HIV and Syphilis Testing in Non-Clinical Settings, Jamaica

National Public Health Laboratory/National HIV/STI Programme,
Ministry of Health,
Jamaica
January 2014

Preface

The adult HIV prevalence in Jamaica was 1.7% in 2011 with an estimated 32,000 persons living with HIV (PLHIV). Approximately one half of these persons were unaware that they were infected with HIV. Over the past decade, the Joint United Nations Programme on HIV/AIDS (UNAIDS) assessed that there was a 25% decline in new HIV infections in Jamaica. However, as many as 2,100 Jamaicans are estimated to become newly HIV infected each year and AIDS remains a leading cause of death among adults 15-49 years with over 500 reported deaths due to AIDS in 2010.

The introduction of 'opt out' HIV testing in public antenatal and STI clinics, and the use of rapid HIV testing has impacted favourably on the HIV epidemic in Jamaica. The number of HIV tests done annually has more than doubled from less than 100,000 tests per year prior to 2004 to over 200,000 HIV tests per year since 2006. Increased access to HIV testing has contributed to earlier diagnosis of HIV and timelier access to antiretroviral treatment, resulting in improved survival. In order to achieve universal access and halt and reverse the HIV epidemic, persons must know their HIV status, and those in need of treatment must be identified.

Persons who are unaware of their HIV status have been shown to play an important role in transmitting HIV infection. Other sexually transmitted infections, including Syphilis, are also known to increase the risk of HIV transmission. Scaling up of HIV and Syphilis testing in non-traditional settings is therefore critical if we are to begin to reduce the number of late diagnoses of HIV and Syphilis, the complications of Syphilis and HIV-related deaths.

Voluntary Counselling and Testing (VCT)

Only persons trained in counselling and testing should provide pre and post-test counselling in addition to performing the HIV and Syphilis rapid tests.

All sexually active persons should be offered an HIV and a Syphilis test. Individuals at high risk should consider annual HIV and Syphilis testing (at the minimum) and there should be reinforcement of risk reduction leading to safer sexual behaviour.

Pre and Post-Test Counselling Goals

Counseling and Voluntary HIV and Syphilis Testing help persons to:

- Make choices to reduce their risks of HIV and Syphilis infection and transmission-both to others and to the infants of pregnant, HIV-positive/Syphilis infected women
- Make informed choices about contraception and condom use
- Discuss HIV and Syphilis status and testing with their partner(s)

The Role of Education

Education provides clients with the essential information about HIV/AIDS and Syphilis so counsellors can focus on counselling instead of educating their clients. A staff member, volunteer or a community peer educator can conduct education. The following topics are to be covered in education sessions.

- What is HIV/AIDS and Syphilis
- National statistics about HIV/AIDS and Syphilis
- Local myths and misperceptions
- Routes of HIV and Syphilis transmission
- HIV and Syphilis risk behaviours
- Relationship between sexually transmitted infections (especially Syphilis) and HIV transmission/infection
- How to prevent HIV and Syphilis infection
- How to decrease risks of HIV and Syphilis, including talking to partners about testing
- The basic principles of the HIV and Syphilis tests and procedures.
- Mother-to-child transmission
- The benefits of Mother to Child Transmission Prevention interventions.
- Availability of VCT
- Special care and services for HIV-positive women
- Treatment for persons infected with Syphilis

Counseling Area

1. The area designated for pre-test counseling should as best as possible be private.

2. All post-test counseling must be conducted in an enclosed area to allow for privacy.

Individuals Who Test HIV and Syphilis Negative

Counselling provides an opportunity for the client who has received a negative result following the HIV and Syphilis test to:

- Make choices to reduce his/her risks of HIV and Syphilis infections in the future (including talking to partners about testing, decreasing the number of partners, etc.)
- Understand and maintain safer sex behaviour (including condom use) in order to prevent HIV and Syphilis infections in the future

Individuals Who Test HIV and/or Syphilis Positive

Counselling provides an opportunity for the client who has received a preliminary positive result following an HIV and/or Syphilis test to:

- React to a positive result and receive empathy and support from a counsellor
- Learn more about HIV/Syphilis infection and its implications for his/her health
- Prepare to talk to his/her partner about his/her status and discuss HIV/Syphilis testing
- Make informed choices about sexual behaviour (abstinence, partner reduction and condom use) and future fertility, including tubal ligation or other long-term method such as Depo Provera, Norplant etc.
- Be referred to a Laboratory and/or an HIV/STI Treatment Site for confirmatory testing and follow up

HIV and SYPHILIS TESTING PROTOCOL*

1. Register client using prescribed form (Registration Form and result log)

2. Conduct pre- test counselling and obtain oral consent

3. Collect sample and conduct the HIV and Syphilis rapid tests (based on the standard operating procedure provided)

4. Document the HIV and Syphilis tests results on Registration form and laboratory result log or the patient's record.

5. Conduct post- test counselling

6. Provide the HIV and Syphilis tests results to client on the prescribed card.

7. Indicate date and place for follow up testing on card

8. Refer persons with HIV and/or Syphilis positive/inconclusive (HIV) results for confirmation and follow up.

9. Complete Class 1 Notification Form for persons with HIV and/or Syphilis positive/and HIV inconclusive results, immediately, to be handed/sent to the Parish Medical Officer of Health at the Parish Health Department.

10. Provide list of test results (from register) to respective lab for documentation.

*documentation methodologies vary in the private setting

SAFETY PRECAUTIONS

Standard precautions for handling infectious agents should be observed when conducting HIV rapid testing.

1. Wear protective clothing such as lab coats and disposable gloves and closed toe shoes when handling specimen and assay reagent.
2. Wash hands thoroughly before and after use (where there is no water available hand sanitizer can be used).
3. In case of contact of reagent and/or sample with eyes, rinse immediately with plenty of water and seek medical advice.
4. In case of needle stick injury or accidental exposure please follow procedure for accidental exposure.
5. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimen are handled.
6. Do not recap needles
7. Do not reuse pipettes or testing devices.
8. Dispose of all specimens, used devices and pipettes as though capable of transmitting infection.
    a. Place sharps in sharps or puncture proof containers
    b. Place other devices or contaminated material in biohazard bags
    c. Transport to the nearest laboratory for disposal
9. All spills should be wiped thoroughly using a 10% bleach solution.

QUALITY CONTROL

1. Good laboratory practice necessitates the use of control specimens (positive and negative) to ensure proper kit performance. This should be done on a daily basis by the local laboratory which will be responsible for distribution of kits.
2. Ensure that the relevant information is correctly recorded on the results log and review result log at the end of each working day.
3. Ensure the Standard Operating Procedures for testing are followed at all times.
4. Quality control tests to be performed on each batch.
5. All test kits must be stored between 2-27°C. In addition to this, the temperature at the time the test is being performed must be recorded on the result log sheet.
6. Transport test kits in a Styrofoam/igloo with a cool pack.
7. Keep kits away from extreme heat and humidity.
8. Do not use test kits beyond the expiry date.
9. Do not mix reagents from different kits.
10. Document the expiry dates and kit lot number of the kits in use.
11. A built in procedural control on the test indicates that the test is functioning properly. A purple (SD Bioline Syphilis 3.0) or pink or red band (Determine/OraQuick) should always appear at the control window. The test must be considered invalid if this does not occur. The test must then be repeated using a new testing kit.
12. Persons conducting test must participate in the competency assessment programme which will be facilitated through the laboratory.

HIV Testing Algorithm and Interpretation

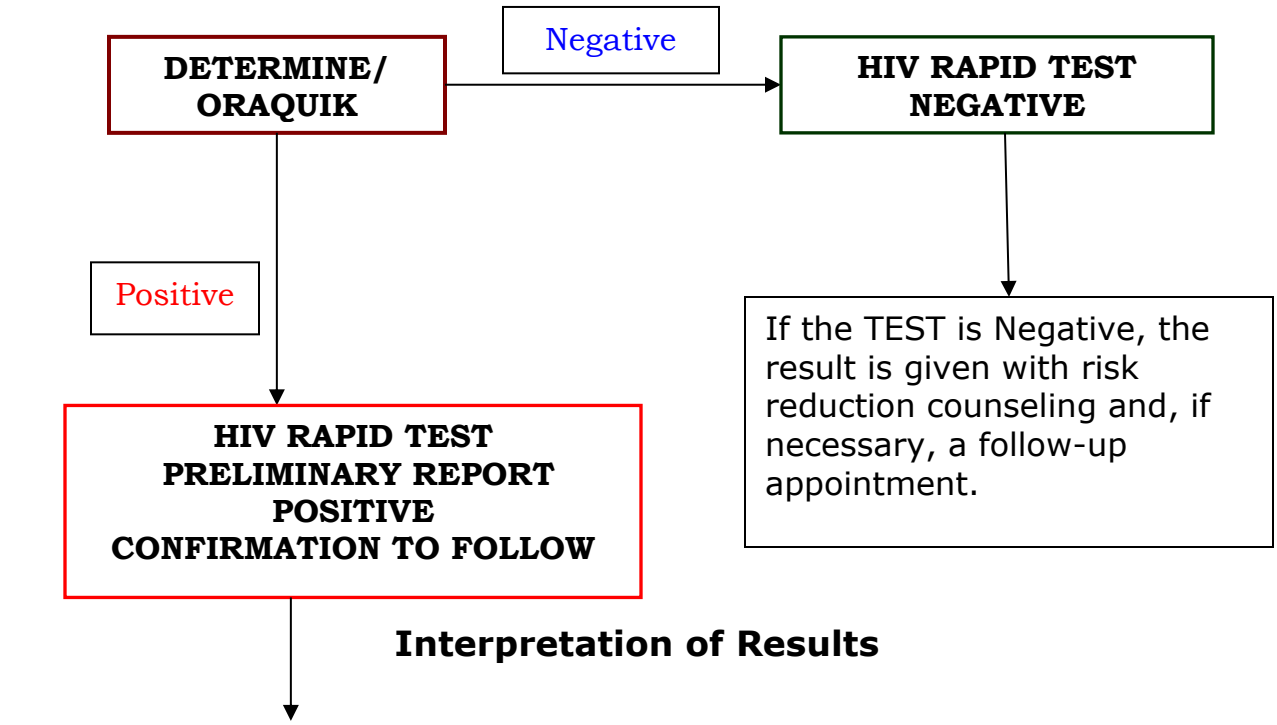
HIV tests should be administered with pre and post-test counseling and informed oral consent.

Rapid HIV testing methods for use in the non-laboratory setting

- Blood test (Determine)
- Oral test (OraQuick)

Determine is the preferred choice for testing in the non-clinical setting. However, OraQuick may be used for example, in cases where safety requirements cannot be met..

HIV Outreach Testing Serial Algorithm



Interpretation of Results

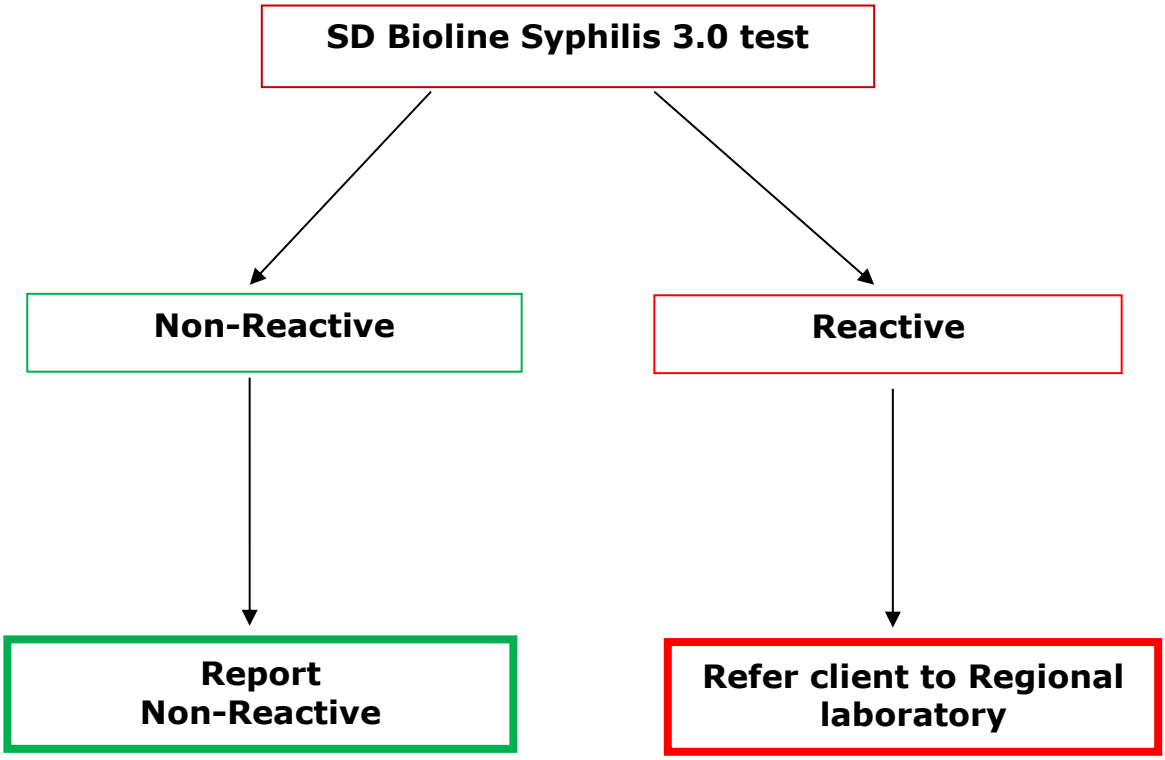
If result is reactive, counsel and refer client for confirmation and follow up. Refer with appropriate documentation to the nearest public Health Facility or private clinician of client's choice.

SYPHILIS Testing Algorithm and Interpretation

Syphilis testing should be administered with pre and post-test counseling and informed oral consent.

SYPHILS RAPID testing method: Standard SD Bioline Syphilis 3.0

Syphilis Outreach Testing Algorithm[1]



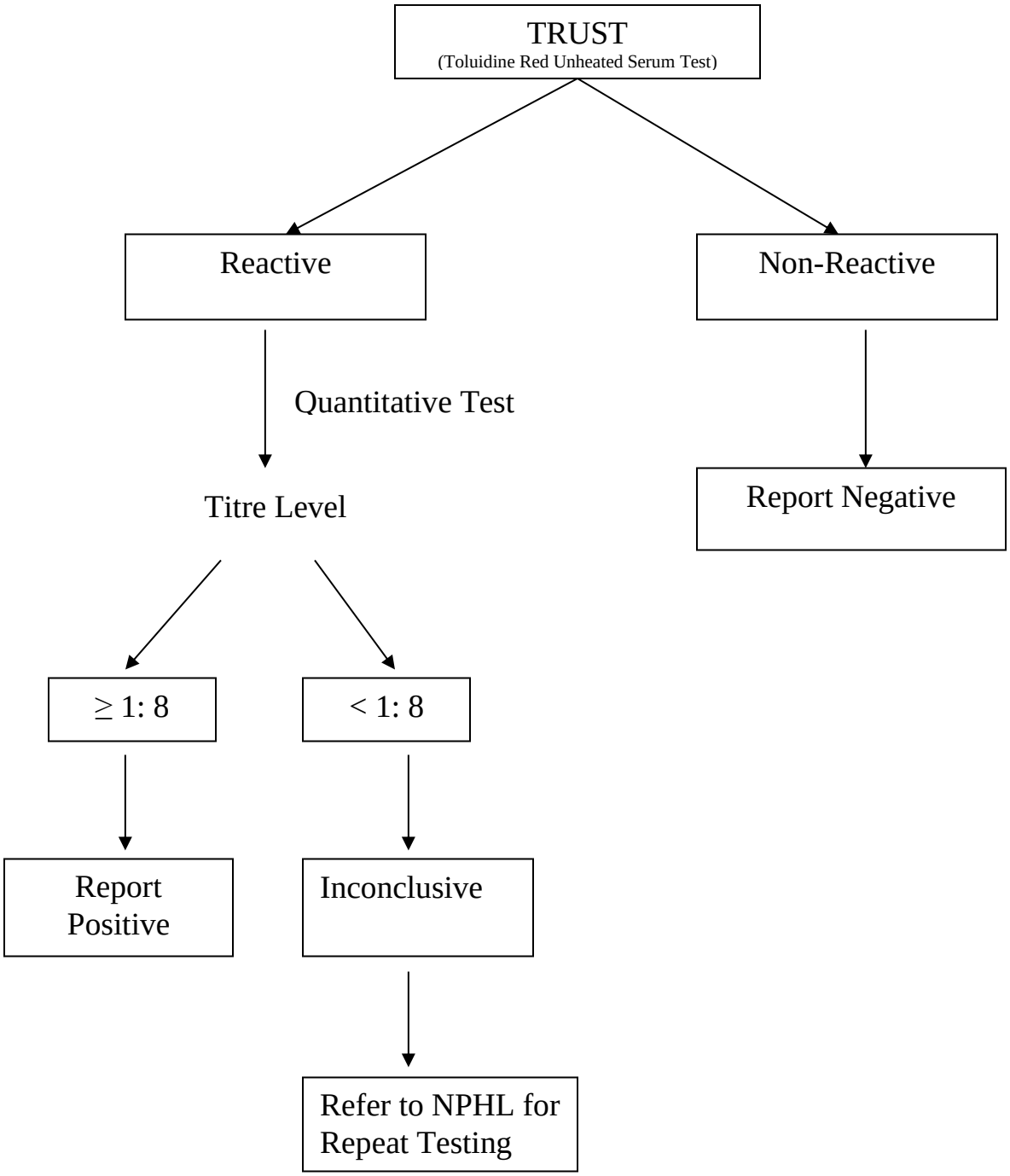
Interpretation of Results

(i) If the SD Bioline Syphilis test is negative, result is given with risk reduction counseling and if necessary, follow-up appointment.

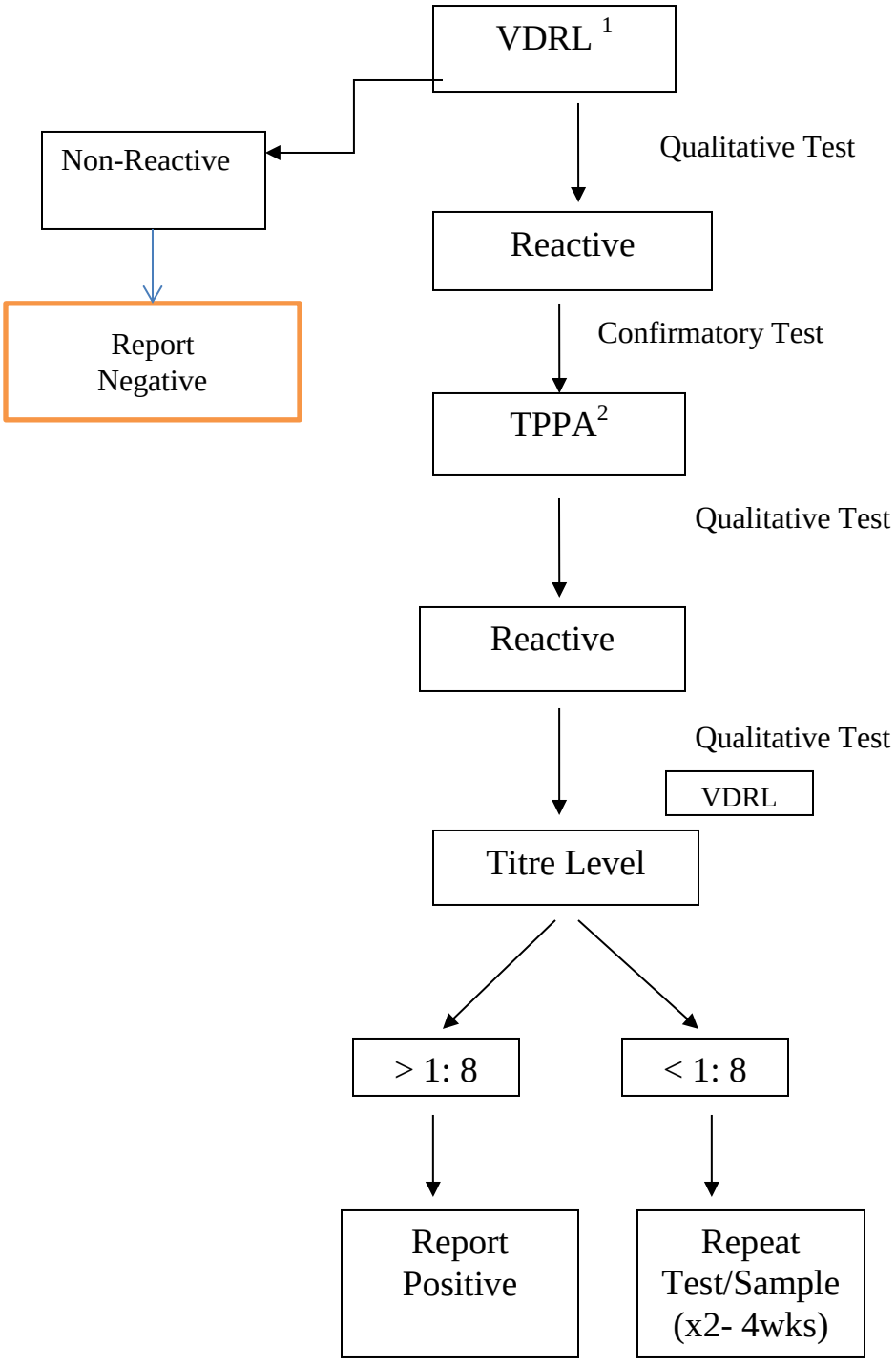
(ii) If the SD Bioline Syphilis test is positive, the client is counseled and sent for confirmatory testing.

[1] Specimen is whole blood ONLY

(iii) At the Regional Laboratory



(iv) At the National Public Health Laboratory



[1] Veneral Disease Research Laboratory
[2] *Treponema Pallidum* Particle Agglutination

Standard Operating Procedure
Obtaining Blood by Finger Prick

1. Choose the fingertip of the middle, ring, or index finger (whichever is the least callused) for adults and children older than one year.

2. Clean fingertip with alcohol; allow to air dry. Position the hand palm-side up.

3. Use a new lancet for each person. Place the lancet off-center on the fingertip. Firmly press the lancet against the finger and puncture the skin. Dispose of the lancet immediately in an appropriate biohazard sharps container.

4. Wipe away the first drop of blood with a sterile gauze pad.

5. Hold the finger lower than the elbow to facilitate blood flow. *. Avoid air bubbles.

6. If EDTA Capillary Tubes (No. 7D22-22) are being used touch the tip of the EDTA Capillary Tube to the drop of blood and , fill the tube with blood between the 2 marked lines avoid air bubbles.

7. In the absence of EDTA Tube No. 7D22-22, standard 50ul capillary tubes may be utilised.

Finger Prick – Finger Preparation

2. Position hand palm-side up. Choose whichever finger is least calloused.

3. Apply intermittent pressure to the finger to help the blood to flow

4. Clean the fingertip with alcohol. Start in the middle and work outward to prevent contaminating the area. Allow the area to dry.

5. Hold the finger and firmly place a new sterile lancet off-center on the fingertip

6

Finger Prick – Collecting Blood

6. Firmly press the lancet to puncture the fingertip

7. Wipe away the first drop of blood with a sterile gauze pad or cotton ball

8. Collect the specimen. Blood may flow best if the finger is held lower than the elbow.

9. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops

7

Standard Operating Procedure
DETERMINE HIV Rapid Test

1. Remove the DETERMINE test devices from their protective wrappers

2. Label each test with the appropriate client information

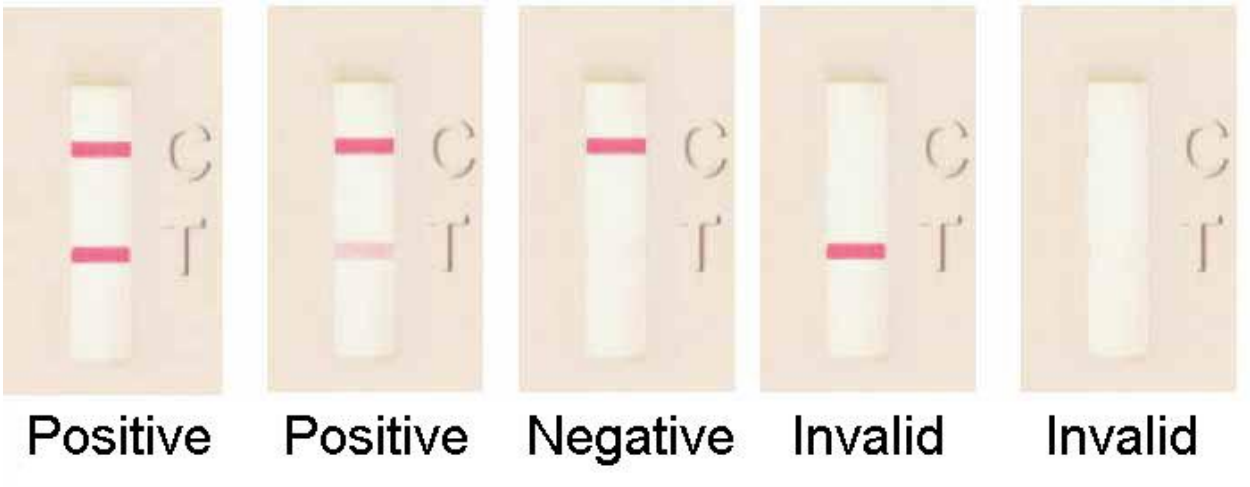
3. Using one of the disposable capillary tubes supplied, fill up to the mark with whole blood

4. Hold the capillary tube over the sample port and add 50ul (1 drop) of sample

5. After 1min use the dropper provided add 1 drop of the Chase buffer to sample the port

6. Allow 15 minutes from the time of Chase buffer addition for reaction to occur. The result should be read immediately after the end of the 15-minute incubation time but is stable for a further 5 minutes after the incubation time. **Do not read after 20 minutes following buffer addition.**

NB. In a small number of cases it has been noted that the control or the test line may appear "broken". It is recommended that the testing of that sample be repeated.



Standard Operating Procedure
ORAQUICK HIV Rapid Test

1. Collect test items and other necessary test supplies

a) Allow the test kit to come to operating temperature (15-37˚C, 59-99˚F)

b) Set the reusable stand on a flat, level surface.

c) Tear open the foil pouch containing the test device and developer vial. Remove the developer vial.

d) Carefully uncap the vial by rocking back and forth while pulling it off

e) Place cap on workbench.

f) Place the uncapped vial into the stand.

2. Remove the test device from the foil pouch without touching the collection pad. ***Check to see if the desiccant pack is present. If not present, discard the unit.***

3. Swab completely around the outer gums with the test device, by gently wiping the porous flat pad completely across the upper and lower gums, one time around. Both sides of the flat pad may be used. **Do not swab the roof of the mouth, the inside of the cheek or the tongue.**

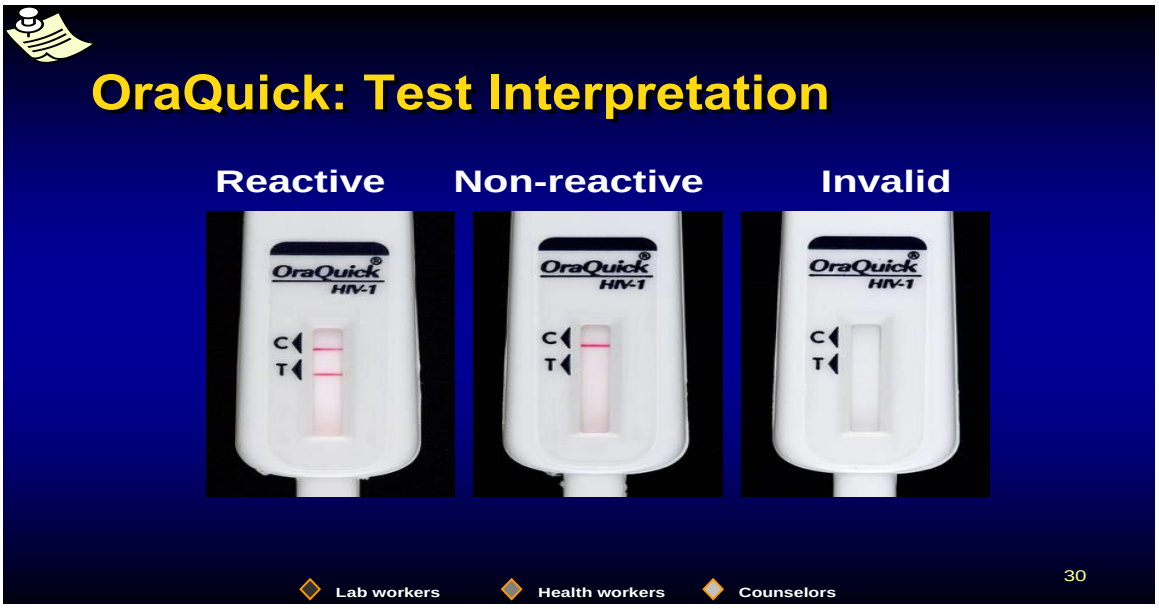
4. a) After swabbing the gums, insert the pad end of the test device all the way down in the vial.

b) Be sure the result window faces forward (towards you) so it can be read.

c) Start timer and note time.

5. Read test result in 20-40 minutes in a fully lit area.

Sample Collection



N.B

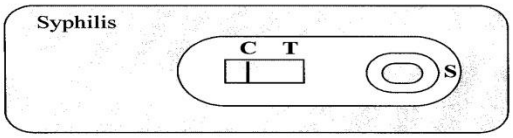
1. Clinical data has not been collected to demonstrate the performance of OraQuick in persons under 12 years of age.

2. Individuals infected with HIV-1 or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.

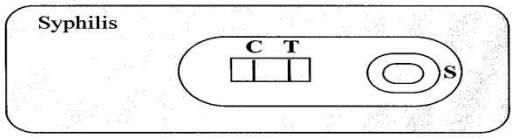
Standard Operating Procedure
SD Bioline Syphilis Rapid Test

Standard SD Bioline Syphilis 3.0
Equipment required but not supplied: capillary tubes and lancets

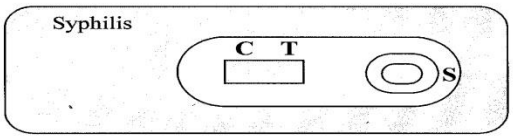
SOP:
1. Remove the test from the foil pouch and place on a flat dry surface
2. Slowly add 20 µl of whole blood to the sample well
3. Add 4 drops of assay diluent to the sample well
4. Read the test at 5-20 minutes as follows:



Non Reactive
The presence of only one band within the result window indicates a negative result



Reactive
The presence of two colour bands ("T" and "C") within the result window, no matter which band appears first, indicates a positive result for TP antibodies.



Invalid result
If the purple colour band is not visible within the result window after performing the test, the result is considered invalid.

Ministry of Health	*Approved by* *Quality Manager* *F. Gordon*	*080-TP-500* **Edition1**
National Laboratory Service *Quality Assurance*	*Date Approved December 3, 2010*	

CHECKLIST FOR OUTREACH TESTING

(If Applicable)

Testing Event and Location

_____

Item	Y/N	Quantity required	Quantity issued
Igloo			
Ice packs			
Gloves (small,medium,large)			
Hand sanitizer			
Hand towels & Tissues			
10% Bleach solution			
Soap			
Cotton swabs			
Alcohol			
Dry cotton			
Band aids			
Outreach Register			
Class I Reporting Forms			
Patient Results Cards			
Grease pencil			
File jackets			
Date stamp			
Stamp pad			
Result stamps			
Disposable bags			
Sharp disposal container			
OraQuick test kits			
Colloidal Gold pouches			
Timer			
Specimen racks			
Tape			
Scissors			
Numbers			
Thermometers			
Lancets			
Test Requisition forms			
Voluntary Testing and counseling protocol			