

ESTABLISHING ONGOING COMPETENCY ASSESSMENT TO MAINTAIN HIV TESTING SKILLS



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Background:

Government supported HIV testing in San Francisco



- SF Dept. of Public Health, HIV Prevention Section, supports 17 counseling/testing programs.
- Over 16,000 HIV tests/year; between 1.5% and 2% positivity.
- Approximately 80% of all our tests are POC rapid HIV tests 20% are conventional.

Background:

Government supported HIV testing in San Francisco

- We currently support 4 different Rapid Test Algorithm (RTA) models:
 - OraQuick finger stick/confirmatory (4 agencies)
 - OraQuick oral fluid/OraQuick finger stick /confirmatory (9 agencies)
 - OraQuick oral fluid/Stat-Pak blood/OraQuick blood (venipuncture)/confirmatory (2 agencies)
 - OraQuick finger stick/Stat-Pak blood (venipuncture) /confirmatory (1 agency)

Government supported HIV testing in SF

- All reactive rapid tests conducted using oral fluid are followed up with a rapid test using a blood specimen (finger stick/venipuncture) to rule out false positives.
- Confirmatory IFA is conducted on all reactive first tests.
- RNA test run on all discordant tests.

It helps to have a good foundation!



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

TEMPLATE

San Francisco Department of Public Health
AIDS Office, HIV Prevention Section
HIV CTL Network

Special 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 also 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.

- ❑ Solid training of HIV testing staff to run, read and record test results.
- ❑ Tracking certification of trained staff.
- ❑ Clear written policies & procedures and QA measures.
- ❑ Staff assigned to ensure that policies/procedures and QA measures are followed at all testing sites.

It helps to have a good foundation!

- A system of ordering/tracking POC test kits, controls, testing supplies.
- A good data system for recording and tracking testing data.
- A good working relationship with the lab that provides confirmatory HIV testing.



Maintaining ongoing QA of POC Testing

The image shows three overlapping competency assessment checklists for HIV rapid testing. The top checklist is for the OraQuick Advance HIV Rapid Test (finger stick). The middle checklist is for the Stat-Pak Competency Assessment Test (CAT) Checklist. The bottom checklist is for the OraQuick Advance HIV Rapid Test (CAT) Checklist. Each checklist includes sections for Reader's Name, Date, Test Reader's Name, Site Name and Number, and Couns/Tech ID. The bottom checklist also includes a section for 'Does one of the following:' with two options (A and B) and two photographs (A3 and A4) showing the correct technique for inserting the test kit into the vial. The bottom checklist also includes a section for 'Notes:' and a section for 'Authorized Evaluator Name:' and 'Evaluator's Signature:'.

- **Observed** competency assessment for all testing personnel:
 - At certification,
 - Prior to starting at the testing program,
 - At 6 months, and
 - Annually thereafter.
- In addition, MPEP (CDC's Model Performance Evaluation Program: HIV Rapid Testing) for Testing Supervisor at each rapid testing program.

OraQuick Advance Competency Assessment Test (CAT) Checklist –Oral Fluid

Competency Assessment testing is required for the OraQuick Advance HIV Rapid Test initially on site after certification training, at 6 months and annually thereafter to maintain certification. The CAT must be directly observed and signed by the Authorized Evaluator. Completed CAT checklists must be filed in the technicians personnel file and a copy must be faxed to 415-934-4868.

Date: _____ Site Name and Number: _____

Test Reader's Name: _____ Couns/Tech ID: _____

- Gathers/arranges all materials
- Examines test kit pouch (unopened, room temperature, absorbent packet)
- Accurately records lot number
- Accurately records expiration date
- Accurately records Counselor/Tech ID
- Affixes client number to back of vial
- Successfully opens and positions vial in stand (no spillage, vial to bottom of stand)

Does one of the following:

OR

- A) Asks the client to clear his/her mouth (finish eating/drinking if applicable; swallow)
- Wears gloves for all subsequent steps
- Inserts test kit between upper gum and upper lip and swabs top gum, then bottom gum, as shown in picture
- B) Asks the client to clear his/her mouth (finish eating/drinking if applicable; swallow)
- Instructs the client correctly to insert test kit between upper gum and upper lip and swab top gum, then bottom gum, as shown in picture (visually demonstrates)



- Does not swab the inside of the cheek, tongue, or roof of mouth
- Successfully inserts test kit (no spillage, window forward, pad touching bottom of vial)
- Did NOT touch flat pad when inserting test kit
- Instructs the client to not swab the inside of the cheek, tongue, or roof of mouth
- Instructs the client to insert the test kit back into the sterile foil pouch, which the test reader holds open for him/her.
- Successfully removes test kit from pouch and inserts test kit into vial (no spillage, window forward, pad touching bottom of vial)
- Accurately records start time and temperature on lab slip. (temperature range within 59 – 99 °F)
- Verifies that client number on lab slip and vial match
- Accurately records end time and temperature on lab slip. (time range within 20- 40 minutes)
- Checks lab slip for completeness and accuracy of information including test result
- Successfully completes all steps (if not, note what was missing/incorrect below):

Notes: _____

Authorized Evaluator Name: _____
(Print Full Name)

Evaluator's Signature: _____

Maintaining ongoing QA

- Site visits 2x/year, using checklist, to assess:
 - ▣ CLIA certificate,
 - ▣ Test kit storage,
 - ▣ Control logs/control storage,
 - ▣ Testing area,
 - ▣ Testing process,
 - ▣ Policy & procedures,
 - ▣ Forms, and
 - ▣ Counseling (observation of session).



Maintaining ongoing QA

RAPID HIV ANTIBODY TEST
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

Unique Office of AIDS Client Number ▶ 871-6236-3

LAB SLIP NUMBER: SPECIMEN DATE: (mm/yy)

GENDER: Male Female M/F M/F-32

DATE OF BIRTH: (mm/yy)

CONFIDENTIAL TESTING USE ONLY

NAME: (last, first)

RAPID TEST

LOT NUMBER:

EXPIRATION DATE: (mm/yy)

COUNSELOR/TECH ID:

SPECIMEN: Oral Finger Stick Venopuncture

RESULT:

Preliminary Positive (indicate if confirmatory specimen given)
 Negative
 Invalid (complete an HIV Testing Incident Report)

CONFIRMATORY SPECIMEN GIVEN:

Yes (attach Lab Copy to Conventional HIV Antibody Test Lab Slip)
 No (complete an HIV Testing Incident Report)

PREVIOUS LAB SLIP ID: (attach copy of lab slip)
Unique Office of AIDS Client Number

MARK IF CLIENT EVER IN AN HIV VACCINE TRIAL

ATTACH LABEL TO REPORT FORM AND SPECIMEN

LABORATORY COPY

871-6236-3	871-6236-3
871-6236-3	871-6236-3
871-6236-3	871-6236-3
871-6236-3	871-6236-3
871-6236-3	871-6236-3

- Data reports, visual double checks and data validation to ensure:
 - Time and temperature are within the manufacturer's acceptable range (info on lab slip)
 - Tests/lot numbers have not expired

Maintaining ongoing QA

- Regular communication with the Lab processing the confirmatory lab tests – working as a team:
 - ▣ To discuss discordant results and determine next steps
 - In SF we run a quantitative viral load on discordant tests.
 - ▣ To troubleshoot and resolve problems.
 - ▣ To review data and evaluate the POC testing program.
 - ▣ To review ongoing QA measures and discuss new rapid testing technology... planning for the future.

Maintaining ongoing QA

- Perhaps the best QA for HIV rapid testing accuracy is the ability to run a second rapid test, preferably from a different manufacture, when the first rapid test is reactive.

Special Thanks

- To the dedicated staff in the HIV Counseling, Testing and Linkage Unit.
- The dedicated counseling and testing staff at the organizations in the CTL Network.
- The dedicated staff at the San Francisco Microbiology Lab who continue to work with us to set the lab quality bar high.
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Materials referenced in this presentation are available
on the following website: www.sfhiv.org