and running the rapid test. Will counselors also certified as test technicians collect the OraQuick from the client in the counseling room, then walk it to the lab area? Or will they walk the client to the lab area to collect the sample and run the test? Will you have separate staff members providing counseling from those collecting the OraQuick specimen and running the test in the lab room (this is required if you are using the OraQuick/Stat-Pak Algorithm)? Also, what supplies will be maintained in the laboratory area (gauze, bench protectors, sharps containers, etc.)? How will the area be secured from unauthorized entry, and how will client confidentiality be maintained? Where will confirmatory blood draws take place? Will this be done by a qualified counselor or will it be a different staff person entirely. Provide any other site-specific details here about the laboratory setup.*]

Universal Precautions will be followed at all times in the laboratory area and during specimen collection. For purposes of rapid testing, use of universal precautions includes:

1. All specimens and material containing specimens must be handled as if they are capable of transmitting an infectious organism. This includes control vials, and all rapid test kits, even if used only with oral specimens.
2. During testing, certified technicians must use protective equipment such as gloves and lab coats.
3. All certified technicians must follow procedures for biohazard safety such as hand washing, use of gloves, sharps and biohazardous waste disposal, and spill containment and disinfections.

Handwashing is a vital component of biohazard control and good lab practices. All certified technicians will:

1. Wash hands before and after every client contact; before and after meals, breaks and the toilet; and before going home.
2. Remove jewelry before washing hands and forearms or using hand sanitizer. Water should be a warm gentle stream and hands and wrists should be made wet.
3. Lather hands and wrists using plenty of soap. Hands must be kept lower than elbows so that the water runs from the least contaminated area (forearms) to the most contaminated area (fingers).
4. Wash hands, wrists and between fingers for 15 seconds using friction and rinsing thoroughly.
5. Dry hands and wrist with paper towels.
6. Turn off the faucet with a paper towel, avoiding direct contact with the contaminated faucet.
7. If soap and water are not available, at a minimum sanitize hands with Bacdown no-rinse antimicrobial skin cleanser or a similar product.

Gloving is required of all certified technicians, as a central tenet of universal precautions. All certified technicians will:

1. Wear gloves to prevent transmission of organisms when anticipating contact with body substances or non-intact skin.
2. Wear gloves to collect oral swab samples, and when handling used test kits and vials or any other materials that have come into contact with potentially infectious fluids.
3. Remove and discard gloves after each individual task involving body substance contact. Wash hands as soon as possible after glove removal
4. Use hypoallergenic and powder free gloves for individuals who are allergic to latex or powder. These gloves are provided at the site and are available upon request.
5. Have various sizes of gloves available and accessible to ensure a proper fit.

OraQuick Testing Procedure *(to be performed only by a certified technician*

Preparation

1. Gather equipment. Equipment for rapid testing includes:
    a. OraQuick Advance test kit (must be at room temperature)
    b. Gloves
    c. Bench protector (absorbent workspace cover)
    d. Blue test kit stand
    e. Lab slip
    f. Pen
    g. Biohazard container
    h. Thermometer
    i. Digital clock
    j. Timer (if desired)
    k. If applicable, fingerstick items (specimen loop, lancet, alcohol pad, gauze, band-aid, sharps container)
2. Examine test kit pouch for unopened, room temperature absorbent pack.
3. Record lot number and expiration date on outside of foil pouch onto the lab slip.
4. The certified technician must record his/her 4-digit technician ID number on lab slip. If a fingerstick will be performed, this must also be the 4-digit technician ID for someone eligible to perform fingersticks.
5. Feel the test kit pouch to determine which side contains the vial of reagent. Open only that side of the pouch. Remove vial and set pouch aside. Open the vial gently by rocking the lid back and forth, and set it in the blue test kit stand.
6. Remove an ID sticker from the lab slip and place it on the vial so that the unique 8-digit code is visible.
7. From the same sheet of numbers affix a sticker to the CIF and any other paperwork, which must be linked.

OraQuick Advance HIV-1/2 Specimen Collection

8. Put on gloves to collect any fingerstick or oral swab sample.
9. Open the other side of the foil pouch and remove the test kit without touching the absorbent pad.
10. If a fingerstick sample will be collected, the test technician must also be a California certified phlebotomist, a limited phlebotomist, or be occupationally exempt (RN, MD, and some medical assistants, for example). The first drop of blood following the fingerstick should be wiped away. The second drop is collected with the specimen loop, which must then be stirred into the open vial. Ensure

that the vial turns pink, indicating proper addition of the blood specimen. The lancet must be disposed of in a sharps container, and the specimen loop must be placed into the biohazard waste container.

11. If an <u>oral sample</u> will be collected, the technician can either collect the specimen him/herself, or instruct the client to properly collect his/her own specimen. To collect the specimen, place the flat pad of the kit above the teeth against the outer gum. Gently swab completely around the outer gums, from left to right on both the top and bottom gums. DO NOT swab the roof of the mouth, the inside of the cheek or the tongue.
12. After oral specimen collection, the test kit can either be inserted directly into the vial (ONLY if the technician collected the oral sample) or can be placed by the client or technician back into the foil pouch. The technician then must remove it from the foil pouch when ready, and place it in the opened test kit vial. Once an oral specimen is collected, the test kit must be inserted into the vial within 10 minutes, and cannot be transported in any way outside of the foil pouch.
13. Carefully insert the test kit into the vial. DO NOT touch the flat absorbent pad before inserting into the vial. Ensure that the pad is touching the bottom of the vial. The test kit window should be facing forward, unless there are concerns about confidentiality, in which case it can be placed in the vial with the window facing backward, and turned around when the test result is about to be read.
14. Record the time on the lab slip in the space labeled "Begin Test-Time".
15. Record the temperature on the lab slip in the space labeled "Begin Test-Temperature".
16. Do not move the test kit or vial for the entire time the result is developing.

<u>Reading & Interpreting Results</u>

17. Read results after 20 minutes but no more than 40 minutes.
18. Test is non-reactive if a pink line appears next to the triangle labeled "C" and NO line appears next to the triangle labeled "T". A non-reactive test means that the HIV-1 or HIV-2 antibodies were not detected in the specimen. The test is interpreted as **NEGATIVE** for HIV-1 and HIV-2 antibodies.

OraQuick NEGATIVE

OraQuick PRELIMINARY POSITIVE

19. Test is reactive if a pink line appears next to the triangle labeled C and a pink line appears next to the triangle labeled T. One of these lines may be darker than the other. **NOTE:** The test is preliminary positive/reactive if **<u>ANY</u>** pink line appears next to both the "T" and "C" triangles MATTER HOW FAINT THESE LINES ARE. A reactive test result means that HIV-1 or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as **PRELIMINARY POSITIVE/REACTIVE** for HIV-1 or HIV-2 antibodies.
    a. If this test is an oral fluid rapid test, using the OraQuick Rapid Testing Algorithm, it must be immediately repeated with a fingerstick whole blood sample to determine the likelihood that the client is truly HIV positive. Regardless, the test must be confirmed via blood draw sent out to a laboratory.
    b. If the test is a finger stick/whole blood, blood is drawn for confirmatory or Stat-Pak can be used in the OraQuick/Stat-Pak Algorithm
    c. If this test is an oral fluid rapid test, using the OraQuick/Stat-Pak Rapid Testing Algorithm, blood must be drawn for confirmation in the off-site lab and a Stat-Pak HIV rapid test must be run from that blood. If there is a discordant result between the OraQuick and Stat-Pak rapid tests, a finger stick OraQuick Advance Rapid Test must be run. (see appendix XX for counseling messages using this Algorithm).
20. Test is invalid if NO pink line appears next to the triangle labeled "C" or a pink background in the results window makes it difficult to read the result after 20 minutes, or if any of the lines are NOT inside the "C" or "T" triangle areas. An invalid test result means that there was a problem running the test either related to the specimen or to the device. An invalid result cannot be interpreted.

21. If a test is invalid repeat the test with a new test kit, and new specimen. <u>If the second test is also invalid,</u> encourage the client to submit a conventional test sample, or refer them to another location for a rapid test. A set of external controls must be run to verify that the test kits are functioning properly, before any other rapid tests are conducted. An invalid test case report form must be completed and sent to the HIV Prevention Section.
22. Record the time the result is read on the lab slip in the space labeled "End Test-Time".
23. Record the temperature on the lab slip in the space labeled "End Test-Temperature".
24. Record the result and double-check the lab slip to ensure that the information is clear, complete & accurate.
25. Place the test kit and all other used materials into the biohazard waste container and clean area as needed.

Stat-Pak Testing Procedure *(to be performed only by a Stat-Pak certified technician following a reactive OraQuick Advance HIV-1/2 Rapid Test using oral fluid or whole blood)*

<u>Preparation</u>

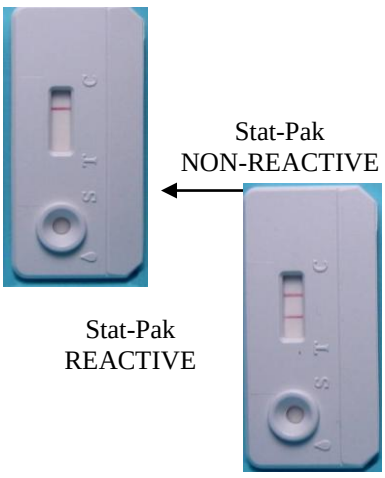
1. Gather equipment. Equipment for rapid testing includes:
    a. Stat-Pak test kit (must be at room temperature)
    b. Loop for gathering specimen from the vacutainer tube
    c. Stat-Pak buffer solution
    d. Gloves
    e. Bench protector (absorbent workspace cover)
    f. Supplemental Lab Slip
    g. Pen
    h. Thermometer
    i. Digital clock
    j. Timer (if desired)
    k. Biohazard Waste Container
2. Record lot number and expiration date on outside of foil pouch onto the lab slip.
3. The certified technician must record his/her 4-digit technician ID number on lab slip.
4. Take a sticker from the OraQuick lab slip and place it on the supplemental lab slip, to link the two.

<u>Specimen Collection</u>

5. Open the foil pouch, remove the Stat-Pak kit, and set it on the bench protector.
6. Put on gloves to collect the sample from the vacutainer tube (should be already drawn).
7. Carefully remove the top of the vacutainer tube and insert the loop to gather the specimen.
8. Be sure the loop is full of specimen and then touch the loop to the Sample well in the Stat-Pak kit.
9. Add **three** drops of buffer solution to the sample well, holding the bottle vertically to dispense properly.
10. Record the time on the lab slip in the space labeled "Begin Test-Time".
11. Record the temperature on the lab slip in the space labeled "Begin Test-Temperature".
12. Do not move the test kit for the entire time the result is developing.

<u>Reading & Interpreting Results</u>

13. Read results after 15 minutes but at no more than 20 minutes.
14. Test is **NON-REACTIVE** if a pink line appears next to the triangle labeled "C" and NO line appears next to the triangle labeled "T". A non-reactive test means that the HIV-1 or HIV-2 antibodies were not detected in the specimen. **A finger stick OraQuick Advance HIV-1/2 test must**



be run immediately, before results of this test are disclosed to the client

15. Test is **REACTIVE** if a pink line appears next to the triangle labeled C and a pink line appears next to the triangle labeled T. One of these lines may be darker than the other. **NOTE:** The test is reactive if **ANY** pink line appears next to both the "T" and "C" triangles, NO MATTER HOW FAINT THESE LINES ARE. A reactive test result means that HIV-1 or HIV-2 antibodies have been detected in the specimen. **THE CLIENT IS CONSIDERED TO BE HIV-POSITIVE. DISCLOSE THE RESULT AND LINK THIS CLIENT TO MEDICAL CARE.**
16. Test is invalid if NO pink line appears next to the triangle labeled "C" or if any of the lines are NOT next to the "C" or "T" areas. An invalid test result means that there was a problem running the test either related to the specimen or to the device. An invalid result cannot be interpreted.
17. If a test is invalid repeat the test with a new test kit, and new specimen. If the second test is also invalid, proceed directly to running the OraQuick Advance HIV-1/2 test with whole blood. A set of external controls must be run to verify that the test kits are functioning properly, before any other rapid tests are conducted.
18. Record the time the result is read on the lab slip in the space labeled "End Test-Time".
19. Record the temperature on the lab slip in the space labeled "End Test-Temperature".
20. Record the result and double-check the lab slip to ensure that the information is clear, complete & accurate.
21. Place the test kit and all other used materials into the biohazard waste container and clean area as needed.

Disclosure

All clients who are tested shall receive private, individualized disclosure counseling which will include

- Provision of test results in a clear, direct, and neutral manner
- Support in coping with the test results
- Explanation of the meaning of the test results (especially the window period, for a negative result)
- Assessment of the client's psychological and emotional reaction to the test results
- A review of behavior goals which client identified earlier for risk reduction
- Referrals and linkages if test result is negative
- Referral and linkage to medical care if test result is preliminary positive/reactive or confirmed positive.
- Partner Services options discussed and selected

Conventional HIV Positive Test Results

Clients who test confirmed HIV positive on a conventional HIV test (OraSure or Venipuncture) by an external laboratory will have already been scheduled for a return appointment to receive their HIV test results. This client will receive individual disclosure counseling outlined above. If the person does not return for their results, at least three attempts will be made to contact the client to disclose their results.

OraQuick "Preliminary Positive" Results & Confirmatory Testing

Clients who test preliminary positive will receive an explanation of the meaning of a preliminary positive result. Clients who are preliminary positive with an OraSure oral fluid rapid test will be told something like the following: "*Your oral rapid test came back preliminary positive. This usually means that you have antibodies to HIV. However, this test can sometimes produce a false positive result, so we'd like to run the test again with*

a fingerstick sample now, to see if we get the same result. Either way we would like to draw blood and send it to our lab for confirmation – but this extra fingerstick test will give you more information about whether it is likely that you have HIV."

Clients will then be immediately re-tested with a OraQuick fingerstick whole blood sample on another rapid test. If the result of that fingerstick test is also preliminary positive, the client will be told, "*Both rapid tests we ran today were preliminary positive. It is likely that you have HIV. We always want to make absolutely sure, though, so we are going to draw blood today and send it to our lab so they can run confirmatory testing. We will run an antibody test, and it is possible we will run an RNA test as well – this test looks for presence of the virus. The results of the tests our lab runs will be ready in 1 week. In the meantime, you should assume that you are infected with HIV, and take all necessary precautions to protect your partners.*"

If the result of the fingerstick test is negative, the client will be told, "*Although the oral rapid test we ran today was preliminary positive, the fingerstick test we did afterward was negative. Because the fingerstick test is a more accurate test, it's likely that you don't have HIV. In order to know for sure, we need to draw blood and send it to our lab for confirmation. We will run both an antibody test and an RNA test, which looks for the virus. The results of those tests will be ready in 1 week. In the meantime, you should assume that you may be infected with HIV, and take all necessary precautions to protect your partners.*"

Regardless of the result of the fingerstick rapid test, clients will then be verbally re-consented for collection of a confirmatory specimen. When the client is ready, they will receive a blood draw for confirmatory testing in a **completely full 8ml purple-top "North Carolina" tube** (purple with a yellow ring on the top, and a gel separator). For more information about this procedure, refer to the Interim San Francisco Algorithm for Oral Rapid HIV Testing. *Include information here about the site-specific procedure for confirmatory blood draws. Will it be done in the counseling room? Will the client move to the lab area? etc. If you will only be conducting fingerstick rapid tests at your site, include this information here and modify the paragraphs above.*]

OraQuick and Stat-Pak "Reactive" Results & Confirmatory Testing

Clients who test reactive on the OraQuick oral fluid rapid test will be told something like the following: "*Your result was reactive. This usually means you HIV antibodies to HIV. Before you leave today I should be able to give you some solid information about whether or not you have HIV. We will run up to two more rapid HIV tests, which could take up to a half hour after we draw blood. We will also send that blood to a laboratory for even further confirmation. We can talk as much as you want while we wait.*"

Clients will then have their blood drawn for official confirmation in the SFDPH lab, and be immediately tested with a fingerstick whole blood sample on the Stat-Pak HIV test. If the result of that test is also reactive, the client will be told, "*Both rapid tests we ran today were reactive. Based on this, we believe you have HIV. It is very important for you to be able to access medical care in order to do to some lab work to know the status of your health at the present time. This news can be overwhelming for you. I want you to know that we can work together and know that you are not alone in any part of this. One of our staff will contact you and let you know the results of these tests and check in with you to see if you are having any trouble seeing a provider. Does that work for you? I want to make sure I have the right contact information for you."*

If the result of the Stat-Pak is non-reactive, blood from the vacutainer tube (already drawn) will be used to run the OraQuick (whole blood) HIV rapid test, before any results are disclosed. If the Uni-Gold test is reactive, the client will be told, "*The first test was reactive, and we ran a second rapid test, which was non-reactive. Since those two tests didn't agree, we ran a third test which was also reactive. At this point, we believe that you have*

HIV. It is very important for you to be able to access medical care in order to do to some lab work to know the status of your health at the present time. This news can be overwhelming for you. I want you to know that we can work together and know that you are not alone in any part of this. We will send the blood we drew to our lab for further testing. If you would like the results of that test you can make an appointment to return here in a week or we can send it to your doctor directly if you sign a medical release form. Regardless, one of our staff will contact you soon to see if you are having any trouble seeing a provider or need any other assistance from us. Does that work for you? I want to make sure I have the right contact information for you."

If the result of the OraQuick HIV-1/2 rapid test is reactive, the client will be told: "*The first rapid test was reactive, and we ran a second rapid test which was non-reactive then we ran a third test that was reactive. Since these tests didn't agree, we can't be sure about your HIV status. We are sending the blood we drew today to an off-site lab for confirmation. We encourage you to make an appointment to come back to us and get those results in a week. However, we can also work with you to see a doctor who can run more testing, if you would like. We can also, with your permission sent the results of the blood tests we will be processing to your medical provider. I want you to know that we can work together and know that you are not alone in any part of this. I want to make sure I have the right contact information for you. (Explore risk behavior further if appropriate.)*

If the result of the OraQuick HIV -1/2 rapid test is also non-reactive, the client will be told, "*Although the first rapid test we ran today was reactive, we ran a second rapid test that was non-reactive. When then re-ran the first test with a blood specimen, which is more sensitive. This was also non-reactive. Based on this we think that the first result was false positive and you do not have HIV. However, we are going to send the blood we drew to the lab for further confirmation and I will make an appointment with you now to come back and hear those results. I want to make sure I have the right contact information for you. (Explore risk behavior further if appropriate).*

Clients who test reactive on the OraQuick <u>fingerstick</u> rapid test will be told something like the following: "*Your result was reactive. This usually means you HIV antibodies to HIV. Before you leave today I should be able to give you some solid information about whether or not you have HIV. We will run up to two more rapid HIV tests, which could take up to a half hour after we draw blood. We will also send that blood to a laboratory for even further confirmation. We can talk as much as you want while we wait.*"

Clients will then have their blood drawn for official confirmation in the SFDPH lab, and be immediately tested with a fingerstick whole blood sample on the Stat-Pak HIV test. If the result of that test is also reactive, the client will be told, "*Both rapid tests we ran today were reactive. Based on this, we believe you have HIV. It is very important for you to be able to access medical care in order to do to some lab work to know the status of your health at the present time. This news can be overwhelming for you. I want you to know that we can work together and know that you are not alone in any part of this. One of our staff will contact you and let you know the results of these tests and check in with you to see if you are having any trouble seeing a provider. Does that work for you? I want to make sure I have the right contact information for you."*

If the result of the Stat-Pak is <u>non-reactive</u>, the client will be told, "*The first test was reactive, and we ran a second rapid test, which was non-reactive. Since those two tests didn't agree, we can't be sure about your HIV status. We are sending the blood we drew today to an off-site lab for confirmation. We encourage you to make an appointment to come back to us and get those results in a week. However, we can also work with you to see a doctor who can run more testing, if you would like. We can also, with your permission sent the results of the blood tests we will be processing to your medical provider. I want you to know that we can work together and know that you are not alone in any part of this. I want to make sure I have the right contact information for you. (Explore risk behavior further if appropriate.)*

Confirmatory testing will be routinely done, because this is currently the gold standard for diagnosing HIV infection. Other than a likely false positive, the effort here by staff should be to arrange medical care/further testing and follow up to see that this happens. Therefore a return appointment does not need to be scheduled for disclosure of these results, unless the client requests. However, it is imperative that good contact information be collected, so that the client can be contacted should the confirmatory results not be as expected.

IMPORTANT: Because the OraQuick Advance and the Stat-Pak tests for antibodies to both HIV-1 and HIV-2 but does not distinguish between the two, after a person tests preliminary positive the counselor must ask a series of questions to screen them for risk factors to HIV-2 (a strain of HIV that is very rare in the United States). This should be done before or at the time that the confirmatory specimen is collected.

The questions that must be asked are as follows:

1. *Have you ever had sex or shared needles with someone you knew was infected with HIV-2?*
2. *Have you had unprotected sex or shared needles with a person who lives in or is from a country in West Africa?*
3. *Did you ever have sex, receive a blood transfusion or a nonsterile injection in a country located in West Africa?*

If the client answers "yes" to any of those questions and/or is reporting an illness that suggests HIV infection (such as an HIV-associated opportunistic infection), then mark in the "Note" section of the lab slip (where it says "Laboratory Use Only") that the client is at risk for HIV-2, and list the specific risk factor or symptom. If a note is not made in the lab slip, the laboratory will most likely be unable to refer the specimen to the State Lab for testing for HIV-2 but could instead return a discordant result.

Notify the client at that time that if their blood needs to be tested for HIV-2, it could take three to four weeks before the confirmatory result is available, because this testing cannot be done in our lab in San Francisco. Make sure to gather comprehensive contact information so that the client can be contacted when an HIV-2 confirmatory result is available, should their HIV-1 confirmatory test be negative or indeterminate. A regular post-disclosure appointment for results ([insert time frame for results here]) should be scheduled regardless, in the more likely event that the confirmatory test is confirmed positive for HIV-1.

For clients with positive results (preliminary or reactive), special attention will be given to referrals as appropriate for:

- Partner Services (all 4 options must be presented to all positive clients)
- Medical care
- Professional mental health services
- Suicidal or homicidal ideation
- Education (such as demonstration and discussion of effective barrier techniques) in direct relation to the risk reduction goals client created during the risk assessment, if this seems appropriate.

[If you are a site offering only the OraQuick HIV rapid test include here information about your site's procedures for scheduling someone to return for their confirmatory results. Will an appointment be made? Who will make the appointment? How many days are needed for results to be ready for the client? etc.]

Contacting OraQuick Rapid HIV-1/2 only "Preliminary" Positive Clients Who Fail To Return For Confirmatory Results

With confidential HIV testing, all reasonable attempts will be made to have clients receive confirmatory results.

Clients shall be advised during disclosure that they must return in person to receive confirmatory results, and that results will not be given out to anyone except the client who tested.

The counselor shall request a telephone number to contact the client in the event that the client fails to keep the confirmatory results appointment. Clients will be encouraged to give a correct telephone number. If the client fails to keep an appointment, the counselor will make 3 attempts to reschedule appointments. [*Include information here about your site-specific procedures for ensuring confidentiality is maintained during follow-up phone calls. Also indicate how your site will document and track attempts to reschedule appointments.*]

A letter may be sent to the client if they have left an address for their contact information, in the event they cannot be reached by telephone. The letter will only state to return for results and will not mention HIV.

No HIV test results shall be given out over the telephone under any circumstances.

If Clients Want to Receive Results of their OraQuick/Stat-Pak Confirmatory Testing from the SFDPH Lab

[What is the process at your agency for clients who want to receive results of their confirmatory testing? This is not routinely scheduled except with anonymous clients; however, it should be an option for any client who requests it. This could be done in person via walk-in or appointment. Explain here what this process looks like at your agency and exactly how a counselor should communicate this process to a client.]

Case Reporting of Clients Who Are Confirmed HIV Positive

According to California State Law, all positive HIV test results must be reported to the local health department by name **within 7 days of confirmation**. In San Francisco, HIV confidential case reports must be completed by each HIV testing site and called in or mailed to the Coordinator for Linkage/Partner Services, Nyisha Underwood, HIV Prevention Section within 7 days of receipt of the lab report that confirms a clients' positive HIV test result.

Handling of Psychological Crisis Due to HIV CTL results

[*Include information here about how a client should handle a client who becomes overly hysterical or despondent, or reports suicidal or homicidal ideation. Who should they contact? What should they do?*]

Provision of Written Test Results to the Client

With confidential testing, written results for persons testing HIV positive or negative can be provided to the client, if they are printed on agency-specific letterhead.

Copies of the lab report or lab slip should not be provided to the client.

For sites providing confidential HIV rapid tests, written results for a "confirmed positive" test must include the names of the rapid tests run and the results of each of those tests plus the results of the confirmatory test.

If a written result is being provided following a confidential "reactive result" on the OraQuick/Stat-Pak HIV rapid tests and before official confirmatory results are provided from the SFDPH lab, the following disclaimer should be included:

> *The HIV antibody test results indicates that antibodies were present on multiple rapid HIV tests run at [site] as part of a rapid HIV testing algorithm. This result is considered to be accurate; however, it has not yet been confirmed with and IFA or Western Blot in a microbiology laboratory, as used in current HIV testing practice in the United States.*

Written results for a negative test must include the date that the antibody test was conducted, as well as a disclaimer about antibody testing. The following disclaimer should be used as a model:[2]

> *This HIV antibody test result indicates whether antibodies to HIV were present only at the time the specimen was tested.* ***If the result is negative or indeterminate, it may not reflect a person's current HIV status****. If an individual was exposed to HIV less than 6 months before this antibody test was conducted, it is possible that s/he may be infected with HIV but still have a negative antibody test result.*

Written results may not be provided following an anonymous test under any circumstances

[*Insert here all other agency-specific guidelines regarding written test results*].

Partner Services

After a client tests HIV positive, it is the responsibility of the counselor to provide information about the four Partner Service options available to them. The four options are:

1) **Self-Disclosure**: The client will disclose his/her status to partners independently. The counselor will offer coaching or other assistance as appropriate and desired to facilitate self-disclosure to current, past, and future partners.
2) **Dual-Disclosure**: The client will disclose his/her status to partners in the presence of the counselor or another third party. Although the counselor will never be the one to disclose the client's status, s/he will be present to offer support and information to both the client and his/her partner(s).
3) **Anonymous Provider Notification**: The client wishes his/her partners to know that they may have been infected with HIV, but wants to remain anonymous. In this case, trained field staff at City Clinic will provide anonymous notification to partners. The counselor at [*Site*] works with the client to elicit partner information, including name, address and/or telephone number and/or email address, age and physical description. This information is provided by the counselor to the DAPS Coordinator at City Clinic by secure phone (415-487-5516), fax (415-431-4628), or email (Giuliano.Nieri@sfdph.org). Field staff will then notify partners and offer CTL services. The HIV positive person who named the partner(s) will never be identified, nor will information linking the partner to the original client be revealed.

[2] DHS/OA HIV Counseling and Testing Guidelines (1997), p. VI.B.17.; Larkin Street Youth Clinic template (2005).

4) **In-Spot**: The client will go online to http://www.inspot.org and send e-postcards to his or her partners, either anonymously or by identifying him or herself. These postcards alert the recipient that they may have been exposed to HIV or STDs and should be tested.

All Partner Services are completely voluntary, but must be offered to every client who tests positive at [*Site*].

Discordant Test Results (for OraQuick HIV-1/2 Rapid Testing)

Although rare, it sometimes happens with rapid testing that a result will be preliminary positive, but the confirmatory specimen sent to [*Insert laboratory name*] will yield a negative or inconclusive result. In this event, it can be challenging to disclose the confirmatory results to the client. One of two things is possible: either 1) they are in the process of seroconverting, and do in fact have HIV although their antibodies have not yet appeared in sufficient numbers to react with the confirmatory test, or 2) they had a false positive reading on their rapid test and in fact do not have HIV.

When the first rapid test is oral fluid (a preliminary positive) and the second finger stick rapid test is negative, for most clients this discordant result indicates a false positive result on the oral fluid test. Therefore, when the confirmatory test is negative, the discordant result will not be a surprise. If their confirmatory antibody testing is negative and their viral load is undetectable, the client will be notified that they are in fact HIV negative, keeping the window period of testing in mind.

In extremely rare situations, more follow-up testing may be needed. Some examples of this are if the oral fluid rapid test was positive and the fingerstick rapid test was negative but confirmatory antibody testing was positive, if the fingerstick rapid test was preliminary positive but confirmatory antibody testing was negative or indeterminate, or if RNA testing run on the client specimen yields a detectable viral load of less than 10,000 copies (indicating a possible false positive result on the RNA test). In any of these cases, direct communication will be made between *[Insert name and/or position of HIV rapid testing coordinator]* and the Department of Public Health Laboratory and/or the agency Technical Assistant Lead prior to disclosure of results to the client, so that appropriate next steps and counseling messages can be determined.

For more information about these protocols, refer to the Interim San Francisco Algorithm for Oral Rapid HIV Testing.

Referrals & Follow Up

All counselors must be prepared to provide a variety of in-house and out-of-agency referrals for clients testing both positive and negative, before beginning to provide CTL for clients. These referrals include but are not limited to:

- Psychological counseling
- Medical evaluation including TB, STD, and pregnancy testing
- Family planning services
- Social services
- Legal services
- Domestic violence support and prevention services
- Drug and alcohol treatment programs
- Social support
- Hotline telephone numbers
- Specific AIDS medical service providers and information

- Specific Partner Services referrals and support
- [*Include here other resources as appropriate for your site and clientele*]

Referrals should be provided in writing in most cases, and should be tailored to the specific needs of a client. Referrals should specifically include multi-lingual and multi-cultural services where available and applicable. Minimally, referrals should be made which address HIV risk co-factors as well as primary risk behaviors, including HIV prevention, mental health and psychosocial services, substance use treatment and harm reduction services, services and health care for people with HIV, and other health care tangentially related to HIV risk.

Current and accurate referrals lists are continuously created and made available at [*Site*] in [*insert languages appropriate to your site's client population*]. [*Name and/or position*] is responsible for the maintenance and distribution of these referrals lists to counselors.

[*Include here any additional site-specific protocols or information regarding referrals*].

In order to ensure that clients receive the services needed, [*insert your site's plan for creating linkages instead of simple referrals. This may mean accompanying the client to services, following up with the client and/or referred agency, or other means of supporting linkages*].

Linkage to Medical Care Following a Positive Result

After a client tests HIV positive, there is a minimum of four things that must be provided to them:

1. Offer to help link client to care
2. Attempt to make a medical appointment on the spot
3. Provide the client the primary medical care/provider handout
4. Follow up with the client 1 week later to see whether they are in care

Remember to always try to obtain the most comprehensive contact information possible, in order to be able to follow up with the client.

For more information about the minimum requirements for linkage to medical care following a positive result in San Francisco, see Protocol for Linkage to Care and Partner Services.

Tracking of Referrals and Linkages

[*Include information here about your site's plan for tracking and documenting referrals and linkages. How will you follow-up to determine whether a client accessed a referral? What will you do if you know they did not access that referral? What mechanisms are in place to facilitate linkages of needed services, especially for positive and high-risk negative clients? etc.*]

<u>Documentation and Record Keeping</u>

[*Site*] shall maintain all clients HIV antibody testing records in a manner so as to assure that client confidentiality is maintained in accordance with current law.

[*Include information here about how record confidentiality will be maintained. Where will forms be stored? How will that area be secured? Who will have access to the records?*]

After a counselor and/or test technician completes the documentation for a test, the paperwork should be [*include details here about the procedure for your site. To what location are forms initially returned? When are they retrieved for QA, copying, and filing into a more permanent storage location?*] The following documents will be used in each rapid CTL session and together will make up a client record:

1. Informed consent form
2. SFCIF
3. Lab slip (s) for rapid testing on the SFCIF
4. Lab slip (s) red for confirmatory or conventional HIV test
5. Lab report of confirmatory test result for anyone testing preliminary positive
6. HIV Confidential Case Report for anyone confirmed HIV positive (confidential tests only)
7. [*Enter other forms as appropriate for your site*]

Originals or copies of the SFCIF, and original lab slips **(pages 1 or 2)**, the lab report for all conventional and confirmation for preliminary positive clients, will be forwarded to the Coordinator CTL Data Management (Nayla Raad) at the HIV Prevention Section within 7 days of a confirmed positive test result. All negative records (SFCIF, lab slips and lab report for a conventional test) must be submitted to Nayla Raad by the 21st of the month for the previous month. For example, records for all tests done in March will be sent to the HIV Prevention Section no later than April 21st. For a quick reference sheet that shows what paperwork is due for any type of HIV test, see the San Francisco CTL Paperwork Due Dates document.

In addition to client records, other documentation must be maintained for rapid testing. This includes:

1. Monthly testing summary sheets
2. External control logs (OraQuick/Stat-Pak)
3. Test kit and control storage temperature logs (for each manufactured rapid test/control)
4. Test kit inventory logs (for each manufactured rapid test)
5. [*Enter other forms as appropriate for your site*]

The monthly testing summary sheets must be mailed or faxed to the Coordinator for CTL Data Management (Nayla Raad) at the HIV Prevention Section on the 21st of the month following the month of service. This information may also be sent via email if it is easier (to Nayla.Raad@sfdph.org).

In addition to client records, a confidential laboratory log shall be maintained which lists:

- [*List fields that your site is choosing to collect in the laboratory log. Examples would be date of risk assessment, client name and/or client ID number from the lab slip, age of client, sex of client, etc. At a minimum, this log should allow you to easily identify the number of tests provided between certain dates, and for confidential testing, allow you to find contact information in the event that clients must be contacted for re-tests (such as after failed controls indicate that the test kits have not been functioning properly). This will also facilitate completion of the monthly testing summary sheet and external control logs*].

CONVENTIONAL TESTING

Clients who do not wish to receive their HIV test results the same day as their specimen collection will be offered two options: OraSure and venipuncture [*adjust per agency capacity; if your site does not offer these options, include information about how referrals will be made to sites that have these options available*].

Risk Assessment

Information Addressed Prior to Informed Consent

All clients requesting conventional HIV CTL will be counseled individually in a private, confidential counseling room. In order to obtain informed consent, the counselor must ensure that the client has a full and accurate understanding of the following:

- The purpose of HIV antibody testing
- The difference between anonymous and confidential testing in the State of California, especially as this relates to current HIV reporting laws
- The forms that will be completed in the course of their HIV test, and why
- The risks and benefits of HIV antibody testing
- Information regarding different HIV testing options e.g., conventional vs. rapid testing
- The manner in which a conventional specimen is collected (OraSure vs. blood draw)
- The timeframe of obtaining test results
- The importance of obtaining test results
- What steps will be taken if the client does not return for his/her test results [*specific to agency*]
- What negative results indicate (taking special note of the window period)
- The accuracy of conventional HIV antibody testing

Once all aspects of the testing process have been discussed, the client will then be able to provide written informed consent [*unless your site has anonymous testing - adjust as applicable*].

Client-Centered Counseling

Once a client has provided informed consent, s/he shall receive individualized counseling to assist her/him in determining risk factors and behavior modification goals. A risk assessment for a conventional test will vary depending upon the person's risk, but should take an average of 20 minutes per client. If language interpretation services are required, this may take 10 – 15 minutes longer.

Risk Assessment client-centered counseling shall include:

- A neutral stance on the part of the counselor, and flexibility in counseling approach
- Respect for the choices a client has made and will make
- Evidence of the counselor's ability to actively listen to what the client is saying
- Evidence of the counselor's comfort with discussing explicit risk behaviors in the terminology most desirable for the client
- Evidence of the counselor's understanding of harm reduction, stages of change and the continuum of risk
- Exploration of the context of risk behaviors, such as with regard to use of substances or domestic violence
- Clarification of misconceptions about HIV transmission
- Discussion of STDs when relevant to the client's risk
- Discussion of the client's readiness for testing and receipt of results

- Discussion of client's support system after receiving the test results
- Identification of barriers and supports to behavior change
- Provision of opportunity for building skills related to risk reduction for self and others
- No unnecessary information (i.e. health education that is irrelevant to the risks of the client)
- Focus on the counseling rather than data collection, with the recognition that complete and accurate data collection is a vital part of program planning and evaluation of CTL services.
- An individualized risk assessment to develop:
    - An accurate self-perception of risk
    - Acknowledgement and understanding of the details and context of client's risk, including all relevant co-factors for HIV risk, such as psychosocial, socioeconomic, substance use, and relationship considerations
    - Provision of support by the counselor for positive steps that the client has made toward reducing risk
    - Concrete, acceptable and realistic protective measures to reduce personal HIV risk
    - Development of a concrete and achievable behavior-change step that will reduce HIV risk and are acceptable and appropriate to the client's situation. This step should be something that the client can attempt during the period in which they're waiting for their test results.
    - Referrals and linkages to services as needed that meet the client's needs in the most competent and appropriate manner based on the context of their risk

More detail about client-centered counseling can be found in the Basic I and Basic II manuals provided by AIDS Health Project to every counselor who completes their training to become certified.

Post-Exposure Prophylaxis (PEP)

If a client comes in for an HIV test and believes s/he was exposed to HIV within the last 72 hours, counselors should provide information and referrals to a Post-Exposure Prophylaxis (PEP) program. PEP is a 28-day regimen of taking anti-viral medications as soon as possible after exposure to HIV to lower the chances of HIV infection. Ideally, it will be started as soon as 4 hours after infection, but cannot be provided after 72 hours from infection. PEP medications are only available with a prescription. PEP is not usually provided to people who may have been exposed through oral sex, while all other exposures are assessed on a case-by-case basis. Individuals who have had unprotected anal sex or shared syringes are highly recommended to take PEP.

Clients can receive PEP at City Clinic and San Francisco General Hospital. For City Clinic, counselors or clients can call 415-487-5538 to discuss the situation with a counselor before going to the clinic. City Clinic will provide a two-day starter pack, and then a prescription for the remainder of the regimen. This can be filled at any pharmacy, using insurance, paying out-of-pocket (this costs an average of $650, depending on the pharmacy) or registering at San Francisco General Hospital for a sliding scale Community Health Network prescription card (with proof of San Francisco residence and income).

If City Clinic is closed, clients should go to Urgent Care at San Francisco General Hospital. Urgent Care is located at the main campus building (1001 Potrero Avenue) in room 4J. Urgent Care can be contacted by phone at 415-206-8052. Hours PEP is offered at Urgent Care are 5pm – 9pm Monday – Friday and 10am – 5pm Saturdays and Sundays (when City Clinic is closed). If Urgent Care is also closed, clients should go to the SFGH Emergency Room to access PEP as soon as possible after exposure.

[*Include here any site-specific information about PEP. What would you like your counselors to tell clients, and under what conditions should they offer PEP to clients? What else would you like them to know about PEP?*]

Specimen Collection

OraSure

The counselor will follow the procedures for universal precautions, handwashing, and gloving outlined on pages 14-15 of this document. Gloves are required for OraSure testing despite the lack of obvious bloodborne pathogens, because small droplets of blood can be contained in oral fluid, and because diseases other than HIV can be easily passed through oral fluid.

In order to collect a proper OraSure specimen for HIV-antibody testing at [*insert name of laboratory your site uses*], the counselor must follow these steps:

1. Wash hands or use hand sanitizer if necessary. Put on gloves.
2. Open OraSure Collection Device Package and remove collection device and vial.
3. Place lab sticker on vial and set aside.
4. Open packaging surrounding collection device and have client pick up the device.
5. Ask client to place the white collection pad between their lower cheek and gum and leave in place for 2 – 5 minutes. The client can talk during this time, because jaw movement does not hinder collection.
6. When 2 – 5 minutes has passed, open the vial and ask the client to place the collection device into the vial, with the pad entering the vial first.
7. Snap off the top of the stick from the collection device, so that the vial can be closed.
8. Cap the vial and place it in a Ziploc biohazard bag.
9. Place the top copy of the lab slip in the front compartment of the biohazard bag.
10. [*Describe here where the counselor should place the full biohazard bag for pick-up or delivery to lab*].
11. Remove gloves and dispose of them in a biohazard waste container.
12. Wash hands or use hand sanitizer if necessary.

Venipuncture

All individuals performing venipuncture at [*Site*] must possess certification as a California Certified Phlebotomy Technician (CPT) or be occupationally exempt (be an RN, NP, MD, or medical assistant under the direct supervision of a physician). **No other individuals may perform phlebotomy under any circumstances after January 1, 2007 in the State of California.**

The phlebotomist will follow the procedures for universal precautions, handwashing, and gloving at all times during venipuncture specimen collection.

In order to collect a proper blood draw specimen for HIV-antibody testing at [*insert name of laboratory your site uses*], the counselor must follow these steps

1. Wash hands or use hand sanitizer if absolutely necessary.
2. Put on gloves. Gloves and goggles or glasses shall be worn during entire procedure. Gloves will also be worn during clean up of all blood spills.
3. Position the client so that s/he will not fall should fainting occur. Use a venipuncture chair when possible.
4. Collect a full 10ml of blood in a plastic, tiger-top vacutainer tube (or a red-top tube if a tiger-top is not available) using proper venipuncture procedure.
5. Do not recap, purposely bend or break, or otherwise manipulate needles after the blood draw. Do not remove needles from disposable syringes after use.

6. Place all sharps into a sharps container located in the room. In no event can used needles be carried from the room where the blood draw occurs, without being inside a proper sharps container.
7. Immediately label the vacutainer tube with the lab sticker.
8. Place the tube in a Ziploc biohazard bag.
9. Place the top copy of the lab slip in the front compartment of the biohazard bag.
10. [*Describe here where the counselor should place the full biohazard bag for pick-up or delivery to lab*].
11. Remove gloves and dispose of them in a biohazard waste container.
12. Wash hands or use hand sanitizer if absolutely necessary.

Disclosure

In compliance with the State Office of AIDS guidelines and San Francisco HIV Prevention Section policy, clients who have chosen conventional testing will be required to receive their results within 45 days. In the event that an individual returns after 45 days and their results are negative, they will not be given their test results and instead will be encouraged to test again. If the client's original test results are positive, the result will be disclosed regardless of how much time has passed between risk assessment/test date and disclosure date

Whenever possible, the same counselor should provide the risk assessment and disclosure for a client. This is particularly important for any client that tests HIV positive.

All clients who are tested shall receive private, individualized disclosure counseling which will include

- Provision of test results
- Support in coping with the test results
- Explanation of the meaning of the test results (especially the window period, for a negative result)
- Assessment of the client's psychological and emotional reaction to the test results
- A review of behavior goals which client identified earlier for risk reduction
- Referrals and linkages as appropriate (and, if positive, according to minimum standards for linkage)

Contacting Clients Who Fail To Return For Results

With confidential HIV testing, all reasonable attempts will be made to have clients receive HIV test results.

Clients shall be advised during the risk assessment that they must return in person to receive their test results, and that results will not be given out to anyone except the client who tested.
The counselor shall request a telephone number to contact the client in the event that the client fails to keep the disclosure appointment. Clients will be encouraged to give a correct telephone number. If the client tests HIV positive but fails to keep an appointment, the counselor will make 3 attempts to reschedule appointments.
[*Include details about your site's protocol for contacting clients who test negative. Also include information here about your site-specific procedures for ensuring confidentiality is maintained during follow-up phone calls.*]

A letter may be sent to the client if they have left an address for their contact information, in the event they cannot be reached by telephone. The letter will only state to return for results and will not mention HIV.

No HIV test results shall be given out over the telephone under any circumstances.

Case Reporting of Clients Who Are Confirmed HIV Positive

According to California State Law, all positive HIV test results must be reported to the local health department by name **within 7 days of confirmation**. In San Francisco, HIV confidential case reports must be completed by each HIV testing site and called in or mailed to the Coordinator for Linkage and Partner Services (Nyisha Underwood) with 7 days of receipt of the lab report that confirms a clients' positive HIV test result.

Handling of Psychological Crisis Due to HIV CTL Results

[*Include information here about how a client should handle a client who becomes overly hysterical or despondent, or reports suicidal or homicidal ideation. Who should they contact? What should they do?*]

Provision of Written Test Results to the Client

With confidential testing, written results for persons testing HIV positive or negative can be provided to the client, if they are printed on agency-specific letterhead. **Copies of the lab report or lab slip should not be provided to the client.** Written results for a negative test must include the date that the antibody test was conducted, as well as a disclaimer about antibody testing. The following disclaimer should be used as a model:[3]

> This HIV antibody test result indicates whether antibodies to HIV were present only at the time the specimen was tested. **If the result is negative or indeterminate, it may not reflect a person's current HIV status**. If an individual was exposed to HIV less than 6 months before this antibody test was conducted, it is possible that s/he may be infected with HIV but still have a negative antibody test result.

Written results may not be provided following an anonymous test under any circumstances.

Partner Services

After a client tests HIV positive, it is the responsibility of the counselor to provide information about the four options for Partner Services available to them. The four options are:

1) **Self-Disclosure**: The client will disclose his/her status to partners independently. The counselor will offer coaching or other assistance as appropriate and desired to facilitate self-disclosure to current, past, and future partners.
2) **Dual-Disclosure**: The client will disclose his/her status to partners in the presence of the counselor or another third party. Although the counselor will never be the one to disclose the client's status, s/he will be present to offer support and information to both the client and his/her partner(s).
3) **Anonymous Provider Notification**: The client wishes his/her partners to know that they may have been infected with HIV, but wants to remain anonymous. In this case, trained field staff at City Clinic will provide anonymous notification to partners. The counselor at [*Site*] works with the client to elicit partner information, including name, address and/or telephone number and/or email address, age and physical description. This information is provided by the counselor to the DAPS Coordinator at City Clinic by secure phone (415-487-5516), fax (415-431-4628), or email (Giuliano.Nieri@sfdph.org). Field staff will then notify partners and offer CTL services. The HIV positive person who named the partner(s) will never be identified, nor will information linking the partner to the original client be revealed.

[3] DHS/OA HIV Counseling and Testing Guidelines (1997), p. VI.B.17.; Larkin Street Youth Clinic template (2005).

4) **In-Spot**: The client will go online to http://www.inspot.org and send e-postcards to his or her partners, either anonymously or by identifying him or herself. These postcards alert the recipient that they may have been exposed to HIV or STDs and should be tested.

Partner Services are completely voluntary, but must be offered to every client who tests positive at [*Site*].

Referrals & Follow Up

All counselors must be prepared to provide a variety of in-house and out-of-agency referrals for clients testing both positive and negative, before beginning to provide CTL for clients. These referrals include but are not limited to:

- Psychological counseling
- Medical evaluation including TB, STD, and pregnancy testing
- Family planning services
- Social services
- Legal services
- Domestic violence support and prevention services
- Drug and alcohol treatment programs
- Social support
- Hotline telephone numbers
- Specific AIDS medical service providers and information
- Specific Partner Service referrals and support
- [*Include here other resources as appropriate for your site and clientele*]

Referrals should be provided at both risk assessment and disclosure sessions when possible and appropriate. They should be provided in writing in most cases, and should be tailored to the specific needs of a client. Referrals should specifically include multi-lingual and multi-cultural services where available and applicable. Minimally, referrals should be made which address HIV risk co-factors as well as primary risk behaviors, including HIV prevention, mental health and psychosocial services, substance use treatment and harm reduction services, services and health care for people with HIV, and other health care tangentially related to HIV risk.

Current and accurate referrals lists are continuously created and made available at [*Site*], in [*insert languages appropriate to your site's client population*]. [*Name and/or position*] is responsible for the maintenance and distribution of these referrals lists to counselors.

[*Include here any additional site-specific protocols or information regarding referrals*].

In order to ensure that clients receive the services needed, [*insert your site's plan for creating linkages instead of simple referrals. This may mean accompanying the client to services, following up with the client and/or referred agency, or other means of supporting linkages*].

Linkage to Medical Care Following a Positive Result

After a client tests HIV positive, there is a minimum of four things that must be provided to them:

1. Offer to help link client to care
2. Attempt to make a medical appointment on the spot
3. Provide the client the primary medical care/provider handout
4. Follow up with the client 1 week later to see whether they are in care

Remember to always try to obtain the most comprehensive contact information possible, in order to be able to follow up with the client.

For more information about the minimum requirements for linkage to medical care following a positive result in San Francisco, see Protocol for Linkage to Care and Partner Services.

Tracking of Referrals and Linkages

[*Include information here about your site's plan for tracking and documenting referrals and linkages. How will you follow-up to determine whether a client accessed a referral? What will you do if you know they did not access that referral? What mechanisms are in place to facilitate linkages of needed services, especially for positive and high-risk negative clients? etc.*]

Documentation and Record Keeping

The [*agency name*] shall maintain all clients HIV antibody testing records in a manner so as to assure that client confidentiality is maintained in accordance with current law.

[*Include information here about how record confidentiality will be maintained. Where will forms be stored? How will that area be secured? Who will have access to the records?*]

After a counselor and/or test technician completes the documentation for a test, the paperwork should be [*include details here about the procedure for your site. To what location are the forms initially returned? When are they retrieved for QA, copying, and filing into a more permanent storage location?*] The following documents will be used in each conventional CTL session and together will make up a client record:

1. Informed consent form
2. SFCIF
3. Lab slip (s) for rapid HIV test on the SFCIF
4. Lab slip (s) for confirmatory/conventional use red lab slip
5. Lab report of confirmatory test result for anyone testing preliminary positive
6. HIV Confidential Case Report for anyone confirmed HIV positive
7. [*Enter other forms as appropriate for your site*]

For clients testing HIV positive, the Original or copies of the SFCIF, and original lab slip **(pages 1 or 2)**, the lab report for all confirmed positive clients, will be forwarded to the CTL Data Manager (Nayla Raad) at the HIV Prevention Section within 7 days of a confirmed HIV positive test. All negative records (SFCIF, lab slip, lab report) must be submitted to Nayla Raad by the 21st of the month follow the month service was delivered. For example, records for all tests done in March will be sent to the HIV Prevention Section no later than April 21st.

For a quick reference sheet that shows what paperwork is due for any type of HIV test, see the San Francisco CTL Paperwork Due Dates document.
A monthly testing summary sheet must be mailed or faxed to the Coordinator for CTL Data Management (Nayla Raad) at the HIV Prevention Section at the end of the month, or no later than 5pm on the first workday of the following month. This information may also be sent via email if it is easier (to Nayla.Raad@sfdph.org).

[*Insert only if your site is choosing to keep a laboratory specimen log in combination with or in addition to any log for rapid testing*] In addition to client records, a confidential laboratory log shall be maintained which lists:

- [*List fields that your site is choosing to collect in the laboratory log. Examples would be date of risk assessment, client name and/or client ID number from the lab slip, age of client, sex of client, etc*].

LABORATORY REQUIREMENTS & SERVICES

CLIA Waiver

To ensure quality laboratory testing and meet federal requirements, all agencies providing rapid HIV testing must have at least a valid CLIA certificate of waiver. To meet this requirement, [*Site*] holds a CLIA [*Insert type of certificate held by your agency. Could be a Certificate of Waiver, a Certificate of Provider-Performed Microscopy Procedures, or a Certificate of Compliance*].

A copy of the valid CLIA certificate can be found in [*location*]. [*Person and/or Position*] is responsible for handling the renewal process for the CLA certificate. This must be done every two years through the California Lab Field Services.

Possession of the CLIA certificate establishes [*Site*] as a clinical laboratory. As such, [*Site*] is held to strict standards of laboratory practice. [*Site*] must comply with the requirements of the Dept. of Health and Human Services and California State Lab Field Services at all times. [*Site*] agrees to announced and unannounced inspections by Lab Field Services at any time, in accordance with State and Federal regulations. A CLIA certificate can be suspended or revoked by Lab Field Services at any time for failure to comply with requirements.

Examples of laboratory requirements that must be followed include but are not limited to: 1) following proper safety procedures at all times for all laboratory personnel, 2) following the manufacturer's guidelines without exception for any laboratory test covered by the CLIA certificate, 3) not performing any laboratory tests not covered by the CLIA certificate, and 4) correctly documenting all laboratory testing, so that process and results of testing can be clearly determined at all times. No laboratory records may contain changes to original entries without a single cross-out line, corrected entry written clearly above, and initials of the individual making the change. At no time should an original entry be obliterated or otherwise made illegible by a change on the record.

Off-site Laboratory Services

[*Site*] has an agreement with [*Laboratory*] to process all rapid confirmatory and conventional blood or oral fluid testing specimens. [*Laboratory*] will test all specimens using the Enzyme-linked Immunosorbant Assay (ELISA) or other California State-approved Enzyme Immunoassay (EIA) test procedures. For all specimens producing a reactive EIA, the specimen will be repeat-tested in duplicate with the EIA.

All specimens that are repeatedly reactive on the EIA, as well as all rapid confirmatory specimens (regardless of the EIA result) will be confirmed with a supplemental test. This supplement test shall be the Western Blot or Immunofluorescent Antibody (IFA).

Results of the antibody testing will be provided to [*Site*] within a period of [*enter timeframe here*]. The lab report will include at a minimum the types of tests run, the results of those tests, and the final laboratory interpretation of HIV status (Positive, Negative, Indeterminate, or Inconclusive).

LABORATORY SAFETY

Bloodborne Pathogen Exposure Control Plan

To protect employees from occupational exposure to bloodborne pathogens or any other potentially infectious materials, [*Site*] is required to have on-site a Bloodborne Pathogen Exposure Control Plan. This plan is located [*insert location*]. [*Name and/or Position*] is responsible for ensuring that the Bloodborne Pathogen Exposure Control Plan is updated as needed and kept in an accessible location.

In addition to protocols to prevent and control occupational exposure to bloodborne pathogens, this plan contains:

1. A mechanism for ensuring employee's compliance to the plan
2. A plan for annual education and training for all employees at risk for exposure to blood and other potentially infectious materials in the course of their work
3. Employee records showing proof of Hepatitis B vaccination or a written declination of vaccination.
4. Documentation of all post-exposure follow-up after any occupational exposure to bloodborne pathogens.

Exposure Prevention

- ✓ Universal Precautions shall be observed by all employees to minimize or prevent exposure to blood and other infectious materials (see page 14 for more details on Universal Precautions).
- ✓ Appropriate protective clothing shall be worn whenever there is potential exposure to infectious materials, including disposable latex gloves and lab coats.
- ✓ Hands will be thoroughly cleaned with soap and water before donning gloves for client contact, and as soon as possible after removal of gloves or other personal protective equipment. If soap and water are not available, hands must be sanitized with an antiseptic hand cleaner (Bacdown, Purel, or similar).
- ✓ Contaminated needles and other contaminated specimen collection devices shall not be bent, recapped, or clipped. Shearing or breaking of contaminated needle is prohibited. Used lancets or other sharps must be placed in regulation sharps containers immediately after use.
- ✓ Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work area where there is reasonable likelihood of occupational exposure.
- ✓ Food and drink shall not be kept in refrigerators, shelves, and cabinets or on countertops where specimens or control units are stored, or other potentially infectious materials are present.

Biohazardous Materials

All potentially infectious waste must be placed in red plastic biohazard bags and disposed of in a clearly labeled biohazard waste container. This container must have a top with a tight seal so that material will not leak out if the container is inadvertently tipped over. All other trash should be placed in a separate receptacle.

All sharps must be disposed of in regulation sharps containers, and those containers must not be overfilled such that needles are protruding from the container.

Sharps containers and biohazard waste containers, when full, are disposed of [*enter site-specific procedure*].

Biohazard Spills

[*Insert information here about how biohazard spills will be handled in your agency. Is there a specific person designated for spill clean-up? Do you have a standard spill kit? If so, where is it located? If not, what should staff members do to adequately and safely clean up a spill?*]

Needlestick Injuries

All new employees must be oriented to [*Site*]'s needlestick exposure protocol prior to beginning work.

If a needlestick should occur, employees should immediately document the stick and contact the SFDPH Occupational Infectious Diseases Program's 24-Hour Needlestick Hotline at 415-429-4411. The testing site should also contact their technical assistance lead at the HIV Prevention Section.

[*Insert any other site-specific protocols for dealing with occupational needlesticks*].

Biohazard Exposure Response and Follow-Up

Because exposure to blood and other body fluids in the course of HIV CTL could lead to infection with hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV) and other infectious diseases, this protocol is to be followed in the event of any biohazard exposure to assure the timely evaluation and follow up of events [*Modify these steps as appropriate according to your site protocol*]:

1. Immediately wash wound with copious amounts of cold water. For eye splashes, flush with water for approximately ten minutes.
2. Notify supervisor immediately.
3. If an occupational exposure occurs call the 24-hour Hotline at 415-469-4411 to review your exposure as soon as possible with the clinician on-call. The clinician will advise you of your treatment options.
4. Follow the hotline clinician's advice regarding immediate treatment and follow-up with the Occupational Infectious Diseases Program at the Occupational Health Service Worker's Compensation clinic. Call 415-206-5507 to schedule an appointment.
5. If HIV post-exposure prophylaxis (PEP) is indicated you will be directed to pick up your 3-day starter pack at the San Francisco General Hospital Inpatient Pharmacy (open 24-hours day; located on the 4th floor of the main hospital).
6. All employees who incur an exposure incident will be offered post-exposure evaluation and follow up by a health care provider designated by [*Site*].
7. The supervisor and employee shall initiate an incident report as soon as exposure incident occurs.
8. Each exposure incident will be reviewed and reported to the supervisor.

CONTINUOUS QUALITY IMPROVEMENT

Continuous Quality Improvement (CQI) refers to planned and systematic activities designed to ensure that services are being delivered effectively and that errors are detected and corrected to avoid adverse outcomes. Continuous Quality Improvement activities are applied to all aspects of service delivery, including both counseling and testing procedures. An effective CQI program is one that is integrated into the policies and procedures performed in a given setting rather than conducted sporadically when a particular issue arises.

Confidentiality Requirements

All employees of [*Site*] shall follow written protocols to assure the strict client confidentiality of HIV antibody testing services in accordance with current law.

[*Include information here about your site's protocols to protect client confidentiality and/or anonymity. Some topics to include may be records systems protections, or written confidentiality agreements that staff must sign*].

Staff Training and Certification

All counselors and technicians who provide CTL must adhere to the training requirements of the California State Office of AIDS. At a minimum, this includes timely completion of the Basic I and Basic II trainings from the AIDS Health Project in order to provide conventional testing, as well as completion of a Rapid Testing CET for all counselors who completed Basic I prior to September 17, 2004, for all those providing rapid testing counseling. It is the responsibility of the testing site to also provide on-site orientation for all newly trained counselor and techs providing the HIV rapid test. All individuals running and reading the OraQuick rapid HIV test must also complete a one-day technician's training through AIDS Health Project and successfully pass the proficiency test.

<u>Continuing Education for Counselors</u>

In order to maintain active status as a CTL counselor in the State of California, all counselors must complete Basic II within 6 months of their Basic I training. From that point forward, counselors must attend a minimum of one Continuing Education Training (CET) through the AIDS Health Project or other approved source each year. Failure to complete these requirements before the deadlines will result in expiration of counselor certification. It is the responsibility of [*Name, and/or Position*] to track and file written proof of counselor certification at [*Site*], and to ensure that no counseling is performed by an individual who does not hold current and active counselor certification.

<u>Qualification of new techs to perform Stat-Pak.</u>

All individuals who will draw blood in order to run the Stat-Pak rapid test must be legally qualified to draw blood in the State of California. All individuals who will run the Stat-Pak rapid test with blood from these vacutainer tubes must be qualified to do so by completing a training to run the Stat-Pak HIV rapid test and pass the proficiency training test. This training is provided by the HIV Prevention Section. These individuals must maintain CAT's as are required.

Competency Assessment Testing for Rapid Test Technicians

Before a rapid test technician collects an oral specimen and/or a whole blood finger stick on either the OraQuick Advance and/or Stat-Pak test at [*Site*] on a client alone for the first time (after successful completion of the technician's training) s/he must complete the following steps:

1. Read the entire package insert for the OraQuick *Advance* Rapid HIV-1/2 Antibody Test and/or the Stat-Pak HIV rapid test, available from OraSure Technologies and Inverness.
2. Successfully run a set of three controls (HIV–, HIV-1+, and HIV-2+) for each test that the tech will be running and reading and correctly document the run on the external quality control log.
3. Be observed by [*Name, and/or Position*] the first time s/he collects a specimen (oral or finger stick) from a client (or instructs the client to collect his/her own specimen oral fluid-OraQuick Advance), and/or collects the finger stick or whole blood from a vacutainer and runs the test.

Successful specimen collection and running of the test will be documented on the appropriate Competency Assessment Test Checklist provided by the HIV Prevention Section, and stored in the technician's personnel file. In order to maintain active status as a Rapid Test Technician, after initial observation all technicians must complete a Competency Assessment Test (CAT) 6 months after their original certification, and annually thereafter. Whenever an agency is offering rapid HIV testing, the CAT should include observation of specimen collection with a real client. Successful completion of a CAT must be documented on Competency Assessment Test Checklist and faxed to the Coordinator for QA and Training (Sonia Bailey) at the HIV Prevention Section so that training records can be updated. Failure to complete a CAT before the deadline will result in expiration of test technician certification. It is the responsibility of [*Name, and/or Position*] to track technician certification at [*Site*] and ensure that no tests are run by an individual who does not hold current and active counselor certification.

Phlebotomy Qualifications

Any person providing fingersticks for purposes of the rapid HIV test must be certified through AIDS Health Project as a Rapid Test Technician, as well as holding a California State Limited Phlebotomy Technician certification (or greater). Any person providing blood draws for confirmatory testing and/or conventional venipuncture testing must hold a CA State Certified Phlebotomy Technician certification (or be occupationally exempt). It is the responsibility of [*Name, and/or Position*] to track phlebotomy qualifications at [*Site*] and ensure that no samples are collected by an individual who does not hold current and active phlebotomy qualifications.

[*New Heading*]

[*Include here any other site-specific requirements for staff training both before the Basic training at AHP or after the Basic training at AHP. This is especially useful if your site has volunteers who must meet other training or orientation requirements prior to service.*]

Rapid Test and Rapid Test Algorithm Counseling Messages:

All counselors seeing clients who will receive two or more HIV rapid test as part of a rapid test algorithm will receive an orientation to the counselor messages for clients by the HIV Prevention Section TA lead for that agency. The CTL Coordinator for that agency must provide observation twice yearly of the counselors working with clients receiving a rapid test algorithm.

Rapid Test Kit Storage and Inventory

Receipt of Test Kits and Inventory Monitoring

Test kits will be distributed to [*Site*] by the HIV Prevention Section on an as needed basis.

1. Test kits will not be distributed if [*Site*] is more than 60 days late turning in client data or rapid testing documentation to the HIV Prevention Section, or more than 14 days late in adequately resolving a record that needs to be resubmitted or a rapid test that has been declared invalid.
2. [*Name, and/or Position*] is responsible for contacting the Supplies Coordinator (Alice Heimsoth) at the HIV Prevention Section with at least 3 working days' notice whenever rapid test kits or other rapid testing supplies are needed, and for arranging to have test kits delivered.

Receive Test Kit Delivery	
Responsibilities	Schedule delivery of test kits, and arrange to receive and sign for them. On the [*Test Kit Inventory Log or other log*] enter the date received, lot numbers, expiration dates, number of test received, and initials. Check for damaged or expired test kits.
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]
Corrective action(s)	If the delivery does not match the order, the test kits are damaged, expired, or otherwise problematic [*insert corrective action specific to your site*]. [*Name and/or Position*] will contact the Supplies Coordinator and arrange for test kits to be returned and exchanged with new ones. [*Insert information about documentation procedures, should this occur*].

Monitor Test Kit Inventory	
Responsibilities	[*Enter information about the mechanism for monitoring test kit inventory. Where will it be documented? Exactly what will be documented?*
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]
Corrective action(s)	If the number of test kits in stock does not match that recorded on the inventory [*insert what should be done to address this situation at your site*].

Rapid Test Kit Storage

1. Test kits will be stored [*location*]. The storage area must be secured to prevent unauthorized entry.
2. Test kits must be returned to the HIV Prevention Section when past expiration date. They should **never** be used to run a client test or a control after the expiration date has passed.
3. The areas in which test kits are stored must be temperature controlled to remain within the appropriate temperature range for test kit storage at all times. This is 35F -80F for the OraQuick test and 46F – 86F for the Stat-Pak test. If all kits are stored in the same location, therefore, the storage temperature range must be between 46F and 80F.
4. If test kits are stored in a refrigerator, they must be brought to room temperature of at least 59ºF before use. Stat-Pak test kits cannot be stored in the refrigerator.
5. To ensure the temperature ranges are maintained, temperature of the storage areas must be monitored and documented on a daily basis. If the temperature falls outside of the specified range, testing cannot continue until corrective action has been taken as noted in the chart below.

Test Kit Temperature Monitoring	
Responsibilities	Record temperature from thermometer in [*location*] onto temperature control log.
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]

Corrective action(s) If the temperature of the test kit storage unit falls out of the appropriate temperature range for a particular test kit, [*insert corrective action specific to your site*]. Steps should be taken to adjust the storage area temperature as soon as possible. Suspend client testing until functionality of test kits can be determined.

An external control should be run immediately to determine if test kits are still functioning properly. If controls produce expected results, continue testing. If controls do not produce expected results, run a second set of controls. If they fail again, discard test kits and suspend testing until new kits are received. Contact the Coordinator QA and Training (Sonia Bailey) at the HIV Prevention Section to report the incident and arrange for new test kits to be delivered if needed.

Rapid Testing External Controls

Receipt and Temperature Monitoring of Controls

1. Control units will be distributed to [*Site*] by the HIV Prevention Section on an as needed basis.
2. Control units will not be distributed if [*Site*] is more than 30 days late turning in client data or rapid testing documentation to the HIV Prevention Section, or more than 14 days late in adequately resolving a record that needs to be resubmitted or a rapid test that has been declared invalid.
3. [*Name, and/or Position*] is responsible for contacting the Supplies Coordinator (Alice Heimsoth) at the HIV Prevention Section with at least 3 working days' notice whenever control units or other rapid testing supplies are needed, and for arranging to have controls delivered.
4. Controls must be kept at a controlled temperature as listed in the manufactures package insert. To ensure the temperature ranges are maintained, temperature of the refrigerator where controls are stored must be monitored and documented on a daily basis. If the temperature falls outside of the specified range, controls must be discarded and new controls must be obtained from the HIV Prevention Section.
5. Control units are only good for limited number of days once opened (see manufacturers package insert).. Whenever someone opens a new box of controls, they must record both the date opened and the expiration date on the outside of the box.
6. Control units must **never** be used once they have passed the pre-printed expiration date or have been open for longer than allowed according to the manufacturers insert. .

Control Unit Temperature Monitoring	
Responsibilities	Record temperature from thermometer in [*location*] onto temperature control log.
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]

Corrective action(s) If the temperature of the refrigerator falls out of temperature range, [*insert corrective action specific to your site*]. Steps should be taken to determine the cause of temperature change and to adjust

the refrigerator temperature as soon as possible.

Contact the Coordinator for QA and Training (Sonia Bailey) at the HIV Prevention Section to report the incident and arrange for new control units to be delivered.

Running External Quality Controls

External Quality Controls will be run according to the manufacturer's instructions. Results will be recorded on the External Quality Control Log. External Quality Controls will be run under the following conditions:

- In each new setting for rapid testing, or whenever conditions in a setting have changed significantly
- Whenever opening a new box of test kits, or if a new shipment of test kits is received
- If the temperature of the test kit storage area falls outside of range
- If the temperature of the testing area falls outside of the allowable range
- [*Insert the periodic interval at which your site has decided to run controls (i.e. daily, weekly, monthly)*]
- Whenever there is a reason to suspect test kits may not be functioning properly. [*Insert the threshold for determining this at your site. Two invalid tests in a row? More than two preliminary positives in one shift? etc.*]

Running External Quality Controls is the responsibility of [*Name and/or Position*]. To correctly run controls, the following procedure must be followed:

1. Record on the external quality control log (for each test being used) the site ID, technician ID, reason for running the control (QC code) and date of the control. Gather three test kits and the control unit, and record the test kit lot number and expiration date (from outside of foil pouch), as well as the control unit lot number and expiration date (from outside of box). Record the "open vial expiration date," which should be recorded on the box. This is the day that the control units will expire, 56 days after the vials were first opened.
2. Open three test kit pouches, remove and open the vials, and set them on the stand. Label the vials as HIV–, HIV-1+, and HIV-2+.
3. Put on gloves and open the first control vial. Collect the specimen with the specimen loop and stir it into the appropriately labeled vial.
4. Place a test kit into the vial and begin the test.
5. Record the begin time and begin temperature in the appropriate column on the external control log.
6. Repeat steps 3 – 5 for the other two control vials.
7. Read results for each test after 20 minutes but not more than 40 minutes and record the results, the end time and end temperature for each control in the appropriate column on the external control log.
8. Circle whether the result was acceptable (produced the expected results) or not.
9. Document the number of rapid tests run since the last control (obtained from the laboratory log)
10. Add any notes about the control run as applicable.

To correctly run controls for the Stat-Pak test, the following procedure must be followed:

1. Record on the Stat-Pak section of the RTA external quality control log the technician ID, and reason for running the control (QC code). Gather three test kits and the control unit, and record the test kit lot number and expiration date (from outside of foil pouch).
2. Open three test kit pouches and set the kits on the absorbent workspace cover. Label the kits as HIV– , HIV-1+, and HIV-2+.

3. Put on gloves and open the first control vial. Collect the specimen with the specimen loop and add the specimen to the sample well of the appropriately labeled kit.
4. Add three drops of buffer to the sample well.
5. Record the begin time and begin temperature in the appropriate column on the external control log.
6. Repeat steps 3 – 5 for the other two control vials.
7. Read results for each test at 15-20 minutes and record the results, the end time and end temperature for each control in the appropriate column on the external control log.
8. Circle whether the result was acceptable (produced the expected results) or not.
9. Document the number of Stat-Pak rapid tests run since the last control (obtained from the lab log)
10. Add any notes about the control run as applicable.

Run External Controls	
Responsibilities	Record controls according to the procedure outlined above.
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]

Corrective action(s) If control testing fails to yield the expected results notify [*Name and/or Position*] and repeat with a new control unit to determine whether failure was a result of non-functioning test kits or control units. If a second attempt to run controls fails to produce the expected results, immediately suspend rapid testing. Notify Coordinator for QA and Training (Sonia Bailey) at the HIV Prevention Section to report the problem and obtain new test kits or controls as needed. Do not continue rapid testing until instructed to do so.

If external controls are not run before testing resumes following a condition where controls are required (i.e. a new shipment of test kits, the temperature goes out of range, or in a new setting), contact Coordinator for QA and Training (Sonia Bailey) at the HIV Prevention Section to determine whether clients will need to be contacted for re-testing. [*Insert site-specific corrective action that will occur additionally in this event*].

CTL Counseling CQI

[*Insert information here about how you will ensure the quality of HIV CTL counseling at your site. Counselors should be observed by supervisors at least twice per year, via live observation, audiotape, or role play. What will this look like in your agency? How will immediate feedback be provided to counselors? One example you may choose to use is the HIV CTL Counselor Evaluation Form distributed by the HIV Prevention Section (you could attach it as an appendix to this document). You must also conduct annual client satisfaction surveys specific to CTL and provide written summaries of those surveys. Will you do more in addition to that minimum requirement for client satisfaction monitoring? Will you conduct annual counselor satisfaction surveys for feedback on CTL services? What other techniques will you use to ensure counseling CQI? How will you use peer review in the course of counseling CQI at your site? etc.*]

Counselor Orientation

[*Insert information here about how you will make sure that new counselors are up to speed and ready to begin CTL counseling on their own. This should be all the things you do in addition to sending counselors to training so that they are certified. Will you have a period of shadowing experienced counselors, and then being*

observed by seasoned counselors the first few times they counsel on their own? Will you allow a new counselor to go right into rapid testing, or will you somehow wean them into the process first? etc.]

Counselor Support

[*Insert information here about how you will ensure that your counselors are supported, to prevent burn-out and to assist with difficult cases or challenging experiences. Will it be as-needed? Periodically scheduled group meetings? In-services? Opportunities for case-conferencing and/or client consultation? Other?*]

Oversee Counseling Quality	
Responsibilities	[*Enter information about the exact mechanisms for your site to ensure counseling quality*]
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]
Corrective action(s) If a counselor is determined to have problems with their counseling skills, [*insert site-specific corrective action here. Stop counseling until a resolution is reached? Attend a CET? etc.*].	

CQI of CTL Referrals and Linkages

To provide the highest quality referrals and linkages for CTL, [*Site*] staff will continuously work to be knowledgeable about community resources. [*Insert information here about the ways staff at your site can do this. Examples could be attending SFDPH CTL updates, attending trainings or in-services at your site, etc.*]

In addition, [*Site*] routinely creates and makes available current and accurate referrals lists, in [*insert languages appropriate to your site's client populations*]. [*Insert information here about this mechanism. Who creates the lists? How does this person maintain the lists to ensure that they are accurate and updated as needed?*].

In order to ensure that clients receive the services needed, [*insert a summary of your site's plan for creating linkages instead of simple referrals. This information can be found in more detail on pages 24 and 32. Also include information here about the forms your site will use to track referrals and linkages*].

Oversee Quality of Referrals and Linkages	
Responsibilities	[*Enter information about the ways your site will ensure quality of referrals and linkages*]
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]
Corrective action(s) If a counselor is determined to lack the ability to provide comprehensive and appropriate referrals and linkages [*insert site-specific corrective action here. Visit agencies to which referrals can be provided? Talk with more seasoned counselors about referrals they frequently provide? etc.*].	

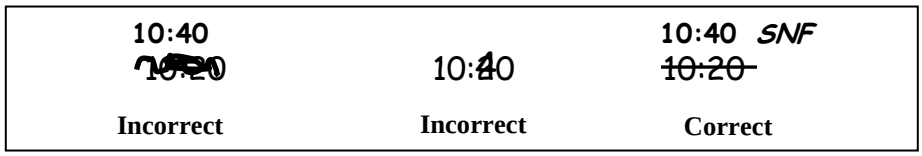
CTL Data CQI

There are two major sets of data that must be turned in monthly to the HIV Prevention Section. See page 25 for more detailed information about this data. Because the data submitted to the HIV Prevention Section is data

entered by staff there and eventually submitted to the State and/or the CDC, it is imperative that this data be legible, accurate, and complete before arriving at the HIV Prevention Section. This is especially true for the lab slips, which can cause a rapid test to be deemed invalid because of insufficient or problematic documentation.

In order to correct an error on a lab slip, changes must be made by placing one single line through the error, writing the correct information above or below, and initialing the change (see below for an example). Failure to make corrections in this way could result in a test being declared invalid and a client recalled for a re-test.

To correct an error on a lab slip:



SF CIFs and lab slips must be reviewed for data quality prior to submission to the CTL Data Manager (Nayla Raad) at the HIV Prevention Section on or before the 21st of each month. Each client record must also be reviewed for completeness, i.e. that all the required forms are stapled together. This includes the SF CIF, lab slip, lab report for conventional tests or rapid tests.

Review Client Data for Quality Before Submitting to HIV Prevention Section	
Responsibilities	Review all SFCIFs and lab slips for completeness and accuracy. Ensure that all client records have the necessary paperwork stapled together before submission.
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]
Corrective action(s) If errors or incomplete data are found on the SFCIFs, the counselor whose ID is on the form will be contacted to determine the correct information to complete the form. [*Insert other corrective action that is specific to your site in this case*]. If errors are found on the times or temperatures of a lab slip, determine whether the test was indeed accurately run. If so, ensure that error corrections are made according to CLIA regulations.. If the accuracy of the test cannot be reasonably determined, change the test result to "invalid" and initiate contact for a re-test.	

Submit Client Data to HIV Prevention Section	
Responsibilities	Submit all client data to Nayla Raad in the HIV Prevention Section on or before the 21st of the month. Must be hand delivered and put in lock box in lobby at 25 Van Ness, 5th floor, or mailed to Ms. Raad at 25 Van Ness, 5th floor, San Francisco, CA 94102.
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]
Corrective action(s) If the deadline for data submission cannot be met, contact Nayla to ask for an extension. [*Insert corrective action if late data submission becomes a continual problem*].	

The SFCIF, all lab report on the SFCIF and the monthly testing summary sheets **must** also be reviewed for data quality prior to submission to the HIV Prevention Section by the 21st of the month following the month of service..

Review Rapid Testing Logs/Reports Before Submitting to HIV Prevention Section	
Responsibilities	Review all logs and reports for completeness and accuracy before submission.
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]
Corrective action(s) If errors or incomplete data are found on the external control log or monthly testing summary, the technician whose ID is on the log or individual who completed the monthly testing report will be contacted to determine the correct information. [*Insert other corrective action that is specific to your site in this case*]. If errors on the external control log cannot be rectified, contact the Coordinator for QA and Training (Sonia Bailey) at the HIV Prevention Section to determine whether clients may need to be contacted for re-testing.	

Submit Rapid Testing Logs/Reports to HIV Prevention Section	
Responsibilities	Submit all required data to Nayla Raad in the HIV Prevention Section at the end of the month.
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]
Corrective action(s) If the deadline for data submission cannot be met, contact Nayla to ask for an extension. [*Insert corrective action if late data submission becomes a continual problem*].	

There are logs for rapid testing that do not need to be sent to the HIV Prevention Section on a monthly basis, but must be available on-site for review should a member of the HIV Prevention Section or Lab Field Services decide to visit. These logs are proof of the high quality of [*Site*]'s rapid testing program. For that reason, it is necessary that these logs be reviewed periodically to ensure the accuracy and completeness of the information they contain.

Review Other Rapid Testing Logs	
Responsibilities	Review the test kit and control storage temperature logs, test kit inventory logs, and [*enter other forms as appropriate for your site*] to ensure accuracy and completeness.
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]
Corrective action(s) If errors or incomplete data are found on any rapid testing logs, [*insert corrective action that is specific to your site in this case*]. If errors on a rapid testing log cannot be rectified, contact the Coordinator for QA and Training (Sonia Bailey) at the HIV Prevention Section to determine whether supplies must be replaced or if clients must be re-tested.	

Collecting a Rapid Testing Specimen and Running the Test

A major benefit of rapid testing is that the test can be run on-site. However, this means that technicians at [*Site*] are solely responsible for producing an HIV test result which will be provided to a client. For this reason, it is

vital that the laboratory processes of rapid testing are of the utmost quality. This includes the collection of the specimen (via oral swab or fingerstick) as well as the running and documentation of the test, and the interpretation of the test result. In order to ensure that all rapid tests are run correctly, [*Name and/or Position*] will provide oversight.

All test technicians must have passed an initial proficiency test, an initial on site CAT, a 6 month CAT and one annually CAT thereafter to remain certified.

Oversee Rapid Testing Specimen Collection and Lab Processes	
Responsibilities	[*Enter your site's plan for observing oral specimen collection and fingersticks, as well as ensuring that every rapid test is run, documented, and interpreted correctly*.]
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]

Corrective action(s) If a technician is determined to have problems with collecting the specimen, documenting or running the rapid test, or correctly interpreting the test result, [*insert site-specific corrective action here. Stop running the rapid test until…? Only run the test in the presence of another person? etc.*].

If the limited phlebotomy certification (or greater) of an individual is determined that have lapsed, no fingersticks may be performed by that individual for any reason until certification has been restored.

OraSure and Venipuncture Specimen Collection

Although staff and volunteers at [*Site*] do not physically run the laboratory tests for conventional or confirmatory testing, the collection of the specimen is an important part of the testing process and must be done with the highest quality. In order to ensure that both OraSure and venipuncture specimens are correctly collected, [*Name and/or Position*] will provide oversight of this process [*This should be a person who is qualified to perform phlebotomy, so that they are able to provide sufficient oversight*].

Oversee Conventional and Confirmatory Specimen Collection	
Responsibilities	[*Enter your site's plan for ensuring the quality of OraSure and venipuncture specimens*].
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]

Corrective action(s) If a counselor or phlebotomist is determined to have problems with their skills for specimen collection, [*insert site-specific corrective action here. Stop collecting specimens until a resolution is reached? Only collect specimens in the presence of another person? etc.*].

If the phlebotomy certification of an individual is determined that have lapsed, no venipuncture specimens may be collected by that individual for any reason until certification has been restored.

Reviewing and Updating the Policies and Procedures / CQI Plan as Needed

The field of HIV CTL is constantly changing. Therefore, plans to ensure good service and high quality testing for clients must be continually revisited to account for new information or regulations, as well as lessons learned.

Reviewing and Updating the Policies and Procedures / CQI Plan	
Responsibilities	Review the entire Policies and Procedures / CQI document and make updates as needed.
When	[*Enter information about frequency of this action, or event that would trigger this action*]
By whom	[*Enter name and/or position of person responsible for this action*]
Corrective action(s) If discrepancies are noted in the document compared to practice, or if disagreements arise about how to make changes to the document, [*insert site-specific corrective action here*].	