OraQuick Rapid HIV Testing Procedures and Quality Assurance Plan

UC Santa Cruz
Site: Student Health Outreach & Promotion (SHOP)
1156 High Street
Santa Cruz, CA 95064

Updated November 2\textsuperscript{nd}, 2017
Introduction

This document outlines site-specific guidelines and quality assurance measures for conducting rapid HIV testing, and serves as a supplement to the California DHS/OA HIV Counseling and Testing Guidelines.

Quality assurance (QA) 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. Quality assurance activities are applied to all aspects of service delivery, including both counseling and testing procedures. An effective quality assurance program is one that is integrated into the policies and procedures performed in a given setting rather than conducted sporadically “as an afterthought.”

Quality assurance guidelines contained in this document are specific to the site named, and focus primarily on quality assurance procedures for OraQuick rapid HIV testing.

Emergency Contacts

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Director</td>
<td>Dr. Drew Malloy</td>
<td>(831) 459-1740</td>
</tr>
<tr>
<td>Site Coordinator</td>
<td>Alison Hayes</td>
<td>(831) 459-2625</td>
</tr>
<tr>
<td>Patient Care Coordinator</td>
<td>Beth Hyde</td>
<td>(831) 459-3952</td>
</tr>
<tr>
<td>SHS Executive Director</td>
<td>Mary Knudtson</td>
<td>(831) 459-2869</td>
</tr>
<tr>
<td>QA lead</td>
<td>Meg Kobe</td>
<td>(831) 459-3772</td>
</tr>
<tr>
<td>Fire emergency</td>
<td>911</td>
<td></td>
</tr>
<tr>
<td>Medical emergency</td>
<td>911</td>
<td></td>
</tr>
<tr>
<td>Biohazard exposure</td>
<td>911</td>
<td></td>
</tr>
</tbody>
</table>
Procedures

Anonymous Test Site Client Flow – Student Health Outreach & Promotion

1. Client will drop in to SHOP anytime between the hours of 9:30-11:30am or 1-3pm Mon – Fri.

2. Test Counselor will accompany client to test counseling room.

3. Counseling session will begin in counseling room. Counselor will let the client know the time frame of the session and let the client know that SHOP is an anonymous HIV testing site and explain the difference between anonymous and confidential testing.

4. Counselor will provide the “OraQuick Advance Subject Information Pamphlet” to clients accessing rapid testing.

5. The counselor will also explain the other four elements that are needed for consent for an HIV test:
   1. Clients must understand that results will be available during the same session.
   2. Counselor will explain accuracy of OraQuick Advance.
   3. Clients must understand that a preliminary positive rapid test result requires confirmatory testing and will be referred to the Student Health Center to submit to a second sample in the event of a preliminary positive result.
   4. If client needs documentation of test result (e.g. for travel purposes), counselor will direct them to confidential HIV testing available through the Student Health Services (SHS) clinic.

6. Once the consent is obtained from client, counselor will complete the lab slip (time/temperature/test kit lot number/ counselors initials.)

7. Collect oral sample for rapid testing (see page 6 – “Oral Collection Procedure”).

8. The counselor will set up the OraQuick Advance HIV Rapid Test and leave the test to process for at least twenty minutes but not longer than forty minutes. The test will be run in an uninterrupted/confidential space at all times.
   - This session should last a minimum of 20 minutes.
   - After 20 minutes but before 40 minutes, the counselor will read the result.

9. Dispose of waste as per protocols.

10. Record client’s results on the lab slip and log sheet.

11. Return to client: a copy of results, assisted referrals and additional STI info.

12. Disclosure of results can have 3 outcomes with rapid testing:
   a. Non reactive
   b. Reactive (Preliminary Positive)
   c. Invalid
Each result will have different steps to disclosure, which are described below.

1. **Non-Reactive** - A non reactive test result indicates that no antibodies to HIV-1/2 were detected. Disclosure should focus on enhancing the client’s intentions to initiate/continue risk reduction activities, and ensuring the client understands the window period, and how it applies to this test result.

2. **Reactive (Preliminary Positive)** - Disclosing a reactive (preliminary positive) result indicates that HIV antibodies were detected; however all preliminary positive results require confirmation with a second independent test. Disclosing a preliminary positive result has 4 steps that must be included in disclosure:
   1. Deliver the test result in direct, neutral tone.
   2. Allow time for the client to process the meaning of the result and the counselor to explore the client’s understanding of the result.
   3. The counselor must indicate “preliminary positive” on lab slip.
   4. Follow all preliminary positive protocols (listed in the testing room) for the Student Health Center; with the final step being a direct hand off to a SHC medical professional who will provide confirmatory blood work and follow up health care.
   5. Notify the director of SHOP or the Sr Health Educator of SHOP immediately after any preliminary positives.

3. **Invalid** - A client who receives an invalid test result may be offered two options:
   1. Have another rapid test done.
   2. If client elects to have another rapid test done and invalid comes up again, encourage client to have a confidential test through SHS. SHOP staff will stop rapid testing and run external quality controls. (See “quality control procedure”)
   3. Refer client to Student Health Services (SHS) confidential HIV antibody testing services in the Lab.

13. After the client leaves, the counselor completes all paper work.

   a. **For negative and preliminary positive results**, the counselor maintains all forms until the end of the testing time period. Counselor files all completed forms in a locked location maintained by the Site Coordinator. **For an invalid result** the counselor would complete all forms and notify the Sr Health Educator during the shift. The Sr Health Educator would then follow protocols (run controls on the same lot number, document results and notify the Director of SHOP if further actions are needed.)

14. Confirmatory Testing (Student Health Center):

   a. If the Western Blot or IFA test result is negative, it is recommended that:
      - For oral fluid specimens, a repeat confirmatory test with blood specimen should be done, since the oral fluid test is less sensitive than the blood test. Refer to confidential testing services through Student Health Services for blood testing.

   b. If Western Blot or IFA test result is indeterminate, it is recommended that:
• For oral fluid specimens, test should be repeated using a blood specimen. Refer to confidential testing services through Student Health Services for blood testing.

15. For oral fluid specimens, test should be repeated using a blood specimen. Refer to confidential testing services through Student Health Services for blood testing.

16. After the client leaves, counselor completes all paperwork.

**Testing Device**

The OraQuick Advance Rapid HIV-1/2 Antibody Test is a manually performed, visually read, 20-minute immunoassay for the qualitative detection of antibodies to HIV-1/2 in oral fluid, human whole blood obtained from finger puncture, human whole blood obtained from venipuncture and plasma specimens. The OraQuick Advance Rapid Test is comprised of a single-use test device and vial containing a pre-measured amount of a buffered developer solution. Each component is sealed in separate compartments of a single pouch to form the test. The device’s plastic housing holds an assay test strip comprised of several materials that provide the matrix for the immunochromatography of the specimen and platform for indication of the test results.

The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region and the goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the Test (T) zone and Control (C) zone, respectively.

Oral fluid is collected on the testing device by person placing the flat pad in the mouth. The testing device is inserted into the developer solution as stated below. The developer solution facilitates the flow of the specimen into the device and onto the strip. As the diluted specimen flows through the device, it rehydrates the protein.

As the specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HIV-1/2 in the specimen.

**Testing Materials**

1. OraQuick Advance Rapid HIV-1/2 Antibody Test Kit
   • Divided pouches, each containing a Test Device, an Absorbent Packet, and a Developer Solution Vial
   • Reusable test stand
   • Specimen collection loops
   • Subject information pamphlets
   • OraQuick Advance- Rapid HIV-1/2 Antibody Test Package Insert
2. Laboratory grade disposable, absorbent paper towels (placed under the test stands).
3. Timer or clock capable of timing 20-40 minutes
4. Latex or Vinyl gloves
5. Digital thermometer (on the tabletop)
6. Waste container
Storage and Handling

1. The OraQuick Advance Rapid HIV-1/2 Antibody tests are stored in a temperature controlled room that remains in the required range for this test (35°- 80°F).

2. HIV Test Counselors are trained to not open the Oraquick Divided Pouch until they are ready to perform the test to ensure accurate results and that the test device must be inserted into the developer solution vial within 60 minutes after introducing the oral sample.

Test Procedure

1. Preparation
   a) Gather all materials needed.
   b) Complete lab slip
   c) Complete SHC Risk Assessment form and verbally review with clients the anonymous testing consent form.
   d) Open two chambers of the divided pouch by tearing at the notches on the top of each side of the pouch. Leave the test device in the pouch until you are ready to use in order to prevent contamination.
   e) Remove the developer solution vial from the pouch. Hold the vial firmly in your hand. Carefully remove the cap from the vial by gently rocking the cap back and forth while pulling it off.
   f) Slide the vial into the top of one of the slots in the stand. Do not force the vial into the stand from the front of the slot to avoid splashing.

2. Collection
   a) Follow Oral Collection Procedure (page 6).

3. Temperature
   a) The testing area must be within 35°- 80°F.

4. Testing
   a) Remove the device from the pouch. Do not touch the Flat Pad. Check that Absorbent Packet is included with the device.
   b) Set the timer and record the time and temperature. Read the results after 20 minutes and not more than 40 minutes, in a fully lighted area.
   c) Complete the HIV testing log sheet and lab slip.

5. Quality Control:
a) Internal control (a built in control): A reddish-purple line in the Control (C) area of the Result Window indicates that specimen was added and that the fluid migrated appropriately through the Test Device.

b) External control (a known reactive and non-reactive specimens controls):
   Positive control will produce a Reactive test result. A Test (T) line. Negative control will produce a Non-Reactive test result.

c) The temperature of the storage area is read and recorded by the Site Coordinator weekly (or other department designee.)

d) Run the kit controls under the following circumstances:
   1) On each new shipment of test kits to be performed by QA assignee.
   2) On each new open test kit lot to be performed by QA assignee.
   3) If the temperature of the storage area and testing area falls outside acceptable range.
   4) When there is a significant environmental change (e.g. the air conditioning shuts down).
   5) At periodic intervals – once a month to be completed by the QA assignee.
   6) Whenever two consecutive invalid test results are obtained on a client, Counselor will refer client to Student Health Services confidential HIV testing services or appropriate clinic for an HIV blood test.

6. Limitation:

   a) Clinical data has not been collected to demonstrate the performance of this method in persons under 12 years of age.
   b) For Reactive results, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.
   c) A Non-Reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.

7. Interpretation of test result.

   a) NEGATIVE for HIV-1/2 antibodies:
      Non-Reactive (anti-HIV-1/2 antibodies were not detected): A reddish-purple line appears next to triangle labeled “C”, and No line appears next to triangle labeled “T”.
   b) PRELIMINARY POSITIVE for HIV-1/2 antibodies:
      Reactive (anti-HIV-1/2 Antibodies have been detected): A reddish-purple line appears next to the triangle labeled “C” and a reddish line appears next to the triangle labeled “T”.
   c) Enlarged photographs of “OraQuick Results” are posted in the HIV test processing room for reference.

Oral Collection Procedure

All counselors must have a complete competency check sheet signed off by the Site Coordinator (occurs during 35 hour HIV Test Counselor Training each September.)

1. Check the expiration date on the test kit package.

2. Open other side of pouch and have client remove the test kit device without touching the absorbent pad.

3. Direct the client to collect the oral fluid sample on the flat pad as described below:
a) Place the flat pad above the teeth against the outer gum. Gently swab completely around the outer gums, both upper and lower, one time around using the flat pad.

b) DO NOT swab the roof of the mouth, the inside of the cheek, the teeth or the tongue.

c) NOTE: Both sides of the flat pad may be used during this procedure.

**Paperwork, documentation procedures**

1. All completed Risk Assessments, consent forms and lab slips for clients will be stapled together and filed in a locked location maintained by the Site Supervisor.

2. Trouble shooting log sheets will be filled out when external controls need to be run, when more than two test results come back as invalid or if test kits fall out of temperature range. (See External quality control procedures, Test Temperature Monitoring below.)

3. The log sheets will be stored in the rapid testing log sheet binder with the site supervisor.

**Counselor Support**

- The HIV Peer Testing Staff will meet weekly to debrief, review and go over any problems that have come up during the past week’s testing program. The Site Coordinator provides weekly check-ins one to one with HIV test counselors as well.

**Referral procedures**

Refer to the SHOP Referral Guidelines in the event of a reactive (preliminary positive) test result.
Quality Assurance Activities

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

Personnel

The personnel designated below are responsible for the specified QA duties listed at Student Health Outreach & Promotion (SHOP) at Student Health Services (SHS).

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Conducted by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop/update site QA plan</td>
<td>Site Coordinator (Alison Hayes)</td>
</tr>
<tr>
<td>Final approval of site QA plan</td>
<td>SHS Medical Director (Dr. Drew Malloy)</td>
</tr>
<tr>
<td>Conduct or assign QA tasks, including external control processes, test kit storage, control unit storage</td>
<td>Site Coordinator (Alison Hayes)</td>
</tr>
<tr>
<td>Provide for test kit distribution and inventory processes</td>
<td>Health Promotion Director (Meg Kobe)</td>
</tr>
<tr>
<td>Initial review of QA documentation</td>
<td>Health Promotion Director (Meg Kobe)</td>
</tr>
<tr>
<td>Final review of QA documentation</td>
<td>Medical Director (Dr. Drew Malloy)</td>
</tr>
<tr>
<td>Oversee testing process</td>
<td>Site Coordinator (Alison Hayes)</td>
</tr>
<tr>
<td>Ensure personnel are qualified for assigned duties</td>
<td>Health Promotion Director (Meg Kobe) &amp; Site Coordinator (Alison Hayes)</td>
</tr>
<tr>
<td>Conduct periodic competency evaluation</td>
<td>Health Promotion Director (Meg Kobe) &amp; Site Coordinator (Alison Hayes)</td>
</tr>
</tbody>
</table>

Test kit storage – Student Health Outreach & Promotion

Test kits will be stored at SHOP (primary location).
**Monitoring test kit inventory**

The Site Coordinator/ Health Promotion Director will monitor the primary supply of test kits located at UC Santa Cruz Health Services, Student Health Outreach & Promotion department.

### Receive test kit delivery

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Receive boxes and record delivery on the inventory log with initials and write the date of delivery and place test kits where they will be stored.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When</strong></td>
<td>These responsibilities will be done the same day as delivery of boxes, to ensure the proper storage of the test kits.</td>
</tr>
<tr>
<td><strong>By whom</strong></td>
<td>Site Coordinator will be responsible for checking in test kits when delivered. If Site Coordinator is absent, designated SHOP staff will record temperatures and logging in delivery.</td>
</tr>
</tbody>
</table>

**Corrective action(s)**

If there is a problem (i.e., delivery does not match order or units are expired) with the delivery, report problem to the Health Promotion Director within the same day of the delivery. The problem with the delivery must be recorded on the Rapid Test Inventory Log and given to the Site Coordinator to be filed in the QA binder. The Health Promotion Director will determine what corrective action will be taken. If test kits are expired, the Site Coordinator will report issues to OraSure Technologies. If test kits are damaged, the test kits will be returned to the shipper OraSure Technologies.

### Next inventory process item

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Run external quality control for new shipment of test kits. Rotate all stored inventory to front of shelf and place the new shipment in the back.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When</strong></td>
<td>This will be done whenever new inventory (test kits/control kits) have been delivered. (See External Control: New Shipment/Lot below.)</td>
</tr>
<tr>
<td><strong>By whom</strong></td>
<td>Site Coordinator will be responsible for rotating inventory prior to storing new shipment of test kits. If site coordinator is absent, other staff designee will record temperatures.</td>
</tr>
</tbody>
</table>

**Corrective action(s)**

(See External Control: New Shipment/Lot below for corrective action).

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**Monitoring test kit storage area temperature – Student Health Outreach & Promotion**

Storage area for test kits must be equipped with an accurate thermometer. Temperature control log must be posted on storage unit.
**Test kit Temperature Monitoring**

<table>
<thead>
<tr>
<th><strong>Responsibilities</strong></th>
<th>Record temperature from thermometer in test kit storage space onto temperature control log. Thermometer is located on the desk in the test counseling room and the log sheets are in a binder in Site Coordinator’s Office.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When</strong></td>
<td>The temperature will be recorded twice monthly in the morning between 8:00am – 11:00am.</td>
</tr>
<tr>
<td><strong>By whom</strong></td>
<td>Site Coordinator will be responsible for checking in test kits when delivered. If site coordinator is absent, other staff designee will record temperatures.</td>
</tr>
<tr>
<td><strong>Corrective action(s)</strong></td>
<td>If temperature is out of the range of 35°- 80°F, there was a power outage or the refrigerator is not working properly, an external quality control test must be done. Record inconsistency with the temperature and run external quality control test. See External Controls: Test Storage Out of Range below. Site Coordinator will be responsible for this. All corrective action must be reported to the Medical Director.</td>
</tr>
</tbody>
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**Monitoring control unit storage area temperature – Student Health Center Pharmacy**

Refrigerated storage area for control units must be equipped with an accurate thermometer. Temperature control log must be posted on storage unit. Control unit storage area must be continuously maintained within temperature range specified by manufacturer in the package insert.

<table>
<thead>
<tr>
<th><strong>Control Unit Temperature Monitoring</strong></th>
<th>Record temperature from thermometer in control unit refrigerator onto temperature control log. The thermometer is located on the top shelf of refrigerator and the log sheets are located on a clipboard on top of refrigerator.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Responsibilities</strong></td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>When</strong></td>
<td>The temperature will be recorded Monday – Friday in the morning.</td>
</tr>
<tr>
<td><strong>By whom</strong></td>
<td>Pharmacy staff</td>
</tr>
<tr>
<td><strong>Corrective action(s)</strong></td>
<td>If temperature is out of the range of 35° - 46°F, there was a power outage or refrigerator is not working properly, remove the external quality control kits from refrigerator.    Record inconsistency with the temperature. Record on log sheet what the inconsistency was and what corrective action was taken. Pharmacy Staff will be responsible for this. All corrective action must be reported to the Health Promotion Director.</td>
</tr>
</tbody>
</table>
**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 or whenever conditions in a setting have changed significantly
- When opening a new test kit lot or a new shipment of test kits is received
- If the temperature of the test storage area falls outside of 35°- 80°F
- If the temperature of the testing area falls outside of 35°- 80°F
- At specified intervals (1 time each month)
- Whenever there is reason to suspect test kits may not be functioning properly (e.g., two invalids in a row; excessive number of unexpected positive results, etc.)
- Additionally, controls are run quarterly when the American Proficiency Institute initiates the process (relates to the Clia Waiver for SHOP.)

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### External Controls: Monthly QC and Quarterly American Proficiency Institute CQ (quarterly for Clia requirements)

| Responsibilities | Run controls.  
| Dispose of all test control units upon expiration date.  
| Record on external quality control log. |
| **When** | 1. Routine Controls will be run every month. 2. American Proficiency Institute (API) Controls are sent quarterly to SHOP Director, for API proficiency testing per Clia requirements. |
| **By whom** | Site Coordinator/ SHOP Director are responsible for running all controls for HIV Oraquick test kits and results and all paperwork are kept on file and reviewed yearly. |

### Corrective action(s)

When the Site Coordinator is running the monthly controls and if notes the control test is invalid, they will immediately notify the SHS Medical Director.

The following personnel will also be notified: Dr. Drew Malloy, SHS Medical Director.

The Site Coordinator will proceed with the following steps:

1. Check that the controls have not expired.
2. Check that the test kit has not expired.
3. Check that the temperature of the refrigerator is valid.
4. Re-run using the same controls and test kit lot number. If the control test is still invalid, open a new set of controls and run another set of control tests on the same lot from another box.
5. If the control test is still invalid, do not allow any rapid tests to occur at that site.
6. The Health Promotion Supervisor will notify Dr. Drew Malloy, Medical Director. Additional notification will be made to the manufacturer (OraSure, technical services 1-
External Controls: Monthly QC and Quarterly American Proficiency Institute CQ (quarterly for Clia requirements)

Provide standard blood testing until appropriate corrective action is taken.

American Proficiency Testing (APT) protocols:

1. SHOP Director will receive correspondence from API 1 week before HIV1/2 controls are sent.

2. API will send controls to be stored at the Student Health Center Pharmacy.

3. The Site Supervisor and SHOP Director will have 1 week to run the controls and provide results electronically to API.

4. The Site Supervisor will keep a copy of the control process, a signed copy of the Attestation Statement and the result findings on file in the QA HIV Testing Binder.

Binder is located at UC Santa Cruz Student Health Services, SHOP.

Documents and Records

Attachments

1. Subject Information Packet
2. Laboratory Slip
3. OraQuick Advance Test Kit Results
4. External Quality Control Log Sheet
5. Consent Forms
6. Test Kit & Control Kit Temperature Log
7. OraQuick Advance Kit Controls Insert, Orasure Technologies, Inc., 2004
8. Rapid Test Result Log Sheet

Storage

Current staff training documentation will remain in personnel files until separation. Other documentation, including QA documents and logs, will be stored in the SHOP department for two years.
**Review of QA documentation**

### Initial Review of QA Documentation

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>The Site Coordinator will review all QA logs (test kit storage temperature log, control unit storage temperature log, external quality control log, problem documentation sheet, and rapid test inventory log).</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When</strong></td>
<td>Monthly log sheets will be completed and on file with the Site Coordinator.</td>
</tr>
<tr>
<td><strong>By whom</strong></td>
<td>Site Coordinator.</td>
</tr>
</tbody>
</table>

### Final Review of QA Documentation

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>On an annual basis the Project Director will review QA logs (test kit storage temperature log, external quality control log, problem documentation sheet, and rapid test inventory log.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When</strong></td>
<td>July of each year.</td>
</tr>
<tr>
<td><strong>By whom</strong></td>
<td>Site Coordinator will be responsible for providing the QA log sheets to the SHOP Project Director for final review.</td>
</tr>
</tbody>
</table>

**Corrective action(s)**

Follow-up with personnel responsible for documenting QA logs, provide a written explanation in troubleshooting log and provide training for personnel to correctly enter information into all QA log sheets. If necessary, revise QA procedures to prevent future documentation errors on log sheets.

### Updating QA Plan

QA plan will be updated on an annual basis to ensure compliance with new requirements and to revise/improve existing procedures.

### Update QA Plan

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>Review product package insert for changes in requirements, manufacturer’s website and check for any changes in rapid testing processes or protocols. Incorporate changes to policies and procedures; include changes to correct problems or difficulties and submit to the SHOP Director for review.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When</strong></td>
<td>The updating of the QA plan will be done annually in September. Some revisions may be done earlier if notification from product company recommends changes in requirements or if staff find that procedures need changing.</td>
</tr>
<tr>
<td><strong>By whom</strong></td>
<td>Site Coordinator will be responsible for updating the QA plan and will submit the updated QA plan to the SHS Medical Director for review.</td>
</tr>
</tbody>
</table>
**Corrective action(s)**

Corrective actions in the QA plan will be made annually, if necessary, by Health Promotion Director.

<table>
<thead>
<tr>
<th><strong>Review Updated QA Plan</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Responsibilities</strong></td>
</tr>
<tr>
<td><strong>When</strong></td>
</tr>
<tr>
<td><strong>By whom</strong></td>
</tr>
</tbody>
</table>

**Corrective action(s)**

Corrective actions in the QA plan will be made annually, if necessary, by SHS Medical Director or other qualified designee.

**Safety**

All appropriate safety measures will be observed, in compliance with the U.S. Department of Labor Occupational Safety and Health Administration (OSHA) standards for blood-borne pathogens, and Universal Precautions, as outlined by the CDC.

Student Health Outreach & Promotion at Student Health Services (SHS) will comply with all County, State and Federal safety measures. Specific details on biohazard handling, training and disposal is included in the site Hazardous Materials Management Protocols.

**UNIVERSAL PRECAUTIONS WILL BE FOLLOWED AT ALL TIMES.**

1. Properly Dispose of Biohazards
2. No food or drink in work area.
3. No smoking in work area.

**Signature Approval**

_________________________          Date: ______________

Drew Malloy, MD
Medical Director, Student Health Services
University of California, Santa Cruz

Effective Date: ______________