

(Enter Agency Name)

(Enter Agency Address)

CLIA # (Enter Agency #)

(Enter Agency Phone Number)

Rapid HIV Test Result Form

Client Name: _____ Date: _____

Date of Birth: _____ Sex: _____ Race: _____

Testing Location: _____

HIV Antibody Screening Test Result:

Reactive Negative/Non-Reactive

Follow-Up Appointment (date/time/location): _____

Client Signature: _____

Counselor Signature: _____

Rapid HIV Test Result Form

Client Name: _____ Date: _____

Date of Birth: _____ Sex: _____ Race: _____

Testing Location: _____

HIV Antibody Screening Test Result:

Reactive Negative/Non-Reactive

Follow-Up Appointment (date/time/location): _____

Client Signature: _____

Counselor Signature: _____

(Enter Agency Name)

Site: (Enter test site)

CLIA # (Enter Agency #)

Rapid HIV Test Devices Storage Temperature Log
 (Check daily, as scheduled, or after trigger event such as power outage.)

Thermometer location: _____

Month/year: _____/_____

Acceptable temperature ranges: Clearview® COMPLETE (8 to 30°C or 46 to 86°F)

Date/Time	Temperature (Indicate C or F)	Corrective action taken when temperature is out of range	Storage location	Initials
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Initial Review _____
 signature / /
 date

Final Review _____
 signature / /
 date

(Enter Agency Name)

Site: (Enter test site)

CLIA # (Enter Agency #)

Rapid HIV Test **Control** Storage Temperature Log

(Check daily, as scheduled, or after trigger event such as power outage.)

Thermometer location: _____ Month/year: ____/____

Acceptable temperature range: Clearview® (36 to 46°F)

Date/Time	Temperature (Indicate C or F)	Corrective action taken when Temperature is out of range	Storage location	Initials
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Initial Review _____ Final Review _____
signature date signature date

Agency Name: _____

Site: _____

CLIA # _____

Rapid HIV Test Result Log

Client Identification	Room Temp	Date Specimen Collected	Time Specimen Collected	Pouch Lot#	Pouch Expiration Date	Test Wait Time*	Test Result N = Non-reactive P = Preliminary Positive** I = Invalid	Initials of Person who Performed Test	Report Time***	Initials of Person who Reviewed Test and date

* Test Wait Time = Time from starting test to reading test results (in minutes)
** Reactive or **Preliminary Positive**. Although it is *very* unlikely that the test is wrong, all reactive results must be confirmed.
*** Report Time = Time that the test result is reported to the client

Control Log for (month) _____ / (year) _____

Date	Site	Initials	QC Code	Test Device		Control Pack		Non-reactive Control			Reactive HIV-1 Control			Reactive HIV-2 Control			Result Acceptable?		
				Lot #	Exp date	Lot # on Control Pack Box	Exp date	Start time/temp	End Time	Circle Result	Start time/temp	End Time	Circle Result	Start time/temp	End time	Circle Result			
											RNI			RNI			RNI	Y	N
											RNI			RNI			RNI	Y	N
											RNI			RNI			RNI	Y	N
											RNI			RNI			RNI	Y	N
											RNI			RNI			RNI	Y	N
											RNI			RNI			RNI	Y	N
											RNI			RNI			RNI	Y	N

<p>QC Code (reason for running external controls)</p> <ol style="list-style-type: none"> 1. New setting 2. New operator 3. New test kit lot 4. New test kit shipment 5. Environmental change – temp outside range in <u>storage</u> area 6. Environmental change – temp outside range in <u>test</u> area 7. Environmental change – low lighting 8. Scheduled, periodic test 9. Other (document reason on back) 	<p>Expiration Date – Control Pack</p> <p><u>Expiration Date</u>: date printed on control pack <u>box</u>.</p> <p><u>Out of fridge more than 2 hours</u>: If a control vial has been out of the refrigerator for more than two hours, the shelf life drops from two years to 90 days.</p> <p>Controls may not be used if the expiration date has passed.</p>	<p>R – reactive</p> <p>N – non-reactive</p> <p>I – invalid</p>	<p>Acceptable Results</p> <p>Non-reactive, reactive HIV-1, and reactive HIV-2 controls must yield correct results. If any one of the three yields an incorrect result, the results are <u>unacceptable</u>.</p> <p>DO NOT conduct any tests until the problem is resolved.</p> <p>Document the problem and corrective action taken on the back of this form.</p>
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Initial Review _____ / _____ / _____
 Signature _____ Date _____

Final Review _____ / _____ / _____
 Signature _____ Date _____

Must be reviewed by someone other than the HIV EIS counselor who ran the controls.

Agency Name) CLIA ID #
Rapid Test Discordant Test Case Report

This form is to be completed for ALL testing situations that involve a reactive rapid HIV test result and an indeterminate or non-reactive Western Blot or IFA test result. If the Western Blot or IFA is non-reactive or indeterminate, please REPEAT the confirmatory test(s) on a new blood specimen collected 4 weeks after the initial confirmatory specimen was collected.

Part 1: To be completed by the testing site

Site name: _____ State: _____

Person completing report: _____ Telephone number: _____

Client Demographics

Client Code: _____ Age: _____

Gender: Male Female M to F Transgender F to M Transgender Unknown

Race (check one): American Indian/Alaskan Native Asian Black or African American White
 Native Hawaiian or Other Pacific Islander Other Unknown

Ethnicity (check one): Hispanic or Latino Not Hispanic or Latino

Client ever previously tested? Yes No Client ever tested positive? Yes No

HIV Risks (check all that apply): Heterosexual Sex MSM IDU Sex with HIV+ person Other

If female, number of births _____ Contact information obtained? Yes No

Vaccination History: Hepatitis A Yes No Unknown Dose 1 Year ___ Dose 2 Year ___
Hepatitis B Yes No Unknown Dose 1 Year ___ Dose 2 Year ___

Rapid HIV-1, 2 Test

Specimen Type: Blood OMT

Date of Reactive Rapid Test: ___/___/___ Kit Lot#: _____

Test Start Time: ___:___ a.m/p.m. Test Read Time: ___:___ a.m/p.m.

Repeat Rapid Test Conducted? Yes No If yes, Test Kit Lot# _____

Test Start Time ___:___ a.m/p.m. Test Read Time: ___:___ a.m./p.m.

Test Result: Reactive Non-reactive Invalid

(Agency Name)

CLIA ID# ()

Rapid Test Invalid Test Case Report

This form is to be completed for ALL testing situations that involve an invalid rapid test result.

Site Name: _____ Date: _____

Person Completing Report: _____ Test Kit Lot#: _____

Client Code: _____ Age: _____

Client Gender: Male Female M to F Transgender F to M Transgender Unknown

Race (check one): American Indian/Alaskan Native Asian Black or African American
 Native Hawaiian or Other Pacific Islander White Other Unknown

Ethnicity (check one): Hispanic or Latino Not Hispanic or Latino

Reason rapid test was invalid (check all that apply):

- No control line appeared in the result window
- A red background in the result window made it difficult to read result after 20 minutes (OraQuick)
- A line was outside of the control area (between the blue lines)
- The test was not read within the allotted period
- Other (specify) _____

Was a rapid test repeated on this client? Yes No

If no, what was the reason a repeat test was not performed?

- Client opted to test at another test site
- Client refused a repeat test
- Client left the testing site
- Client was not ready to receive results
- Client opted for an OraSure (Oral Mucosal Transudate) test
- Client opted for a venipuncture blood test
- Lab technician was unable to obtain an additional specimen
- Do not know
- Other (specify) _____

If yes, what was the result? Reactive Non-reactive Invalid

Were external controls run immediately following the invalid rapid test?

- Yes, after the first test was invalid Yes, after the second test was invalid
- Yes, after the second test was valid No

If yes, what were the results of the control tests run?

- Both positive and non-reactive controls passed Both controls failed
- Non-reactive control failed, positive control passed Controls were not run
- Positive control failed, non-reactive control passed

[Put Referring Facility name, Address and Phone Number here]

Confirmatory Log

Referral Laboratory _____

Specimen Tracking Number	Test Subject ID*	Rapid Test Test Result	Confirmatory Test				Date Confirmed Result Received	Confirm Test Result	Post Test Date
			Date Specimen Collected	Time Specimen Collected	Collected by	Referral Lab Req Completed			

*ID = Identification

*Lab Req = Laboratory Requisition

(NOTE: If you use more than one referral laboratory, add a column to record each one)

(Enter Agency Name) Site: (Enter test site)

Quarterly Staff Observation Checklist

Instructions: If two or more workers are trained to perform rapid testing, they may observe each other. Fill in dates when the employee performs each objective or procedural step, as applicable. If the employee will not be trained to perform a specific task, enter N/A for not applicable. The employee should initial/date when each step has been completed and the observer should initial when he/she agrees that the employee met the objective or performed the specific task competently. This form should remain in the employee's personnel records.

Employee Name: _____

Objective/Procedural Step	Date Observed	Employee's Initials	Observer's Initials
Read testing procedures.			
Read Biohazard Exposure Control Plan.			
Determined if requirements for acceptable testing environment are met (e.g., temperature, lighting, level work space).			
Conducted negative and positive external controls.			
Gave person getting tested the subject information brochure.			
Labeled test device components and appropriate paperwork.			
Collected fingerstick specimen and put specimen in appropriate test device.			
Inserted test device, timed test, and read result.			
Disposed of lancet and other biohazardous waste appropriately.			
Recorded results on report form and log sheet.			
Recorded internal and external quality control (QC) results in QC log.			
Recorded results in QC log.			
Reported test result to the person being tested.			
Referred person or collected specimen for confirmatory testing.			
Sent confirmatory test specimen to referral laboratory and documented submission.			
Received referral laboratory results and recorded results.			
Explained what to do if QC results show a problem.			

(Insert Agency Name) Site: (Insert test site)

Rapid HIV Testing and Prevention Counseling Observation Form

Counselor: _____ Observer: _____ Date: _____

Step 1:

Introduce/ orient client. *Did the counselor:*

- Introduce him/herself by name
- Explain role
- State duration of session
- Explain test options
- Explain procedures

Provide information. *Did the counselor provide information about:*

- Test benefits
- Test results
- Importance of results
- HIV risk and transmission
- Sources of additional information

Obtain informed consent. *Did the counselor:*

- Determine if client understood the written consent.
- Offer verbal consent if testing is anonymous.

Assess client readiness. *Did the counselor assess the client's:*

- Readiness to receive test result the same day
- Support system
- Possible reaction to a reactive test result
- Emotional state
- Mental status

Conduct the test. *Did the counselor:*

- Explain what he/she was doing
- Appear organized
- Follow test procedures
- Complete labeling
- Document
- Use safety precautions.

Step 2:**Identify current risk behaviors and circumstances (while test is processing)**

Did the counselor help the client identify risk behaviors with regard to:

- Sex or needle-sharing partner(s)
- Circumstances
- Timeframes

Behaviors/patterns identified:

Step 3:**Identify safer goal behaviors that the client is willing to adopt**

Behavior(s) identified:

Interpret test result. Did the counselor correctly interpret the result?

- Yes
- No

Report test results. Did the counselor:

- Explain the meaning of a non-reactive test and the need for further testing based on date of last risk exposure
- Explain the meaning of a reactive screening test result and the importance of a confirmatory test
- Explain the meaning of an invalid test outcome and the need to be retested
- Assess the client's emotional reaction to the test result

Step 4:**Identify a personal action plan. Did the counselor help identify a plan that:**

- Is realistic for the client
- Included small steps
- Included a follow-up plan

Steps identified:

Step 5:**Provide support and referrals. Did the counselor:**

- Assess the client's referral needs
- Make any referrals
- Choose appropriate referrals
- Refer client to known/trusted sources
- Facilitate an active referral
- Document the referral(s)
- Make a follow-up plan

Referrals made:

Step 6:**Summarize and close the session. Did the counselor:**

- Ask the client for questions or comments
- Summarize the action plan
- Summarize the referral plan
- Offer support
- Offer his/her business card or contact information

General Questions:

Did the counselor keep the session focused on HIV risk reduction? Yes No

Did the counselor ask open-ended questions? Yes No

Did the counselor avoid 'information overload' by clarifying only major misconceptions and giving information simply? Yes No

Did the counselor provide skill-building opportunities for the client when appropriate? Yes No

Agency Name _____ Test Site _____ CLIA # _____

Contact Person _____ Phone _____

Sharps Injury Log, Year _____

Date	Location where injury occurred (facility name, room #, etc.)	Brief description of how the injury occurred: procedure being done, action being performed—fingerstick, venipuncture, waste-disposal. Include area of the body injured.	Type of device (lancet, syringe, etc.)	Brand name of device

OSHA's Bloodborne Pathogens Standard requires an employer to establish and maintain a **Sharps Injury Log** for recording all punctures of skin occurring from contaminated sharps.

The purpose of the log is to aid in the evaluation of devices being used in healthcare and other facilities and to identify devices or procedures/techniques requiring additional attention or review.

This log must be kept in addition to the Injury and Illness Log required by OSHA.

The **Sharps Injury Log** should not list the names of affected employees (to maintain confidentiality) but, at a minimum, it should contain the type and brand of device involved in the incident, the department or work area where the exposure incident occurred, and an explanation of how the incident occurred.

The log should include all sharps injuries occurring in a calendar year and it must be retained for 5 years following the end of the year to which it relates.