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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Coordinating Center for Infectious Diseases, Mail Stop G-23
Atlanta, Georgia 30333

HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RAPID TESTING LABORATORY PRACTICES QUESTIONNAIRE FOR NATIONAL AND INTERNATIONAL PARTICIPANTS

MPEP Identification No.: ☐☐☐☐☐

Facility/Testing Site Name: _____

Street:_____

City:_____

State/Province:_____ ZIP /Postal Code:_____

Country:_____

Telephone No.: (_____)_____-_____Fax No.: (_____)_____-_____

E-mail Address:

_____

Person completing form:

Name:_____

Title: _____

RETURNING THE QUESTIONNAIRE BOOKLET

PLEASE NOTE:
If you have entered and submitted your answers online,
Please DO NOT return this booklet!

DEADLINE FOR SUBMISSION: _____ __, 2006

The website for online data submission of results is:
https://www.phppo.cdc.gov/mpep/results/login.aspx
You will need your MPEP identification number and password.

For those laboratories that choose to submit their answers on paper, an addressed envelope has been provided to mail the completed booklet to the MPEP. If you use the envelope provided, please mail your questionnaire booklet so that it reaches the MPEP Survey Coordinator at Constella Group, Inc. by the deadline indicated on the cover. If you use your own envelope, please send your questionnaire by the deadline to:

MPEP Survey Coordinator
Constella Group, Inc.
3 Corporate Blvd.
Suite 600
Atlanta, GA 30329

If you have any questions about submitting your questionnaire, please contact the HIV Rapid Testing Project Coordinator, Leigh Vaughan:
telephone (404) 718-1005
email LVaughan@cdc.gov

MPEP Identification No. ☐☐☐☐☐

1. a) Please indicate the primary classification of your facility/testing site.
(Check **one** primary classification.)

☐ Blood/plasma donor center
(includes mobile units/vans used for donor blood collection)
☐ Drug use treatment center
☐ Family planning center
☐ Community based organization (CBO)
☐ Medical examiner/Coroner's office
☐ Physician office
☐ Oral health
☐ Correctional facility/prison
☐ HMO
☐ HIV Counseling and testing site/Clinic site
☐ HIV Counseling and testing site/Field site
☐ STD clinic
Health dept: ☐ State/Province ☐ Other
☐ Independent laboratory
☐ Military (other than hospital)
☐ Mobile unit/van (other than blood donor donation)
☐ Hospice

Hospital (Indicate all applicable sections/locations within the hospital, as listed below:)

☐ Admissions ☐ Blood Bank ☐ Central Laboratory
☐ Emergency Room ☐ Labor/Delivery ☐ Ward/Floor
☐ Employee health/infection control ☐ Other Hospital Section (specify) _____

☐ Other testing site classification (specify):_____

b) Which of the following services does your organization provide? (Check **all** that apply.)

☐ Medical care for people with HIV/AIDS
☐ Social services for people with HIV/AIDS
☐ HIV/AIDS prevention and education
☐ Reproductive health
☐ STD treatment/prevention
☐ Maternal and child health
☐ Mental/behavioral health
☐ Hemophilia care
☐ Comprehensive/general health clinic
☐ Drug treatment
☐ Housing assistance
☐ Food bank
☐ Other (please specify): _____

1. c) Does your facility currently perform HIV rapid testing?
☐ Yes, go to question 1e
☐ No, please **answer 1d and return your survey**.

d) If your facility does not perform HIV rapid testing, why not?
☐ Our facility is in a low prevalence area
☐ Fears about test performance such as false positives
☐ Lack of funding to purchase tests
☐ Lack of interest
☐ Other: _____

e) When did your facility begin to perform HIV rapid testing?

DATE: **year** ☐☐☐☐

month (circle one) Jan Feb Mar Apr May June July Aug Sept Oct Nov Dec

☐ date unknown, but > 5 years

☐ date unknown

2. a) For what purpose(s) do you offer HIV rapid testing? (Check **all** that apply.)
☐ Initial screen for diagnosis
☐ Voluntary HIV testing (outpatients/clients)
☐ Testing pregnant women of unknown HIV status at the time of delivery
☐ For making decisions on post-exposure treatment for healthcare workers after an accidental exposure
☐ Emergency room screening
☐ Other _____

b) What is the target population for your rapid testing program?

Any client/patient who requests an HIV test	☐Yes	☐No
Any high school/college student	☐Yes	☐No
Any high risk client/patient	☐Yes	☐No
Certain types or categories of high risk client	☐Yes	☐No

If "Yes" to high risk client/patients, please specify (Check **all** that apply):
☐ Gay/bisexual men or men who have sex with men
☐ High risk women (e.g., sex workers)
☐ Injection drug users
☐ Adolescents
☐ Homeless individuals
☐ African Americans
☐ Hispanic or Latino
☐ Other (please specify): _____

c) Approximately how many unique clients does your organization serve per year, across all programs, onsite and offsite? _____

2. d) Approximately what percentage of clients/patients at your organization (round to nearest whole number):

	Percent	Don't know*
Have incomes at or below the Federal poverty level[§]?	_____	____
Are African American?	_____	____
Are Hispanic or Latino?	_____	____
Are White/Caucasian?	_____	____
Are HIV-positive?	_____	____

*** information not available to laboratory**

[§] ***Note: The federal poverty guideline is $9,570 for a 1-person household (HH), $12,830 for a 2-person HH, $16,000 for a 3-person HH, and $19,350 for a 4-person HH)***

e) Who PRIMARILY funds your testing site? (Check only **ONE BEST** answer)

☐ CDC funded
☐ State/Province funded
☐ County, city or other government (non-federal, non-state)
☐ Federal, other than CDC
☐ Private, non-profit
☐ Private, for profit
☐ Other (please specify):_____

3. a) Of all HIV testing performed in your facility over the past year, what percentage was performed using <u>HIV rapid test kits</u>?

☐ ≤5%
☐ 6-10%
☐ 11-15%
☐ 16-20%
☐ 21-30%
☐ 31-40%
☐ 41-50%
☐ 51-60%
☐ 61-74%
☐ 75-99%
☐ 100%

b) How many client/patient specimens were tested using HIV rapid tests in your facility during the most recent representative **MONTH**?

_____ number of **specimens** per **MONTH**

c) Of the specimens reported in 3b above, how many were initially reactive (preliminary positive) during the same most recent representative **MONTH**?

_____ total number of initially reactive (preliminary positive) specimens per **MONTH**

d) Of the above (see answer 3c) initially reactive (preliminary positive) HIV rapid test results for which a confirmatory test was performed, how many were **<u>confirmed</u>** as positive?

_____ OR

☐ Confirmatory testing is not required
☐ We do not perform confirmatory testing
☐ We have not had any reactive (preliminary positive) HIV rapid test results
☐ N/A – client is referred elsewhere for confirmatory testing (results unknown)

3. e) In the last 6 months, how many persons received preliminary positive results, but did not return for confirmatory test results?

_____ # of persons with initially reactive results

_____ total # of persons not returning for confirmatory results

☐ N/A, we do not require confirmatory testing.

☐ N/A, persons are sent elsewhere for confirmatory testing and we do not receive those results.

☐ No information available to us on confirmatory testing.

f) If HIV screening tests **other than rapid tests** are offered in your facility, what percentage of patients/clients in the last 6 months with preliminary positive results from these other tests do not return for confirmatory results?

☐ N/A, other HIV tests are not performed in our facility.

☐ N/A, confirmatory testing is not required for our other (not rapid) HIV screening test(s).

☐ N/A, persons sent elsewhere for confirmatory testing and we do not receive test results.

☐ Don't know; no information available on confirmatory testing for our other (not rapid) HIV screening test(s).

4. a) Does your facility provide anonymous HIV rapid testing?
☐ Yes
☐ No

b) Does your facility have procedures for protecting the confidentiality of HIV results?
☐ Yes
☐ No

5. What test kit(s) do you currently use for HIV rapid testing? (Check **all** that apply.)

Abbott:	☐	(0101)	Determine HIV-1/2	Genelabs Diagnostics:	☐ (0601) HIV-Spot
Bio-Rad:	☐	(0301)	Multispot HIV-1/HIV-2	J. Mitra & Co. Ltd:	☐ (1301) HIV- TRIDOT
	☐	(0302)	Genie II HIV-1/HIV-2		
Chembio	☐	(0401)	Sure Check HIV (previously Hemastrip HIV 1/2)	OraSure:	☐ (0801) OraQuick Rapid HIV-1 Ab Test
					☐ (0802) OraQuick ADVANCE Rapid HIV-1/2 Antibody test
	☐	(0402)	HIV 1/2 Stat-Pak **(Cassette)**		
	☐	(0403)	HIV 1/2 Stat-Pak **(Dipstick)**		
Efoora :	☐	(1201)	HIV Rapid Test	Trinity Biotech:	☐ (0901) Capillus HIV
Fujirebio:	☐	(0501)	Serodia-HIV-1/2		☐ (0902) SeroCard HIV
	☐	(0502)	Espline HIV-1/2		☐ (0903) Uni-Gold HIV
MedMira:	☐	(0701)	Reveal G2 Rapid HIV-1 Antibody Test		☐ (0904) Uni-Gold Recombigen HIV
	☐	(0702)	Reveal Rapid HIV-1 Antibody Test	Other (please specify ***both*** manufacturer & kit)	☐ (9900) _____ _____
	☐	(0703)	MedMira Rapid HIV Test (**Canada only**)		

6. What sample type(s) do you currently use for HIV rapid testing? (Check **all** that apply.)

☐ Serum ☐ Whole blood, finger-stick
☐ Plasma ☐ Whole blood, venous
☐ Oral fluid (from swabbing gums) ☐ Other (please specify): _____

7. a) Where are specimens collected and HIV rapid testing performed? (Check **one** best answer.)

Please note: ON-SITE = within our facility
OFF-SITE = outside our facility; e.g., outreach, mobile units/vans, & other facilities

☐ Specimens Collected ON-SITE and Testing performed ON-SITE
☐ Specimens Collected ON-SITE & OFF-SITE and Testing performed ON-SITE
☐ Specimens Collected ON-SITE & OFF-SITE and Testing performed ON-SITE & OFF-SITE
☐ Specimens Collected OFF-SITE and Testing performed ON-SITE
☐ Specimens Collected OFF-SITE and Testing performed OFF-SITE
☐ Specimens Collected OFF-SITE and Testing performed ON-SITE & OFF-SITE

b) For **Hospitals only**: In what hospital setting are specimens ***collected***? (Check **all** that apply.) (Indicate all applicable sections within the hospital, as listed below)

☐ Admissions ☐ Blood Bank ☐ Central Laboratory
☐ Emergency Room (ER) ☐ Labor/Delivery ☐ Ward/Floor
☐ Employee health/infection control ☐ Other Hospital Section (specify) _____

c) For **Hospitals only**: In what hospital setting are specimens ***tested***? (Check **all** that apply.) (Indicate all applicable sections within the hospital, as listed below)

☐ Admissions ☐ Blood Bank ☐ Central Laboratory
☐ Emergency Room (ER) ☐ Labor/Delivery ☐ Ward/Floor
☐ Employee health/infection control ☐ Other Hospital Section (specify) _____

Note: Question 7d is ONLY for sites that **collect specimens off-site** for HIV rapid testing.

d) If you perform HIV rapid testing on specimens collected off-site (outside your facility), please indicate where these specimens are collected. (Check **all** that apply.)

☐ Blood/plasma donor center (includes mobile units/vans used for donor blood collection)
☐ Correctional facility
☐ HMO
☐ HIV Counseling and testing site
☐ Drug use treatment center
☐ STD Clinic
☐ Family planning center
☐ Health Department
☐ Community Based Organization (CBO)
☐ Independent Laboratory
☐ Medical Examiner/Coroner's office
☐ Military (Other than Hospital)
☐ Physician Office
☐ Mobile Unit/Van (other than blood donor donation)

☐ **Other off-site collection site** (specify):_____

7. e) In which off-site settings does your organization perform rapid HIV tests? (Check **all** that apply.)

☐ No off-site settings
☐ In a mobile facility (e.g., van)
☐ In stores
☐ In booths, e.g., at a health fair or festival
☐ In bars or clubs
☐ In bathhouses
☐ On the street
☐ Other setting(s) (please specify): _____

8. To detect HIV infection, do you currently perform a test in your facility other than an HIV rapid test?

☐ No Yes: (Check **all** that apply.)
☐ Enzyme Immunoassay (EIA)
☐ Western blot
☐ Immunofluorescence assay
☐ Other (please specify): _____

9. Has HIV rapid testing replaced some other method of HIV testing in your facility?
Please note: This does not refer to changing to another HIV rapid test method.

☐ Yes. Specify method: ☐ EIA EIA kit name: _____
☐ Western blot (WB) WB kit name: _____
☐ Other HIV test: _____
☐ No
☐ Do not know

10. Who performs HIV rapid testing in your facility on a regular basis? (Check **all** that apply.)

☐ Physician
☐ Physician Assistant
☐ Nurse Practitioner
☐ Person with M.S. or Ph.D. in medical or laboratory science
☐ Person with Bachelors of Science/Arts in clinical laboratory science, chemistry, biology, physics, immunology, microbiology
☐ Person with Associate Degree
☐ High School Graduate (with no post graduate education)
☐ Medical Technologist (MT) or Clinical Laboratory Scientist/Specialist (CLS)
☐ Medical Technician
☐ Medical Assistant other than Medical Technologist/Technician
☐ Nurse (RN/LPN)
☐ Volunteer with formal medical/laboratory training
☐ Volunteer with no formal medical/laboratory training
☐ HIV counselor
☐ Phlebotomist
☐ Other (please specify): _____

11. a) How many staff in your organization are trained to do HIV rapid tests? _____

b) What type of training is required for personnel performing HIV rapid testing in your facility/testing site? (Check **all** that apply.) Please round to nearest whole numbers.

☐ No training required. ***Go to Question 11d***

☐ Training by test kit manufacturer representative
Length of training: _____ hours

☐ In-house training (conducted by your own facility personnel or institution)
Length of training: _____ hours

☐ Training by State Health Department
Length of training: _____ hours

☐ Course given by CDC or other federal agency
Length of training: _____ hours

☐ Personnel must test and pass a proficiency/performance evaluation sample panel before testing patient/client specimens.
Minimum number of samples tested: ☐

☐ Other type of training (please specify): _____

c) What is covered in the HIV RT training?

☐ Reading package insert
☐ External quality assessment (performance evaluation or proficiency testing [PT])
☐ Practice test
☐ Quality Control (QC) issues
☐ Standard operating procedures
☐ Other _____

d) Is there a 'site-specific' Standard Operating Procedure (SOP) manual for rapid testing at the testing site?

☐ Yes
☐ No

If not, why not? (Choose **ONE BEST** answer.)

☐ Do not have an SOP for HIV RT in our facility.
☐ Not familiar with SOPs.
☐ We have an SOP, but it is not posted or located at the testing site.
☐ We are testing in an outreach site where an SOP is inconvenient or could be intimidating to clients/patients.
☐ Other: _____

12. a) Is confirmatory testing performed (either in your facility or another facility) on initially reactive (preliminary positive) HIV rapid tests?

☐ Yes
☐ No, **Go to question 12f (page 12)**

12.b) Many laboratories/testing sites use multiple tests simultaneously or in a step-wise fashion to derive an initially reactive (preliminary positive) result and/or a confirmed positive result. What is the typical algorithm, or order of tests, you use in your laboratory/testing site for HIV rapid testing and confirmatory testing? Please complete the table below by placing an 'X' in the boxes that correspond to your algorithm or order of tests. Check only <u>one</u> box for each step (row) in your algorithm. If you use less than 5 steps, leave those rows blank. For help in completing the table, please refer to the EXAMPLE in the box below of how one laboratory completed this table <u>based on its testing algorithm.</u>

The following is an <u>EXAMPLE</u> of how to complete the table given a particular scenario.
STEP 1: A patient specimen is tested using one rapid test kit. *The result is reactive.*
STEP 2: Specimen from the same patient is run in a second rapid test from a different manufacturer. *The result is reactive.*
STEP 3: Specimen from the same patient is sent to another facility to be run in Western blot for confirmation. *The result is confirmed positive.*

Sequence of Tests <u>Performed</u>	One HIV Rapid <u>Test</u>	Two HIV rapid tests, simultaneously <u>same test kit</u>	Two HIV rapid tests, simultaneously <u>different kits</u>	2nd/3rd HIV rapid test <u>same test kit</u>	2nd/3rd HIV rapid test <u>different kit</u>	EIA our <u>facility</u>	EIA other <u>facility</u>	WB our <u>facility</u>	WB other <u>facility</u>	IFA our <u>facility</u>	IFA other <u>facility</u>	Other test* our <u>facility</u>	Other test* other <u>facility</u>
1st step	[**X**]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
2nd step	[ ]	[ ]	[ ]	[ ]	[**X**]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
3rd step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[**X**]	[ ]	[ ]	[ ]	[ ]
4th step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
5th step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

*Other HIV test, please specify: _____

Sequence of Tests <u>Performed</u>	One HIV Rapid <u>Test</u>	Two HIV rapid tests, simultaneously <u>same test kit</u>	Two HIV rapid tests, simultaneously <u>different kits</u>	2nd/3rd HIV rapid test <u>same test kit</u>	2nd/3rd HIV rapid test <u>different kit</u>	EIA our <u>facility</u>	EIA other <u>facility</u>	WB our <u>facility</u>	WB other <u>facility</u>	IFA our <u>facility</u>	IFA other <u>facility</u>	Other test* our <u>facility</u>	Other test* other <u>facility</u>
1st step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
2nd step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
3rd step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
4th step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
5th step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

*Other HIV test, please specify: _____

12.c) Please complete the table below to show the algorithm you use when the secondary or confirmatory test result is negative or indeterminate (IND) **AFTER** an initially reactive (preliminary positive) result. What is the typical algorithm, or order of tests, you use in your laboratory/testing site for HIV rapid testing and confirmatory testing? Please complete the table below by placing an 'X' in the boxes that correspond to your algorithm or order of tests. Check only one box for each step (row) in your algorithm. If you use less than 5 steps, leave those rows blank. For help in completing the table, please refer to the EXAMPLE in the box below of how one laboratory completed this table based on its testing algorithm.

The following is an EXAMPLE of how to complete the table given a particular scenario.
STEP 1: A patient specimen is tested using one rapid test kit. *The result is reactive.*
STEP 2: Specimen from the same patient is run in a second rapid test from a different manufacturer. *The result is negative*
STEP 3: Specimen from the same patient is run in a third rapid test from a different manufacturer. *The result is positive..*
STEP 4: Specimen from the same patient is sent to another facility to be run in Western blot for confirmation. *The result is confirmed positive.*

Sequence of Tests Performed	One HIV Rapid Test	Two HIV rapid tests, simultaneously same test kit	Two HIV rapid tests, simultaneously different kits	2nd/3rd HIV rapid test same test kit	2nd/3rd HIV rapid test different kit	EIA our facility	EIA other facility	WB our facility	WB other facility	IFA our facility	IFA other facility	Other test* our or other facility	Test Outcome (Result)
1st step	[**X**]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	**Positive**
2nd step	[ ]	[ ]	[ ]	[ ]	[**X**]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	**Neg/IND**
3rd step	[ ]	[ ]	[ ]	[ ]	[**X**]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	Positive
4th step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[**X**]	[ ]	[ ]	[ ]	Positive
5th step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

Example

*Other HIV test, please specify test and location (our facility or other facility): _____

Sequence of Tests Performed	One HIV Rapid Test	Two HIV rapid tests, simultaneously same test kit	Two HIV rapid tests, simultaneously different kits	2nd/3rd HIV rapid test same test kit	2nd/3rd HIV rapid test different kit	EIA our facility	EIA other facility	WB our facility	WB other facility	IFA our facility	IFA other facility	Other test* our or other facility	Test Outcome (Result)
1st step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	**[Positive]**
2nd step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[**Neg/IND**}
3rd step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
4th step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
5th step	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

*Other HIV test, please specify test and location (our facility or other facility) _____

12. d) What specimen type do you use to confirm initially reactive HIV rapid test results? (Check **all** that apply.)

☐ Serum
☐ Plasma
☐ Whole blood, finger-stick
☐ Whole blood, venous
☐ Oral fluid (from swabbing gums)
☐ Dried blood spot
☐ Other (please specify): _____
☐ Do not know

e) Which of the following procedures are used to obtain a specimen for a confirmatory test? (Check **all** that apply.)

☐ Specimens are used from a prior blood draw.
☐ New blood specimens are taken for the confirmatory test.
☐ Oral fluid specimens (from swabbing gums) are taken.
☐ Other: _____
☐ Do not know

Note: The following three questions (12f – 12h) refer to specimens which give an INITIALLY negative or indeterminate rapid test result.

f) If the **initial** HIV rapid test result is negative or indeterminate, is further HIV testing performed for that client/patient (either in your facility or another facility)?

☐ Yes
☐ No, **Go to question 13.**

g) What specimen type do you use to perform further HIV testing after an **initial** negative or indeterminate HIV rapid test result? (Check **all** that apply.)

☐ Serum
☐ Plasma
☐ Whole blood, finger-stick
☐ Whole blood, venous
☐ Oral fluid specimens (from swabbing gums)
☐ Dried blood spot
☐ Other (please specify): _____
☐ Do not know

12. h) Please list in a step-wise fashion the steps you take when further HIV testing specimens which give a negative or indeterminate initial HIV rapid test result, by placing a number on the line corresponding to the step taken.

__1__ HIV rapid test – negative/indeterminate result

_____ 2nd HIV rapid test

_____ EIA (Enzyme-linked Immuno Assay)

_____ Pooled HIV viral load (RNA) testing

_____ Other 1st HIV test (please specify): _____

_____ Other 2nd HIV test (please specify): _____

13. a) On average, how much time passes from collection of the specimen for HIV rapid testing at your facility until **preliminary positive** results are reported (given) to the client/patient? (Check only **one**.)

☐ Less than 1 hour ☐ 4-8 hours

☐ 1 hour ☐ 9-24 hours

☐ between 1 and 2 hours ☐ 25-72 hours

☐ 2-3 hours ☐ Other (please specify): _____

b) On average, how much time passes from collection of the specimen for HIV rapid testing at your facility until **negative** results are reported (given) to the client/patient? (Check only **one**.)

☐ Less than 1 hour ☐ 4-8 hours

☐ 1 hour ☐ 9-24 hours

☐ between 1 and 2 hours ☐ 25-72 hours

☐ 2-3 hours ☐ Other (please specify): _____

Reporting procedures for Initially Reactive (preliminary positive) HIV Rapid Tests

14. a) For **Initially Reactive *(preliminary positive)*** HIV rapid tests, is this test result given the same day to the patient/client (the person whose sample was tested for HIV)?

☐ YES (go to question 14b)

☐ NO (go to question 14c)

☐ I don't know (go to question 14d)

14. b) **If "yes" to part (a):** Who gives the result of the HIV rapid test to the patient/client (the person whose sample was tested for HIV)? (Check **all** that apply.)

☐ the person who performed the HIV rapid test.

☐ the client/patient's doctor or other health care professional responsible for the client/patient (the person whose sample was tested for HIV).

☐ a counselor (NOT the person who performed the test).

☐ other (please specify):_____

☐ I don't know

14. c) **If "no" to part (a),** (Check **all** that apply.)

☐ initially reactive (preliminary positive) HIV rapid test results are NOT reported to the client/patient (the person whose sample was tested for HIV).

☐ initially reactive (preliminary positive) HIV rapid test results are NOT reported directly to the client/patient; initially reactive results are reported ONLY AFTER CONFIRMATION.

☐ initially reactive results are reported to the client/patient's physician or other health care provider.

☐ initially reactive results are reported to employee/occupational health OR infection control.

☐ OTHER initially reactive result reporting procedure(s), specified:_____

☐ I don't know.

14. d) Where do the reporting procedures for initially reactive (preliminary positive) HIV rapid tests occur? (Check **all** that apply.)

☐ in our facility, in the department where HIV rapid testing is performed

☐ at another area of our facility (NOT the site/department of HIV rapid testing)

☐ externally (NOT at our facility)

☐ I don't know

14. e) Do you have the same test result reporting procedures for **all** Reactive (preliminary positive) HIV rapid tests? (Check only **one**.)

☐ Yes

☐ No, our result reporting procedures depend on the purpose for which the HIV rapid test is ordered.

☐ I do not know the reporting procedures for reactive (preliminary positive) HIV rapid tests

Reporting procedures for NON-Reactive HIV Rapid Test results

15. a) For **NON-Reactive *(Negative)*** HIV rapid tests, is this test result given the same day to the patient/client (the person whose sample was tested for HIV)?

☐ YES (go to question 15b)

☐ NO (go to question 15c)

☐ I don't know (go to question 15d)

15. b) **If "yes" to part (a):** Who gives the result of the HIV rapid test to the patient/client (the person whose sample was tested for HIV)? (Check **all** that apply.)

☐ the person who performed the HIV rapid test.

☐ the client/patient's doctor or other health care professional responsible for the client/patient (the person whose sample was tested for HIV).

☐ a counselor (NOT the person who performed the test).

☐ other (please specify):_____

☐ I don't know.

15. c) **If "no",** please check **all** that apply:

☐ non-reactive (negative) HIV rapid test results are NOT reported to the client/patient (the person whose sample was tested for HIV).

☐ non-reactive results are reported to the client/patient's physician or other health care provider.

☐ non-reactive results are reported to employee/occupational health OR infection control.

☐ OTHER non-reactive result reporting procedure(s), specified:_____

☐ I don't know.

15. d) Where do the reporting procedures for non-reactive (negative) HIV rapid tests occur? (Check **all** that apply.)

☐ in our facility, in the department where HIV rapid testing is performed

☐ at another area of our facility (NOT the site/department of HIV rapid testing)

☐ externally (NOT at our facility)

☐ I don't know

15. e) Do you have the same test result reporting procedures for all non-reactive (negative) HIV rapid tests? (Check only **one**.)

☐ Yes

☐ No, our result reporting procedures depend on the purpose for which the HIV rapid test is ordered.

☐ I do not know the reporting procedures for non-reactive (negative) HIV rapid tests

PLEASE NOTE:
The following questions on **referral procedures** concern procedures by which the **Client/patient (the person whose sample was tested for HIV)** is referred for follow-up health care, counseling, etc.

Referral Procedures (follow-up) for client/patients after having HIV Rapid testing

16. a) For **Initially Reactive *(preliminary positive)*** HIV rapid tests, what is the typical referral procedure for the patient/client (the person whose sample was tested for HIV)? (Check **all** that apply.)

- ☐ No referral procedure **(go to question 16b)**
- ☐ Refer client to health department
- ☐ Refer to HIV counseling center (on-site or off-site)
- ☐ Refer to the health care provider or physician
- ☐ Refer to employee/occupational health or infection control
- ☐ Client is given a list of HIV resources for care
- ☐ Client arranges own follow-up care
- ☐ Other (please specify): _____

b) For **confirmed positive** HIV rapid test results:

If a client/patient has a preliminary positive rapid test that is confirmed positive, is there a formal or informal protocol to refer this client/patient for follow-up care (medical, counseling, etc.)? (Check all that apply.)

- ☐ No protocol in place – referral on a case-by-case basis
- ☐ Yes, we have a protocol/procedure for referral.

If yes, which of the following does the protocol include? (Check **all** that apply.)

- ☐ Referral of client to health department
- ☐ Refer to HIV counseling center (on-site or off-site)
- ☐ Refer to the health care provider or physician
- ☐ Refer to employee/occupational health or infection control
- ☐ Client is given a list of HIV resources for care
- ☐ Client arranges own follow-up care
- ☐ Other (specify): _____

c) For **NON-REACTIVE HIV rapid test results**:
What is the typical referral procedure for the client/patient tested? (Check **all** that apply.)

- ☐ No referral procedure
- ☐ Refer to HIV counseling center (on-site or off-site)
- ☐ Refer to the health care provider or physician
- ☐ Refer to employee/occupational health or infection control
- ☐ Other (please specify): _____

Counseling procedures for client/patients after having HIV Rapid testing

17. a) Does your facility/testing site provide onsite HIV counseling to clients/patients?

☐ Yes

☐ No

b) At your facility/testing site, who provides client/patient consultation for **initially reactive** (preliminary positive) HIV rapid testing results? (Check **all** that apply.)

☐ No counseling/consultation provided
☐ Physician
☐ Psychologist
☐ Counselor
☐ Other (please specify): _____
☐ Physician Assistant
☐ Nurse Practitioner
☐ RN/LPN
☐ Lab Tech

18. a) Is there a procedure at your facility to report reactive (preliminary positive) HIV rapid testing results to an outside entity for purposes of surveillance?

☐ No; **Go to Question 19**

☐ I do not know; **Go to Question 19**

☐ Yes.

☐ Yes, but only after the HIV rapid testing results are confirmed.

If "Yes", is reporting for surveillance mandatory? ☐ Yes ☐ No

b) What is the typical HIV rapid testing results reporting procedure for the purposes of HIV surveillance? (Check **one best** answer for each column.)

Preliminary positive/reactive results

☐ Report directly to Health Department
☐ Report to Health Department and physician/health care provider simultaneously
☐ Report to physician first; physician reports to Health Department
☐ Other (please specify): _____
☐ Not reported

HIV positive/confirmed results

☐ Report directly to Health Department
☐ Report to Health Dept. and phys./health care provider simultaneously
☐ Report to physician first; physician reports to Health Department
☐ Other (please specify): _____
☐ Not reported

18. c) To which health department(s) do you report HIV rapid testing results? (Check **all** that apply, for each column.)

Preliminary positive/reactive results	**HIV confirmed results**
☐ None	☐ None
☐ Local	☐ Local
☐ State/Provincial	☐ State/Provincial
☐ Federal surveillance system	☐ Federal surveillance system
☐ Ministry of Health/National health authority	☐ Ministry of Health/National health authority
☐ National Reference Laboratory	☐ National Reference Laboratory
☐ Other (specify): _____	☐ Other (specify): _____
☐ N/A – client is referred elsewhere for confirmatory testing (results unknown)	

19. a) How often does your facility/testing site run control material purchased separately (**positive or negative controls not included in the test kit**) when performing HIV rapid testing? (Check **all** that apply.)

☐ Never; **Go to Question 20**

☐ With each run, set or batch of patient tests

☐ By each new operator prior to testing client/patient specimens

☐ When opening new lot number of test kits

☐ When opening new box of test kits

☐ Whenever new shipment of test kits is received

At periodic intervals:

- ☐ With every shift change
- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ After every _____ (number) tests; please round to nearest whole number.
- ☐ Other _____

☐ When the temperature of the test kit storage area falls outside the acceptable range stated by the manufacturer

☐ When the temperature of the testing area falls outside the acceptable range stated by the manufacturer

b) What is the source of the above control material?

☐ A different HIV rapid test kit

☐ Purchased separately from same manufacturer as test kits

☐ Purchased separately from different manufacturer

☐ Prepared in-house

☐ Other (please specify): _____

20. a) In which external quality assurance (EQA) HIV rapid testing proficiency testing (PT) or performance evaluation (PE) program(s) does your facility participate? (Check **all** that apply.)

☐ None

☐ CDC Model Performance Evaluation Program (MPEP)

☐ College of American Pathologists (CAP)

☐ American Association of Bioanalysts (AAB)

☐ American Proficiency Institute (API)

☐ New York State Department of Health Proficiency Program

☐ Wisconsin State Laboratory of Hygiene Proficiency Testing Program

☐ Other State Program (please specify): _____

☐ Provincial Program (please specify): _____

☐ National Program (please specify): _____

☐ Other (please specify): _____

b) If you are a U.S. testing site, does your site have a government-issued CLIA certificate of waiver or another type of CLIA certificate that allows you to test? ☐ Yes ☐ No ☐ Not U.S. site

If yes, what type of CLIA certificate?

☐ Certificate of waiver ☐ Registration certificate

☐ Certificate of compliance ☐ Certificate for provider-performed microscopy

☐ Certificate of accreditation

c) Who performs proficiency testing or performance evaluation testing for HIV rapid testing in your testing site? (Check **all** that apply.)

☐ Medical Technologist/Clinical Laboratory Scientist

☐ Medical Technician

☐ Person with BS/BA in laboratory science

☐ HIV Counselor

☐ Person with Associate Degree

☐ Nurse/Nurse Practitioner

☐ Other: _____

21. a) Approximately how much does your facility charge to perform an HIV rapid test? (Round off to nearest U.S. Dollar. Put $0.00 in the box if there is no charge.)

☐ Typical charge: $ _____

☐ Variable fee schedule: _____

b) Do you accept insurance reimbursement only, so that there is no actual charge to the patient?

☐ Yes

☐ No

☐ N/A – all testing is free (no charge)

☐ I don't know

22. a) In your opinion, what are the advantages and disadvantages of HIV rapid testing for patient/clients, as compared to traditional, non-rapid HIV testing? (check all that apply)

☐ In comparison to traditional HIV tests, rapid tests increase clients' anxiety about HIV.

☐ It is easy to explain the rapid test to clients with low literacy skills.

☐ Clients may not feel prepared to receive HIV test results so quickly.

☐ Rapid testing allows more people to know their HIV status.

b) In your opinion, what are the administrative advantages and disadvantages of HIV rapid testing, as compared to traditional, non-rapid HIV testing? (check all that apply)

☐ My organization's administration encourages the use of rapid tests.

☐ Rapid tests have been easily integrated into my organization.

☐ Rapid test kits cost too much.

☐ It is expensive to start up a rapid testing program.

☐ It was difficult to design a rapid testing protocol for my organization.

☐ Other: _____

c) In your opinion, what are the advantages and disadvantages of HIV rapid testing when used in field settings such as mobile units/vans? (check all that apply)

☐ It is difficult to maintain client confidentiality in field settings.

☐ Test kit temperatures are hard to regulate in field settings.

☐ It is challenging to read rapid test results in field settings.

☐ Rapid HIV tests are more appropriate to use in the field than non-rapid HIV tests.

☐ My organization is unable to provide confirmatory tests to clients in the field.

Thank you for your participation!