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

OMB Form No. 0920-0274
Expiration Date: 10/31/2007

HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) ANTIBODY TESTING

WARNING ☐☐☐☐☐

Because no test method can offer complete assurance that HIV-1, HTLV-I/II, hepatitis B and C viruses, or other infectious agents are absent, these samples should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control and Prevention (CDC) National Institutes of Health (NIH) manual entitled, "Biosafety in Microbiological and Biomedical Laboratories," 1999, 4th edition, HHS publication No. (CDC) 93-8395, pages 8-14 and pages 19-26 and in the Occupational Safety and Health Administration (OSHA) Final Rule on Occupational Exposure to Bloodborne Pathogens published December 6, 1991 (Federal Register Volume 56, Number 235, pages 64175-64182).
The HIV-1 antibody-positive samples in this panel have been heated at 56□C for 60 minutes to inactivate bloodborne viruses including HIV-1, human T-lymphotropic virus types I and II (HTLV-I/II), and hepatitis B and C viruses. The HIV-1 antibody-negative samples have not been heated at 56□C for 60 minutes.

MPEP Laboratory Identification No.: *(Number can be found on your sample box)*

Laboratory Name:_____

Shipping address of Laboratory (address to which samples should be sent):
Street:_____

City:_____ Country:_____

State/Province:_____ ZIP /Postal Code:_____

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

E-mail Address: _____

☐ Check if this address differs from that on the shipping label.

Person completing form:

Name/Title:_____

Results Forms should be received at CDC by February 16, 2007, for results to be included in the final aggregate report. DO NOT FAX RESULTS.

FOR INTERNAL USE ONLY

FORM NUMBER ☐☐ SHIPMENT NUMBER ☐☐☐☐

SAMPLE PANEL CODE ☐ MPEP NUMBER ☐☐☐☐☐

☐☐ ☐☐ ☐☐☐

☐

GENERAL INSTRUCTIONS

PLEASE READ ALL INSTRUCTION SHEETS COMPLETELY BEFORE PROCEEDING WITH ANY SAMPLE TESTING.

RECORD ALL INFORMATION LEGIBLY AND WITHIN THE APPROPRIATE SPACES.
(RECORD FROM LEFT TO RIGHT)

Perform the test procedure(s) on these samples in the same manner in which your laboratory tests patient specimens. DO NOT HEAT INACTIVATE ANY OF THESE SAMPLES.

If you would like to record additional test control values and results, you may photocopy the appropriate blank Laboratory Results page(s) for any procedure before entering results.

1. Enter your Model Performance Evaluation Program (MPEP) laboratory identification number in the boxes provided at the top of each results form in this booklet. **Your MPEP number can be found on the identification label affixed to the panel box containing your samples.**

2. If you do not test the samples by one of the procedures for which results forms have been provided, enter the appropriate Nonreporting Code (see below) on the results form in the spaces provided and return to the Centers for Disease Control and Prevention (CDC). Do not use a Nonreporting Code in any field other than the **NONREPORTING CODE BOX** at the top of each Test Type results form. Do not use a Nonreporting Code if **ANY** sample test results are reported for a particular Test Type.

NONREPORTING CODES

CODE	*REASONS FOR NOT REPORTING RESULTS*
T	Test not performed in this laboratory
L	Samples lost or destroyed in laboratory
R	Test reagents not available
S	Patient specimens not currently being tested in this laboratory
D	Not interested in participating; please delete my laboratory from the HIV-1 program (please specify reason for deleting on results form)
Q	Insufficient sample volume to perform test
G	Other (please specify on results form)

For test methods **NOT** performed in your laboratory, please enter a nonreporting code in the appropriate section. For example, if you do not perform IFA testing, enter “T” in the IFA results section.

INSTRUCTIONS FOR *REAGENTS/CONTROLS/DILUENTS*

1. Enter the Manufacturer code, appropriate to the procedure used, in the blocks provided (Manufacturer Codes appropriate for each test procedure are given in the Specific Instructions for each test procedure). For **code 99**, also enter the manufacturer's name. Enter the lot number of the reagents and controls used.

2. Enter the NAME of the test kit and/or other reagents, appropriate to the procedure used, in the spaces provided.

3. Place an "X" in the appropriate box for the sample diluent or buffer that is used in the test(s) you perform.

INSTRUCTIONS FOR *SURVEY SAMPLES*

1. Enter in the spaces provided the complete sample code (two-digit code) exactly as it appears on each vial, (e.g., [A][1], [A][6]; [B][1], [B][6]).

2. For each sample, circle an Interpretation Code indicating your interpretation of the test results you are reporting. Interpretation Codes appropriate for each test procedure are found in the Specific Instructions sections for each test.

3. **NOTE:** If you need assistance in completing these forms, please call the CDC Model Performance Evaluation Program at **(404) 718-1006**.

Please Note:
If you have entered and submitted your results online,
please DO NOT return this booklet!

An addressed envelope has been provided for you to mail your completed results form to CDC. If you use the envelope provided, please mail the form so that it reaches CDC by the deadline indicated on the first page. If you use your own envelope, please send your results form to:

Model Performance Evaluation Program
Division of Laboratory Systems
Coordinating Center for Infectious Diseases
Centers for Disease Control and Prevention
Mail Stop G-23
1600 Clifton Road, NE
Atlanta, GA 30333

EIA . . . EIA . . . EIA . . .
EIA . . .

SPECIFIC INSTRUCTIONS FOR ENZYME IMMUNOASSAY (EIA)

1. Enter the name of the test kit in the spaces provided; for code 99, also enter the manufacturer's name.

2. If you use a combination **HIV-1/HIV-2 EIA kit**, the HIV-2 test control data can be recorded in the spaces provided on the EIA results form for the "Weakly Reactive Control."

3. Record all results as absorbance (optical density) units (e.g. 1 7 0 6 8, 1 1 7 5 8). However, if your spectrophotometer records the absorbance of a sample as "OVER" or "****", use the highest value limit for your instrument for the EIA test results for that sample.

4. For the initial and repeat test controls, record the "mean" absorbance values in the "Initial EIA" and the "Repeat EIA" portions, respectively, of the "Test Controls" section of the results form.

5. If you routinely test in duplicate in the initial EIA, record both of the absorbance (optical density) values in the spaces provided. If you routinely perform a repeat EIA on your samples, record those results under "Repeat EIA," and if you perform repeat tests in duplicate, record both of the absorbance values in the spaces provided.

6. For each sample, circle a code (see Interpretation Codes below) for the INITIAL EIA interpretation, and another for the FINAL EIA interpretation. NOTE: if you do not perform a repeat EIA, and your initial EIA interpretation can be considered as your final EIA interpretation, then circle a FINAL EIA interpretation.

7. **NOTE:** If your laboratory uses Quality Control material in addition to the controls that are included in manufactured EIA test kits, please complete the Quality Control Testing section of the EIA result form.

Please Note: Abbott AxSYM, Abbott IMx, Abbott PRISM, Abbott HIV 1/2 gO, bioMérieux VIDAS HIV DUO, and Ortho Vitros ECi AntiHIV 1+2 have been moved to the EIA portion of the result booklet. **Record results for these tests on the EIA results page** (page **6**).

EIA…(Cont'd)

Manufacturer Codes for EIA

CODE	MANUFACTURER	CODE	MANUFACTURER
21	Abbott HIV-1/HIV-2 (rDNA)	70	Bio-Rad Genscreen Plus HIV Ag-Ab
06	Abbott AxSYM HIV-1/2 gO	32	Dade Behring Enzygnost Anti-HIV-1/2 Plus
30	Abbott HIV-1/HIV-2 3rd Generation Plus	71	Dade Behring Enzygnost HIV Integral
55	Abbott HIV1/2 gO	53	Genetic Systems HIV-2 EIA
40	Abbott IMx	37	Murex Ag/Ab Combination
17	Abbott PRISM	62	Murex HIV-1.2.O
18	Adaltis Detect HIV	56	Ortho Vitros ECi Anti-HIV-1+2
83	bioMérieux Vironostika HIV-1	48	Ortho HIV-1/HIV-2 Ab-Capture
36	bioMérieux Vironostika Uni-form II Ag/Ab	19	Trinity Biotech Recombigen HIV-1/HIV-2
31	bioMérieux Vironostika Uni-form II Plus O	01	Vironostika HIV-1 Plus O
49	bioMérieux VIDAS HIV DUO Ultra Ag/Ab	97	In House (prepared by your laboratory)
51	Bio-Rad Genetic Systems HIV-1/HIV-2 Peptide	98	Noncommerical (e.g., supplied by the State Laboratory)
08	Bio-Rad Genetic Systems HIV-1/2 Plus O		
44	Bio-Rad Genetic Systems rLAV	99	Other (specify on the result form)
54	Bio-Rad Genscreen HIV-1/2		

INITIAL AND FINAL EIA TEST INTERPRETATION CODES

CODE	*INITIAL* EIA	CODE	*FINAL* EIA
R	Reactive	R	Reactive
E	Equivocal	N	Nonreactive
N	Nonreactive		

MPEP No. ☐☐☐☐

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

ENZYME IMMUNOASSAY LABORATORY RESULTS FORM

NONREPORTING CODE (Specify reason if code "D" or "G"): _____

INITIAL EIA

REAGENTS

Manufacturer _____ Mfr. Code ☐☐

Lot #_____

Kit Name_____

DILUENTS

Kit ☐

In House (please specify): ☐
_____

Other (please specify): ☐
_____

TEST CONTROLS

Reactive
Manufacturer _____ Mfr. Code ☐☐

Lot #_____

Weakly Reactive
Manufacturer _____ Mfr. Code ☐☐

Lot #_____

Nonreactive
Manufacturer _____ Mfr. Code ☐☐

Lot # _____

REPEAT EIA

REAGENTS

Manufacturer _____ Mfr. Code ☐☐

Lot #_____

Kit Name_____

DILUENTS

Kit ☐

In House (please specify): ☐
_____

Other (please specify): ☐
_____

TEST CONTROLS

Reactive
Manufacturer _____ Mfr. Code ☐☐

Lot #_____

Weakly Reactive
Manufacturer _____ Mfr. Code ☐☐

Lot #_____

Nonreactive Mfr. Code

Manufacturer _____ ☐☐

Lot # _____

TEST CONTROLS

INITIAL EIA	***ABSORBANCE***	***REPEAT EIA***	***ABSORBANCE***
Reactive (Mean)	☐☐.☐☐☐	Reactive (Mean)	☐☐.☐☐☐
Weakly Reactive (Mean)	☐☐.☐☐☐	Weakly Reactive (Mean)	☐☐.☐☐☐
Nonreactive (Mean)	☐☐.☐☐☐	Nonreactive (Mean)	☐☐.☐☐☐
Cutoff Value	☐☐.☐☐☐	Cutoff Value	☐☐.☐☐☐

SURVEY SAMPLES

	INITIAL EIA		***INITIAL* EIA**	**REPEAT EIA**		***FINAL* EIA**
Sample Code	**Absorbance 1**	**Absorbance 2**	**Interpretation (Circle One)**	**Absorbance 1**	**Absorbance 2**	**Interpretation (Circle One)**
☐☐	☐☐.☐☐☐	☐☐.☐☐☐	R E N	☐☐.☐☐☐	☐☐.☐☐☐	R N
☐☐	☐☐.☐☐☐	☐☐.☐☐☐	R E N	☐☐.☐☐☐	☐☐.☐☐☐	R N
☐☐	☐☐.☐☐☐	☐☐.☐☐☐	R E N	☐☐.☐☐☐	☐☐.☐☐☐	R N
☐☐	☐☐.☐☐☐	☐☐.☐☐☐	R E N	☐☐.☐☐☐	☐☐.☐☐☐	R N
☐☐	☐☐.☐☐☐	☐☐.☐☐☐	R E N	☐☐.☐☐☐	☐☐.☐☐☐	R N
☐☐	☐☐.☐☐☐	☐☐.☐☐☐	R E N	☐☐.☐☐☐	☐☐.☐☐☐	R N

1. What supplemental/confirmatory test(s) do you normally run for repeatedly reactive results obtained using the EIA test kit listed in the Repeat EIA section (or Initial EIA if no Repeat EIA is performed) on the opposite page? Check all that apply.

☐ A. Supplemental/Confirmatory test not run in our laboratory
☐ B. Western blot (WB)
☐ C. Immunofluoresence Assay (IFA)
☐ D. Gen-Probe Aptima HIV-1 RNA Qualitative Assay
☐ E. HIV-1 or HIV-1/2 Rapid Test
☐ F. Send to reference laboratory
☐ G. Other, specify______________________________

2. If you indicated "Gen-Probe Aptima HIV-1 RNA Qualitative Assay" in question 1, for what other purpose(s) do you use this assay? Check all that apply.

☐ A. Only use as Supplemental/Confirmatory test for EIA repeat reactive samples
☐ B. Use as method for screening blood or plasma donors
☐ C. Use to aid in diagnosis of acute or primary HIV infection
☐ D. Other use ____________________________________

3. Please indicate your normal testing sequence for samples to be tested for HIV antibody by placing a number in the box corresponding to the step (1st, 2nd, 3rd, etc.) of the testing algorithm. If two assays occur simultaneously in the testing sequence (e.g., WB and IFA), give both assays the same number.

- ☐ Initial EIA in singlicate
- ☐ Initial EIA in duplicate
- ☐ Repeat EIA, if initial EIA is reactive
- ☐ WB
- ☐ IFA
- ☐ Gen-Probe Aptima HIV-1 RNA Qualitative Assay
- ☐ HIV-1 or HIV-1/2 Rapid Test

[ ] No, we are not planning to change or add EIA test kits.

In performing EIA, does your laboratory use quality control material in addition to controls that are included in manufactured EIA test kits?

NO☐ YES☐ If yes, please complete the following section.

QUALITY CONTROL TESTING

DO NOT *describe the positive and negative controls provided in the EIA test kit.*

Source of Quality Control (QC) Material

☐ In House (prepared by own laboratory)

☐ Commercial Manufacturer (please specify):_____

Frequency of Use of QC Material

☐ With each EIA plate ☐ With each set/run of EIA plates

☐ With each new EIA kit lot ☐ Daily with the first EIA run

☐ Other (please specify):_____

Description of QC Material (Please mark only **ONE** box**)**

☐ Single serum/plasma (i.e., just **ONE** reactivity material is used for either each EIA plate, for each set/run of EIA plates, for each new EIA kit lot, or daily with the first EIA run.)

☐ Multiple sera/plasma (i.e., **MORE THAN ONE** reactivity material is used for either each EIA plate, for each set/run of EIA plates, for each new EIA kit lot, or daily with the first EIA run.)

☐ Other (please specify):_____

Reactivity of QC Material

(Note: If single serum/plasma was checked above, only <u>one</u> box should be checked here. If multiple sera/plasma was checked above, then <u>one or more</u> boxes can be checked here.)

☐ Strongly positive

☐ Weakly positive

☐ Negative

☐ All of the above

☐ Other (please specify):_____

WB . . . WB . . . WB . . . WB . . . WB . . .

SPECIFIC INSTRUCTIONS FOR WESTERN BLOT (WB)

1. Enter the name of the test kit or individual reagents in the spaces provided; for code 99, also enter the manufacturer's name. Please indicate with an "X" in the appropriate box the type of conjugate used.

2. Mark the appropriate box(es) with an "X" to indicate the molecular weight of the protein(s) detected **that have a band intensity equal to or greater than the weak positive control provided in the test kit and are used in interpreting your WB results**. For those protein(s) detected **that have a band intensity less than the weak positive control and are not used in interpreting your WB results, please mark with a "W" (indicating +/- reactivity).** If additional proteins are detected, please indicate their molecular weights in the spaces provided under "Other," for example:

17/18	24	31/32	41	51	55	65/66	120	160	**OTHER**
X	X	X	X						38 110 ___ ___

3. **NOTE: If your laboratory uses Quality Control material, in addition to the controls that are included in manufactured WB test kits, please complete the Quality Control Testing Section of the WB result form.**

WESTERN BLOT MANUFACTURER CODES

CODE	*MANUFACTURER*
44	Bio-Rad Genetic Systems HIV-1
84	Bio-Rad New LAV Blot 1
09	Cambridge Biotech (Biotin-Avidin)
28	Genelabs Diagnostics HIV-1 Blot
97	In House (prepared by own laboratory)
98	Noncommercial (e.g., supplied by the state laboratory)
99	Other (**Specify on results form**)

Note: *Report any Line Immunoassay (e.g., INNO-LIA, Liatek) or Dipstick test results on the "Other" procedures results form, pages 17-20.*

WESTERN BLOT INTERPRETATION CODES

CODE	***INTERPRETATION***
R	Reactive
I	Indeterminate
N	Nonreactive

MPEP No. ☐☐☐☐

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

WESTERN BLOT LABORATORY RESULTS FORM

NONREPORTING CODE ☐ (Specify reason if code "D" or G"):_____

Note: *Report any Line Immunoassay (e.g., INNO-LIA, Liatek) or Dipstick test results on the "Other" procedures results form, pages 17-20.*

REAGENTS

KIT (OR PREBLOTTED STRIPS)

Mfr.Code

Manufacturer_____ ☐☐

Lot #_____

Kit Name_____

CONJUGATE

Mfr.Code

Manufacturer_____ ☐☐

Lot #_____

(If conjugate is contained in a kit, use **ONLY** the **kit lot number**.)

TEST CONTROLS

Reactive

Mfr.Code

Manufacturer_____ ☐☐

Lot #_____

Weakly Reactive

Mfr.Code

Manufacturer_____ ☐☐

Lot #_____

Nonreactive

Mfr Code

Manufacturer_____ ☐☐

Lot #_____

BLOTTING BUFFERS

Kit _____ ☐

In-House _____ ☐

Other (please specify) _____ ☐

TEST CONTROLS

Molecular Weight of Proteins Detected

REACTIVE CONTROL

17/18	24	31/32	41	51	55	65/66	120	160	OTHER
☐	☐	☐	☐	☐	☐	☐	☐	☐	_____ _____ _____

WEAKLY REACTIVE CONTROL

☐	☐	☐	☐	☐	☐	☐	☐	☐	_____ _____ _____

NONREACTIVE CONTROL

☐	☐	☐	☐	☐	☐	☐	☐	☐	_____ _____ _____

SURVEY SAMPLES

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.....

SURVEY SAMPLES

Sample Code	***Molecular Weight of Proteins Detected*** 17/18 24 31/32 41 51 55 65/66 120 160	**OTHER**	**Interpretation (Circle One)**
☐☐	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	____ ____ ____ ____	R I N
☐☐	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	____ ____ ____ _____	
	R I N		
☐☐	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	____ ____ ____ ____	R I N
☐☐	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	____ ____ ____ ____	R I N
☐☐	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	____ ____ ____ _____	R I N
☐☐	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	____ ____ ____ _____	R I N

Western Blot Interpretive Criteria

☐ Please indicate in this box the **letter** that corresponds to the organization whose criteria you used to interpret these HIV-1 Western blot results.

A. Association of Public Health Laboratories/Centers for Disease Control and Prevention (APHL/CDC)
B. Consortium for Retrovirus Serology Standardization (CRSS)
C. World Health Organization (WHO)
D. OTHER (please specify):_____

In performing WB, does your laboratory use quality control material in addition to controls that are included in manufactured WB test kits?

NO YES If yes, please complete the following section.

QUALITY CONTROL TESTING

DO NOT *describe the positive and negative controls provided in the WB test kit.*

Source of Quality Control (QC) Material

☐ In House (prepared by own laboratory)
☐ Commercial Manufacturer (please specify):_____

Frequency of Use of QC Material

☐ With each tray of strips
☐ With each new WB kit lot
☐ With each set/run of strips
☐ Daily with the first WB run
☐ Other (please specify):_____

Description of QC Material (Please mark only **ONE** box**)**

☐ Single serum/plasma (i.e., just **ONE** reactivity material is used for either each tray of strips, for each set/run of strips, for each new WB kit lot, or daily with the first WB run.)
☐ Multiple sera/plasma (i.e., **MORE THAN ONE** reactivity material is used for either each tray of strips, for each set/run of strips, for each new WB kit lot, or daily with the first WB run.)
☐ Other (please specify):_____

Reactivity of QC Material

(Note: If single serum/plasma was checked above, only one box should be checked here. If multiple sera/plasma was checked above, then one or more boxes can be checked here.)

☐ Strongly positive ☐ Weakly positive ☐ Negative
☐ All of the above
☐ Other (please specify): _____

IFA . . . IFA . . . IFA . . . IFA . . . IFA . . .

SPECIFIC INSTRUCTIONS FOR IMMUNOFLUORESCENCE ASSAY (IFA)

1. If you do not use a commercial kit for IFA, enter the names, manufacturer, and lot numbers of the reagents and controls used.

2. Circle the intensity of fluorescence; e.g., 0, 1+, 2+, 3+, 4+, for both the infected and uninfected cells for test controls and survey samples.

3. **NOTE: If your laboratory uses Quality Control material <u>in addition</u> to the controls that are included in manufactured IFA test kits, please complete the <u>Quality Control Testing Section</u> of the IFA result form.**

IFA MANUFACTURER CODES

CODE	MANUFACTURER	CODE	MANUFACTURER
92	Sanochemia Fluorognost	98	Noncommercial (e.g., supplied by the State Laboratory)
97	In House (prepared by own laboratory)	99	Other (please specify on results form)

IFA INTERPRETATION CODES

CODE	***INTERPRETATION***
R	Reactive
I	Indeterminate
N	Nonreactive

MPEP No. ☐☐☐☐☐

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

IMMUNOFLUORESCENCE ASSAY LABORATORY RESULTS FORM

NONREPORTING CODE ☐ (Specify reason if code "D" or "G"):_____

REAGENTS

KIT

Mfr.Code

Manufacturer_____ ☐☐

Lot #_____

Kit Name_____

CONJUGATE

Mfr.Code

Manufacturer_____ ☐☐

Lot #_____

CELL LINE

Mfr.Code

Manufacturer_____ ☐☐

Name of
Cell Line _____

Lot #_____

TEST CONTROLS

Reactive

Mfr.Code

Manufacturer_____ ☐☐

Lot
#_____

Weakly Reactive

Mfr.Code

Manufacturer_____ ☐☐

Lot
#_____

Nonreactive

Mfr.Code

Manufacturer_____ ☐☐

Lot
#_____

DILUENTS

Kit ☐

In House (please specify):

_____ ☐

Other (please specify):

☐

TEST CONTROLS

FLUORESCENCE INTENSITY

	INFECTED CELLS (Circle One)	UNINFECTED CELLS (Circle One)
REACTIVE CONTROL	0 1+ 2+ 3+ 4+	0 1+ 2+ 3+ 4+
WEAKLY REACTIVE CONTROL	0 1+ 2+ 3+ 4+	0 1+ 2+ 3+ 4+
NONREACTIVE CONTROL	0 1+ 2+ 3+ 4+	0 1+ 2+ 3+ 4+

SURVEY SAMPLES

Sample Code	**INFECTED CELLS** (Circle One)	**UNINFECTED CELLS** (Circle One)	**Interpretation** (Circle One)
☐☐	0 1+ 2+ 3+ 4+	0 1+ 2+ 3+ 4+	R I N
☐☐	0 1+ 2+ 3+ 4+	0 1+ 2+ 3+ 4+	R I N
☐☐	0 1+ 2+ 3+ 4+	0 1+ 2+ 3+ 4+	R I N
☐☐	0 1+ 2+ 3+ 4+	0 1+ 2+ 3+ 4+	R I N
☐☐	0 1+ 2+ 3+ 4+	0 1+ 2+ 3+ 4+	R I N
☐☐	0 1+ 2+ 3+ 4+	0 1+ 2+ 3+ 4+	R I N

In performing IFA does your laboratory use quality control material in addition to controls that are included in manufactured IFA test kits?

NO ☐ YES ☐ If "YES", please complete the following section.

QUALITY CONTROL TESTING

***DO NOT** describe the positive and negative controls provided in the IFA test kit.*

Source of Quality Control (QC) Material

☐ In House (prepared by own laboratory)

☐ Commercial Manufacturer (please specify):_____

Frequency of Use of QC Material

☐ With each IFA slide ☐ With each set/run of IFA slides

☐ With each new IFA kit lot ☐ Daily with the first IFA run

☐ Other (please specify):_____

Description of QC Material (Please mark only **ONE** box**)**

☐ Single serum/plasma (i.e., just **ONE** reactivity material is used for either each IFA slide, for each set/run of IFA slides, for each new IFA kit lot, or daily with the first IFA run.)

☐ Multiple sera/plasma (i.e., **MORE THAN ONE** reactivity material is used for either each IFA slide, for each set/run of IFA slides, for each new IFA kit lot, or daily with the first IFA run.)

☐ Other (please specify):_____

Reactivity of QC Material

(Note: If single serum/plasma was checked above, only <u>one</u> box should be checked here. If multiple sera/plasma was checked above, then <u>one or more</u> boxes can be checked here.)

☐ Strongly positive

☐ Weakly positive

☐ Negative

☐ All of the above

☐ Other (please specify):_____

OTHER . . . OTHER . . . OTHER . . .

SPECIFIC INSTRUCTIONS FOR *"OTHER"** PROCEDURES

"Other" procedures include all tests other than Enzyme Immunoassay, Western Blot or Immunofluorescence Assay. Please do not enter results for any HIV rapid tests on this form.

1. Enter the name of the procedure used in the blocks provided. **(Please attach a copy of your procedure to the results form.)**
2. Place an "X" in the appropriate box that indicates the source of your reagents.
3. Enter the name of the three most essential reagents used in your procedure in the blocks provided; for code 99, also enter the manufacturer's name. Enter the lot numbers of reagents and controls used.
4. Record the results for the test controls and survey samples using units of measure or description applicable to your procedure.
5. Circle an Interpretation Code for each sample.
6. **NOTE: If your laboratory uses Quality Control material in addition to the controls that are included in manufactured "Other" procedures, please complete the Quality Control Testing Section of the "Other" procedures result form.**

MANUFACTURER CODES FOR *"OTHER"* PROCEDURES

CODE	*MANUFACTURER*	*CODE*	*MANUFACTURER*
23	bioMérieux Liatek	97	In House (prepared by own laboratory)
25	Chiron RIBA HIV-1/HIV-2 SIA	98	Noncommercial (e.g., from state laboratory)
27	Innogenetics INNO-LIA HIV-I/II	99	Other (specify on results form)

Note: Abbott AxSYM, Abbott IMx, Abbott PRISM, Abbott HIV 1/2 gO, bioMérieux VIDAS HIV DUO, and Ortho Vitros ECi AntiHIV 1+2 have been moved to the EIA portion of the result booklet. **Please record results for these tests on the EIA results page** (see EIA manufacturer codes on page 5).

INTERPRETATION CODES

CODE	*INTERPRETATION*
R	Reactive
I	Indeterminate
N	Nonreactive

Continued…

MPEP No. ☐☐☐☐☐

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

RESULTS FORM FOR PROCEDURES *"OTHER"* THAN ENZYME IMMUNOASSAY, WESTERN BLOT OR IMMUNOFLUORESCENCE ASSAY (DO NOT REPORT HIV RAPID TESTS ON THIS FORM.)

NONREPORTING CODE ☐ (Specify reason if code "D" or "G"):_____

Name of Procedure: _____

REAGENTS

REAGENT OBTAINED

In House ☐

Commercial ☐

REAGENT OR KIT DESCRIPTION

_____

Mfr.Code

Manufacturer_____ ☐☐

Lot #_____

Kit Name_____

Note: Abbott AxSYM, Abbott IMx, Abbott PRISM, Abbott HIV 1/2 gO, bioMérieux VIDAS HIV DUO, and Ortho Vitros ECi AntiHIV 1+2 have been moved to the EIA portion of the result booklet. **Please record results for these tests on the EIA results page** (see EIA manufacturer codes on page 5).

TEST CONTROLS

Reactive

Mfr.Code

Manufacturer_____ ☐☐

Lot #_____

Weakly Reactive

Mfr.Code

Manufacturer_____ ☐☐

Lot #_____

Nonreactive

Mfr.Code

Manufacturer_____ ☐☐

Lot #_____

DILUENTS

Kit ☐

In House (please specify): ☐

_____

Other (please ☐

specify):_____

TEST CONTROLS

Enter Results Applicable To Your Procedure

REACTIVE CONTROL

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

WEAKLY REACTIVE CONTROL

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

NONREACTIVE CONTROL

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

CUTOFF VALUE

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

SURVEY SAMPLES

Sample Code	***Enter Results Applicable To Your Procedure (Specify Units)***	Interpretation (Circle One)
☐☐	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	R I N
☐☐	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	R I N
☐☐	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	R I N
☐☐	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	R I N
☐☐	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	R I N
☐☐	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	R I N

In performing tests OTHER than EIA, WB, or IFA, does your laboratory use quality control material in addition to controls that are included in manufactured tests?

NO ☐ YES ☐ If yes, please complete the following section.

QUALITY CONTROL TESTING

DO NOT *describe the positive and negative controls provided in the "other" test kit.*

Source of Quality Control (QC) Material

☐ In House (prepared by own laboratory)

☐ Commercial Manufacturer (please specify):_____

Frequency of Use of QC Material

☐ With each Other test method ☐ With each set/run of Other test

☐ With each new kit lot of Other test ☐ Daily with the first run of Other test

☐ Other (please specify):_____

Description of QC Material (Please mark only **ONE** box**)**

☐ Single serum/plasma (i.e., just **ONE** reactivity material is used for either each Other test, for each set/run of Other test, for each new kit lot of Other test, or daily with the first run of Other test.)

☐ Multiple sera/plasma (i.e., **MORE THAN ONE** reactivity material is used for either each Other test, for each set/run of Other test, for each new kit lot of Other test, or daily with the first run of Other test.)

☐ Other (please specify):_____

Reactivity of QC Material

(Note: If single serum/plasma was checked above, only <u>one</u> box should be checked here. If multiple sera/plasma was checked above, then <u>one or more</u> boxes can be checked here.)

☐ Strongly positive

☐ Weakly positive

☐ Negative

☐ All of the above

☐ Other (please specify):_____