



**Model Performance Evaluation Program (MPEP)
For HIV Rapid Testing**



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

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

WORKSHEET

To enter your results online, you will need:

- 1. Your MPEP I.D. number**
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Enter results at: <http://wwwn.cdc.gov/mpep/results/login.aspx>

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**If you have questions please contact:
the MPEP at 1-877-360-8502**

OR

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DEADLINE FOR SUBMISSION: Month xx, 2010

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

(Check **one** primary classification.)

- | | |
|---|--|
| <input type="checkbox"/> Ambulance | <input type="checkbox"/> Hospice |
| <input type="checkbox"/> Ambulatory surgery center | <input type="checkbox"/> Independent laboratory |
| <input type="checkbox"/> Ancillary test site | <input type="checkbox"/> Industrial |
| <input type="checkbox"/> Assisted living facility | <input type="checkbox"/> Insurance |
| <input type="checkbox"/> Blood/plasma donor center
(includes mobile units/vans used
for donor blood collection) | <input type="checkbox"/> Intermediate care facility |
| <input type="checkbox"/> Community based organization (CBO) | <input type="checkbox"/> Medical examiner/Coroner's office |
| <input type="checkbox"/> Correctional facility/prison | <input type="checkbox"/> Military (other than hospital) |
| <input type="checkbox"/> Drug use treatment center | <input type="checkbox"/> Mobile unit/van (other than blood donor donation) |
| <input type="checkbox"/> End stage renal disease dialysis | <input type="checkbox"/> Nursing facility/ skilled nursing |
| <input type="checkbox"/> Federally qualified health center | <input type="checkbox"/> Oral health |
| <input type="checkbox"/> Family planning center | <input type="checkbox"/> Pharmacy |
| Health dept: <input type="checkbox"/> State/Province <input type="checkbox"/> Other | <input type="checkbox"/> Physician office |
| <input type="checkbox"/> Health fair | <input type="checkbox"/> Other practitioner |
| <input type="checkbox"/> HIV Counseling & testing/Clinic site | <input type="checkbox"/> Public health laboratory |
| <input type="checkbox"/> HIV Counseling & testing/Field site | <input type="checkbox"/> Rural health care clinic |
| <input type="checkbox"/> HMO | <input type="checkbox"/> School/student health service |
| <input type="checkbox"/> Home health agency | <input type="checkbox"/> STD clinic |
| | <input type="checkbox"/> Tissue bank/repositories |

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

- | | | |
|--|---|---|
| <input type="checkbox"/> Admissions | <input type="checkbox"/> Blood Bank | <input type="checkbox"/> Central Laboratory |
| <input type="checkbox"/> Emergency Room | <input type="checkbox"/> Labor/Delivery | <input type="checkbox"/> Ward/Floor |
| <input type="checkbox"/> Employee health/infection control | <input type="checkbox"/> 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 2a
- No, please **answer 1d and return your survey.**

2. a) **What is your purpose for offering HIV rapid testing?** (Check **all** that apply.)

Screening for HIV infection:

- All patient/clients seen in our facility
- Initial screen for diagnosis
- Prior to specific facility procedure(s) (e.g. surgery or labor & delivery)
- 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 primary target population for your rapid testing program? (check only one)

- All persons between ages 13-64 years
- Gay/bisexual men or men who have sex with men
- Adult women (ages 25-44 years)
- Pregnant women
- Injection or intravenous drug users
- Adolescents (ages 10-24 years)
- Persons who have had unprotected vaginal or anal intercourse with more than one partner, exchange money or gifts for sex, or had unprotected sex with someone who might have HIV
- Persons who have been diagnosed or treated for STDs, hepatitis, or tuberculosis
- Homeless individuals
- African Americans
- Asian
- Native Americans
- Hispanic or Latino
- Other (please specify): _____
- NO specific target population _____

c) Approximately how many clients does your HIV rapid testing site serve per year?

d) Who PRIMARILY funds your testing facility? (Check all that apply)

- | | |
|---|---|
| <input type="checkbox"/> CDC funded | <input type="checkbox"/> Federal, other than CDC |
| <input type="checkbox"/> State/Province funded | <input type="checkbox"/> Private, non-profit |
| <input type="checkbox"/> County, city or other government
(non-federal, non-state) | <input type="checkbox"/> Private, for profit |
| | <input type="checkbox"/> Other (please specify):_____ |

3.

a) What is the average monthly testing volume of HIV rapid tests done at your testing site?

- | | |
|-----------------------------------|-----------------------------------|
| <input type="checkbox"/> < 5 | <input type="checkbox"/> 61 to 90 |
| <input type="checkbox"/> 6 to 30 | <input type="checkbox"/> 91 to 99 |
| <input type="checkbox"/> 31 to 60 | <input type="checkbox"/> ≥ 100 |

b) Of the specimens reported in 3b above, what percent (%) were initially reactive (preliminary positive)?

_____ % monthly average of initially reactive (preliminary positive) HIV rapid tests

c) Of the above (see answer 3c) initially reactive (preliminary positive) HIV rapid test results for which a confirmatory test was performed, how many were confirmed 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)

d) Does your facility also use EIA (enzyme-linked immunoassay) as an HIV screening test?

- No. Go to question # 4(a)
- Yes. **If yes, what percent (%) of patient/clients with reactive EIA results return for their confirmatory test results?**
 - 0 - 20%
 - 21 - 40%
 - 41 - 60%
 - 61 - 80%
 - 81 - 99%
 - 100%
- 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.
- Do not 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 patient results?

- Yes
 No

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

Abbott:	<input type="checkbox"/>	Determine HIV-1/2	Inverness Medical	<input type="checkbox"/>	Clearview HIV 1/2 Stat-Pak Clearview Complete HIV 1/2
Bio-Rad:	<input type="checkbox"/>	Multispot HIV-1/HIV-2	Genelabs	<input type="checkbox"/>	HIV-Spot
	<input type="checkbox"/>	Genie II HIV-1/HIV-2	Diagnostics:		
Chembio:	<input type="checkbox"/>	Sure Check HIV (previously Hema-Strip HIV-1/2)	J. Mitra & Co. Ltd:	<input type="checkbox"/>	HIV- TRIDOT
Chembio:	<input type="checkbox"/>	HIV 1/2 Stat-Pak(Cassette)	OraSure:	<input type="checkbox"/>	OraQuick ADVANCE Rapid HIV-1/2 Antibody test
	<input type="checkbox"/>	HIV 1/2 Stat-Pak(DIPSTICK)			
Efoora :	<input type="checkbox"/>	HIV Rapid Test	Trinity Biotech:	<input type="checkbox"/>	Capillus HIV-1/HIV-2
Fujirebio:	<input type="checkbox"/>	Serodia-HIV-1/2		<input type="checkbox"/>	SeroCard HIV
	<input type="checkbox"/>	Serodia-HIV		<input type="checkbox"/>	Uni-Gold HIV
	<input type="checkbox"/>	SDF HIV 1/2 PA			
MedMira:	<input type="checkbox"/>	MiraCare HIV Test		<input type="checkbox"/>	Uni-Gold Recombigen HIV
	<input type="checkbox"/>	Reveal G3 Rapid HIV-1 Antibody Test			
			Other: (please specify <i>both</i> manufacturer & kit)	<input type="checkbox"/>	_____

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

- Serum: fresh Plasma: fresh Whole blood: finger-stick
 frozen frozen venous

Oral fluid (from swabbing gums) Other (please specify): _____

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

ON-SITE = within our facility

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

- Specimens Collected ON-SITE
 Specimens Collected OFF-SITE
 Specimens Collected BOTH ON-SITE & OFF-SITE

b) Where do you perform your HIV rapid testing?

ON-SITE = within our facility

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

- Specimens tested ON-SITE
- Specimens tested OFF-SITE
- Specimens tested BOTH ON-SITE & OFF-SITE

7. c) 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) _____

d) 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 7e is ONLY for sites that **collect specimens off-site** for HIV rapid testing.

e) 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): _____

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

- | | |
|---|---|
| <input type="checkbox"/> Blood/plasma donor center
(includes mobile units/vans used
for donor blood collection) | <input type="checkbox"/> Correctional facility |
| <input type="checkbox"/> Drug use treatment center | <input type="checkbox"/> HMO |
| <input type="checkbox"/> Family planning center | <input type="checkbox"/> HIV Counseling and testing site |
| <input type="checkbox"/> Community Based Organization (CBO) | <input type="checkbox"/> STD Clinic |
| <input type="checkbox"/> Medical Examiner/Coroner's office | <input type="checkbox"/> Health Department |
| <input type="checkbox"/> Physician Office | <input type="checkbox"/> Independent Laboratory |
| | <input type="checkbox"/> Military (Other than Hospital) |
| | <input type="checkbox"/> Mobile Unit/ Van (other than blood donor donation) |
| <input type="checkbox"/> Other off-site collection site (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 routinely performs HIV rapid testing at your facility on a regular basis? (Check all that apply.)

- Clinical Laboratory Scientist/Specialist (CLS)
- HIV counselor
- Medical Technologist (MT)
- Medical Technician
- Medical Assistant
- Nurse (RN/LPN)
- Nurse Practitioner
- Phlebotomist
- Physician
- Physician Assistant
- Volunteer with formal medical/laboratory training
- Volunteer with no formal medical/laboratory training

Educational degrees:

- Associate Degree
- Bachelors of Science/Arts in in medical or laboratory science
- High School Graduate (with no post graduate education)
- MPH
- M.S. in medical or laboratory science
- Ph.D. in medical or laboratory science

- Other (please specify): _____

11. a) How many staff at your facility perform HIV rapid testing? _____

b) How many staff at your facility have received specific HIV rapid testing training? _____

c) What type of training is required for personnel performing HIV rapid testing in your facility/testing site? (Check all that apply.)

- No training required. *Go to Question 11e*
- Training by test kit manufacturer representative
- In-house training (conducted by your own facility personnel or institution)
- Training by State Health Department
- Course given by CDC or other federal agency
- Personnel must test and pass a proficiency/performance evaluation sample panel before testing patient/client specimens.
- Other type of training (please specify): _____

d) What is covered in the HIV RT training? (Check all that apply.)

- | | |
|--|---|
| <input type="checkbox"/> Reading package insert | <input type="checkbox"/> External quality assessment (performance evaluation or proficiency testing [PT]) |
| <input type="checkbox"/> Practice test | <input type="checkbox"/> Quality Control (QC) issues |
| <input type="checkbox"/> Standard operating procedures | <input type="checkbox"/> Other _____ |

e) 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.)

- 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.
 We do not have an SOP for HIV RT in our facility.
 I am not familiar with SOPs.
 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 12g (page 14)**

12. b) 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.

12.c) 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 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 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 Performed	One HIV Rapid Test	Two HIV rapid tests, simultaneously same test kit	Two HIV rapid tests, simultaneously different kits	2 nd /3 rd HIV rapid test same test kit	2 nd /3 rd 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 facility	Other test* other facility
1st step	[X]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
2nd step	[]	[]	[]	[]	[X]	[]	[]	[]	[]	[]	[]	[]	[]
3rd step	[]	[]	[]	[]	[]	[]	[]	[]	[X]	[]	[]	[]	[]
4th step	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
5th step	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]

*Other HIV test, please specify: _____

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

*Other HIV test, please specify: _____

12.d) 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	2 nd /3 rd HIV rapid test same test kit	2 nd /3 rd 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	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]

*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	2 nd /3 rd HIV rapid test same test kit	2 nd /3 rd 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. e) **What specimen type do you use to confirm initially reactive HIV rapid test results? (Check all that apply.)**

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

f) **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 (12g – 12i) refer to specimens which give an INITIALLY negative or indeterminate rapid test result.

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

- Yes
- No, **Go to question 13.**

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

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

12. i) 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

 3rd HIV rapid test

 EIA (Enzyme-linked Immuno Assay)

 Other 1st HIV test (please specify): _____

 Other 2nd HIV test (please specify): _____

 Other 3rd HIV test (please specify): _____

13. a) What is the turnaround time for obtaining an HIV rapid test result? (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) What is the amount of time for the total testing process (sample collection, testing and reporting results to th patient/client)? (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/patient 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/patient is given a list of HIV resources for care
- Client/patient 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 specific 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/patient 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/patient is given a list of HIV resources for care
- Client/patient 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 Assistant

Physician Nurse Practitioner

Psychologist RN/LPN

Counselor Lab Tech

Other (please specify): _____

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

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

HIV confirmed results

- None
- Local
- State/Provincial
- Federal surveillance system
- Ministry of Health/National health authority
- National Reference Laboratory
- Other (specify): _____

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? (Check all that apply.)**

- Packaged in the HIV rapid test kit
- Purchased separately from the same manufacturer as test kits
- Purchased separately from a 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.)

- American Association of Bioanalysts (AAB)
- American Proficiency Institute (API)
- CDC Model Performance Evaluation Program (MPEP)
- College of American Pathologists (CAP)
- National Program (please specify): _____
- New York State Department of Health Proficiency Program
- Other State Program (please specify): _____
- Provincial Program (please specify): _____
- Wisconsin State Laboratory of Hygiene Proficiency Testing Program
- Other (please specify): _____
- None

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? (Check only **one**)

- 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 payment for the HIV rapid test by the Client/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 client/patients, as compared to traditional, non-rapid HIV testing? (Check all that apply.)**
advantages:

It is easy to explain the rapid test to client/patients with low literacy skills.

Rapid testing allows more people to know their HIV status.

Other advantages: _____

disadvantages:

In comparison to traditional HIV tests, rapid tests increase client/patients' anxiety about HIV.

Client/patients may not feel prepared to receive HIV test results so quickly.

Other disadvantages: _____

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.)**
advantages:

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

Rapid tests have been easily integrated into my organization.

Other advantages: _____

disadvantages:

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 disadvantages: _____

22c) 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.)
advantages:

- Rapid HIV tests are more appropriate to use in the field than non-rapid HIV tests.
- Other advantages: _____

disadvantages:

- It is difficult to maintain client/patient 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.
- My organization is unable to provide confirmatory tests to client/patients in the field.
- Other disadvantages: _____

Thank you for your participation!