National HIV Surveillance System (NHSS)

Attachment 4(a)

Technical Guidance for HIV Surveillance Programs:
Adult HIV Confidential Case Report Form

Technical Guidance for HIV Surveillance Programs

Adult HIV Confidential Case Report Form

HIV Surveillance Branch
Atlanta, Georgia

Contents

Instructions for Completion

Purpose of Case Report Form

The Adult HIV Confidential Case Report (CDC 50.42A) form (ACRF) 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 time of diagnosis. This form reflects data that are required to be collected and some that are recommended or optional. This guidance applies to all HIV infection data collection even if state or local surveillance programs use a different form or medium for HIV case surveillance.

The Case Report Form in the Context of Document-Based Surveillance

Unlike case-based data management, document-based data management allows all documents to be stored and retained electronically in their original formats. Instead of completing one form for a reported case, fill out the applicable part of the form for each data source contributing information to that HIV case.

Patients for Whom Form is Indicated

- Each person, greater than or equal to 13 years of age, who meets the HIV infection case definition (available at https://ndc.services.cdc.gov/conditions/hiv-infection-aids-has-been-reclassified-as-hiv-stage-iii/).
- Each person with HIV infection progressing from an earlier or unknown stage to stage 3 (AIDS) diagnosis.
- Each person with HIV infection who has been reported but for whom updated information is available such as new CD4 tests, viral load tests, or drug resistance tests (genotypic) reported from a medical provider, additional risk factor information, updated current address information, or a change in vital status.

If the data are collected electronically and can be imported, recording the information on a hardcopy form is not necessary.

Definition of Variable Designators

- **Required**: Variables that must be collected by all programs. Please note that for some of these variables there must be a known value reported in order to meet the eligibility criteria for data associated with the patient to be transmitted to the Centers for Disease Control and Prevention (CDC) through the CDC-supplied enhanced HIV/AIDS Reporting System (eHARS). The *eHARS Technical Reference Guide* details the specific variables required to meet the eligibility criteria at the beginning of Chapter 3. The *eHARS Technical Reference Guide* can be accessed through SharePoint: https://cdcpartners.sharepoint.com/sites/NCHHSTP/HICSB/default.aspx.
- **Recommended**: Variables that programs are strongly encouraged to collect but are not absolutely required.
- **Optional**: Variables that programs may or may not choose to collect.
- **System generated**: Variables where the value is generated by eHARS.

Disposition of Form

- The completed form is for state or local health agency use and is not to be sent to CDC. The Pacific Islands are the only jurisdictions that send forms to CDC for data entry and all patient identifiers must be removed before they are sent.
- Data obtained from these forms are entered into standardized computer software provided by the Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC, and then transferred without identifiers to CDC by encrypted electronic

transfer via a secure access management service.

1. Patient Identification

I. Patient Identification (record all dates as mm/dd/yyyy)

*First Name	*Middle Name	*Last Name	Last Name Soundex
Alternate Name Type (ex: Alias, Married)	*First Name	*Middle Name	*Last Name
Address Type ☐ Residential ☐ Bad address ☐ Correctional facility ☐ Foster home ☐ Homeless ☐ Military ☐ Other ☐ Postal ☐ Shelter ☐ Temporary	*Current Address, Street		Address Date __ __/__ __/__ __ __ __
*Phone ( )	City	County	State/Country	*ZIP Code
*Medical Record Number	*Other ID Type	*Number	

- Patient identifier information is for state and local health department use only and is not transmitted to CDC if marked with an * on the form.

1.1 FIRST NAME (**Required**, applies to health department & health care providers)
- Enter patient's first name.

1.2 MIDDLE NAME (**Optional**, applies to health department & health care providers)
- Enter patient's middle name.

1.3 LAST NAME (**Required**, applies to health department & health care providers)
- Enter patient's last name.

1.4 LAST NAME SOUNDEX (**System generated**)
- After patient name is entered into eHARS, the software automatically generates this variable by using the patient's last name. After the code is generated, health department staff should fill this field on the form.
- This variable is a phonetic, alphanumeric code calculated by converting a surname into an index letter and a three-digit code. The index letter is the first letter of the surname. The *eHARS Technical Reference Guide* describes exactly how the Last Name Soundex is created. You can access the *eHARS Technical Reference Guide* through SharePoint: https://cdcpartners.sharepoint.com/sites/NCHHSTP/HICSB/default.aspx

1.5 ALTERNATE NAME TYPE (**Optional**, applies to health department & health care providers)
- If available, write in the alternate name type (such as Alias, Married).

1.6 ALTERNATE FIRST NAME (**Optional**, applies to health department & health care providers)
- Enter patient's alternate first name.

1.7 ALTERNATE MIDDLE NAME (**Optional**, applies to health department & health care providers)
- Enter patient's alternate middle name.

1.8 ALTERNATE LAST NAME (**Optional**, applies to health department & health care providers)
- Enter patient's alternate last name.

1.9 ADDRESS TYPE (**Required**, applies to health department & health care providers)
- Select one of the address types for the patient's current address.

1.10 CURRENT ADDRESS, STREET (**Required**, applies to health department & health care providers)
- Enter the patient's current street address.

1.11 ADDRESS DATE (**Required**, applies to health department & health care providers)
- Enter the earliest date that the patient was known to be residing at the current address

specified in 1.10. If the patient has resided at an address more than once (and has evidence that they resided elsewhere in between), the address date captured should be the earliest date that the patient moved to the address in the most recent instance.
- You may enter the most recent date the patient was known to be residing at the address in the Comments section. In eHARS, enter the address with the most recent address date on a separate ACRF document on the "Identification" tab.
- Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

1.12 PHONE (**Required** if patient has a telephone, applies to health department & health care providers)
- Enter patient's primary area code and telephone number associated with the current address specified in 1.10.

1.13 CITY (**Required**, applies to health department & health care providers)
- Enter patient's current city.

1.14 COUNTY (**Required**, applies to health department & health care providers)
- Enter patient's current county.

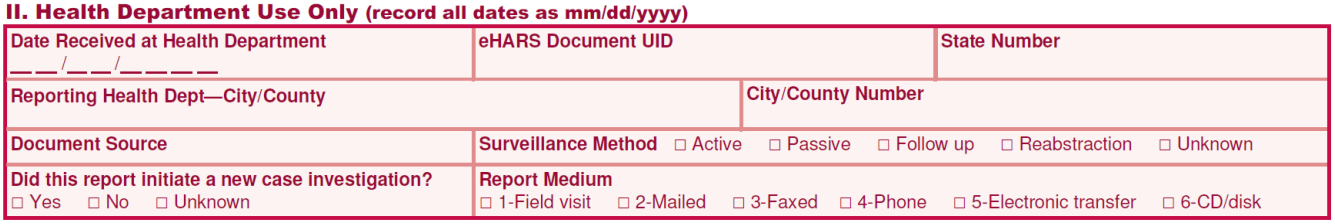
1.15 STATE/COUNTRY (**Required**, applies to health department & health care providers)
- Enter patient's current state and country name.

1.16 ZIP CODE (**Required**, applies to health department & health care providers)
- Enter patient's current zip code.

1.17 MEDICAL RECORD NUMBER (**Optional,** applies to health department & health care providers)
- Enter medical record number of the patient if available.
- This field may be left blank unless patient was hospitalized as an inpatient or treated as an outpatient in a hospital, community health center, or health department clinic.
- If the patient has more than one medical record number, enter the number of the primary record that has HIV infection or stage 3 (AIDS) documentation. Additional numbers can be noted in the Comments section annotating which facility is associated with which record number. In eHARS, enter the additional medical record numbers on the "Identification" tab.

1.18–1.19 OTHER ID TYPE and NUMBER (**Optional,** applies to health department & health care providers)
- Enter any additional patient identifier type (such as social security number) and the number of the other identifier. For a list of ID types, please reference the *eHARS Technical Reference Guide*.

2. Health Department Use Only



II. Health Department Use Only (record all dates as mm/dd/yyyy)

Date Received at Health Department __/__/____	eHARS Document UID	State Number
Reporting Health Dept—City/County		City/County Number
Document Source	Surveillance Method ☐ Active ☐ Passive ☐ Follow up ☐ Reabstraction ☐ Unknown	
Did this report initiate a new case investigation? ☐ Yes ☐ No ☐ Unknown	Report Medium ☐ 1-Field visit ☐ 2-Mailed ☐ 3-Faxed ☐ 4-Phone ☐ 5-Electronic transfer ☐ 6-CD/disk	

2.1 DATE RECEIVED AT HEALTH DEPARTMENT (**Recommended,** applies to health department)
- Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

2.2 eHARS DOCUMENT UID (**System generated)**
- Enter UID after eHARS generates this variable.

2.3 STATE NUMBER (**Required,** applies to health department)

- Enter the assigned state number.
- Each patient must have a unique state number throughout the course of HIV infection in each state/jurisdiction where they are reported. If the patient was a pediatric "Seroreverter" and was later infected with HIV, the patient must be given two different state numbers; one associated with the "Seroreverter" and another associated with the HIV infection diagnosis. Refer to Appendix 4.1.4 in Technical Guidance File *Pediatric HIV Confidential Case Report Form* for the definition of a pediatric "Seroreverter". Jurisdictions must use the "Same as" field on the "Duplicate Review" tab in eHARS to link the two cases. Enter the state number associated with diagnosed HIV infection on the case report form.
- Assigned numbers **must not** be reused, even if the case is later deleted.
- This variable is used, along with the state of report, to uniquely identify cases reported to CDC and to merge state datasets without duplication.

2.4 REPORTING HEALTH DEPARTMENT -CITY/COUNTY (**Required,** applies to health department)

- Enter name of city and county of the health department that receives the report from providers of surveillance data.

2.5 CITY/COUNTY NUMBER (**Optional,** applies to health department)

- Enter the assigned city/county number.
- Each patient must have a unique city/county number throughout the course of HIV infection assigned by the separately funded city in which they are reported. If the city/county number is the primary identifier and the patient was a pediatric "Seroreverter" and was later infected with HIV, the patient must be given two different city/county numbers; one associated with the "Seroreverter" and another associated with the HIV infection diagnosis. Refer to Appendix 4.1.4 in Technical Guidance File *Pediatric HIV Confidential Case Report Form* for the definition of a pediatric "Seroreverter". If the city/county number is the primary identifier, the jurisdiction must use the "Same as" field on the "Duplicate Review" tab in eHARS to link the two cases. Enter the city/county number associated with diagnosed HIV infection on the case report form.
- Assigned numbers **must not** be reused, even if the case is later deleted.

2.6 DOCUMENT SOURCE (**Required**, applies to health department)

- Enter the code for the document source that provided the information for this report (formerly report source).
- To clearly identify multiple data sources for a given HIV case (all stages), use a separate case report form for each source.
- Refer to the *eHARS Technical Reference Guide* for a list of the document source codes available in eHARS.

2.7 SURVEILLANCE METHOD (**Required,** applies to health department)

- Enter the method the case report was ascertained.
- For definitions of active, passive, follow up, re-abstraction see Technical Guidance File *Source Data and Completeness of Reporting*.

2.8 DID THIS REPORT INITIATE A NEW INVESTIGATION? (**Optional,** applies to health department)

- Enter whether this case report initiated a new investigation by the health department.

2.9 REPORT MEDIUM (**Optional,** applies to health department)

- Health department staff review medical records at provider facilities (i.e., field visits) or

receive information over the telephone, by fax, US mail, or other method, to establish an HIV case and to elicit information for HIV case report forms. The health department can also receive HIV case reports from physicians, laboratories, or other individuals or institutions through electronic transfer or CD/disks. Enter the medium in which the case report was submitted.

3. Facility Providing Information

III. Facility Providing Information (record all dates as mm/dd/yyyy)

Facility Name			*Phone ( )
*Street Address			
City	County	State/Country	*ZIP Code
Facility Type	*Inpatient:* ☐ Hospital ☐ Other, specify _____	*Outpatient:* ☐ Private physician's office ☐ Adult HIV clinic ☐ Other, specify _____	*Screening, Diagnostic, Referral Agency:* ☐ CTS ☐ STD clinic ☐ Other, specify _____
			Other Facility: ☐ Emergency room ☐ Laboratory ☐ Corrections ☐ Unknown ☐ Other, specify _____
Date Form Completed __ __/__ __/__ __ __ __		*Person Completing Form	*Phone ( )

- Facility information is for state and local health department use only and is not transmitted to CDC if marked with an * on the form.

3.1 FACILITY NAME (**Recommended**, applies to health department & health care providers)
- Enter name of the facility providing the information.
- If data was reported from different facilities, enter name of each on separate forms.

3.2 PHONE (**Recommended**, applies to health department & health care providers)
- Enter facility's current area code and telephone number.

3.3 STREET ADDRESS (**Recommended**, applies to health department & health care providers)
- Enter facility's street address.

3.4 CITY (**Recommended**, applies to health department & health care providers)
- Enter city where facility providing information is located.

3.5 COUNTY (**Recommended**, applies to health department & health care providers)
- Enter county where facility providing information is located.

3.6 STATE/COUNTRY (**Recommended**, applies to health department & health care providers)
- Enter state and country name where facility providing information is located.

3.7 ZIP CODE (**Recommended**, applies to health department & health care providers)
- Enter ZIP code where facility providing information is located.

3.8 FACILITY TYPE (**Required**, applies to health department & health care providers)
- Select the type of facility providing information.
- Refer to the *eHARS Technical Reference Guide* for additional information regarding facility types available in eHARS.

3.9 DATE FORM COMPLETED (**Required**, applies to health department & health care providers)
- Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

3.10 PERSON COMPLETING FORM (**Optional**, applies to health department & health care providers)
- Enter the name of the person completing the form who can be contacted to clarify entries and supply additional information.

3.11 PHONE (**Recommended**, applies to health department & health care providers)

- Enter the telephone number of the person completing the form.

4. Patient Demographics

IV. Patient Demographics (record all dates as mm/dd/yyyy)

Sex Assigned at Birth ☐ Male ☐ Female ☐ Unknown		**Country of Birth** ☐ US ☐ Other/US dependency (specify) _____	
Date of Birth __ __/__ __/__ __ __ __		**Alias Date of Birth** __ __/__ __/__ __ __ __	
Vital Status ☐ 1-Alive ☐ 2-Dead	**Date of Death** __ __/__ __/__ __ __ __	**State of Death**	
Gender Identity	☐ Man ☐ Woman ☐ Transgender man ☐ Transgender woman ☐ Additional gender identity (specify) _____ ☐ Declined to answer ☐ Unknown		
Date Identified	__ __/__ __/__ __ __ __		
Sexual Orientation	☐ Straight or heterosexual ☐ Lesbian or gay ☐ Bisexual ☐ Additional sexual orientation (specify) _____ ☐ Declined to answer ☐ Unknown		
Date Identified	__ __/__ __/__ __ __ __		
Ethnicity	☐ Hispanic/Latino ☐ Not Hispanic/Latino ☐ Unknown		**Expanded Ethnicity**
Race (check all that apply)	☐ American Indian/Alaska Native ☐ Asian ☐ Black/African American ☐ Native Hawaiian/Other Pacific Islander ☐ White ☐ Unknown		**Expanded Race**

4.1 SEX ASSIGNED AT BIRTH (**Required**, applies to health department & health care providers)

- Select patient's sex assigned at birth.
- If search for this datum was completed and sex assigned at birth could not be assigned as "Male" or "Female", select "Unknown".

4.2 COUNTRY OF BIRTH (**Recommended**, applies to health department & health care providers)

- Select applicable response.
- For patients born in US minor outlying areas, specify the name of the US dependency from the following table:

US Dependencies	
Baker Island	Midway Islands
Howland Island	Navassa Island
Jarvis Island	Palmyra Atoll
Johnston Atoll	Wake Island
Kingman Reef	

- For patients born in any other area outside of the US and US minor outlying areas, specify the country/US dependency name.

4.3 DATE OF BIRTH (**Required**, applies to health department & health care providers)

- Enter patient's date of birth in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

4.4 ALIAS DATE OF BIRTH (**Optional**, applies to health department & health care providers)

- If available, enter the alias date of birth in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

4.5 VITAL STATUS (**Required**, applies to health department & health care providers)

- Enter vital status at time of this report.
- For further guidance on death ascertainment, see Technical Guidance File *Death Ascertainment*.

4.6 DATE OF DEATH (**Required,** if applicable, applies to health department & health care providers)

- If patient is deceased, enter date of death in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- For further guidance on death ascertainment, see Technical Guidance File *Death Ascertainment*.

4.7 STATE OF DEATH (**Required,** if applicable, applies to health department & health care providers)

- If patient is deceased, enter the state name where the death occurred. If the death occurred outside of the US, enter "Foreign Country".

4.8 GENDER IDENTITY and DATE IDENTIFIED (**Required,** applies to health department & health care providers)

- Enter the gender identity of the patient.
- If the patient's stated gender identity differs from the selections provided or the patient's stated gender identity at a point in time includes more than one of the selections provided, select "Additional gender identity" and specify the gender identity or gender identities.
- If documented that the patient declined to provide their gender identity, select "Declined to answer".
- If search for this datum was completed and gender identity could not be determined or if gender identity was documented to be unknown, select "Unknown".
- Refer to the lookup codes in the *eHARS Technical Reference Guide* for gender identity values available in eHARS.
- For date identified, please enter the date the patient indicated identifying as the selected gender identity, if documented. If this date is unknown, enter the date of service (e.g., medical appointment, partner services interview) for when the information on gender identity was obtained. If that date is unknown, enter the most recent date of service. You may also enter the most recent date associated with the patient's gender identity in the Comments section. In eHARS, enter the gender identity value associated with the most recent date on a separate ACRF document on the "Demographics" tab. Record the date in mm/dd/yyyy format using ".." for unknown values (e.g., 03/../2011).
- If the patient's gender identity has changed over time, record the other gender identities and associated dates identified in the Comments section. In eHARS, enter each additional value on separate ACRF documents on the "Demographics" tab.

4.9 SEXUAL ORIENTATION and DATE IDENTIFIED (**Required**, applies to health department & health care providers)

- Enter sexual orientation of the patient.
- If the patient's stated sexual orientation differs from the selections provided or the patient's stated sexual orientation at a point in time includes more than one of the selections provided, select "Additional sexual orientation" and specify the sexual orientation or sexual orientations.
- If documented that the patient declined to provide their sexual orientation, select "Declined to answer".
- If search for this datum was completed and sexual orientation could not be determined or if the sexual orientation was documented to be unknown, select "Unknown".
- Refer to the lookup codes in the *eHARS Technical Reference Guide* for sexual orientation values available in eHARS.
- For date identified, please enter the date the patient indicated identifying as the selected sexual orientation, if documented. If this date is unknown, enter the date of service for when the information on sexual orientation was obtained. If that date is unknown, enter the most recent date of service. You may also enter the most recent date associated with the patient's

sexual orientation in the Comments section. In eHARS, enter the sexual orientation value associated with the most recent date on a separate ACRF document on the "Demographics" tab. Record it in mm/dd/yyyy format using ".." for unknown values (e.g., 03/../2011).

- If the patient's sexual orientation has changed over time, record other sexual orientations and associated dates identified in the Comments section. In eHARS, enter each additional value on separate ACRF documents on the "Demographics" tab.

4.10 ETHNICITY (**Required**, applies to health department & health care providers)

- If search for this datum was completed and ethnicity could not be determined or if ethnicity was documented to be unknown, select "Unknown".
- If no search for this datum was completed, leave this field blank.
- Regardless of the availability of data on race, collect data on ethnicity.
- As of January 2003, the US Office of Management and Budget (OMB) required that race and ethnicity (Hispanic/Latino, Not Hispanic/Latino) for a person be collected as separate variables.
- A wide variety of ethnicities may be selected from values available in eHARS. These ethnicities and codes are documented in the *eHARS Technical Reference Guide.*

4.11 EXPANDED ETHNICITY (**Optional,** if applicable, applies to health department & health care providers)

- Enter more specific ethnicity information for greater detail such as "Hispanic or Latino.Cuban" or "Hispanic or Latino.Puerto Rican".
- Refer to the *eHARS Technical Reference Guide* for listing of expanded ethnicity.

4.12 RACE (**Required**, applies to health department & health care providers)

- Select patient's race even if information was submitted for ethnicity.
- Select more than one race if applicable.
- If no race information is available, select "Unknown".
- As of January 2003, the US Office of Management and Budget (OMB) required that systems collect multiple races for a person (OMB Policy Directive 15 updated standards); at a minimum, collect data on the following five categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White.
- Refer to the *eHARS Technical Reference Guide* for further details.

4.13 EXPANDED RACE (**Optional,** if applicable, applies to health department & health care providers)

- Enter more specific race information for greater detail such as "American Indian or Alaska Native.Navajo" or "White.Middle Eastern or North African".
- Refer to the *eHARS Technical Reference Guide* for listing of expanded race.

5. Residence at Diagnosis

V. Residence at Diagnosis (add additional addresses in Comments) (record all dates as mm/dd/yyyy)

Address Event Type (check all that apply to address below) ☐ Residence at HIV diagnosis ☐ Residence at stage 3 (AIDS) diagnosis ☐ Check if SAME as current address			
Address Type ☐ Residential ☐ Bad address ☐ Correctional facility ☐ Foster home ☐ Homeless ☐ Military ☐ Other ☐ Postal ☐ Shelter ☐ Temporary			
***Street Address**			
City	**County**	**State/Country**	***ZIP Code**

- Residence information is for state and local health department use only and is not transmitted to CDC if marked with an * on the form.
- Refer to Appendix 5.0 for further guidance.
- If patient's residence at HIV diagnosis and stage 3 (AIDS) diagnosis are different, enter the address information associated with the stage 3 (AIDS) diagnosis in the Comments section.

In eHARS, enter the address information associated with stage 3 (AIDS) diagnosis on the "Demographics" tab with the applicable address event type.

5.1 ADDRESS EVENT TYPE (**Required**, applies to health department & health care providers)
- Select the address event type for the patient's residence at diagnosis.
- If the patient's residence at HIV diagnosis and stage 3 (AIDS) diagnosis was the same, you may check both.

5.2 ADDRESS TYPE (**Required**, applies to health department & health care providers)
- Select one of the address types for the patient's address of residence at diagnosis.

5.3 STREET ADDRESS (**Required**, applies to health department & health care providers)
- Enter street address of residence at diagnosis.

5.4 CITY (**Required**, applies to health department & health care providers)
- Enter city of residence at diagnosis.

5.5 COUNTY (**Required**, applies to health department & health care providers)
- Enter county of residence at diagnosis.

5.6 STATE/COUNTRY (**Required**, applies to health department & health care providers)
- Enter the state and country name of residence at diagnosis.

5.7 ZIP CODE (**Required**, applies to health department & health care providers)
- Enter the ZIP code of residence at diagnosis.

6. Facility of Diagnosis

VI. Facility of Diagnosis (add additional facilities in Comments)

Diagnosis Type (check all that apply to facility below) ☐ HIV ☐ Stage 3 (AIDS) ☐ Check if SAME as facility providing information			
Facility Name			***Phone** ( )
***Street Address**			
City	**County**	**State/Country**	***ZIP Code**
Facility Type *Inpatient*: ☐ Hospital ☐ Other, specify _____	*Outpatient*: ☐ Private physician's office ☐ Adult HIV clinic ☐ Other, specify _____	*Screening, Diagnostic, Referral Agency*: ☐ CTS ☐ STD clinic ☐ Other, specify _____	*Other Facility*: ☐ Emergency room ☐ Laboratory ☐ Corrections ☐ Unknown ☐ Other, specify _____
***Provider Name**	***Provider Phone** ( )		**Specialty**

- Facility information is for state and local health department use only and is not transmitted to CDC if marked with an * on the form.
- If the patient's HIV diagnosis and stage 3 (AIDS) diagnosis occurred at different facilities, enter the stage 3 (AIDS) facility information in the Comments section. In eHARS, enter the facility information associated with stage 3 (AIDS) diagnosis on the "Facility" tab with the applicable diagnosis type.

6.1 DIAGNOSIS TYPE (**Recommended**, applies to health department & health care providers)
- Enter the diagnosis type that corresponds to the facility of diagnosis being reported.

6.2 FACILITY NAME (**Recommended**, applies to health department & health care providers)
- Enter name of the facility where patient was first diagnosed which corresponds with the "Diagnosis Type" reported in 6.1.
- Refer to Appendix 6.2 for further details.

6.3 PHONE (**Recommended**, applies to health department & health care providers)
- Enter area code and telephone number of the facility of diagnosis.

6.4 STREET ADDRESS (**Recommended**, applies to health department & health care providers)
- Enter street address of the facility of diagnosis.

6.5 CITY (**Recommended**, applies to health department & health care providers)

- Enter city of the facility of diagnosis.

6.6 COUNTY (**Recommended**, applies to health department & health care providers)

- Enter county of the facility of diagnosis.

6.7 STATE/COUNTRY (**Recommended**, applies to health department & health care providers)

- Enter state and country name of the facility of diagnosis.

6.8 ZIP CODE (**Recommended**, applies to health department & health care providers)

- Enter ZIP code where the facility of diagnosis is located.

6.9 FACILITY TYPE (**Required** applies to health department & health care providers)

- Select the type of facility of diagnosis.
- Refer to the *eHARS Technical Reference Guide* for listing of facility types.

6.10 PROVIDER NAME (**Recommended**, applies to health department & health care providers)

- Enter provider's name where the patient was first diagnosed which corresponds with the "Diagnosis Type" reported in 6.1.

6.11 PROVIDER PHONE (**Recommended**, applies to health department & health care providers)

- Enter area code and telephone number for provider selected in 6.10.

6.12 SPECIALTY (**Optional**, applies to health department & health care providers)

- Enter provider's specialty for provider selected in 6.10.

7. Patient History

VII. Patient History (respond to all questions) (record all dates as mm/dd/yyyy) □ **Pediatric Risk (enter in Comments)**

After 1977 and before the earliest known diagnosis of HIV infection, this patient had:	
Sex with male	□ Yes □ No □ Unknown
Sex with female	□ Yes □ No □ Unknown
Injected nonprescription drugs	□ Yes □ No □ Unknown
Received clotting factor for hemophilia/coagulation disorder Specify clotting factor: Date received __ __/__ __/__ __ __ __	□ Yes □ No □ Unknown
HETEROSEXUAL relations with any of the following:	
HETEROSEXUAL contact with person who injected drugs	□ Yes □ No □ Unknown
HETEROSEXUAL contact with bisexual male	□ Yes □ No □ Unknown
HETEROSEXUAL contact with person with hemophilia/coagulation disorder with documented HIV infection	□ Yes □ No □ Unknown
HETEROSEXUAL contact with transfusion recipient with documented HIV infection	□ Yes □ No □ Unknown
HETEROSEXUAL contact with transplant recipient with documented HIV infection	□ Yes □ No □ Unknown
HETEROSEXUAL contact with person with documented HIV infection, risk not specified	□ Yes □ No □ Unknown
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments)	□ Yes □ No □ Unknown
First date received __ __/__ __/__ __ __ __ Last date received __ __/__ __/__ __ __ __	
Received transplant of tissue/organs or artificial insemination	□ Yes □ No □ Unknown
Worked in a healthcare or clinical laboratory setting	□ Yes □ No □ Unknown
If occupational exposure is being investigated or considered as primary mode of exposure, specify occupation and setting: _____	
Other documented risk (include detail in Comments)_____	□ Yes □ No □ Unknown

- These data yield information about how patients may have acquired their infections.
  - Check box at the top of this section if the risk factor was a pediatric risk factor and enter additional information in the Comments section. In eHARS, on the ACRF select the "Show Pediatric Risk Factors" check box on the "History tab to display and record the pediatric risk factor.
  - Respond to each risk factor, selecting "Yes" for all factors that apply; "No" for those

that do not apply (only select "No" if medical record specifically states this is not a risk factor); and "Unknown" for those for which investigation failed to yield an answer. If an investigation for a particular item was not performed, then you should leave it blank. Collect data about risk factors that occurred before the earliest known diagnosis of HIV infection. For further guidance, see Technical Guidance File *Risk Factor Ascertainment*.
    - See Appendix 7.0 for further guidance on risk factor ascertainment.

7.1 SEX WITH MALE (**Required**, applies to health department & health care providers)
- Select applicable response based on the partner's sex assigned at birth. If search for this datum was completed and the partner's sex assigned at birth cannot be determined, select "Unknown".
- Some examples of information from the medical record which would strongly indicate sex with a male are below.
    - For male patient:
        - Married to or divorced from a male;
        - Rectal gonorrhea.
    - For female patient:
        - Married to or divorced from a male;
        - Boyfriend referenced in the medical record;
        - Living with a male partner;
        - History of pregnancy;
        - History of another sexually transmitted infection (in addition to HIV);
        - Sex worker (either current or in the past).

7.2 SEX WITH FEMALE (**Required**, applies to health department & health care providers)
- Select applicable response based on the partner's sex assigned at birth. If search for this datum was completed and the partner's sex assigned at birth cannot be determined, select "Unknown".
- Some examples of information from the medical record which would strongly indicate sex with a female are below.
    - For male patient:
        - Married to or divorced from a female;
        - Has a biological child
    - For female patient:
        - Married to or divorced from a female.

7.3 INJECTED NON-PRESCRIPTION DRUGS (**Required**, applies to health department & health care providers)
- Select applicable response.
- Select "Yes" if the patient injected illicit or nonprescription drugs at any time in the past or if a drug prescribed to the patient was injected when there is evidence that injection equipment was shared (e.g., syringes, needles, cookers).

7.4-7.6 RECEIVED CLOTTING FACTOR FOR HEMOPHILIA/COAGULATION DISORDER, SPECIFY CLOTTING FACTOR, and DATE RECEIVED (**Required**, applies to health department & health care providers)
- Select applicable response.
- "Coagulation disorder" or "hemophilia" refers only to a disorder of a clotting factor; factors are any of the circulating proteins named Factor I through Factor XII. These disorders include Hemophilia A and Von Willebrand's disease (Factor VIII disorders) and Hemophilia B (a Factor IX disorder).

- This risk factor is generally documented in the history and physical section of the patient's medical chart.
- They do not include other bleeding disorders, such as thrombocytopenia, treatable by platelet transfusion.
- If only a transfusion of platelets, other blood cells, or plasma was received by the partner, then select "No".
- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection and cases of public health importance (COPHI).
- Alert state/local COPHI coordinator if select "Yes".
- If "Yes", specify the clotting factor and enter date received. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

7.7 HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING:

- This section, addressed at 7.7.1–7.7.6, relates to ascertainment of risk among persons who had heterosexual contact (had sex with) with the case patient.
- Heterosexual contact is defined as the patient having sexual contact with a partner whose sex assigned at birth is different from the patient's sex assigned at birth.
- Verification of sex partner's HIV infection status is not necessary.

7.7.1 PERSON WHO INJECTED DRUGS (**Required**, applies to health department & health care providers)
- Select applicable response.
- Select "Yes" if the partner injected illicit or nonprescription drugs at any time in the past or if a drug prescribed to the partner was injected when there is evidence that injection equipment was shared (e.g., syringes, needles, cookers).

7.7.2 BISEXUAL MALE (**Required**, applies to health department & health care providers)
- Select applicable response only if patient's sex assigned at birth is female. "Yes" should be selected only if the partner's sex assigned at birth is male and there is evidence that the partner also had sex with another person whose sex assigned at birth was male.

7.7.3 PERSON WITH HEMOPHILIA/COAGULATION DISORDER WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- Select applicable response.
- Refer to 7.4-7.6 for additional information.

7.7.4 TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- Select applicable response.
- Consider documenting the reason for transfusion in the Comments section. In eHARS, enter on the "Comments" tab.

7.7.5 TRANSPLANT RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- Select applicable response.
- Consider documenting the reason for transplant in the Comments section. In eHARS, enter on the "Comments" tab.

7.7.6 PERSON WITH DOCUMENTED HIV INFECTION, RISK NOT SPECIFIED (**Required**, applies to health department & health care providers)
- Select applicable response.
- Select "Yes" only if HETEROSEXUAL sex partner is known to be HIV positive and

that partner's risk factor for HIV is unknown.

7.8-7.10 RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR), FIRST DATE RECEIVED, and LAST DATE RECEIVED (**Required**, applies to health department & health care providers)

- Select applicable response.
- Blood is defined as a circulating tissue composed of a fluid portion (plasma) with suspended formed elements (red blood cells, white blood cells, platelets).
- Blood components that can be transfused include erythrocytes, leukocytes, platelets, and plasma.
- It is often helpful to document the reason for the transfusion in the Comments section. In eHARS, enter on the "Comments" tab.
- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection and COPHI.
- If the last transfusion was after March 1985, then alert state/local COPHI coordinator.
- If "Yes", enter the dates first and last received in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

7.11 RECEIVED TRANSPLANT OF TISSUE/ORGANS OR ARTIFICIAL INSEMINATION (**Required**, applies to health department & health care providers)

- Select applicable response.
- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection and COPHI.
- Alert the state/local COPHI coordinator if select "Yes".

7.12-7.13 WORKED IN HEALTH CARE OR CLINICAL LABORATORY SETTING and IF OCCUPATIONAL EXPOSURE IS BEING INVESTIGATED OR CONSIDERED AS PRIMARY MODE OF EXPOSURE, SPECIFY OCCUPATION AND SETTING (**Required** applies to health department & health care providers)

- Select applicable response.
- Investigate apparent occupational exposures to determine if this was the only risk factor present.
- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection and COPHI.
- Alert state/local COPHI coordinator if select "Yes".
- If "Yes", specify occupation and setting.

7.14 OTHER DOCUMENTED RISK (**Required** applies to health department & health care providers)

- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on unusual transmission history that could be considered as potential COPHI.
- Select applicable response.
- Document details of the risk information in the Comments section. In eHARS, enter on the "Comments" tab.

8. Clinical: Acute HIV Infection and Opportunistic Illnesses

VIII. Clinical: Acute HIV Infection and Opportunistic Illnesses (record all dates as mm/dd/yyyy)

Suspect acute HIV infection? *If YES, complete the two items below; enter documented negative HIV test result data in Laboratory Data section, and enter patient or provider report of previous negative HIV test result in HIV Testing History section*	☐ Yes ☐ No ☐ Unknown
Clinical signs/symptoms consistent with acute retroviral syndrome (e.g., fever, malaise/fatigue, myalgia, pharyngitis, rash, lymphadenopathy)? Date of sign/symptom onset __ __/__ __/__ __ __ __	☐ Yes ☐ No ☐ Unknown
Other evidence suggestive of acute HIV infection? *If YES, describe:* _____ Date of evidence __ __/__ __/__ __ __ __	☐ Yes ☐ No ☐ Unknown

Opportunistic Illnesses

Diagnosis	Dx Date	Diagnosis	Dx Date	Diagnosis	Dx Date
Candidiasis, bronchi, trachea, or lungs		Herpes simplex: chronic ulcers (>1 mo. duration), bronchitis, pneumonitis, or esophagitis		M. tuberculosis, pulmonary[1]	
Candidiasis, esophageal		Histoplasmosis, disseminated or extrapulmonary		M. tuberculosis, disseminated or extrapulmonary[1]	
Carcinoma, invasive cervical		Isosporiasis, chronic intestinal (>1 mo. duration)		Mycobacterium, of other/unidentified species, disseminated or extrapulmonary	
Coccidioidomycosis, disseminated or extrapulmonary		Kaposi's sarcoma		Pneumocystis pneumonia	
Cryptococcosis, extrapulmonary		Lymphoma, Burkitt's (or equivalent)		Pneumonia, recurrent, in 12 mo. period	
Cryptosporidiosis, chronic intestinal (>1 mo. duration)		Lymphoma, immunoblastic (or equivalent)		Progressive multifocal leukoencephalopathy	
Cytomegalovirus disease (other than in liver, spleen, or nodes)		Lymphoma, primary in brain		Salmonella septicemia, recurrent	
Cytomegalovirus retinitis (with loss of vision)		Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary		Toxoplasmosis of brain, onset at >1 mo. of age	
HIV encephalopathy				Wasting syndrome due to HIV	

[1]If a diagnosis date is entered for either tuberculosis diagnosis above, provide RVCT Case Number:

8.1 CLINICAL: ACUTE HIV INFECTION

- Collection of acute HIV infection information is **recommended** for all state and local health departments.
- The purpose of this section is to facilitate the identification of persons with acute HIV infection for more urgent follow-up, as applicable according to state and local health department policies and practices. Acute HIV infections are more transmissible than other HIV infections. Clinical criteria for acute HIV infection may overlap the surveillance case definition of stage 0 (early HIV infection).
    - Persons more likely to have acute HIV infection may be identified by a shorter interval (relative to the stage-0-defining period of up to 180 days) between a negative or indeterminate HIV test result and the first HIV-positive test result associated with diagnosis. The maximum length of the interval between these two tests could range from 30 to 90 days and may be determined locally.
    - This section includes clinical (non-laboratory) data to supplement the laboratory-based criteria for stage 0 to identify persons with probable or possible acute HIV infection for follow-up as applicable.
- These variables indicative of probable or possible acute HIV infection may be used separately or in combination with the eHARS stage 0 variable (*stage_zero_dx*) to inform epidemiologic analyses.
- For further information about acute HIV infection, see Technical Guidance File *Early HIV Infection, HIV-2, and Other Diagnostic Considerations*.

8.1.1 SUSPECT ACUTE HIV INFECTION? (**Recommended,** applies to health department & health care providers)

- This variable is meant to encompass all sources of available information that might indicate acute HIV, and its use could vary with each state or local jurisdiction's policies and practices. For further information about the sources of information, see Technical Guidance File *Source Data and Completeness of Case Reporting*. The information about acute HIV status could include laboratory-documented evidence from the laboratory-based HIV testing algorithm, such as having a positive initial immunoassay result followed by a negative or indeterminate type-differentiating supplemental test and a subsequent positive NAT; or it could include a laboratory-documented or patient or provider reported history of a previous negative HIV test before diagnosis. Additionally, it could include information from a provider reporting

that the patient had acute HIV, or include provider notes about symptoms of acute HIV, or there may have been clear information about a specific exposure that occurred just before diagnosis and no possibility of exposure prior to that specific occurrence.
    - Select "Yes" if there is any evidence to suspect that the patient had acute HIV infection at diagnosis. If "Yes" is selected, then ensure the following:
        - Complete the items below for "Clinical signs/symptoms consistent with acute retroviral syndrome" and "Other evidence suggestive of acute HIV infection".
        - Documented negative or indeterminate HIV test results that include the type of test and date should be entered in the Laboratory Data section.
        - Patient or provider reports of a previous negative HIV test should be entered in the HIV Testing History section.
    - "No" indicates sufficient evidence that the patient did not have acute HIV infection at diagnosis.
    - "Unknown" indicates there is insufficient evidence to indicate whether the patient had acute HIV infection at diagnosis, after searching for the information, consulting with the provider, or asking the patient.

8.1.2 CLINICAL SIGNS/SYMPTOMS CONSISTENT WITH ACUTE RETROVIRAL SYNDROME (**Recommended,** applies to health department & health care providers)
- This field is intended for collecting evidence of the 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). For a more complete list of the clinical symptoms associated with acute HIV, refer to Appendix 8.1.2.
- This information would typically be found in the clinical record and could be explicitly stated as acute retroviral syndrome (ARS) or primary HIV infection (PHI), or that the provider suspects acute infection, or there could just be a description of the case's presenting symptoms at the time of HIV testing together with plausible information about a recent HIV exposure. Ideally, ARS or PHI would be determined by a clinician who has ruled out other illness.
- If it is unclear whether any symptoms are related to acute HIV, consult with medical professionals.
- Select "Yes" if there is clear evidence that the patient had clinical signs/symptoms consistent with acute retroviral syndrome.
- "No" indicates sufficient evidence that the patient did not clinical signs/symptoms consistent with acute retroviral syndrome.
- "Unknown" indicates there is insufficient evidence to indicate whether the patient had clinical signs/symptoms consistent with acute retroviral syndrome, after searching for the information, consulting with the provider, or asking the patient.

8.1.3 DATE OF SIGN/SYMPTOM ONSET (**Recommended,** applies to health department & health care providers)
- Record the earliest date of sign/symptom onset.
- Enter date in *mm/dd/yyyy* format. If day is unknown, use ".." for the unknown value (e.g., 03/../2017).

8.1.4 OTHER EVIDENCE SUGGESTIVE OF ACUTE HIV INFECTION? (**Recommended,** applies to health department & health care providers)
- Select "Yes" if there is any other evidence of acute HIV that is not based on diagnostic HIV-related test information or signs/symptoms of acute HIV. An example would be a patient who had a high viral load (>500,000 copies/mL) at or within 6 weeks after diagnosis, or a clear exposure to HIV that occurred just before diagnosis

in the setting where an earlier source of infection is unlikely (e.g., a rape or an occupational exposure).
    - Viral load data should be entered in the Laboratory Data section.
    - Note that an occupational exposure would also be followed up as a COPHI.
- "No" indicates sufficient information to indicate no other evidence of acute HIV infection.
- "Unknown" indicates there is insufficient evidence to indicate whether there was any other evidence of acute HIV infection, after searching for the information, consulting with the provider, or asking the patient.

8.1.5 OTHER EVIDENCE SUGGESTIVE OF ACUTE HIV INFECTION (SPECIFY) (**Recommended,** applies to health department & health care providers)
- Enter a brief description of the exposure leading to the determination of a presumptive acute HIV diagnosis, (e.g., "High viral load—980,000 copies/mL", or "Patient raped in Feb, HIV diagnosis in March").

8.1.6 DATE OF EVIDENCE (**Recommended,** applies to health department & health care providers)
- Record the date associated with the other evidence.
- Enter date in *mm/dd/yyyy* format. If day is unknown, use ".." for the unknown value (e.g., 03/../2017).

8.2 CLINICAL: OPPORTUNISTIC ILLNESSES

8.2.1–8.2.26 (**Optional,** applies to health department & health care providers)
- Select all that apply and enter diagnosis dates. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- For additional information, refer to the most recent case definition for HIV infection (available at https://ndc.services.cdc.gov/conditions/hiv-infection-aids-has-been-reclassified-as-hiv-stage-iii/).

8.2.27 RVCT CASE NUMBER (**Optional,** applies to health department & health care providers)
- If this patient has a verified case of tuberculosis (TB), health department staff enter the nine-digit alphanumeric code from the TB case report or TB data management system. Providers in the private and public sectors diagnosing tuberculosis in their stage 3 (AIDS) patients may get this number from TB surveillance staff.

9. Laboratory Data

IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy)

HIV Immunoassays

TEST ☐ HIV-1 IA ☐ HIV-1/2 IA ☐ HIV-1/2 Ag/Ab ☐ HIV-2 IA
Test Brand Name/Manufacturer _____ **Lab Name** _____
Facility Name _____ **Provider Name** _____
Result ☐ Positive ☐ Negative ☐ Indeterminate **Collection Date** __ __ /__ __ /__ __ __ __
Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy) *(cont)*

TEST ☐ HIV-1/2 Ag/Ab differentiating immunoassay (differentiates between HIV Ag and HIV Ab)
Test Brand Name/Manufacturer _____ **Lab Name** _____
Facility Name _____ **Provider Name** _____
Result ***Overall:*** ☐ Reactive ☐ Nonreactive **Collection Date** __ __ /__ __ /__ __ __ __
Analyte results: HIV-1 Ag: ☐ Reactive ☐ Nonreactive HIV-1/2 Ab: ☐ Reactive ☐ Nonreactive
Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

TEST ☐ HIV-1/2 Ag/Ab and type-differentiating immunoassay (differentiates among HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab)
Test Brand Name/Manufacturer _____ **Lab Name** _____
Facility Name _____ **Provider Name** _____
Result[3] ***Overall interpretation***: ☐ Reactive ☐ Nonreactive ☐ **Index Value** _____ **Collection Date** __ __ /__ __ /__ __ __ __
Analyte results: HIV-1 Ag: ☐ Reactive ☐ Nonreactive ☐ Not reportable due to high Ab level **Index Value** _____
HIV-1 Ab: ☐ Reactive ☐ Nonreactive ☐ Reactive undifferentiated **Index Value** _____
HIV-2 Ab: ☐ Reactive ☐ Nonreactive ☐ Reactive undifferentiated **Index Value** _____
Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

TEST ☐ HIV-1/2 type-differentiating immunoassay (supplemental) (differentiates between HIV-1 Ab and HIV-2 Ab)
Test Brand Name/Manufacturer _____ **Lab Name** _____
Facility Name _____ **Provider Name** _____
Result[4] ***Overall interpretation***: ☐ HIV positive, untypable ☐ HIV-1 positive with HIV-2 cross-reactivity ☐ HIV-2 positive with HIV-1 cross-reactivity
☐ HIV negative ☐ HIV indeterminate ☐ HIV-1 indeterminate ☐ HIV-2 indeterminate ☐ HIV-1 positive ☐ HIV-2 positive
Analyte results: HIV-1 Ab: ☐ Positive ☐ Negative ☐ Indeterminate **Collection Date** __ __ /__ __ /__ __ __ __
HIV-2 Ab: ☐ Positive ☐ Negative ☐ Indeterminate
Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

TEST ☐ HIV-1 WB ☐ HIV-1 IFA ☐ HIV-2 WB
Test Brand Name/Manufacturer _____ **Lab Name** _____
Facility Name _____ **Provider Name** _____
Result ☐ Positive ☐ Negative ☐ Indeterminate **Collection Date** __ __ /__ __ /__ __ __ __
Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

HIV Detection Tests

TEST ☐ HIV-1/2 RNA NAAT (Qualitative) **Lab Name** _____
Test Brand Name/Manufacturer _____ **Provider Name** _____
Facility Name _____ **Collection Date** __ __ /__ __ /__ __ __ __
Result ☐ HIV-1 ☐ HIV-2 ☐ Both (HIV-1 and HIV-2) ☐ HIV, not differentiated (HIV-1 or HIV-2) ☐ Neither (negative)
Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

TEST ☐ HIV-1 RNA NAAT (Qualitative and Quantitative)
Test Brand Name/Manufacturer _____ **Lab Name** _____
Facility Name _____ **Provider Name** _____
Result ***Qualitative:*** ☐ Reactive ☐ Nonreactive **Collection Date** __ __ /__ __ /__ __ __ __
Analyte results: HIV-1 Quantitative: ☐ Detectable above limit ☐ Detectable within limits ☐ Detectable below limit
Copies/mL _____ **Log** _____
Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

TEST ☐ HIV-1 RNA/DNA NAAT (Qualitative) ☐ HIV-1 culture ☐ HIV-2 RNA/DNA NAAT (Qualitative) ☐ HIV-2 culture
Test Brand Name/Manufacturer _____ **Lab Name** _____
Facility Name _____ **Provider Name** _____
Result ☐ Positive ☐ Negative ☐ Indeterminate **Collection Date** __ __ /__ __ /__ __ __ __
Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

TEST ☐ HIV-1 RNA/DNA NAAT (Quantitative) ☐ HIV-2 RNA/DNA NAAT (Quantitative)
Test Brand Name/Manufacturer _____ **Lab Name** _____
Facility Name _____ **Provider Name** _____
Result ☐ Detectable above limit ☐ Detectable within limits ☐ Detectable below limit ☐ Not detected **Copies/mL** _____ **Log** _____
Collection Date __ __ /__ __ /__ __ __ __
Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

Drug Resistance Tests (Genotypic)

TEST ☐ HIV-1 Genotype (Unspecified) **Test Brand Name/Manufacturer** _____
Lab Name _____ **Facility Name** _____
Provider Name _____ **Collection Date** __ __ /__ __ /__ __ __ __

Immunologic Tests (CD4 count and percentage)

CD4 count _____ cells/μL **CD4 percentage** _____ % **Collection Date** __ __ /__ __ /__ __ __ __
Test Brand Name/Manufacturer _____ **Lab Name** _____
Facility Name _____ **Provider Name** _____

Documentation of Tests

Did documented laboratory test results meet approved HIV diagnostic algorithm criteria? ☐ Yes ☐ No ☐ Unknown
If YES, provide specimen collection date of earliest positive test result for this algorithm __ __ /__ __ /__ __ __ __
*Complete the above only if none of the following were positive for **HIV-1**: Western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen, or nucleotide sequence.*

Is earliest evidence of HIV infection diagnosis documented by a physician rather than by laboratory test results? ☐ Yes ☐ No ☐ Unknown
If YES, provide date of diagnosis by physician __ __ /__ __ /__ __ __ __

Date of last documented negative HIV test result (before HIV diagnosis date) __ __ /__ __ /__ __ __ __
Specify type of test: _____
Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

[2]Results not directly observed by a provider should be recorded in HIV Testing History.
[3]Complete the overall interpretation and the analyte results.
[4]Always complete the overall interpretation. Complete the analyte results when available.

- Throughout this section, "Collection Date" refers to the date when the specimen was collected or drawn. Enter collection dates in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- Record all laboratory test results. Include results all diagnostic tests, viral load tests, CD4 tests, and drug resistance tests (genotypic) where possible. Where the number of test results exceeds the number of fields available on the form, record such results in the Comments section. In eHARS, enter the additional test results on the "Lab Data" tab with the applicable test type.
- Include tests with negative or indeterminate results that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). For information on the current HIV diagnostic testing algorithm, please refer to https://stacks.cdc.gov/view/cdc/50872.
- In the absence of laboratory tests, record HIV infection or stage 3 (AIDS) diagnostic evidence documented in the chart by a physician.

9.1 HIV IMMUNOASSAYS (IA)

- Assuming active case finding, review patient's chart and laboratory reports for the earliest date of documented HIV positivity.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Enter results and collection dates for all tests (including negative or indeterminate test results) that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). (**Required,** applies to health department & health care providers)
    - Enter specimen collection date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- Enter testing option for all tests. (**Optional**, applies to health department & health care providers)
    - Enter "Point-of-care test by provider" if the test was performed by the provider either in a healthcare setting or other testing venue.
    - Enter "Self-test, result directly observed by provider" if the test was performed by the patient but directly observed by a provider (including via a telemedicine appointment).
    - Enter "Lab-test, self-collected sample" if the patient collected the sample (blood or oral fluid) and sent it to the laboratory for testing.

9.1.1 HIV-1 IA

- Enter result and collection date of first HIV-1 IA. (**Required**, applies to health department & health care providers)
- "Positive IA" means a result of repeatedly reactive on a single sample.

9.1.2 HIV-1/2 IA

- Enter result and date of first HIV-1/2 IA. (**Required**, applies to health department & health care providers)
- "Positive IA" means a result of repeatedly reactive on a single sample.

9.1.3 HIV-1/2 AG/AB

- Enter result and collection date of first HIV-1/2 combination IA test. (**Required**, applies to health department & health care providers)
- "Positive IA" means a result of repeatedly reactive on a single sample.

9.1.4 HIV-2 IA

- Enter result and collection date of first HIV-2 IA. (**Required**, applies to health

department & health care providers)
    - "Positive IA" means a result of repeatedly reactive on a single sample.

9.1.5 HIV-1/2 AG/AB-DIFFERENTIATING IMMUNOASSAY
- Enter collection date of first HIV-1/2 Ag/Ab-Differentiating IA. (**Required**, applies to health department & health care providers)
- Enter the Overall interpretation of the test. (**Required**, applies to health department & health care providers)
- Record the result for each analyte (HIV-1 Ag and HIV-1/2 Ab). That is, one result should be recorded for HIV-1 Ag, one result for HIV-1/2 Ab result. (**Required**, applies to health department & health care providers)

9.1.6 HIV-1/2 AG/AB AND TYPE-DIFFERENTIATING IMMUNOASSAY
- Enter collection date of first HIV-1/2 Ag/Ab and Type-Differentiating IA. (**Required**, applies to health department & health care providers)
- Enter the Overall interpretation of the test. (**Required**, applies to health department & health care providers)
- If provided, enter index value for the overall interpretation. (**Optional**, applies to health department & health care providers)
- Record the result for each analyte (HIV-1 Ag and HIV-1 Ab and HIV-2 Ab). That is, one result should be recorded for HIV-1 Ag, one result for HIV-1 Ab and one result should be recorded for HIV-2 Ab. (**Required**, applies to health department & health care providers)
- Enter the index value for each analyte. (**Optional**, applies to health department & health care providers)

9.1.7 HIV-1/2 TYPE-DIFFERENTIATING IMMUNOASSAY (supplemental)
- Enter collection date of first HIV-1/2 Type-Differentiating IA. (**Required**, applies to health department & health care providers)
- Enter the overall interpretation of the test. (**Required**, applies to health department & health care providers)
- Record the result for each analyte (HIV-1 Ab and HIV-2 Ab). That is, one result should be recorded for HIV-1 Ab and one result should be recorded for HIV-2 Ab. (**Required**, applies to health department & health care providers)

9.1.8 HIV-1 WESTERN BLOT
- Enter the result and collection date of first HIV-1 western blot. (**Required**, applies to health department & health care providers)
- Western blot banding patterns should be interpreted according to the CDC/Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) recommendations *Interpretation and use of the western blot assay for serodiagnosis of human immunodeficiency virus type 1 infections*. MMWR Suppl. 1989 Jul 21;38(7):1-7. PMID: 2501638.

9.1.9 HIV-1 IFA
- Enter the result and collection date of first HIV-1 IFA. (**Required**, applies to health department & health care providers)

9.1.10 HIV-2 WESTERN BLOT
- Enter the result and collection date of first HIV-2 western blot. (**Required,** applies to health department & health care providers)

9.2 HIV DETECTION TESTS
- All varieties of such tests establish the presence of the pathogen, HIV. By contrast, HIV tests such as an immunoassay or western blot establish the presence of the immune system's

response to the pathogen (i.e., HIV antibodies).

- Assuming active case finding, review patient's chart and laboratory reports for the earliest date of documented HIV positivity.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Enter results and collection dates for all tests (including negative or indeterminate test results) that are part of a diagnostic testing algorithm whose overall interpretation is positive (that the patient is HIV-infected). (**Required**, applies to health department & health care providers)
    - Enter specimen collection date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- Enter testing option for all tests. (**Optional**, applies to health department & health care providers)
    - Enter "Point-of-care test by provider" if the test was performed by the provider either in a healthcare setting or other testing venue.
    - Enter "Self-test, result directly observed by provider" if the test was performed by the patient but directly observed by a provider (including via a telemedicine appointment).
    - Enter "Lab-test, self-collected sample" if the patient collected the sample (blood or oral fluid) and sent it to the laboratory for testing.

9.2.1 HIV-1/2 RNA NAAT (QUALITATIVE)

- Enter result and collection date of earliest nucleic acid amplification test (NAAT). (**Required**, applies to health department & health care providers)

9.2.2 HIV-1 RNA NAAT (QUALITATIVE and QUANTITATIVE)

- Enter the collection date of earliest NAAT. (**Required**, applies to health department & health care providers)
- Enter the qualitative result of the test. (**Required**, applies to health department & health care providers)
- For all reactive qualitative results, record the result for the analyte (quantitative result). (**Required**, applies to health department & health care providers)
    - Where results are reported as "Detected" above the limit of quantification (LOQ), select "Detectable above limit" and the result value in the copies/mL field. For example, a result of ">10,000,000 cp/mL detected" should be entered into the copies/ml field as "greater than detectable by this assay - 10,000,000 cp/mL".
    - Where results are reported as "Detected", select "Detectable within limits" and the result value in the copies/mL field.
    - Where the results reported as "Detected" below the LOQ, select "Detectable below limit" and the result value in the copies/mL field. For example, a result of "<20 cp/mL detected" should be entered into the copies/ml field as "fewer than detectable by this assay - 20 cp/mL".

9.2.3 HIV-1 RNA/DNA NAAT (QUALITATIVE)

- Enter result and collection date of earliest NAAT. (**Required**, applies to health department & health care providers)

9.2.4 HIV-1 Culture

- Enter result and collection date of earliest culture result. (**Required**, applies to health department & health care providers)

9.2.5 HIV-2 RNA/DNA NAAT (QUALITATIVE)

- Enter result and collection date of earliest NAAT. (**Required**, applies to health

department & health care providers)

9.2.6 HIV-2 Culture

- Enter result and collection date of earliest culture result. (**Required**, applies to health department & health care providers)

9.2.7 HIV-1 RNA/DNA NAAT (QUANTITATIVE)

- Enter date of earliest NAAT. (**Required**, applies to health department & health care providers)
- Enter the result of the test. (**Required**, applies to health department & health care providers)
    - Where results are reported as "Detected" above the limit of quantification (LOQ), select "Detectable above limit" and the result value in the copies/mL field. For example, a result of ">10,000,000 cp/mL detected" should be entered into the copies/ml field as "greater than detectable by this assay - 10,000,000 cp/mL".
    - Where results are reported as "Detected", select "Detectable within limits" and the result value in the copies/mL field.
    - Where the results reported as "Detected" below the LOQ, select "Detectable below limit" and the result value in the copies/mL field. For example, a result of "<20 cp/mL detected" should be entered into the copies/ml field as "fewer than detectable by this assay - 20 cp/mL".
    - Where the results reported as "Not detected", select "Not detected".

9.2.8 HIV-2 RNA/DNA NAAT (QUANTITATIVE)

- Enter date of earliest NAAT. (**Required**, applies to health department & health care providers)
- Enter the result of the test. (**Required**, applies to health department & health care providers)
    - Where results are reported as "Detected" above the limit of quantification (LOQ), select "Detectable above limit" and the result value in the copies/mL field. For example, a result of ">10,000,000 cp/mL detected" should be entered into the copies/ml field as "greater than detectable by this assay - 10,000,000 cp/mL".
    - Where results are reported as "Detected", select "Detectable within limits" and the result value in the copies/mL field.
    - Where the results reported as "Detected" below the LOQ, select "Detectable below limit" and the result value in the copies/mL field. For example, a result of "<20 cp/mL detected" should be entered into the copies/ml field as "fewer than detectable by this assay - 20 cp/mL".
    - Where the results reported as "Not detected", select "Not detected".

9.3 DRUG RESISTANCE TESTS (GENOTYPIC)

- This section should be completed if there is evidence of a drug resistance test (genotypic), regardless of the type of drug resistance test, in the patient's medical or other record.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Enter the collection date of the earliest test. (**Required**, applies to health department & health care providers)
- When entering this information in eHARS, you should use the "Lab Data" tab and choose "HIV-1 Genotype (Unspecified)" as the test type. You will not be able to enter a genotype sequence since this test type only captures evidence of a drug resistance test (genotypic). If a corresponding genotype sequence is subsequently received, you should import this

information as a separate laboratory document using the test type that reflects the type of drug resistance test that was conducted (e.g., HIV-1 Genotype (PR/RT RNA Nucleotide Sequence-Sanger method)).

9.4 IMMUNOLOGIC TESTS (CD4 COUNT AND PERCENTAGE)

- Enter the results of *all* HIV-related CD4 tests that are available from the source where information is being collected to complete the form. At minimum, the first CD4 results closest to the date of initial HIV infection diagnosis should be reported and the first CD4 results indicative of stage 3 (AIDS) should be reported if available.
- Enter the brand name of the test and/or its manufacturer, laboratory name, facility name and provider name. (**Optional**, applies to health department & health care providers)
- Whenever CD4 count and percentage are both available for the same specimen collection date, record both.
- Enter specimen collection date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011). (**Required**, applies to health department & health care providers)

9.4.1 CD4 COUNT

- Enter result and specimen collection date of all CD4 counts. (**Required**, applies to health department & health care providers)

9.4.2 CD4 PERCENTAGE

- Record result and specimen collection date of all CD4 percentages. (**Required**, applies to health department & health care providers)

9.5 DOCUMENTATION OF TESTS

9.5.1 DID DOCUMENTED LABORATORY TEST RESULTS MEET APPROVED HIV DIAGNOSTIC ALGORITHM CRITERIA? (**Required** if applicable, applies to health department & health care providers)

- This section captures diagnoses through novel algorithms and should only be completed if none of the following were positive for **HIV-1**: western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen test, or nucleotide sequence.
- HIV-1 antigen analyte results from combination antigen/antibody tests in which the antigen result can be differentiated from the antibody result, such as an "HIV-1/2 Ag/Ab differentiating immunoassay" or an "HIV-1/2 Ag/Ab and type-differentiating immunoassay", are *not* considered stand-alone p24 antigen tests. Refer to sections 9.1.5 and 9.1.6 for more information regarding combination Ag/Ab IA.
- "Yes" indicates that the test results were determined to be part of a diagnostic testing algorithm that satisfies the HIV surveillance case definition for HIV-1 or HIV-2 (refer to the most recent case definition for HIV infection available at https://ndc.services.cdc.gov/conditions/hiv-infection-aids-has-been-reclassified-as-hiv-stage-iii/), regardless of whether the tests were approved for other purposes such as laboratory-based HIV testing or point-of-care HIV screening.
    - If "Yes", enter date of earliest positive test result for this algorithm in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011). (**Required** if applicable, applies to health department & health care providers).
- "No" indicates that the test results were determined to *not* be a part of a diagnostic testing algorithm that satisfies the HIV surveillance case definition for HIV-1 or HIV-2.

- "Unknown" indicates that you are unable to determine whether the test results were part of a diagnostic testing algorithm that satisfies the HIV surveillance case definition for HIV-1 or HIV-2.
- Values of "No" and "Unknown" should generally not be selected. This form is intended to be used to ascertain that two tests *are* part of an algorithm that meet the HIV surveillance case definition. Carefully review all "No" and "Unknown" responses before entering into the surveillance system.

9.5.2 IS EARLIEST EVIDENCE OF HIV INFECTION DIAGNOSIS DOCUMENTED BY A PHYSICIAN RATHER THAN BY LABORATORY TEST RESULTS? (**Required** if applicable, applies to health department & health care providers)

- If laboratory evidence of an HIV test is unavailable or was insufficient to meet surveillance case definition in the patient's medical or other record and written documentation of laboratory evidence of HIV infection consistent with the HIV case definition is noted by the physician, enter "Yes"; otherwise enter "No" or "Unknown".
- IF "YES" TO 9.5.2, PROVIDE DATE OF DIAGNOSIS BY PHYSICIAN (**Required** in the absence of laboratory results, applies to health department & health care providers)
- Date of diagnosis is defined as the date (at least the year) of diagnosis reported in the content of the medical record. If the diagnosis date was not reported in the note, the date when the note was written can be used as a proxy. For example, if a health care provider writes a note in a medical chart on 4/10/2010 stating the patient had received a diagnosis of HIV infection on 2/11/2010, then 2/11/2010 should be recorded as the date of diagnosis by the physician.

9.5.3 DATE OF LAST DOCUMENTED NEGATIVE HIV TEST RESULT (SPECIFY TYPE) (**Required**, applies to health department & health care providers)

- This represents the last documented date when the patient was considered not to be HIV infected, as documented by laboratory or medical record evidence accompanied by test type information.
- Patient self-report of last negative test result is not considered "documented" and thus should not be entered in this field but rather in the HIV Testing History section (see sections 12.6 and 12.7 below).
- Enter the specimen collection date for the date of the last negative HIV test result in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011). (**Required**, applies to health department & health care providers)
- Enter the type of test that yielded the last negative HIV test result. (**Required**, applies to health department & health care providers)
- Include the last negative HIV laboratory test result before the patient was known to be infected. Do not include in this field a negative test result as part of a sequence of tests in an algorithm that has a final interpretation indicating that the patient was infected with HIV. Negative test results that are part of a sequence of HIV tests in an algorithm should be recorded in the appropriate laboratory test fields above.
- If it is unclear how to interpret a negative test result that is part of a testing algorithm, it may be necessary to contact the provider ordering the tests.
- Do not include an undetectable viral load result, unless there is evidence that the patient was **not** receiving antiretroviral therapy at the time the viral load specimen was obtained. A viral load result alone is not considered sufficient evidence of the absence of HIV infection (e.g., the patient may have been receiving antiretroviral therapy when the specimen was obtained, or may naturally have a suppressed viral load without antiretroviral therapy).

- Do not include tests with indeterminate, inconclusive, or unknown results in this field. Any indeterminate HIV test results that are part of a diagnostic testing algorithm should be recorded in the appropriate laboratory test fields above.

10. Treatment/Services Referrals

X. Treatment/Services Referrals (record all dates as mm/dd/yyyy)

Has this patient been informed of his/her HIV infection? ☐ Yes ☐ No ☐ Unknown	**This patient's partners will be notified about their HIV exposure and counseled by** ☐ 1-Health dept ☐ 2-Physician/Provider ☐ 3-Patient ☐ 9-Unknown	
Evidence of receipt of HIV medical care other than laboratory test result (select one; record additional evidence in Comments) ☐ 1-Yes, documented ☐ 2-Yes, client self-report, only Date of medical visit or prescription __ __/__ __/__ __ __ __		
For Female Patient		
This patient is receiving or has been referred for gynecological or obstetrical services ☐ Yes ☐ No ☐ Unknown	**Is this patient currently pregnant?** ☐ Yes ☐ No ☐ Unknown	**Has this patient delivered live-born infants?** ☐ Yes ☐ No ☐ Unknown
For Children of Patient (record most recent birth in these boxes; record additional or multiple births in Comments)		
***Child's Name**		**Child's Date of Birth** __ __/__ __/__ __ __ __
Child's Last Name Soundex	**Child's State Number**	
Facility Name of Birth (if child was born at home, enter "home birth")		***Phone** ( )
Facility Type *Inpatient:* ☐ Hospital ☐ Other, specify_____	*Outpatient:* ☐ Other, specify _____	*Other Facility:* ☐ Emergency room ☐ Corrections ☐ Unknown ☐ Other, specify _____
***Street Address**		***ZIP Code**
City	**County**	**State/Country**

- Treatment/services referrals information is for state and local health department use only and is not transmitted to CDC if marked with an * on the form.

10.1 HAS THIS PATIENT BEEN INFORMED OF HIS/HER HIV INFECTION (**Optional**, applies to health department & health care providers)
- 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.

10.2 THIS PATIENT'S PARTNERS WILL BE NOTIFIED ABOUT THEIR HIV EXPOSURE AND COUNSELED BY (**Optional**, applies to health department & health care providers)
- Select applicable response.

10.3 EVIDENCE OF RECEIPT OF HIV MEDICAL CARE OTHER THAN LABORATORY TEST RESULT (**Optional**, applies to health department & health care providers)
- Select applicable response.
- Additional evidence may be recorded in the Comments section. In eHARS, enter on the "Comments" tab.

10.4 DATE OF MEDICAL VISIT OR PRESCRIPTION
- Enter date in *mm/dd/yyyy* format. If day is unknown, use ".." for the unknown value (e.g., 03/../2017).

10.5 FOR FEMALE PATIENT
- Complete if the patient's sex assigned at birth is female.

10.5.1 THIS PATIENT IS RECEIVING OR HAS BEEN REFERRED FOR GYNECOLOGICAL OR OBSTETRICAL SERVICES (**Optional**, applies to health department & health care providers)
- Select applicable response.

10.5.2 IS THIS PATIENT CURRENTLY PREGNANT (**Required,** applies to health department & health care providers)
- Response is dependent on which date was selected for populating the field 3.9 (DATE

FORM COMPLETED). If patient was pregnant on that date, select "Yes".

10.5.3 HAS THIS PATIENT DELIVERED LIVE-BORN INFANTS (**Optional**, applies to health department & health care providers)
- Select applicable response.
- If "Yes", provide birth information for the most recent birth as described at 10.6 below.

10.6 FOR CHILDREN OF PATIENT

- Record information related to the most recent birth in this section. Record additional or multiple births in the Comments section. In eHARS, enter the additional births on the "Treatment" tab.

10.6.1 CHILD'S NAME (**Recommended,** applies to health department & health care providers)
- Enter child's first name, middle name, and last name.

10.6.2 CHILD'S DATE OF BIRTH (**Recommended,** applies to health department & health care providers)
- Enter child's date of birth in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

10.6.3 CHILD'S LAST NAME SOUNDEX (**System generated**)
- After the child's name is entered into eHARS, the software automatically generates this variable by using the child's last name. After the code is generated, health department staff should fill this field on the form.
- This variable is a phonetic, alphanumeric code calculated by converting a surname into an index letter and a three-digit code. The index letter is the first letter of the surname. The *eHARS Technical Reference Guide* describes exactly how the Last Name Soundex is created.

10.6.4 CHILD'S STATE NUMBER (**Recommended,** applies to health department)
- Enter the assigned state number, if applicable. This number is typically assigned by state/local health department personnel if the child is known to have received a diagnosis of HIV infection. Some jurisdictions also assign numbers for children classified as "Perinatally HIV Exposed" or "Seroreverter".
- If a child was a pediatric "Seroreverter" and was later infected with HIV, the child must be given two different state numbers, one associated with the "Seroreverter" and another associated with the HIV infection diagnosis. Refer to Appendix 4.1.4 in the Technical Guidance File *Pediatric HIV Confidential Case Report Form* for the definition of a pediatric "Seroreverter". Enter the child's state number associated with the "Seroreverter" on the case report form.
- Assigned numbers **must not** be reused, even if the case is later deleted.
- This variable is used, along with the state of report, to uniquely identify cases reported to CDC and to merge the state datasets without duplication.

10.6.5 FACILITY NAME OF BIRTH (**Optional**, applies to health department & health care providers)
- Enter the name of the facility where the child was born.
- If the child was born at home, enter "home birth".

10.6.6 PHONE (**Optional**, applies to health department & health care providers)
- Enter area code and telephone number of the facility of birth.

10.6.7 FACILITY TYPE (**Optional**, applies to health department & health care providers)
- Select the type of facility of birth.

- Refer to the *eHARS Technical Reference Guide* for listing of facility types.

10.6.8 STREET ADDRESS (**Optional**, applies to health department & health care providers)
- Enter street address of the facility of birth.

10.6.9 ZIP CODE (**Optional**, applies to health department & health care providers)
- Enter ZIP code where the facility of birth is located.

10.6.10 CITY (**Optional**, applies to health department & health care providers)
- Enter city of the facility of birth.

10.6.11 COUNTY (**Optional**, applies to health department & health care providers)
- Enter county of the facility of birth.

10.6.12 STATE/COUNTRY (**Optional**, applies to health department & health care providers)
- Enter state and country name of the facility of birth.

11. Antiretroviral Use History

XI. Antiretroviral Use History (record all dates as mm/dd/yyyy)

Main source of antiretroviral (ARV) use information (select one) ☐ Patient interview ☐ Medical record review ☐ Provider report ☐ NHM&E ☐ Other			**Date patient reported information** __ __/__ __/__ __ __ __
Ever taken any ARVs? ☐ Yes ☐ No ☐ Unknown			
If yes, reason for ARV use (select all that apply)			
☐ HIV Tx	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __
☐ PrEP	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __
☐ PEP	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __
☐ PMTCT	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __
☐ HBV Tx	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __
☐ Other (specify reason)_____			
	ARV medications_____	Date began __ __/__ __/__ __ __ __	Date of last use __ __/__ __/__ __ __ __

- ARV use history data are used to assess the prevalence of acquired and transmitted HIV drug resistance.
- Unlike other sections on the ACRF, patient self-reported information is accepted for all answers.

11.1 MAIN SOURCE OF ANTIRETROVIRAL (ARV) USE INFORMATION (**Required,** applies to health department & health care providers)
- Check only one source (the main source from which the information in this section was obtained).
  - "*Patient Interview*" should be selected only if the patient was directly asked a series of questions from this or another structured form. Interviewer should have been trained on the proper collection of ARV use history data.
  - "*Medical Record Review*" indicates that this information was obtained through abstraction of medical charts, electronic medical records or databases.
  - "*Provider Report*" indicates this form was filled out by a health care provider.
  - "*NHM&E"* indicates that data were abstracted from the National HIV Monitoring and Evaluation (NHM&E) project forms or databases.
  - "*Other"* indicates that information came from a source other than those listed above.

11.2 DATE PATIENT REPORTED INFORMATION (**Required**, applies to health department & health care providers)
- The appropriate date to enter depends on the MAIN SOURCE OF ARV USE INFORMATION. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- If there was a structured patient interview, enter the date of interview.
- For a medical record review, enter the date of the most recent patient encounter that contributed to the ARV information collected. If there was no patient encounter, then enter

the date the medical record was reviewed. If the ACRF was completed by a health care provider, enter the date of the most recent patient encounter during which the ARV information was obtained from the patient. If the provider information was obtained from another data source, enter the date of receipt of the information. If these dates are not available, enter the date the ACRF was completed.

- For information obtained through NHM&E, use the date entered on the HIV testing form.
- If there are no data available from the above sources, enter the date the ACRF was completed.

11.3 EVER TAKEN ANY ARVS (**Required**, applies to health department & health care providers)

- This variable indicates whether the patient has ever taken any antiretroviral medication. "Yes" indicates there is evidence that the patient has taken ARVs, including self-report.
- If "Yes", it is important to enter the dates when use began and, if appropriate, ended. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- "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.
- Leave the field blank if there was no attempt to find the information.

11.4 IF YES, REASON FOR ARV USE (**Required**, applies to health department & health care providers)

- Select all that apply.
- "HIV Tx" indicates that the patient used ARVs to treat HIV infection.
- "PrEP" indicates that the patient used ARVs prior to HIV diagnosis for HIV preexposure prophylaxis (PrEP). If "PrEP" is selected, please refer to the updated clinical practice guideline for PrEP at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. For surveillance activities, additional follow up with health care providers may be required for certain test results for final determination of HIV status.
- "PEP" indicates that the patient used ARVs as postexposure prophylaxis (PEP).
- "PMTCT" indicates that the patient used ARVs to prevent HIV mother-to-child-transmission during pregnancy.
- "HBV Tx" indicates that the patient used ARVs to treat hepatitis B virus infection.
- "Other" indicates that the patients used ARVs for a reason other than those indicated above.

11.5 ARV MEDICATIONS (**Recommended**, applies to health department & health care providers)

- For each ARV use reason indicated in 11.4, list the medications taken.
- This variable is used to verify that the medication taken was actually an antiretroviral.
- It is not necessary to list every drug combination that may have been used; record at least one ARV. Enter "unspecified" if an ARV was taken but the name is not known.

11.6 DATE BEGAN (**Required,** applies to health department & health care providers)

- For each ARV use reason indicated in 11.4, enter the earliest date that the patient took the ARVs, even if ARV use was sporadic.
- If the first time ARVs were taken occurred after HIV diagnosis, it is very important to enter a date, even an estimated date, later than the date of HIV diagnosis.
- Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

11.7 DATE OF LAST USE (**Required**, applies to health department & health care providers)

- For each ARV use reason indicated in 11.4, enter the most recent date of ARV use.
- For patients currently on ARVs, record the date of the most recent prescription or known usage. If the information was collected during a patient interview, the date would be the interview date. If the information was collected as part of a medical record review, record the

date of the most recent prescription or date of the most recent physician's note.
- Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

12. HIV Testing History

XII. HIV Testing History (record all dates as mm/dd/yyyy)

Main source of testing history information (select one) ☐ Patient interview ☐ Medical record review ☐ Provider report ☐ NHM&E ☐ Other	**Date patient reported information** __ __/__ __/__ __ __ __
Ever had previous positive HIV test result? ☐ Yes ☐ No ☐ Unknown **Date of first positive HIV test result** __ __/__ __/__ __ __ __ **Was the first positive test result from a self-test performed by the patient?** ☐ Yes ☐ No ☐ Unknown	
Ever had a negative HIV test result? ☐ Yes ☐ No ☐ Unknown **Date of last negative HIV test result** *(if date is from a lab test with test type, enter in Lab Data section)* __ __/__ __/__ __ __ __ **Was the last negative test result from a self-test performed by the patient?** ☐ Yes ☐ No ☐ Unknown	
Number of negative HIV test results within the 24 months before the first positive test result __ __ ☐ Unknown **How many of these negative test results were from self-tests performed by the patient?** __ __ ☐ Unknown	

- Unlike other sections on the ACRF, patient self-reported information is accepted for all answers.

12.1 MAIN SOURCE OF TESTING HISTORY INFORMATION (**Required**, applies to health department & health care providers)
- Check only one source (the main source from which the information in this section was obtained).
  - "*Patient Interview*" should be selected only if the patient was directly asked a series of questions from this or another structured form. Interviewer should have been trained on the proper collection of testing history data.
  - "*Medical Record Review*" indicates that this information was obtained through abstraction of medical charts, electronic medical records, or databases. Information may also have come from a database of HIV test results or pharmacy records.
  - "*Provider Report*" indicates this form was filled out by a health care provider.
  - "*NHM&E*" indicates that data were abstracted from the National HIV Monitoring and Evaluation (NHM&E) project forms or databases.
  - "*Other*" indicates that information came from a source other than those listed above.

12.2 DATE PATIENT REPORTED INFORMATION (**Required,** applies to health department & health care providers)
- The appropriate date to enter depends on the MAIN SOURCE OF TESTING HISTORY INFORMATION. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- For a medical record review, enter the date of the last patient encounter that contributed to the testing history information collected. If only a laboratory report was accessed, enter the date of receipt of the laboratory results. If there was no patient encounter or laboratory test receipt date, then enter the date the medical record review was performed.
- If there was a structured patient interview, enter the date of the interview.
- If the ACRF was completed by a health care provider, enter the date of the last patient encounter when the most recent testing history information was obtained from the patient. If provider's information only came from another data source, such as a laboratory report, enter the date of receipt of the information. If there are no such dates, enter the date the ACRF was completed.
- For information obtained through NHM&E, use the date entered on the HIV Test Form.
- If there are no data available from the above sources, enter the date the ACRF was completed.

12.3 EVER HAD PREVIOUS POSITIVE HIV TEST RESULT (**Required**, applies to health department & health care providers)

- The purpose of this variable is to ascertain whether a positive HIV test result occurred earlier than the current HIV diagnosis date but was not reported to the HIV surveillance system. For example, a patient could have been diagnosed in another state/country or tested anonymously.
- Self-reported information is acceptable.
- "Yes" indicates sufficient evidence that there was a previous positive HIV test result.
- "No" indicates sufficient evidence that there was no previous positive HIV test result.
- "Unknown" indicates that there is lack of evidence about previous HIV test results. Select "Unknown" if the patient refused to answer the question, if the facility refused to permit medical record review, or if the patient, chart reviewer, or provider had no knowledge of whether or not there was a previous positive HIV test result after searching for the information or asking the patient.
- The field should be left blank if the medical record was not searched or the question was not asked.
- Do not include indeterminate HIV test results, false positive test results, and tests with inconclusive or unknown results.

12.4 DATE OF FIRST POSITIVE HIV TEST RESULT (**Required,** applies to health department & health care providers)

- "Yes" indicates that there was a known previous positive HIV test result. Record the date of the earliest known positive HIV test result, including patient self-reported dates and anonymous tests. It is acceptable to enter an estimated or incomplete date, as long as it contains a year. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- "No" indicates there were no known previous positive HIV test results. Enter the date of the current positive HIV test result (i.e., the collection date of the current diagnostic HIV test).
- If you do not know the date of HIV diagnosis, enter the earliest known positive HIV test result.
- Do not include indeterminate HIV test results, false positive test results, and tests with inconclusive or unknown results.

12.5 WAS THE FIRST POSITIVE TEST RESULT FROM A SELF-TEST PERFORMED BY THE PATIENT (**Required,** applies to health department & health care providers)

- "Yes" indicates that first positive test was a self-test performed by the patient.
- "No" indicates the first positive test result was not a self-test performed by the patient.

12.6 EVER HAD A NEGATIVE HIV TEST RESULT (**Required**, applies to health department & health care providers)

- This variable ascertains whether or not the patient ever had a negative HIV test result at any time in the past that indicated the patient was not HIV infected. The mere absence of information about previous tests in a medical record should not be recorded as "No", since tests can occur in other venues. Do not include a negative test result as part of a sequence of tests in an algorithm that has a final interpretation indicating that the patient was infected with HIV.
- Self-reported information is acceptable for this data field.
- "Yes" indicates there is knowledge of a previous negative HIV test result, either self-reported or confirmed by a laboratory report.
- "No" indicates there is evidence that the patient never had a negative HIV test result (e.g., patient states they have never been tested before). Do not enter "No" if there is simply no evidence either way about a previous HIV test result.

- "Unknown" indicates there is insufficient evidence supporting or denying the occurrence of a negative HIV test result, after searching for the information or asking the patient. Leave the field blank if there was no attempt to find the information.
- Do not include an undetectable viral load result, as this result alone is not considered sufficient evidence of the absence of HIV infection (e.g., the patient may have been receiving antiretroviral therapy when the specimen was obtained or may naturally have a suppressed viral load without antiretroviral therapy).
- Do not include tests with indeterminate, inconclusive, or unknown results.

12.7 DATE OF LAST NEGATIVE HIV TEST RESULT (**Required**, applies to health department & health care providers)

- This variable represents the last date when the patient was considered not to be HIV infected, based on self-reported information, or by physician or testing site reports that do not have documented laboratory test result and type information.
- Negative HIV test result dates documented by a laboratory report or medical record accompanied by test type information should be entered in the Laboratory Data section (9.6.3) and not here. Incomplete dates are acceptable if the year is included. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- Do not include a negative test result as part of a sequence of tests in an algorithm that has a final interpretation indicating that the patient was infected with HIV.
- Do not include an undetectable viral load result, as this result alone is not considered sufficient evidence of the absence of HIV infection (e.g., the patient may have been receiving antiretroviral therapy when the specimen was obtained or may naturally have a suppressed viral load without antiretroviral therapy).
- Do not include tests with indeterminate, inconclusive, or unknown results.

12.8 WAS THE LAST NEGATIVE TEST RESULT FROM A SELF-TEST PERFORMED BY THE PATIENT (**Required,** applies to health department & health care providers)

- "Yes" indicates that first positive test was a self-test performed by the patient.
- "No" indicates the first positive test result was not a self-test performed by the patient.

12.9 NUMBER OF NEGATIVE HIV TEST RESULTS WITHIN 24 MONTHS BEFORE FIRST POSITIVE TEST RESULT (**Required**, applies to health department & health care providers)

- Count the number of negative HIV test results in the 24 months before 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 result. Do not enter "0" if there is simply no evidence about a previous HIV test result.
- "Unknown" indicates there is evidence that the patient refused to answer the question, the facility refused to permit medical record review, the patient does not remember whether they had a negative test result, or the provider or abstractor has no evidence about whether or not there was a previous test result. Leave the field blank if there was no attempt to find the information.
- Do not include a negative test result as part of a sequence of tests in an algorithm that has a final interpretation indicating that the patient was infected with HIV.
- Do not include an undetectable viral load result, as this result alone is not considered sufficient evidence of the absence of HIV infection (e.g., the patient may have been receiving antiretroviral therapy when the specimen was obtained or may naturally have a suppressed viral load without antiretroviral therapy).
- Do not include tests with indeterminate, inconclusive, or unknown results.

12.10 HOW MANY OF THESE NEGATIVE TEST RESULTS WERE FROM SELF-TESTS

PERFORMED BY THE PATIENT? (**Required**, applies to health department & health care providers)

- Of the total number of negative HIV test results within 24 months before first positive test result from 12.9, enter the number of tests that were self-tests performed by the patient.
- Enter "0" if it is known that the patient has never had a self-test with a negative test result. Do not enter "0" if there is simply no evidence about a previous self-test with a negative test result.
- "Unknown" indicates there is evidence that the patient refused to answer the question, the facility refused to permit medical record review, the patient does not remember whether they had a negative test result, or the provider or abstractor has no evidence about whether or not there was a previous test result. Leave the field blank if there was no attempt to find the information.

13. Comments (Optional, applies to health department & health care providers)

- This section can be used for information not requested on the form or for information requested but where there might not be room in the space provided.
- As appropriate, information collected in this section can be entered in existing fields on the ACRF of eHARS.
- Information entered into the "Comments" tab on the ACRF of eHARS will not be transmitted to CDC.

14. Local/Optional Fields (Optional, applies to health department)

- This section is for collection of data that are not on the form at the state and local level.
- This information is not sent to CDC.

Appendix: Adult HIV Confidential Case Report (CDC 50.42A)

Instructions for Completion

5. Residence at Diagnosis

- Residence may be identical to that listed above in Patient Identification, unless otherwise noted in the chart.
- For HIV, stage 0, 1, 2, and unknown case reports, enter residence at the date of HIV infection diagnosis. The date of diagnosis of HIV infection is the earliest date on which the surveillance case definition for HIV infection, any stage, was satisfied in accordance with laboratory and clinical criteria (see the Revised Surveillance Case Definition for HIV Infection at http://www.cdc.gov/mmwr/pdf/rr/rr6303.pdf).
- If a test result is not available, enter patient's residence at the date of *physician diagnosis* of HIV infection.
- For HIV, stage 3 (AIDS) case reports, enter patient's residence at the date of the first stage 3 (AIDS) diagnosis based on the applicable case definition.

Residence assignment can be problematic for patients who:

- Have multiple residences
- Are on vacation
- Reside at a school
- Are foster children
- Are members of the armed forces
- Are institutionalized in correctional or other types of facilities
- Are foreign to the United States
- Are US citizens diagnosed abroad

- For further guidance about residency assignment, see Technical Guidance File *Date and Place of Residence*.

6. Facility of Diagnosis

6.2 FACILITY NAME

- For HIV, stage 0, 1, 2, and unknown case reports, enter the name of the facility associated with the date of HIV infection diagnosis. The date of diagnosis of HIV infection is the earliest date on which the surveillance case definition for HIV infection, any stage, was satisfied in accordance with laboratory and clinical criteria (see the Revised Surveillance Case Definition for HIV Infection at http://www.cdc.gov/mmwr/pdf/rr/rr6303.pdf).
- If test results are not in the medical record, enter the name of the facility where the patient's HIV infection was diagnosed and documented by the health care provider.
- For HIV, stage 3 (AIDS) case reports, enter the name of the facility associated with the date of the first stage 3 (AIDS) diagnosis based on the applicable case definition.
- Enter facility uniformly to prevent the occurrence of multiple names for a given facility.

7. Patient History

- This information is often found in a discharge summary, history and physical, social service notes, HIV testing notes, and STD diagnosis notes.
- Where not explicitly annotated, contact patient's provider about risk factor information.

- See Technical Guidance File *Risk Factor Ascertainment* for further guidance on risk factor data collection.
- This information can be difficult to find, particularly if the patient has not been interviewed. States should have risk factor ascertainment procedures tailored to their jurisdictions.

8. Clinical: Acute HIV Infection and Opportunistic Illnesses

8.1. CLINICAL: ACUTE HIV INFECTION

8.1.2 CLINICAL SIGNS/SYMPTOMS CONSISTENT WITH ACUTE RETROVIRAL SYNDROME

- Acute HIV infection may be suspected in persons with signs and symptoms of acute retroviral syndrome (ARS) at or just before diagnosis and within 6 weeks after a possible exposure to HIV. Signs and symptoms of acute HIV infection may include but are not limited to one or more of the following from the list below; typically, ARS may be suspected if fever and one or more signs/symptoms are present, or in the absence of fever, two or more signs/symptoms, and differential diagnosis rules out other illness such as Epstein-Barr virus (EBV) and non-EBV infectious mononucleosis syndromes, influenza, viral hepatitis, streptococcal infection, or syphilis (Reference: Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/guidelines-adult-adolescent-arv.pdf). However, ARS may also be clinically determined in atypical circumstances by a single sign or symptom, and include other signs or symptoms not listed below, such as opportunistic illness or unusual clinical manifestations. (Reference: Braun DL, Kouyous RD, Blamer B, Grube C, Weber R, Gunthard HF. Frequency and spectrum of unexpected clinical manifestations of primary HIV-1 infection. CID 2015; 61:1013-1021).
- Signs/symptoms:
  - Clinical manifestation
    - Fever
    - Malaise/fatigue
    - Pharyngitis
    - Rash
    - Lymphadenopathy
    - Weight loss
    - Headache
    - Diarrhea
    - Night sweats
    - Myalgia
    - Nausea
    - Arthralgia
    - Cough
    - Vomiting
    - Oral ulcers
    - Neurological symptoms
    - Genital ulcers
  - Elevated liver enzymes
  - Thrombocytopenia