September 2009

HIV Rapid Testing Form EZ
WORKSHEET

Form Approved
OMB No. 0920-0595
Exp. Date. 03/31/2010

Report your results Online (password required) at:

http://wwwn.cdc.gov/mpep/results/login.aspx

MPEP number: _____ (you will need this to enter your results online)

DEADLINE for submission October 26, 2009

Please Note: **Test procedures on these samples should be performed in the same manner as the test procedures used for patient specimens.**

WARNING: The HIV-1 antibody-positive samples in this panel have been heated at 56°C for 60 minutes to inactivate bloodborne viruses. Because no inactivation method can offer complete assurance that infectious agents are absent, these samples should be handled as if potentially infectious. Follow the U.S. Department of Labor Occupational Health and Safety Administration (OSHA) standards for bloodborne pathogens (29CFR Part 1910),

Person completing this form: Name_____

Title (circle ALL that apply)

MT CLS MLT CLT RN/LPN PhD MD Volunteer Counselor

Other (please specify)_____

Accreditation/license of above person, if applicable (circle ALL that apply)

ASCP NCA HEW OTHER (please specify)_____

NOTE: ***If more than one HIV rapid test kit is used, print a copy of this form for each test kit.***

If you have questions regarding online submission, please contact the MPEP at: 1-877-360-8502

or contact the HIV Rapid Testing Project Coordinator Leigh Vaughan at: 404-498-2246 or email LVaughan@cdc.gov

Use this worksheet as an aid to record results for the rapid HIV test kit used in testing the Performance Sample Panel.

1. Rapid HIV test kit used in testing the Performance Sample Panel

Check ONE box (see below) corresponding to Manufacturer and HIV Rapid Test Kit used

PLEASE NOTE: *If more than one HIV Rapid Test Kit is used, a* ***separate online*** *form for each test kit is required.*

Abbott:	☐	Determine HIV-1/2
Bio-Rad:	☐	Multispot HIV-1/HIV-2
	☐	Genie II HIV-1/HIV-2
Chembio:	☐	Sure Check HIV (previously Hema-Strip HIV-1/2)
Chembio:		***NON-U.S. labs only!***
	☐	HIV 1/2 Stat-Pak(**Cassette**)
	☐	HIV 1/2 Stat-Pak(**DIPSTICK**)
Efoora :	☐	HIV Rapid Test
Fujirebio:	☐	Serodia-HIV-1/2
	☐	Serodia-HIV
	☐	SDF HIV 1/2 PA
MedMira:	☐	MiraCare HIV Test
	☐	Reveal G3 Rapid HIV-1 Antibody Test

Inverness Medical	☐	Clearview HIV 1/2 Stat-Pak
	☐	Clearview Complete HIV 1/2
Genelabs Diagnostics:	☐	HIV-Spot
J. Mitra & Co. Ltd:	☐	HIV- TRIDOT
OraSure:	☐	OraQuick **ADVANCE** Rapid HIV-1/2 Antibody test
Trinity Biotech:	☐	Capillus HIV-1/HIV-2
	☐	SeroCard HIV
	☐	Uni-Gold HIV
	☐	Uni-Gold Recombigen HIV
Other: (please specify ***both***	☐	_____ ___ _____

Please specify: ➡ Test Kit Lot#_____ Test Kit Version (if applicable):_____

For the rapid HIV test kit listed above, please indicate:

a) the specimen type(s) normally tested in your facility (check all that apply)

Serum: ☐ Fresh ☐ Frozen

Plasma: ☐ Fresh ☐ Frozen

Whole Blood: ☐ Finger Stick ☐ Venous

☐ Oral fluid (from swabbing gums)

☐ Other (please specify)_____

b) for what purpose do you use the above HIV rapid test kit

☐ HIV initial testing
(e.g. for patients/clients, needlestick, source patient)

☐ non-clinical HIV testing (e.g. research, training, etc.)
☐ to determine HIV-1 versus HIV-2 reactivity
☐ confirmation of a prior reactive HIV test

3. PERFORMANCE PANEL RESULTS Date of testing:_____

SAMPLE CODE (from sample vial) Letter	#	FINAL RESULT/INTERPRETATION REACTIVE	NONREACTIVE	INDETERMINATE	INVALID	Comments
		☐	☐	☐	☐	_____
		☐	☐	☐	☐	_____
		☐	☐	☐	☐	_____
		☐	☐	☐	☐	_____
		☐	☐	☐	☐	_____
		☐	☐	☐	☐	_____

4. For the kit specified in question #1, does your facility normally run Quality Control (QC) samples (positive and/or negative controls) when performing HIV rapid testing?

☐ No. Thank you for your participation. (***go to question #5***)

☐ Yes. Please complete the following section:

(a) Please indicate the ***Source*** of your QC material(s) for the kit specified in question #1:

Same Manufacturer as Test Kit:
QC material packaged in test kit (included as part of test kit order)
☐ HIV-1 Positive Control Lot#_____ ☐ HIV-2 Positive Control Lot#_____
☐ Negative Control Lot#_____

Same Manufacturer, but QC material ORDERED SEPARATELY (not included with test kit)
☐ HIV-1 Positive Control Lot#_____ ☐ HIV-2 Positive Control Lot#_____
☐ Negative Control Lot#_____

Other Commercial Source (please specify):
Manufacturer:_____
☐ HIV-1 Positive Control Lot#_____ ☐ HIV-2 Positive Control Lot#_____
☐ Negative Control Lot#_____

In-House (prepared by own facility):
☐ HIV-1 Positive Control Prep Date_____ ☐ HIV-2 Positive Control Prep Date_____
☐ Negative Control Prep Date_____

(b) ***Description*** of your QC material (for the kit specified in question #1):

☐☐ **Fill in boxes with numbers (see below) corresponding to type of material used**

01. Serum/Plasma
02. Whole Blood
03. Other (e.g. urine, culture media, etc.) Please specify_____

(c) ***Frequency of Use*** of QC material for the kit specified in question #1 (check ALL that apply)

☐ With each Run/Set/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:
☐ Every shift ☐ Daily ☐ Weekly ☐ Monthly
☐ After every ____ (number) tests ☐ Other _____

Continued on back

5. For the rapid HIV test kit you specified in question #1, what confirmatory test(s) does your facility require to confirm a preliminary positive (REACTIVE) HIV Rapid Test result?

(a) ☐ No confirmatory testing required for the kit specified in question #1. ***Please submit your results***.

(b) Yes, confirmatory testing ***is*** required (check all that apply below):

Confirmatory test(s) performed AT OUR FACILITY (test done in-house)

- ☐ 2ND rapid test, same test kit
- ☐ 2ND rapid test, different test kit (***specify*** manufacturer & kit_____
- ☐ Enzyme Immunoassay (EIA)
- ☐ Western blot (WB)
- ☐ Immunofluorescence assay (IFA)
- ☐ Other ***test*** (please specify): _____

Confirmatory test(s) performed at another facility (test sent out)

- ☐ 2ND rapid test, same test kit
- ☐ 2ND rapid test, different test kit (***specify*** manufacturer & kit_____
- ☐ Enzyme Immunoassay (EIA)
- ☐ Western blot (WB)
- ☐ Immunofluorescence assay (IFA)
- ☐ Other ***test*** (please specify): _____

PLEASE DO NOT MAIL THIS FORM!!

The MPEP is currently ONLY accepting results online.
Please submit your results at:

http://wwwn.cdc.gov/mpep/results/login.aspx

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

OR

Leigh Vaughan, HIV-RT MPEP Project Coordinator
email: LVaughan@cdc.gov
phone:404-498-2246