Guidance for Completion of the Delaware Adult HIV Confidential Case Report Form

Revised February 2021

To Our Providers:

This Confidential HIV/AIDS Adult Case Report Form was developed to assist with timely reporting of HIV cases by diagnosing provider. The form is designed to collect information that promotes understanding of HIV infection morbidity and mortality among patients greater than or equal to 13 years of age at the time of diagnosis. In some cases, staff of the Division of HIV and STD Programs, will be required to contact the provider for additional information. Case reports may also be made over the phone by calling:

Surveillance Officer: 302-744-1005/302-744-1006

Please include as much information as is available. Partial or approximate dates are acceptable for historical information. This guidance document will assist in the completion of the Adult Case Report Form.

Reporting Requirements:

Please visit our HIV Surveillance website at http://delcode.delaware.gov/title16/c007/sc01/index.html

for all information regarding Delaware HIV reporting laws.

Completed forms should be mailed to:

DELAWARE HIV SURVEILLANCE OFFICE

417 FEDERAL STREET

DOVER, DE 19901

To protect patient confidentiality, please make sure you either use two envelopes, a security envelope, or wrap a sheet of plain white paper around the case report form. Finally, to minimize the likelihood that it will be opened inadvertently, mark the inner envelope "Confidential".

Completed forms may also be faxed to the Delaware Division of Public HIV Surveillance Office. Our fax number is 302-739-2250. Please send the form to the attention of DE HIV Surveillance.

Section I: Health Department Use only

Section II: Patient Identifier Information

Name – Enter the patient's last name, first, and middle name/initial.

Alias (Chosen name, Preferred Name, Nickname, Previous Last Name, etc) – If available, enter patient's alternative name(s).

SSN – Enter patient's Social Security if available.

Current Street Address – Enter the patient's current street address.

City/County/State/Zip – Enter patient's current city, county, state, and zip code.

Phone – Enter patient's primary area code and telephone number associated with current address.

Section III: Form Information

Date form completed – Enter date form was completed in MM/DD/YYYY format.

Person completing form – Enter the name of the person completing this form who may be contacted to clarify information.

Phone – Enter the phone number of the person completing this form who may be contacted to clarify information.

Section IV: Current Provider Information

Physician – Enter the name of the physician providing care.

Facility – Enter the phone number of the facility providing the information.

City/State – Enter facility's city and state of location

Phone – Enter the phone number of the facility.

Section V: Demographic Information

Diagnostic Status – Please check the appropriate box to indicate whether you are reporting an HIV or AIDS case.

> Note: If "AIDS" is selected, diagnostic evidence of stage 3 HIV (AIDS) infection is required in the Immunologic Lab Tests table field of Section X: Documented Laboratory Data (i.e., CD4 result <200 cells/uL) and/or Opportunistic Illness(es) in Section XI: Stage 3 HIV Indicator Diseases box(es) must be checked.

Sex at Birth – Indicate the biological sex the patient was assigned at birth.

Date of Birth – Indicate MM/DD/YYYY of birth.

Country of Birth – Check appropriate box and specify country if other than United States or US Territory.

Vital Status – Please select the vital status at the time of report.

Marital Status – Please select the marital status at time of the report.

Race – Ethnicity and race are two different variables. At least one box MUST be checked for race, unless patient is Hispanic/Latinx. Please select more than one race if applicable.

Ethnicity – Ethnicity and race are two different variables. Select patient's ethnicity as Hispanic/Latinx, non-Hispanic/non-Latinx, or unknown.

Residence of HIV Diagnosis – If the patient was residing somewhere different than current residence when they were first diagnosed as HIV positive provide full address where patient was living.

Residence of AIDS Diagnosis – If the patient was residing somewhere different than current residence when they were first diagnosed with AIDS (Stage 3) provide full address where patient was living.

> Note: If this report is from the first site of HIV diagnosis OR first site of AIDS diagnosis, check the **Same as Current** box indicating that the patient address of HIV and/or AIDS diagnosis is the same as their current address listed in Section II.

Section VI: Facility of Diagnosis

HIV Facility/Address/City, State, Country/Phone – Please list the facility name, address, city, state, zip code, and phone number. A box for facility type should also be marked below on the left-hand side title (HIV).

Example for HIV Facility Type table:

HIV	Facility Type	AIDS
	Private Physician	
X	Hospital Inpatient	
	Outpatient	
	Emergency Department	
	Other: _____	

AIDS Facility/Address/City, State, Country/Phone – Please list the facility name, address, city, state, zip code, and phone number. A box for facility type should also be marked below on the right-hand side titled AIDS.

Example for AIDS Facility Type table:

HIV	Facility Type	AIDS
	Private Physician	
	Hospital Inpatient	
	Outpatient	x
	Emergency Department	
	Other: _____	

Note: If patient is diagnosed with both HIV and AIDS simultaneously, please mark both the HIV and AIDS
columns in the Facility Type table.

Section VII: Patient History

Check ALL appropriate risk factor boxes in each column with Yes (Y), No (No) or Unknown (U). If there is
no information for a specific risk factor, please check "unknown" rather than leaving it blank. Blanks
indicate you did not look for this information.

Note: If a patient or health care provider believes the mode of transmission includes clotting
factor, transfusion, transplant or health care/laboratory exposure please provide details in the
bottom part of this section. Indicate first and last dates of any blood transfusions, if applicable.
Write in specific occupation if patient is (or was) a healthcare worker and believes he/she was
exposed to HIV in a healthcare setting. If you need more room for notes, please include them
Section IX: Comments.

Please indicate if patient was having high risk sex – unless another risk has already been noted.
This includes exchanging sex for drugs, money, etc., sex with anonymous partners, recurrent
STIs, or an unusually high number of sex partners. These notes can be included in Section IX:
Comments.

Section VIII: Duplicate Review – Health Department Use only

Section IX: Comments

Please add any additional laboratory, clinical, partner information or other relevant information in the
comments box.

Section X: Documented Laboratory Data

For laboratory results listed in this section, please indicate the State or Out of Country residence of the patient at the time of that lab if other than Delaware.

Review patient's chart and lab reports for the **earliest date of documented HIV positivity**. Providers are required to attach lab report copies (if possible). If lab report copies cannot be attached, document the specimen collection dates and lab results indicating HIV infection and/or Stage 3 HIV (AIDS) in this section. For each test reported, please enter the test result: positive (pos), antigen reactive (Ag+), negative (neg), or indeterminate (indet). Also, include the specimen collection date in test date columns with month(M), date(D), and year(Y). Please note that the grayed boxes for each Test Type indicate that result is not possible for that given test.

Call (302) 744-1006 or (302) 744-1016 with any questions on reporting lab results.

a. Please see table below for more information on each HIV diagnostic test type and how to record the results for each.

HIV Diagnostic Tests		
Test Type	**Test Information**	**Recording results for this Test Type (to be followed by entering the specimen collection date)**
HIV-1/2 Ag/Ab **Lab** IA (4th Gen P24-Distinguishing)	This screening test detects and differentiates between HIV antibodies and HIV-1 p24 antigen. There are two components: • HIV Antibodies: Reactive or Non-Reactive • HIV-1 p24 Antigen: Reactive, Non-Reactive	1. To record an antibody reactive test result, please mark the Positive (Pos) box. 2. To record an antigen reactive result, please mark the Ag+ box for this test type and record the specimen collection date. 3. To record a result that was reactive for both antibody and antigen, please mark the Positive (Pos) **and** Ag+ boxes.
HIV-1/2 Ag/Ab **Rapid** (4th Gen P24-Distinguishing) (Alere Determine)	This is a point-of-care rapid screening test detects and differentiates between HIV antibodies and HIV-1 p24 antigen. There are two components: • HIV Antibodies: Reactive or Non-Reactive • HIV-1 p24 Antigen: Reactive, Non-Reactive	1. To record an antigen reactive result, please mark the Ag+ box for this test type and record the specimen collection date. 2. To record an antibody reactive test result for HIV-1, please mark the Positive (Pos) box. (Due to infrequency, the HIV-2 analyte is omitted from the Case Report Form). 3. To record a result that was reactive for both antibody and antigen, please mark the Positive (Pos) **and** Ag+ boxes.

HIV-1/2 Ag/Ab **Lab** IA 4th Gen	This screening test detects both HIV-1/2 antibody and HIV-1 p24 antigen but does not distinguish between them.	To record a positive result simply mark the positive (Pos) box.
HIV-1/2 Ag/Ab **Lab** IA (4th Gen P24-Distinguishing and Type Differentiating) (Bio-Plex 2200)	This screening test detects and differentiates between HIV-1 antibody, HIV-2 antibody, and HIV-1 p24 antigen. There are four components/analytes: • Overall Interpretation: Reactive or Non-Reactive • HIV-1 Antigen: Reactive, Non-Reactive or Not reportable due to high HIV Ab level • HIV-1 Antibody: Reactive, Non-Reactive or Reactive Undifferentiated • HIV-2 Antibody: Reactive, Non-Reactive or Reactive Undifferentiated	1. To record an antigen reactive result, please mark the Ag+ box for this test type and record the specimen collection date. 2. To record an antibody reactive test result for HIV-1, please mark the Positive (Pos) box **and** check the HIV-1 box under the test type on the left-hand column. 3. To record an antibody reactive test result for HIV-2, please mark the Positive (Pos) box **and** check the HIV-2 box under the test type on the left-hand column. 4. To record a reactive result for both HIV-1 and HIV-2 antibodies, please mark the Positive (Pos) box **and** check the Both box on the left-hand column.
HIV-1/2 Ab IA (2nd/3rd Gen)	This test detects HIV-1 and HIV-2 antibodies. *Please indicate if this test was a point-of-care rapid test.	To record a positive result simply mark the positive (Pos) box.
HIV-1/2 (Type Differentiating) **(Multispot or Geenius)**	This test is typically used as a confirmatory test. It distinguishes between HIV-1 and HIV-2 antibodies. This type differentiating test has replaced the Western Blot as the confirmatory antibody test in the standard laboratory testing sequence. <u>If this confirmatory test is indeterminate or negative (but the initial screening test was reactive), the physician must order a HIV-1 RNA/DNA NAAT (Qualitative) to confirm or rule out HIV infection.</u> ***Note: HIV-2 results are very rare. Call the Health Department directly at 302-744-1006 to report any positive HIV2 results.**	1. To record an antibody reactive test result for HIV-1, please mark the Positive (Pos) box and check the HIV-1 box under the test type on the left-hand column. 2. To record an antibody reactive test result for HIV-2, please mark the Positive (Pos) box and check the HIV-2 box under the test type on the left-hand column. 3. To record a reactive result for both HIV-1 and HIV-2 antibodies, please mark the Positive (Pos) box and check the Both box on the left-hand column.

HIV-1 EIA or Other	This test detects HIV-1 Antibodies.	To record a positive result simply mark the positive (Pos) box.
HIV-2 EIA or Other	This test detects HIV-2 Antibodies.	To record a positive result simply mark the positive (Pos) box.
HIV-1 RNA/DNA QUAL NAAT	The HIV-1 Nucleic Acid Amplification Test (NAAT) detects the RNA or DNA of the HIV virus. This test can either be negative or positive. As noted under HIV-1/2 (Type Differentiating), this test must be ordered to rule out HIV infection if confirmatory testing is indeterminate or negative.	To record a positive result simply mark the positive (Pos) box.
Last Pre-DX Negative Test Test Type:	Please record the date of last documented negative HIV test (before HIV diagnosis date) and specify the type of test. *Please indicate if this test was a point-of-care rapid test.	

b. Viral Load Tests: (Earliest and Most Recent Viral Load)

Record both the earliest and most recent viral load tests. Include date of collection.
• Select "Undetectable" if results of viral load are below limit of detection and record <20 in the Copies/mL field.
• Select "Detectable" if results of viral load are within limit of detection and enter the results in unites of viral copies per millimeter (mL).
• Select "Detectable" if results of viral load are above limit of detection the record >10 million in the Copies/mL field.

c. Immunologic Lab Tests: (At or closest to current diagnostic status)
Earliest CD4, Most Recent CD4, and First CD4 <200- Record the CD4 cell count and percent closest to the initial diagnostic status (regardless of stage), the most recent CD4, as well as the first CD4 count/percent less than 200 cells/ul. Include collection date for each response.

d. Physician Diagnosis:

If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician?

If laboratory documentation of a positive HIV test is unavailable in the medical record, enter the earliest date the clinical care provider documented the patient's HIV infection. A care provider diagnosis is made by clinical and/or laboratory evaluation and should be clearly documented (e.g., in progress notes). Prescription of anti-retroviral drugs for HIV treatment (not PrEP or PEP) is sufficient evidence of a care provider diagnosis of HIV infection.

e. Documentation of Tests:
   Complete this section only if none of the following were positive: HIV 1 Western Blot, IFA, culture, viral load, qualitative NAAT (RNA or DNA)

Section XI: Stage 3 HIV Indicator Diseases

For Stage 3 HIV (AIDS) reports, check the box of the appropriate illness and enter the date of diagnosis in MM/DD/YYYY format using '..' for unknown values (e.g., 03/../2011).

Section XII: Treatment/Services Referrals

a. Has this patient been informed of their HIV infection?
   Select applicable response. If notification is not documented, select "Unknown" unless the person completing the form knows with certainty that the patient is aware of the infection.

b. If known – Please select how the patient's partners will be notified about their HIV exposure.
c. If known – Please select how this patient's medical treatment is primarily reimbursed by.
d. If known – Please indicate if this patient is enrolled in a clinical trial and provide necessary details.
e. Please indicate whether or not the patient is receiving or has been referred to: HIV related medical services, substance abuse treatment services, anti-retroviral therapy, or PCP prophylaxis.

Section XIII: Women Only

a. If known – Please indicate if patient is receiving or has been referred for OB/GYN services and provide necessary details.
b. Please indicate whether the patient is currently pregnant and list their expected delivery date.
c. Please indicate whether the patient has delivered a live-born infant.
   If Yes – please provide the necessary information on their most recent birth.

Section XIV: Additional Comments

Please provide any additional laboratory, clinical, partner information or other relevant information in the comments box.

Additional Note:

Suspect Acute HIV?

Is there any evidence to suspect that the person had acute HIV infection at diagnosis?

- If "Yes" please record the following information in the either comments section:
    - Indicate if the patient had any clinical signs/symptoms consistent with acute retroviral syndrome (e.g., fever, malaise/fatigue, myalgia, pharyngitis, rash, and/or lymphadenopathy, generally two or more symptoms such as these are present) and the date of onset.