



# GUIDANCE FOR COMPLETION OF THE NEW COUNTY OF LOS ANGELES, CONFIDENTIAL PROVIDER HIV/AIDS ADULT CASE REPORT FORM

#### **Revised March 2020**

### **To Our Providers:**

This Confidential Provider HIV/AIDS Adult Care Report Form (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 (213) 351-8516. 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:**

In accordance with California Health and Safety Code (HSC) 121022(a), CCR Title 17, Section 2643.5 and 2643.10, the State requires health care providers to report all patients with evidence of HIV infection, including Stage 3 infection (AIDS), within 7 calendar days of receipt of a patient's confirmed HIV test from a laboratory. For patient's residing in the County of Los Angeles, the confirmed HIV test shall be reported to Public Health by completing a copy of the Adult Case Report Form. In addition, acute HIV infection must be reported within one (1) working day to Public Health by phone to (213)-351-8516 (17 CCR 2500(h) and (k)). Reporting does not require patient consent (HIPAA, 45 CFR 164.512(b)(1)(i)).

Completed forms should be mailed to:

COUNTY OF LOS ANGELES, DEPARTMENT OF PUBLIC HEALTH 600 S. COMMONWEALTH AVE 10TH FLOOR - SUITE 1260 LOS ANGELES, CA 90005

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".

### **SECTION I: PROVIDER/FACILITY INFORMATION**

<u>Person completing form-</u> Enter name and phone number of person completing this form who may be contacted to clarify information.

<u>Date completed</u>- Enter date form was completed in mm/dd/yyyy format.

<u>Physician</u>- Enter name and phone number of physician providing care.

Facility Name- Enter name and phone number of the facility providing the information.

<u>Facility Address/City/State/Zip-</u> Enter facility's street address, city, state, and ZIP code where facility providing information is located.

<u>Facility Type-</u> Check one of the boxes for the type of facility providing information.

## **SECTION 2: PATIENT INFORMATION**

Patient Last Name, First Name, Middle Name -Enter the patient's last name, first, and middle name/initial.

<u>AKA (Chosen name, Preferred Name, Nickname, Previous Last Name, etc)</u>- If available, enter patient's alternative names.

<u>Address Type</u>- Check one of the boxes for address type of the patient's current address.

<u>Current Street Address-</u> Enter the patient's current street address.

<u>City, Zip Code, State</u>- Enter patient's current city, zip code, and state.

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

<u>Date of Birth</u>- Indicate mm/dd/yyyy of birth. Please also list alias dates of birth.

Social Security #- Enter patient's SSN if available.

Medical Record #- Enter patient's medical record number if available.

Vital Status - Enter vital status at the time of report.

<u>Date of Death/State of Death</u>- If patient is deceased, enter date of death in mm/dd/yyyy format using '..' for unknown values (e.g., 03/../2011). Enter the state name where the death occurred. If outside of the U.S., enter "Foreign County".

<u>Status-</u> check the appropriate box to indicate whether you are reporting an HIV or AIDS case. If "AIDS" is selected, diagnostic evidence of stage 3 (AIDS) infection is required in the CD4 (i.e., CD4 result <200 cells/uL) and/or Opportunistic Illnesses sections.

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

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

<u>Current gender identity</u>- Indicate the gender to which the patient most closely identifies at time form is completed (this may or may not be different than the sex the patient was assigned at birth) or if the patient identifies as a transgender woman (male-to-female), transgender man (female-to-male), non-binary, or additional gender identity. The term transgender includes transgender people regardless of whether they have altered their bodies hormonally and/or surgically.

<u>Race-</u> Ethnicity and race are two different variables. At least one box MUST be checked for race; select more than one race if applicable.

<u>Ethnicity-</u> Ethnicity and race are two different variables. Select patient's ethnicity as Hispanic/Latinx or non-Hispanic/non-Latinx.

<u>Expanded Race/Ethnicity</u>- Enter more specific race information for greater detail (e.g., Navajo for "American Indian or Alaska Native" race or Middle Eastern for "White" race) **OR** enter more specific ethnicity information (e.g. Cuban for Hispanic Ethnicity).

## SECTION 3. RESIDENCE/FACILITY AT HIV/AIDS DIAGNOSIS

If this report is from the first site of HIV diagnosis OR first site of AIDS diagnosis, check the box indicating that the patient address/facility of HIV/AIDS diagnosis are the same as current.

<u>Address at time of diagnosis</u>- If the patient was residing somewhere different than current residence when they were **first diagnosed** (as HIV positive or AIDS, accordingly), provide full address where patient was living.

<u>Facility of diagnosis</u>- If the patient was <u>first diagnosed</u> elsewhere, enter the name of the diagnosing facility along with the phone number, address, city, state, and zip code. A box for facility type should also be checked.

#### **SECTION 4. PATIENT HISTORY AND RISK FACTORS**

Check **ALL** appropriate risk factor boxes in each column with Yes, No or Unknown. 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.

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 comment 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.

Write in 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.

Further, if the patient or health care provider believes the mode of transmission includes heterosexual sex with a person with known HIV/AIDS infection and that sex partner is known to have a clotting factor disorder, a transfusion or transplant please also indicate this in the comment section.

Indicate if patient was perinatally infected and list name of patient's mother.

## SECTION 5. CLINICAL: ACUTE HIV INFECTION AND OPPORTUNISTIC ILLNESSES

### Suspect Acute HIV?

- Select "Yes" if there is any evidence to suspect that the person had acute HIV infection at diagnosis.
  - If "Yes" is selected, indicate whether or not and date the patient had 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.
- "No" indicates sufficient evidence that the person did not have acute HIV infection at diagnosis.
- "Unknown" indicates there is insufficient evidence to indicate whether the person had acute HIV infection at diagnosis.

## Opportunistic illnesses

For Stage 3 (AIDS) reports, check the box of the appropriate illness (or enter name of opportunistic illness from list below) along with date of diagnosis in mm/dd/yyyy format using '..' for unknown values (e.g., 03/../2011).

- Candidiasis, bronchi, trachea, or lungs;
- Candidiasis, esophageal;
- Cervical cancer invasive;
- Coccidioidomycosis, disseminated or extrapulmonary;
- Cryptococcosis, extrapulmonary;
- Cryptosporidiosis, chronic intestinal;
- Cytomegalovirus disease (other than liver, spleen, or nodes);
- Cytomegalovirus retinitis (with loss of vision);
- HIV encephalopathy;
- Herpes simplex: chronic ulcers; or bronchitis, pneumonitis, or esophagitis;
- Histoplasmosis, disseminated or extrapulmonary;
- Isosporiasis, chronic intestinal;
- Kaposi's sarcoma;
- Lymphoma, Burkitt's (or equivalent);
- Lymphoma, immunoblastic (or equivalent);
- Lymphoma, primary in brain;
- Mycobacterium avium complex or M. kansasii, diss. or extrapulmonary;
- M. tuberculosis, pulmonary;
- M. tuberculosis, disseminated or extrapulmonary;
- Mycobacterium of other or unidentified species, disseminated or extrapulmonary;
- Pneumocystis pneumonia;
- Pneumonia, recurrent;
- Progressive multifocal leukoencephalopathy;
- Salmonella septicemia, recurrent;
- Toxoplasmosis of brain;
- Wasting syndrome due to HIV

# **SECTION 6. PREGNANCY**

For women only, indicate whether the patient is currently pregnant and list their expected delivery date.

### **SECTION 7. TREATMENT SERVICES/REFERRALS**

<u>Has this patient been informed of their HIV infection?</u> 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.

<u>Is there evidence of linkage to HIV medical care?</u> Select applicable response. Evidence may include documentation by medical provider of first date of HIV care or date of antiretroviral medical prescription filled.

#### **SECTION 8. HIV DIAGNOSTIC TESTS**

Review patient's chart and lab reports for the <u>earliest date</u> of documented HIV positivity. Providers are required to attach lab report copies (if possible) and check the box to indicate that labs are attached to the case report form.

Optional: Document HIV Immunoassays (Non-differentiating/Type-Differentiating lab results below- If lab report copies cannot be attached, document the specimen collection dates and lab results indicating HIV infection in this section. For each test reported, enter specimen collection date in mm/dd/yyyy format and test results. \*If all relevant labwork are attached, skip to "Documentation of Tests"

Call (213)351-8516 with any questions on reporting lab results.

	8. HIV DIAGNOSTIC TESTS						
	REQUIRED: Attach copies of all relevant laboratory results for HIV diagnosis and ndicate that labs are attached:						
	□ Labs are attached (if checked, the grey boxes in this section can be left blank)  OPTIONAL: Document HIV Immunoassays (Non-differentiating/Type-Differentiating) lab results below.  HIV Immunoassays (Non-differentiating)						
		DATE COLLECTED (MM/DD/YYYY)	Rapid Test	Positive/ Reactive	ESULT (Check one Negative/ Non-Reactive	Indeterminate (IND)	
1	HIV-1/2 Ag/Ab						
2	HIV-1 RNA/DNA NAAT (Qual)						
	Other:						
	HIV Immunoassays (Type-differentiating)						
		DATE COLLECTED	Rapid	RESULTS	(Check one for each column)		
		(MM/DD/YYYY)	Test	Overall Interpretation	HIV-1 Ag	HIV-1 Ab	
3	HIV-1/2 Ag/Ab and Type Differentiating (e.g. Bio-Rad BioPlex 5th Generation)			☐ Reactive ☐ Non-Reactive	☐ Reactive ☐ Non-Reactive	☐ Reactive ☐ Non-Reactive ☐ Reactive, Undifferentiated	
4	HIV-1/2 Type-Differentiating			Overall Interpretation			
	(differentiates between HIV1 Ab & HIV2 Ab)  Role of test in diagnostic algorithm:  Screening/Initial Confirmatory/Supplemental			□ HIV-1 Positive □ HIV IND □ HIV-2 Positive □ HIV-1 IND □ HIV Negative □ HIV-2 IND □ HIV Positive, Untypable □ HIV-2 Positive with HIV-1 Cross-Reactivity			
	DOCUMENTATION OF TESTS						
	Date of last documented negative HIV test (before HIV diagnosis date):  Specify type of test:  If HIV lab tests were NOT documented, is HIV diagnosis confirmed by a clinician?  □ Yes □ No □ Unknown  If Yes → Date of documentation by care provider:  □ Yes □ No □ Unknown						

## **HIV Immunoassay (Non-differentiating) Tests**

- HIV-1/2 AG/AB (4<sup>th</sup> Generation). This screening test detects both HIV-1/2 antibody and HIV-1 p24 antigen but does not distinguish between them. Check the rapid test box if the test is a point-of-care rapid test.
- <u>HIV-1 RNA/DNA NAAT (QUALITATIVE).</u> The HIV-1 Nucleic Acid Amplification Test (NAAT) detects the RNA or DNA of the HIV virus and may be either qualitative or quantitative.

- For HIV-1 RNA/DNA NAAT (Qualitative) tests, indicate if the result is reactive or non-reactive.
- For HIV-1 RNA/DNA NAAT (Quantitative) tests, see "HIV Care Tests" in Section 9, below).

\*If the screening test was positive, but the supplemental test was negative or indeterminate, the physician must order a HIV-1 RNA/DNA NAAT (Qualitative) to confirm HIV diagnosis.

**OTHER.** Use this section to record less common test results such as: HIV-1/2 EIA, HIV-1/2 Ag/Ab Differentiating (e.g. Determined by Alere), Western Blot.

## **HIV Immunoassay (Type-differentiating) Tests**

- HIV-1/2 AG/AB AND TYPE-DIFFERENTIATING IMMUNOASSAY (Bio-Rad BioPlex 5th Generation). 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 (Due to infrequency, this analyte is omitted from the Case Report Form).

This screening test is automatically followed by HIV-1/2 Type-Differentiating Immunoassay.

- 4 HIV-1/2 TYPE-DIFFERENTIATING IMMUNOASSAY (e.g. 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. 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.
  - Check the rapid test box if the test is a rapid test.
  - Enter the role of the test in the diagnostic algorithm, "screening/initial" or "confirmatory/supplemental".
  - Enter the overall interpretation of the test.
  - \*Note, HIV-2 results are very rare. Call the Health Department directly at 213-51-8516 to report any positive HIV-2 results.

## **Documentation of Tests**

<u>Last lab documented negative test?</u> If a prior negative HIV test is documented on a patient, indicate collection of the most recent negative test result. Indicate test type for the last documented negative test (e.g., HIV-1/2 Ag/Ab, HIV-1/2 HIV-1 RNA/DNA NAAT). Note that this is different than the "date of most recent negative test" in Section 10 (HIV Testing History) which is from the patient's recollection.

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.

### **SECTION 9. HIV CARE TESTS**

<u>Earliest and Most Recent Viral Load</u>- Record both the earliest and most recent viral load tests. Include date of collection.

- Select "<" if results of viral load are below limit of detection.
- Select "=" if results of viral load are within limit of detection.
- Select ">" if results of viral load are above limit of detection (e.g.,>10 million).
- Enter results in units of viral copies per milliliter (mL) or Log.

<u>HIV Genotypic Tests-</u> Record collection date if there is evidence of a drug resistance test (genotypic), regardless of the type of drug resistance test, in the patient's medical record.

<u>Earliest CD4, Most Recent CD4, and First CD4 < 200</u>- 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.

## **SECTION 10. HIV TESTING AND TREATMENT HISTORY**

Testing and treatment history information must be completed for ALL HIV reports. Dates are VERY important in this section. Enter patient-reported answers to previous HIV testing and the dates of these tests as reported by the patient. Estimated and partial dates are acceptable.

<u>Date of patient encounter during which testing history was provided</u>- Enter date of patient interview or date of note in medical record when patient provided most of the HIV testing and treatment history. If information is from more than one date, enter most recent date.

<u>Information from-</u> Note where testing and treatment history was obtained: interview, medical record or from medical provider.

- Select "Patient Interview" if the patient was directly asked a series of questions from this form regarding testing and treatment history.
- Select *Medical Record Review*" if this information was obtained through abstraction of medical charts, electronic medical records or databases.
- Select "Provider Report" if this information was filled out by a medical provider.

<u>First Positive Test Reported by Patient-</u> Do not assume that the current positive HIV test is the first positive for the patient. Ask patient if he/she has ever tested positive for HIV in the past. Enter first-ever positive HIV test date in mm/dd/yyyy format using '..' for unknown values (e.g., 12/../2017, or ../../2017).

<u>Negative Tests Reported by Patient-</u> Ask patient if he/she ever tested negative for HIV before testing positive. Enter most recent negative HIV test date in mm/dd/yyyy format using '..' for unknown values (e.g., 12/../2017, or ../../2017). Enter the total number of negative HIV tests the patient recalls in the 24 months preceding the first positive HIV test. Enter "0" if it is known that the patient has never been tested for HIV before or never had a negative test.

### Ever taken ANY antiretroviral medication (ARVs)?

- "Yes" indicates there is evidence that the person has taken ARVs for any purpose, including self-report.
- "No" indicates there is evidence that the patient has never taken ARVs.

• "Unknown" should be used when the person completing the form does not know whether or not the patient has ever taken ARVs, after searching for the information or asking the patient.

## Reason for ARV Use (select all that apply)

If patient EVER received ARV medication, enter at least one medication name, start date and date of last use (if stopped) or most recent use (if still taking ARV) in mm/dd/yyyy format using '..' for unknown values. Indicate reason(s) for ARV use, including:

- To treat HIV infection
- To prevent HIV infection via Pre-Exposure Prophylaxis (PrEP)
- To prevent HIV infection following a possible exposure such as a needle stick or unprotected sex (PEP)
- To prevent transmission from a pregnant woman to her unborn or newly-born baby
- To treat Hepatitis B infection. Some medications overlap with HIV such as tenofovir (Viread,TDF), emtricitabine (Emtriva, FTC), and lamivudine (Epivir, 3TC).

## **SECTION 11. SUBSTANCE USE**

Enter appropriate response(s) to questions about illicit drug use in the past 12 months.

### **SECTION 12. PARTNER INFORMATION**

Under California law, clinical care providers must provide partner notification assistance to persons with HIV infection. This responsibility may be discharged to the local public health department. For assistance in notifying known sex or needle-sharing partners of HIV-infected patients, please provide partner name and contact information in this section. If patient provides more than three partner names, enter additional information in the "Comments" box.

#### **COMMENTS**

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