National HIV Surveillance System (NHSS)

Attachment 4(b)

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

Technical Guidance for HIV Surveillance Programs

Pediatric HIV Confidential Case Report Form

HIV Surveillance Branch
Atlanta, Georgia

Contents

Instructions for Completion

Purpose of Case Report Form

The Pediatric HIV Confidential Case Report (CDC 50.42B) form (PCRF) is designed to collect information that promotes understanding of perinatal HIV exposure and HIV infection morbidity and mortality among patients less than 13 years of age at time of diagnosis. This form reflects data that is required to be collected and some that is recommended or optional. This guidance applies to all perinatal HIV exposure and HIV infection data collection even if state or local surveillance programs use a different form or medium for perinatal HIV exposure and HIV case surveillance. See Appendix for further guidance.

Prior to 2023, CDC provided a separate *Perinatal HIV Exposure Reporting* (PHER) form to facilitate collection of additional standardized data on HIV-exposed children. CDC revised the PCRF to include some additional standardized data on HIV-exposed children and retired the separate PHER form in 2023.

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 perinatal HIV exposure or HIV case.

Accurate data abstraction is critical. For example, the dates of receipt of prenatal care should be before the infant's date of birth. If inconsistent information is found in medical records indicate that in the Comments section on the data abstraction form. This will serve as documentation that the inconsistency was in the medical record and is not an error in abstraction, notation, or data entry. The HIV Surveillance Coordinator in each jurisdiction, or their designee, should review all forms before the data are entered.

Patients for Whom Form is Indicated

- Each child less than 13 years of age, who meets the HIV infection or stage 3 (AIDS) case definition (available at https://ndc.services.cdc.gov/conditions/hiv-infection-aids-has-been-reclassified-as-hiv-stage-iii/).
- For perinatal exposure HIV reporting, all children born to HIV-infected persons. This includes only live births. The definition of a live birth as defined by the World Health Organization is: '...the complete expulsion or extraction from its [birthing person] of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered live born.'
  Thus, if a birth certificate has been completed for the infant and birthing person was HIV-infected, the form should be completed.
- Includes each child whose infection status has not yet been determined, seroconverters, and those exposed but determined not to be infected with HIV; inclusion of such patients is for public health surveillance purposes only.
- Each child with HIV infection progressing from an earlier or unknown stage to stage 3 (AIDS) diagnosis before 13 years of age.
- Each child 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.
- For each follow-up (typically every 6 months) of a child with perinatal HIV exposure whose

infection status has not been determined until the diagnostic status is known or up to 18 months of age.

If the data is collected electronically and can be imported, recording the information on a hardcopy form is not necessary. A federal assurance of confidentiality applies to information on children exposed perinatally with or without consequent infection.

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 (example: Birth, Call Me)	*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.
- Enter the data below for all children reported as perinatally exposed to HIV or reported with HIV infection.

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 (e.g., Alias, Birth Name)

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 PCRF 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 perinatal HIV exposure, 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	

- Enter the data below for all children reported as perinatally exposed to HIV or reported with HIV infection.

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 disease (including perinatal HIV exposure) in each state/jurisdiction where they are reported. However, 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 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 appropriate state number associated with the events being reported on the case report form. For example, if providing information about the "Seroreverter", enter the state number associated with the "Seroreverter".
- 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 disease (including perinatal HIV exposure) assigned by the separately funded city in which they are reported. However, 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 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 appropriate city/county number associated with the events being reported on the case report form. For example, if providing information about the "Seroreverter", enter the city/county number associated with the "Seroreverter".

- 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 perinatal HIV exposure or 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 a perinatal HIV exposure or 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 ☐ Pediatric clinic ☐ Pediatric HIV clinic ☐ Other, specify_____	Other Facility: ☐ Emergency room ☐ Laboratory ☐ 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.
- Enter the data below for all children reported as perinatally exposed to HIV or reported with HIV infection.

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)

Diagnostic Status at Report ☐ 3-Perinatal HIV exposure ☐ 4-Pediatric HIV ☐ 5-Pediatric AIDS ☐ 6-Pediatric seroreverter	**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**
Date of Last Medical Evaluation __ __/__ __/__ __ __ __		**Date of Initial Evaluation for HIV** __ __/__ __/__ __ __ __
Gender Identity ☐ Boy ☐ Girl ☐ Transgender boy ☐ Transgender girl ☐ 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**

- Enter the data below for all children reported as perinatally exposed to HIV or reported with HIV infection.

4.1 DIAGNOSTIC STATUS AT REPORT (**Optional**, applies to health department & health care providers)
- Use one form to capture each event regardless of the interval between diagnostic status dates, and where the same source of these data reported more than one event. Fill out suitable number of case report forms:
  - Fill out the first form completely for the first event.
  - Fill out subsequent forms partially, capturing additional or updated data absent from the first form.
- Status depends on child's age, clinical profile, and laboratory findings. Refer to Appendix

4.1.1–4.1.4 for further guidance.

4.1.1 PERINATAL HIV EXPOSURE
- Select "Perinatal HIV Exposure" if the patient is less than 18 months of age, was born to an HIV-infected person, and has an undetermined HIV infection status.
- Refer to Appendix 4.1.1 for further guidance.

4.1.2 PEDIATRIC HIV
- Select "Pediatric HIV" if the patient meets the criteria specified in the Revised Surveillance Case Definition for HIV Infection in children < 13 years of age and does not meet the current CDC pediatric HIV infection stage 3 (AIDS) case definition.
- Refer to Appendix 4.1.2 for further guidance.

4.1.3 PEDIATRIC AIDS
- Select "Pediatric AIDS" if patient meets the current HIV infection stage 3 case definition for children < 13 years of age.
- Refer to Appendix 4.1.3 for further guidance.

4.1.4 PEDIATRIC SEROREVERTER
- Select "Seroreverter" if the perinatally exposed child initially has a positive HIV test but is found NOT to be HIV-infected through criteria listed in Appendix 4.1.4.
- Of the four diagnostic status categories available on the case report form, "Pediatric Seroreverter" is synonymous with "Not Infected with HIV".

4.2 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".

4.3 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.

4.4 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).

4.5 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).

4.6 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*.

4.7 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*.

4.8 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".

4.9 DATE OF LAST MEDICAL EVALUATION (**Optional**, applies to health department & health care providers)

- Enter the date of the child's last medical evaluation in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011) regardless of reason for exam. This includes emergency room visits.

4.10 DATE OF INITIAL EVALUATION FOR HIV INFECTION (**Optional**, applies to health department & health care providers)

- Enter the date of initial evaluation for HIV infection in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011). This is the date when HIV infection was first considered, either clinically or through laboratory evaluation.
- For a child whose birthing person is known to be HIV infected at the time of birth and for whom assessment of HIV is done at birth, use the date of birth. This assessment does not necessarily include an order for an HIV test, although documentation of an HIV test is often the earliest evidence that the diagnosis was considered.
- Evidence of HIV infection in a child **must be obtained on or after the birth date**.

4.11 GENDER IDENTITY and DATE IDENTIFIED (**Required if not perinatal exposure or perinatal transmission,** 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 PCRF 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 PCRF documents on the "Demographics" tab.

4.12 SEXUAL ORIENTATION and DATE IDENTIFIED (**Required if not perinatal exposure or**

perinatal transmission, 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 PCRF 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 PCRF documents on the "Demographics" tab.

4.13 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.*

4.14 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.

4.15 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.

4.16 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	☐ Residence at perinatal exposure	☐ Residence at pediatric seroreverter	☐ 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.
- Enter the data below for all children reported as perinatally exposed to HIV or reported with HIV infection.
- 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) ☐ Perinatal exposure ☐ 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 ☐ Pediatric clinic ☐ Pediatric HIV clinic ☐ Other, specify _____	*Other Facility*: ☐ Emergency room ☐ Laboratory ☐ 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.
- Enter the data below for all children reported as perinatally exposed to HIV or reported with

HIV infection.

- 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)

Birthing person's HIV infection status (select one): ☐ Refused HIV testing ☐ Known to be uninfected after this child's birth ☐ Known HIV+ before pregnancy ☐ Known HIV+ during pregnancy ☐ Known HIV+ sometime before birth ☐ Known HIV+ at delivery ☐ Known HIV+ after child's birth ☐ HIV+, time of diagnosis unknown ☐ HIV status unknown	
Date of birthing person's first positive test result to confirm infection __ __/__ __/__ __ __ __	**Child breastfed/chestfed by birthing person** ☐ Yes ☐ No ☐ Unknown **Child received premasticated/pre-chewed food from birthing person** ☐ Yes ☐ No ☐ Unknown
After 1977 and before the earliest known diagnosis of HIV infection, the birthing person had:	
Perinatally acquired HIV infection	☐ Yes ☐ No ☐ Unknown
Injected nonprescription drugs	☐ Yes ☐ No ☐ Unknown
Birthing person had 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
Birthing person had:	
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments) First date received __ __/__ __/__ __ __ __ Last date received __ __/__ __/__ __ __ __	☐ Yes ☐ No ☐ Unknown
Received transplant of tissue/organs or artificial insemination	☐ Yes ☐ No ☐ Unknown
Before the diagnosis of HIV infection, this child had:	
Injected nonprescription drugs	☐ Yes ☐ No ☐ Unknown
Received clotting factor for hemophilia/coagulation disorder Specify clotting factor: Date received __ __/__ __/__ __ __ __	☐ Yes ☐ No ☐ Unknown
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments) First date received __ __/__ __/__ __ __ __ Last date received __ __/__ __/__ __ __ __	☐ Yes ☐ No ☐ Unknown
Received transplant of tissue/organs	☐ Yes ☐ No ☐ Unknown
Sexual contact with male	☐ Yes ☐ No ☐ Unknown
Sexual contact with female	☐ Yes ☐ No ☐ Unknown
Been breastfed/chestfed by non-birthing person	☐ Yes ☐ No ☐ Unknown
Received premasticated/pre-chewed food from non-birthing person	☐ Yes ☐ No ☐ Unknown
Other documented risk (include detail in Comments)	☐ Yes ☐ No ☐ Unknown

- Enter all data below for children reported with HIV infection. For children reported as perinatally exposed to HIV, enter data below through 7.7.4; do not enter data under the heading "Before the diagnosis of HIV infection, this child had:".
- These data yield information about how patients may have acquired their infection.
- 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*.
- Information on the child refers to circumstances or behaviors that were thought to have exposed the child to HIV, not to treatments since the child became HIV infected. For example, if the child received a blood transfusion after the documentation of HIV infection, do not enter that information on the form.
- The state or local Cases of Public Health Importance (COPHI) coordinator should contact the CDC COPHI coordinator as soon as possible if any unusual transmission circumstances are suspected. For further guidance, see Technical Guidance File *Risk Factor Ascertainment*.

7.1 BIRTHING PERSON'S HIV INFECTION STATUS (**Required**, applies to health department & health care providers)

- For the birthing person, if HIV infection was diagnosed then select from boxes 3–8 (i.e., box "Known HIV+ before pregnancy" to box "HIV+, time of diagnosis unknown"), depending on information available to determine the timing of diagnosis. Where date of the birthing person's first positive test result to confirm HIV infection is available, select the appropriate box by comparing the date of birth of the child to the date of HIV infection diagnosis of the birthing person.
- Refer to Appendix 7.1 for further guidance.

7.2 DATE OF BIRTHING PERSON'S FIRST POSITIVE TEST RESULT TO CONFIRM INFECTION (**Optional**, applies to health department & health care providers)

- Where the birthing person is known to be HIV infected, enter month, day, and year of the specimen collection date of the first positive test result to confirm HIV infection in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

7.3 CHILD BREASTFED/CHESTFED BY BIRTHING PERSON (**Required**, applies to health department and health care providers)

- Select applicable response.
- Select "Yes" is there is evidence that the patient was fed milk from the birthing person's chest or documentation indicates that the patient was bodyfed by the birthing person.
- When the birthing person was known to be not HIV infected at the time of child's birth an investigation should be initiated and the state/local Cases of Public Health Importance (COPHI) coordinator should be alerted. In all other situations, investigation is not required but the CDC COPHI coordinator can be consulted if interested in further investigating breastfeeding/chestfeeding as the mode of transmission.

7.4 CHILD RECEIVED PREMASTICATED/PRE-CHEWED FOOD FROM BIRTHING PERSON (**Required**, applies to health department and health care providers)

- Select applicable response.
- When the birthing person was known to be not HIV infected at the time of child's birth an investigation should be initiated and the state/local COPHI coordinator should be alerted. In all other situations, investigation is not required, but the CDC COPHI coordinator can be consulted if interested in further investigating premastication/pre-chewing as the mode of transmission.

7.5 AFTER 1977 AND BEFORE THE EARLIEST KNOWN DIAGNOSIS OF HIV INFECTION, THE BIRTHING PERSON HAD:

7.5.1 PERINATALLY ACQUIRED HIV INFECTION (**Required**, applies to health department & health care providers)

- Select applicable response.

7.5.2 INJECTED NON-PRESCRIPTION DRUGS (**Required**, applies to health department & health care providers)

- Select applicable response.
- Select "Yes" if the birthing person injected illicit or nonprescription drugs at any time in the past or if a drug prescribed to the birthing person was injected when there is evidence that injection equipment was shared (e.g., syringes, needles, cookers).

7.6 BIRTHING PERSON HAD HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING:

- This section relates to ascertainment of risk among heterosexual sex partners of the birthing person of the case patient.
- Heterosexual contact is defined as the birthing person 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.

7.6.1 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).

7.6.2 BISEXUAL MALE (**Required**, applies to health department & health care providers)
- Select applicable response. "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.

7.6.3 PERSON WITH HEMOPHILIA/COAGULATION DISORDER WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- "Coagulation disorder" or "hemophilia" refers only to a disorder of a clotting factor, which is any of the circulating proteins named Factor I, Factor II, Factor III, etc., through Factor XII. These disorders include Hemophilia A and Von Willebrand's disease (Factor VIII disorders) and Hemophilia B (a Factor IX disorder).
- Do not include other bleeding disorders, such as thrombocytopenia, treatable by platelet transfusion.
- If a transfusion of only platelets, other blood cells, or plasma was received by the partner, then code "No" and see question 7.6.4 below.
- If yes, alert the state/local COPHI coordinator.

7.6.4 TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- Consider documenting the reason for transfusion in the Comments section. In eHARS, enter on the "Comments" tab.
- Refers to someone with documented HIV infection who received a transfusion of blood cells (red cells, white cells, platelets) or plasma.
- If yes, alert the state/local COPHI coordinator.

7.6.5 TRANSPLANT RECIPIENT WITH DOCUMENTED HIV INFECTION (**Required**, applies to health department & health care providers)
- Consider documenting the reason for transfusion/transplant in the Comments section. In eHARS, enter on the "Comments" tab.
- If yes, alert the state/local COPHI coordinator.

7.6.6 PERSON WITH DOCUMENTED HIV INFECTION, RISK NOT SPECIFIED (**Required**, applies to health department & health care providers)
- Select "Yes" only if partner is known to be HIV-positive and that partner's risk for HIV is unknown.

7.7 BIRTHING PERSON HAD:

7.7.1-7.7.3 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)
- '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.
- If "Yes", specify the month, day, and year of the first and last transfusion before the birthing person received a diagnosis of HIV infection (stage 1,2, unknown) or stage 3 (AIDS). Enter date in *mm/dd/yyyy* format using ".." for unknown values

(e.g., 03/../2011).
- Consider documenting the reason for transfusion/transplant in the Comments section. In eHARS, enter on the "Comments" tab.
- If the last transfusion was after March 1985, alert the state/local COPHI coordinator.

7.7.4 RECEIVED TRANSPLANT OF TISSUES/ORGANS OR ARTIFICIAL INSEMINATION (**Required**, applies to health department & health care providers)
- If this is the only risk factor present and the birthing person did not have HIV infection diagnosed at the time of child's birth, the transmission mode will be initially classified as "risk not reported/identified" pending outcome of the COPHI investigation.
- If yes, alert the state/local COPHI coordinator.

7.8 BEFORE THE DIAGNOSIS OF HIV INFECTION, THIS CHILD HAD
- Alert state/local COPHI coordinator if the child had one or more of the risk factors documented in this section.

7.8.1 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).

7.8.2-7.8.4 RECEIVED CLOTTING FACTOR FOR HEMOPHILIA/COAGULATION DISORDER, SPECIFY CLOTTING FACTOR, and DATE RECEIVED (**Required**, applies to health department & health care providers)
- "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".
- Alert state/local COPHI coordinator if child was born after March 1998 and receipt of clotting factor is the suspected mode of HIV transmission.
- If "Yes", then enter the specific clotting factor and the date the clotting factor was received in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).

7.8.5 RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR) (**Required**, applies to health department & health care providers)
- If child received a transfusion of blood cells (red cells, white cells, and platelets) or plasma, specify month, day, and year of first and last transfusion before the patient was infected with HIV or received a diagnosis of stage 3 (AIDS). Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- It is often helpful to document the reason for the transfusion in the Comments section. In eHARS, enter on the "Comments" tab.

7.8.6 RECEIVED TRANSPLANT OF TISSUE/ORGANS (**Required**, applies to health department & health care providers)
- The case will be initially classified as "risk not reported/identified" pending

outcome of the no identified risk (NIR) investigation.

7.8.7 SEXUAL CONTACT WITH A MALE (**Required**, applies to health department & health care providers)

- If child is known to have had sexual contact/abuse, mark the appropriate box 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".
- If this is the only risk history, the case will be initially classified as "risk not reported/identified" pending outcome of NIR investigation.

7.8.8 SEXUAL CONTACT WITH A FEMALE (**Required**, applies to health department & health care providers)

- If the child is known to have had sexual contact/abuse, mark the appropriate box 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".
- If this is the only risk history, the case will be initially classified as "risk not reported/identified" pending outcome of NIR investigation.

7.8.9 BEEN BREASTFED/CHESTFED BY NON-BIRTHING PERSON (**Required**, applies to health department & health care providers)

- Select applicable response.
- Select "Yes" is there is evidence that the patient was fed milk from the chest of a non-birthing person or documentation indicates that the patient was bodyfed by a non-birthing person.

7.8.10 RECEIVED PREMASTICATED/PRE-CHEWED FOOD FROM NON-BIRTHING PERSON (**Required**, applies to health department & health care providers)

- Select applicable response.

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

- Include detail in Comments section. In eHARS, enter on the "Comments" tab.

8. Clinical: Opportunistic Illnesses

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

Diagnosis	Dx Date	Diagnosis	Dx Date	Diagnosis	Dx Date
Bacterial infection, multiple or recurrent (including Salmonella septicemia)		HIV encephalopathy		Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary	
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		Lymphoid interstitial pneumonia and/or pulmonary lymphoid		Pneumonia, recurrent in 12 mo. period	
Cryptosporidiosis, chronic intestinal (>1 mo. duration)		Lymphoma, Burkitt's (or equivalent)		Progressive multifocal leukoencephalopathy	
Cytomegalovirus disease (other than in liver, spleen, or nodes)		Lymphoma, immunoblastic (or equivalent)		Toxoplasmosis of brain, onset at >1 mo. of age	
Cytomegalovirus retinitis (with loss of vision)		Lymphoma, primary in brain		Wasting syndrome due to HIV	
[1]If a diagnosis date is entered for either tuberculosis diagnosis above, provide RVCT Case Number:					

8.1 CLINICAL: OPPORTUNISTIC ILLNESSES

8.1.1–8.1.27 (**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/).

8.1.28 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

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** _____

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

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 diagnosis documented by a physician rather than by laboratory test results?
HIV-infected ☐ Yes ☐ No ☐ Unknown **Date of diagnosis by physician** __ __ /__ __ /__ __ __ __
Not HIV-infected ☐ Yes ☐ No ☐ Unknown **Date of diagnosis by physician** __ __ /__ __ /__ __ __ __

[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.
- For children reported as perinatally exposed to HIV, record all test results of tests performed to determine the diagnostic status of the child.

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 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".

9.5.2.1 HIV-INFECTED (**Required** if applicable, applies to health department & health care providers)

- IF "YES" TO 9.5.2.1, 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.

9.5.2.2 NOT HIV-INFECTED (**Required** if applicable, applies to health department & health care providers)

- IF "YES" TO 9.5.2.2, 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) when the patient was determined to be "not HIV-infected".

10. Birth History (for patients exposed perinatally with or without consequent infection)

X. Birth History (for patients exposed perinatally with or without consequent infection)

Birth history available? ☐ Yes ☐ No ☐ Unknown			
Residence at Birth	☐ 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**	
Facility of Birth	☐ Check if SAME as facility providing information		
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**	**City**		
County	**State/Country**	***ZIP Code**	
Birth History	**Birth Weight** _____lbs _____oz _____grams	**Type** ☐ 1-Single ☐ 2-Twin ☐ 3-More than two ☐ 9-Unknown	

Delivery ☐ Vaginal ☐ Cesarean ☐ Unknown

If Cesarean delivery, mark all the following indications that apply.

☐ HIV indication (high viral load) ☐ Previous Cesarean (repeat) ☐ Malpresentation (breech, transverse)
☐ Prolonged labor or failure to progress ☐ Birthing person's or physician's preference ☐ Fetal distress
☐ Placenta abruptia or p. previa ☐ Other (e.g., herpes, disproportion) (Specify) _____
☐ Not specified

Birth Information	**Date**	**Time (use military time: noon = 12:00; midnight = 00:00)**
Rupture of membranes	__ __/__ __/__ __ __ __	__ __:__ __
Delivery	__ __/__ __/__ __ __ __	__ __:__ __

Congenital Disorders ☐ Yes ☐ No ☐ Unknown **If YES, specify types**

Neonatal Status ☐ 1-Full-term ☐ 2-Premature ☐ 9-Unknown **Neonatal Gestational Age in Weeks** ____ (99 = Unknown, 00 = None)

Was a toxicology screen done on the infant after birth?
☐ Yes ☐ No ☐ Unknown
(If screening for the same substance was done on more than one occasion, record additional dates and results in Comments)

	Not screened	Date of screen	Result: Positive	Result: Negative	Result: Unknown
Alcohol	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Amphetamines	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Barbiturates	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Benzodiazepines	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Cocaine	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Crack cocaine	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Fentanyl	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Hallucinogens	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Heroin	☐	__ __/__ __/__ __ __ __	☐	☐	☐
K2	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Marijuana (cannabis, THC, cannabinoids)	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Methadone	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Methamphetamines	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Nicotine (any tobacco)	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Opiates	☐	__ __/__ __/__ __ __ __	☐	☐	☐
PCP	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Other (specify) _____	☐	__ __/__ __/__ __ __ __	☐	☐	☐
Specific drug(s) not documented	☐	__ __/__ __/__ __ __ __	☐	☐	☐

- Birth history information is for state and local health department use only and is not transmitted to CDC if marked with an * on the form.
- Enter the data below for all children reported as perinatally exposed with or without consequent HIV infection.

10.1 BIRTH HISTORY AVAILABLE (**Optional**, applies to health department & health care providers)

- If none of the birth history elements in the section are available, proceed to next section, Birthing Person History.

10.2 RESIDENCE AT BIRTH (**Required**, applies to health department & health care providers)

- Select one of the address types for the patient's residence at time of birth.
- Enter the street address, city, county, state, country name, and zip code of the patient's residence at time of birth

10.3 FACILITY OF BIRTH (**Optional**, applies to health department & health care providers)

- Check if same as facility providing information.

- Enter name, address, phone, city, county, state/country and zip code of the hospital/clinic of birth.
- Sites should uniformly record hospital names, including abbreviations.
- If this child was born at home, enter "home birth".

10.4 BIRTH HISTORY

10.4.1 BIRTH WEIGHT (**Optional**, applies to health department & health care providers)
- Enter the birth weight in pounds and ounces, or grams.

10.4.2 TYPE (**Optional**, applies to health department & health care providers)
- Select applicable response. If unknown, select "9".

10.4.3 DELIVERY (**Required**, applies to health department & health care providers)
- Select the applicable response.
- Notes in the child's records are acceptable even if no birth records are available.
- If search for this datum was completed and the delivery method could not be determined or if the delivery method was documented to be unknown, select "Unknown".

10.4.4 IF CESAREAN DELIVERY, MARK ALL THE FOLLOWING INDICATIONS THAT APPLY (**Required**, if applicable, applies to health department & health care providers)
- Select the appliable indications.
- The reason(s) for a cesarean delivery should be documented in the labor and delivery medical record. Notes in the child's records are acceptable even if no birth records are available.
- If search for this datum was completed and the indications could not be determined, select "Not specified".

10.4.5 BIRTH INFORMATION (**Required**, if applicable, applies to health department & health care providers)
- This information may be listed in the labor and delivery record or in a dictated/transcribed labor and delivery summary by the physician. Write time in military hours (e.g., 9:15 a.m. is 09:15, 1:00 p.m. is 13:00). Midnight is 00:00 and noon is 12:00. To calculate military time, count the number of hours and minutes after midnight or 00:00 hours. Enter the date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
  - Rupture of membranes information should be found on the labor and delivery summary sheet. The date and time are necessary to calculate the duration of ruptured membranes and duration of labor. Rupture of membranes refers to the time when the amniotic sac is either purposely broken or ruptures on its own. When a physician/health care provider ruptures the membranes this is referred to as artificial rupture of membranes--often abbreviated as AROM. When membranes rupture on their own, spontaneously, this is referred to as spontaneous rupture of membranes (SROM). Premature rupture of membranes is referred to as PROM. In the case of cesarean section, the rupture of membranes may be almost concurrent with time of delivery.
  - Delivery information should be found on the labor and delivery summary sheet. The date and time are necessary to calculate the duration of ruptured membranes and duration of labor. If the time of delivery is unknown because of a home or out-of-hospital delivery, enter ''..:..". Verify that the delivery date is the same as the date of birth noted on the

first page of the abstraction form. If there is an inconsistency, verify the correct date of birth and update eHARS if necessary.

10.4.6-10.4.7 CONGENTIAL DISORDERS and IF YES, SPECIFY TYPES (**Optional**, applies to health department & health care providers)

- If "Yes", specify type.
- Refer to Appendix 10.4.6 for further guidance.

10.4.8 NEONATAL STATUS (**Optional**, applies to health department & health care providers)

- Select applicable response and record the child's gestational age, if known, in the boxes provided.
- "Full term" is defined as gestational age greater than or equal to 37 weeks.
- "Premature" is defined as gestational age less than 37 weeks.
- If search for gestational age was unsuccessful, then enter "99" for unknown number of weeks.
- Post mature neonatal status (after 40 weeks) should be recorded as full term.
- If search for this datum was completed and the gestational age cannot be determined, select "Unknown".

10.4.8.1 NEONATAL GESTATIONAL AGE IN WEEKS

- Enter weeks of gestation.
- If search for gestational age was unsuccessful, then enter "99" for unknown number of weeks.

10.4.9 WAS A TOXICOLOGY SCREEN DONE ON THE INFANT AFTER BIRTH (**Recommended**, if applicable, applies to health department & health care providers)

- Select applicable response. Include any toxicology screen with a specimen collection date on the child's date of birth or within the 6 days following the child's date of birth.
- If search for this datum was completed but a response of "Yes" or "No" cannot be determined, select "Unknown".
- Most toxicology screens on infants are done using urine. A positive screen at birth indicates drug use by the birthing person before delivery. This information should be noted in the infant's birth chart.
- If the specimen for any toxicology screen was collected for the infant on the date of birth or the following 6 days after birth, complete the following information for each substance.
  - If the substance was not included in any toxicology screen in the 7 days on or after the child's date of birth, select "Not screened" for the particular substance.
  - If the substance was included in any toxicology screen in the 7 days on or after the child's date of birth, enter the date of screen for the substance in mm/dd/yyyy format using ".." for unknown values (e.g., 03/../2011) and select the applicable result; select "Unknown" if a search for the result was completed but the result was not documented.
  - If the same substance was screened more than one time during the 7 days on or after the child's date of birth, enter the subsequent date of screen and result values in the Comments section. In eHARS, enter the additional information on the PCRF on the "Birth History" tab.
  - If screening for 'Other' substance was done, specify the substance in the space provided.

11. Birthing Person History

XI. Birthing Person History (for patients exposed perinatally with or without consequent infection)

Birthing Person Date of Birth __ __ / __ __ / __ __ __ __	**Birthing Person Last Name Soundex**
Birthing Person Country of Birth	**Birthing Person State ID Number**
Birthing Person City/County ID Number	***Other Birthing Person ID (specify type of ID and ID number)**
Prenatal Care—Month of Pregnancy Prenatal Care Began (99 = Unknown, 00 = None)	**Prenatal Care—Total Number of Prenatal Care Visits** (99 = Unknown, 00 = None)

Has the birthing person ever been pregnant before this pregnancy? Include previous pregnancies that ended in a live birth, miscarriage, stillbirth, or induced abortion. □ Yes □ No □ Unknown

If YES, specify how many previous pregnancies _____

	Pregnancy outcome (select one) Live birth	Miscarriage or Stillbirth	Induced abortion	**Year outcome occurred** (9999 = Unknown)
i.	□	□	□	____
ii.	□	□	□	____
iii.	□	□	□	____
iv.	□	□	□	____
v.	□	□	□	____

(Record additional pregnancy outcomes in Comments)

Was a test result (with a specimen collection date within the 6 weeks on or before delivery) documented in the birthing person's labor/delivery record
CD4 □ Yes □ No □ Unknown **Quantitative NAAT (RNA or DNA)** □ Yes □ No □ Unknown

Did birthing person receive any antiretrovirals (ARVs) prior to this pregnancy? □ Yes □ No □ Refused □ Unknown
Date began __ __ / __ __ / __ __ __ __ **Date of last use** __ __ / __ __ / __ __ __ __
If YES, specify all ARVs _____

Did birthing person receive any ARVs during this pregnancy? □ Yes □ No □ Refused □ Unknown
Date began __ __ / __ __ / __ __ __ __ **Date of last use** __ __ / __ __ / __ __ __ __
If YES, specify all ARVs _____
If NO, select reason □ No prenatal care □ Birthing person known to be HIV-negative during pregnancy □ Unknown
□ HIV serostatus of birthing person unknown □ Other (specify) _____

Did birthing person receive any ARVs during labor/delivery? □ Yes □ No □ Refused □ Unknown
Date began __ __ / __ __ / __ __ __ __ **Date of last use** __ __ / __ __ / __ __ __ __
If YES, specify all ARVs _____
If NO, select reason □ Precipitous delivery/STAT Cesarean delivery □ HIV serostatus of birthing person unknown □ Birth not in hospital
□ Birthing person tested HIV negative during pregnancy □ Other (specify) _____ □ Unknown

Was the birthing person screened for any of the following conditions during this pregnancy?
Check test(s) performed before birth

	Yes	**Date of screen** (mm/dd/yyyy)	**No**	**Unknown**
Group B strep	□	__ __/__ __/__ __ __ __	□	□
Hepatitis B (HBsAg)	□	__ __/__ __/__ __ __ __	□	□
Rubella	□	__ __/__ __/__ __ __ __	□	□
Syphilis	□	__ __/__ __/__ __ __ __	□	□

Were any of the following conditions diagnosed for the birthing person during this pregnancy or at the time of labor and delivery?

	Yes	**Date of diagnosis** (mm/dd/yyyy)	**No**	**Unknown**
Bacterial vaginosis	□	__ __/__ __/__ __ __ __	□	□
Chlamydia trachomatis infection	□	__ __/__ __/__ __ __ __	□	□
Genital herpes	□	__ __/__ __/__ __ __ __	□	□
Gonorrhea	□	__ __/__ __/__ __ __ __	□	□
Group B strep	□	__ __/__ __/__ __ __ __	□	□
Hepatitis B (HBsAg)	□	__ __/__ __/__ __ __ __	□	□
Hepatitis C	□	__ __/__ __/__ __ __ __	□	□
PID	□	__ __/__ __/__ __ __ __	□	□
Syphilis	□	__ __/__ __/__ __ __ __	□	□
Trichomoniasis	□	__ __/__ __/__ __ __ __	□	□

Were substances used by the birthing person during this pregnancy? □ Yes □ No □ Unknown

	Used and injected	**Used and did not inject**	**Used and unknown if injected**	**Did not use**	**Unknown if used**
Alcohol	□	□	□	□	□
Amphetamines	□	□	□	□	□
Barbiturates	□	□	□	□	□
Benzodiazepines	□	□	□	□	□
Cocaine	□	□	□	□	□
Crack cocaine	□	□	□	□	□
Fentanyl	□	□	□	□	□
Hallucinogens	□	□	□	□	□
Heroin	□	□	□	□	□
K2	□	□	□	□	□
Marijuana (cannabis, THC, cannabinoids)	□	□	□	□	□
Methadone	□	□	□	□	□
Methamphetamines	□	□	□	□	□
Nicotine (any tobacco)	□	□	□	□	□
Opiates	□	□	□	□	□
PCP	□	□	□	□	□
Other (specify)_____	□	□	□	□	□
Specific drug(s) not documented	□	□	□	□	□

XI. Birthing Person History (for patients exposed perinatally with or without consequent infection) *(cont)*

Was a toxicology screen done on the birthing person (either during this pregnancy or at the time of delivery)? □ Yes □ No □ Unknown
(If screening for the same substance was done on more than one occasion, record additional dates and results in Comments)

	Not screened	**Date of screen**	**Positive**	**Negative**	**Unknown**
Alcohol	□	__ __/__ __/__ __ __ __	□	□	□
Amphetamines	□	__ __/__ __/__ __ __ __	□	□	□
Barbiturates	□	__ __/__ __/__ __ __ __	□	□	□
Benzodiazepines	□	__ __/__ __/__ __ __ __	□	□	□
Cocaine	□	__ __/__ __/__ __ __ __	□	□	□
Crack cocaine	□	__ __/__ __/__ __ __ __	□	□	□
Fentanyl	□	__ __/__ __/__ __ __ __	□	□	□
Hallucinogens	□	__ __/__ __/__ __ __ __	□	□	□
Heroin	□	__ __/__ __/__ __ __ __	□	□	□
K2	□	__ __/__ __/__ __ __ __	□	□	□
Marijuana (cannabis, THC, cannabinoids)	□	__ __/__ __/__ __ __ __	□	□	□
Methadone	□	__ __/__ __/__ __ __ __	□	□	□
Methamphetamines	□	__ __/__ __/__ __ __ __	□	□	□
Nicotine (any tobacco)	□	__ __/__ __/__ __ __ __	□	□	□
Opiates	□	__ __/__ __/__ __ __ __	□	□	□
PCP	□	__ __/__ __/__ __ __ __	□	□	□
Other (specify)_____	□	__ __/__ __/__ __ __ __	□	□	□
Specific drug(s) not documented	□	__ __/__ __/__ __ __ __	□	□	□

- Birthing person history is for state and local health department use only and is not transmitted to CDC if marked with an * on the form.
- Enter the data below regarding the birthing person for all children reported as perinatally exposed with or without consequent HIV infection. If information for the birthing person is not available (e.g., because child is adopted), proceed to the next section, Treatment/Services Referrals.

11.1 BIRTHING PERSON DATE OF BIRTH (**Optional**, applies to health department & health care providers)

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

11.2 BIRTHING PERSON LAST NAME SOUNDEX (**Optional**, applies to health department)

- After the birthing person's last name is entered into eHARS, the software automatically generates this variable by using the birthing person's last name. After the code is generated, health department staff should fill in 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

11.3 BIRTHING PERSON COUNTRY OF BIRTH (**Optional**, applies to health department & health care providers)

- Select applicable response.
- For birthing persons 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 birthing persons born in any other area outside of the US and US minor outlying areas, specify the country name.
- If this information is not available in the child's records, it can be left blank and updated on follow-up.

11.4 BIRTHING PERSON STATE ID NUMBER (**Optional**, applies to health department)

- Enter assigned state number if the birthing person is known to be HIV infected.
- State numbers should not be reused.

11.5 BIRTHING PERSON CITY/COUNTY ID NUMBER (**Optional**, applies to health department)

- Enter the assigned city/county number if the birthing person is known to be HIV infected.
- City/County numbers should not be reused.

11.6 OTHER BIRTHING PERSON ID (**Optional**, applies to health department & health care providers).

- Enter any other ID type (such as social security number) for the birthing person and the number of the other ID.

11.7 PRENATAL CARE

- Prenatal care is defined as any care for the pregnancy beyond pregnancy testing and before delivery, even if no regular follow-up ensued.

11.7.1 MONTH OF PREGNANCY PRENATAL CARE BEGAN (**Optional**, applies to health department & health care providers)

- Record the gestational month of pregnancy (01 to 09) that the birthing person began prenatal care. A prenatal care visit is the first visit where intake information is obtained. Normally a birthing person knows they is pregnant at the time of this first prenatal care visit. A visit to a doctor to confirm pregnancy status would not be considered the first prenatal care visit unless intake data and other services typical of the first prenatal care visit are obtained at the time of that confirmation. Such services would include intake prenatal blood tests, for example. If the birthing person had been seen by more than one prenatal care provider, then the date of the visit to the first prenatal care provider seen should be documented.
- If any fraction of a month is reported, round to the next whole month.
- In the absence of prenatal care, enter "00".
- If search for this datum was unsuccessful, then enter "99" for month of first visit.
- If entry is reported in weeks, convert to appropriate months as follows:

Weeks	Months	Weeks	Months
1–4	1	22–26	6
5–8	2	27–30	7
9–13	3	31–35	8
14–17	4	36–40	9
18–21	5	41+	10

- Abstractors should use the gestational age value available in the record. The method (LMP, ultrasound, infant exam) for assigning gestational age in the medical record might vary.

11.7.2 TOTAL NUMBER OF PRENATAL CARE VISITS (**Optional**, applies to health department & health care providers)

- Record the total number of times the birthing person went to the clinic or doctor for prenatal care; exclude visits unrelated to prenatal care.
- In the absence of prenatal care visits, enter "00".
- In the presence of prenatal care and search for this datum was unsuccessful, then enter "99" for number of prenatal visits.
- Where data source reports a range of visits (e.g., "10–13"), enter the lowest number (e.g., "10").

11.8 HAS THE BIRTHING PERSON EVER BEEN PREGNANT BEFORE THIS PREGNANCY (**Optional**, if applicable, applies to health department & health care providers)

- Select applicable response. If search for this datum was completed but a response of "Yes" or "No" cannot be determined, select "Unknown".

11.8.1 IF YES, NUMBER OF PREVIOUS PREGNANCIES (**Optional**, if applicable, applies to health department & health care providers)

- This number should include all pregnancies, regardless of outcome (e.g., including abortions and miscarriages) up to but EXCLUDING the pregnancy that is being abstracted.

11.8.2. PREGNANCY OUTCOME (**Optional**, if applicable, applies to health department & health care providers)

- For each previous pregnancy where the pregnancy outcome is known, select the applicable response.

- Live birth includes preterm and term births
- Miscarriage or stillbirth includes spontaneous abortions/fetal deaths that occur before 20 weeks (miscarriage) or after 20 weeks (stillbirth).
- Induced abortion includes abortions brought on purposely and may also be known as an 'artificial' or 'therapeutic' abortion (TAB) or referred to as a 'termination of pregnancy' (TOP). the chart may abbreviate this as 'A' or 'Ab' or 'TAB' or 'TOP' followed by a number designating the number of abortions prior to this pregnancy.
- If there are more than 5 previous pregnancies, record the additional information in the Comments section. In eHARS, record additional pregnancies on the PCRF on the "Birthing Person History" tab.

11.8.3 YEAR OUTCOME OCCURRED (**Optional**, if applicable, applies to health department & health care providers)

- For each previous pregnancy where the pregnancy outcome is known, record the four-digit year associated with the pregnancy outcome.
- If the year of the pregnancy outcome is unknown, enter "9999".
- If there are more than 5 previous pregnancies, record the additional information in the Comments section. In eHARS, record additional pregnancies on the PCRF on the "Birthing Person History" tab.

11.9 WAS A TEST RESULT (WITH A SPECIMEN COLLECTION DATE WITHIN THE 6 WEEKS ON OR BEFORE DELIVERY) DOCUMENTED IN THE BIRTHING PERSON'S LABOR/DELIVERY RECORD (**Optional**, applies to health department and health care providers)

- Select applicable response for both the CD4 and quantitative NAAT (RNA or DNA) test types.
- Limited to test results with specimens collected within the 6 weeks on or before delivery.
- If a search for this datum was completed but a response of "Yes" or "No" cannot be determined, select "Unknown"

11.10 DID BIRTHING PERSON RECEIVE ANTIRETROVIRALS (ARVs) PRIOR TO THIS PREGNANCY? (**Recommended**, applies to health department & health care providers)

- 'Pregnancy' is defined as: The condition of having a developing embryo or fetus in the body after union of an ovum and spermatozoon. Labor and delivery occur after this interval, so they are not considered part of the 'pregnancy'.
- Select "Yes" if information is available that states that the birthing person used ARVs prior to this pregnancy. If "Yes", record the date ARV treatment began and the date of last use. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- Select "No" if the birthing person did not use ARVs prior to this pregnancy.
- If a birthing person did not receive ARVs, do not assume it was because they refused. Select "Refused" only if explicit documentation in the medical record indicates that the birthing person was offered the drug, but the birthing person declined.
- Select "Unknown" after an unsuccessful search for this datum.

11.10.1 IF "YES", PLEASE SPECIFY ALL

- Record all ARVs received prior to this pregnancy.

11.11 DID BIRTHING PERSON RECEIVE ARVs DURING PREGNANCY? (**Required**, applies to health department & health care providers)

- Select "Yes" if information is available that states that the birthing person used ARVs any time during pregnancy. If "Yes", record the date ARV treatment began and the date of last use. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- Select "No" if the birthing person did not use ARVs during pregnancy.

- Select "Refused" only if explicit documentation in the medical record indicates that the birthing person was offered the drug, but the birthing person declined.
- Select "Unknown" if it is unknown whether the birthing person ever used ARVs during pregnancy.

11.11.1 IF "YES", PLEASE SPECIFY ALL

- Record all ARVs received during pregnancy.
- For additional information about antiretroviral regimens for pregnant patients with HIV infection refer to *Recommendations for Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States* at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf.

11.11.2 IF NO, SELECT REASON

- Select "No prenatal care" if the birthing person did not receive any prenatal care during pregnancy.
- Select "Birthing person known to be HIV-negative during pregnancy" if the birthing person tested HIV negative during pregnancy and no further testing was documented. There must be evidence of a negative test during pregnancy in the chart; do not use patient report.
- Select "HIV serostatus of birthing person unknown" if the physician did not know the HIV status of the birthing person because the birthing person refused testing or the physician did not offer testing during pregnancy.
- Select "Other" if another reason for not receiving ARVs was documented. If "Other" is selected specify the specific reason.
- Select "Unknown" after an unsuccessful search for this datum.
- If more than one reason applies, enter the additional reason(s) in the Comments section. In eHARS, enter each reason on a separate PCRF document.

11.12 DID BIRTHING PERSON RECEIVE ARVs DURING LABOR/DELIVERY? (**Required**, applies to health department & health care providers)

- Select "Yes" if information is available that states that the birthing person used ARVs any time during labor/delivery. Labor and delivery period is also termed the intrapartum period and refers to the time from which the person was admitted to the hospital for labor to the time of delivery. If "Yes", record the date ARV treatment began and the date of last use. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- Select "No" if the birthing person did not use ARVs during labor/delivery.
- Select "Refused" only if explicit documentation in the medical record indicates that the birthing person was offered the drug, but the birthing person declined.
- Select "Unknown" if it is unknown whether the birthing person ever used ARVs during labor/delivery.

11.12.1 IF "YES", PLEASE SPECIFY ALL

- Record all ARVs received during labor/delivery.
- For additional information about antiretroviral regimens during the intrapartum period refer to *Recommendations for Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States* at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf.

11.12.2 IF NO, SELECT REASON

- Select "Precipitous delivery/STAT Cesarean delivery" if an eminent delivery of an infant may preclude prescription and/or administration of ARV to the birthing

person.
    - Select "HIV serostatus of birthing person unknown" if the physician did not know the HIV status of the birthing person because the birthing person refused testing or the physician did not offer testing during pregnancy.
    - Select "Birth not in hospital" if the birth occurred outside a hospital; in all likelihood ARV would not have been administered.
    - Select "Birthing person tested HIV negative during pregnancy" if the birthing person tested HIV negative during pregnancy and no further testing was documented. There must be evidence of a negative test during pregnancy in the chart; do not use patient report.
    - Select "Other" if another reason for not receiving ARVs was documented. If "Other" is selected specify the specific reason.
    - Select "Unknown" after an unsuccessful search for this datum.
    - If more than one reason applies, enter the additional reason(s) in the Comments section. In eHARS, enter each reason on a separate PCRF document.

11.13 WAS THE BIRTHING PERSON SCREENED FOR ANY OF THE FOLLOWING CONDITIONS DURING THIS PREGNANCY (**Recommended**, applies to health department & health care providers)

- Select "Yes" if the birthing person was screened for the condition during this pregnancy. If screened, enter the date of the screening; if a sample was drawn for the screening use the date of specimen collection. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011). If the birthing person was screened for the same condition more than once during this pregnancy, enter the additional screening dates in the Comments section. In eHARS, enter the additional screening information on the PCRF on the "Birthing Person History" tab.
- Select "No" if the birthing person was not screened for the condition during this pregnancy.
- Select "Unknown" after an unsuccessful search for this datum.
- Refer to Appendix 11.13 for additional information about each condition.

11.14 WERE ANY OF THE FOLLOWING CONDITIONS DIAGNOSED FOR THE BIRTHING PERSON DURING THIS PREGNANCY OR AT THE TIME OF LABOR AND DELIVERY (**Recommended**, applies to health department & health care providers)

- For this question, "diagnosed" refers to newly diagnosed, a recurrence of, or a chronic infection with any of the following conditions. Screening for syphilis, gonorrhea, and chlamydia is typically done during prenatal care. Generally, diagnosis of an STD/STI will be documented in multiple places in the chart including progress notes, a prenatal clinic visit summary sheet (which should include summary of laboratory tests for various sexually transmitted diseases), laboratory results section, or in sexually transmitted disease summary sheets (typical in public health clinics).
- Diagnoses may be presumptive or definitive depending on symptoms and laboratory tests. If a diagnosis is made either presumptively or definitively, note the answer as "Yes". For specific criteria for answering "Yes" to this question refer to Appendix 11.14. If diagnosed, enter the date of diagnosis; if the diagnosis was based on test results, use the date of specimen collection for the date of diagnosis. Enter date in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011). If the same condition was diagnosed for the birthing person more than once during this pregnancy, enter the additional diagnosis dates in the Comments section. In eHARS, enter the additional diagnosis information on the PCRF on the "Birthing Persons History" tab.
- Select "No" if evidence that the birthing person was screened for the condition during pregnancy but the condition was not diagnosed.
- Select "Unknown" after unsuccessful search for this datum.

11.15 WERE SUBSTANCES USED BY THE BIRTHING PERSON DURING THIS PREGNANCY (**Recommended**, applies to health department & health care providers)

- Indicate whether substances were used during this pregnancy by selecting "Yes", "No", or "Unknown".
- If "Yes", indicate for each substance select whether the substance was
    - "Used and injected" if there is evidence that the birthing person used the substance during this pregnancy and the substance was injected,
    - "Used and did no inject" if there is evidence that the birthing person used the substance during this pregnancy but the substance was not injected,
    - "Used and unknown if injected" if there is evidence that the birthing used the substance during this pregnancy but there was no evidence to determine whether the substance was injected,
    - "Did not use" if there is evidence that the birthing person did not use that particular substance during this pregnancy,
    - "Unknown if used" if there is not sufficient evidence to determine whether the birthing person used the particular substance during this pregnancy.
    - Leave blank if you did not search for whether specific substances were used during this pregnancy.
    - The drugs listed here are in alphabetical order and may be checked if there is evidence of a toxicology screen or a notation in records not based on a toxicology screen (e.g., patient self-report).
- Heroin is a semisynthetic narcotic and opiate and should be listed as heroin, opiate, or opioid on the urine toxicology laboratory results sheet.
- Marijuana may be listed on the urine toxicology results as cannabis, a cannabinoid, THC or simply marijuana.
- Methadone is a synthetic narcotic and should be listed as methadone. Any methadone use, whether legal or illegal, should be included as "Yes" to this question.
- If "Other", specify the name of the substance(s) used.

11.16 WAS A TOXICOLOGY SCREEN DONE ON THE BIRTHING PERSON (EITHER DURING PREGNANCY OR AT THE TIME OF DELIVERY) (**Recommended**, applies to health department & health care providers).

- Select "Yes" if a screen was conducted on the birthing pregnancy during this pregnancy or at the time of delivery. The toxicology testing must have been completed during pregnancy, not before pregnancy. Toxicology screens are usually done using urine or serum.
    - For each substance, select "Not screened" if there's evidence that the substance was not included in the toxicology screen. If the substance was screened, enter the date of the toxicology screen in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011). Select "Positive" if there was a positive test result for the substance. Select "Negative" if there was a negative test result for the substance. Select "Unknown" if a search for the test result for the substance was documented but the result could not be determined.
    - If screening was for a substance other than those listed, select "Other" and specify the drug metabolites in the space provided.
    - If a screening for the same substance was done on more than one occasion, record additional dates and results in the Comments section. In eHARS, enter the additional screening information on the PCRF on the "Birthing Person History" tab.
    - Heroin is a semisynthetic narcotic and opiate and should be listed as heroin, opiate, or opioid on the urine toxicology laboratory results sheet.
    - Marijuana may be listed on the urine toxicology results as cannabis, a cannabinoid,

THC or simply marijuana.
    - Methadone is a totally synthetic narcotic and should be listed as methadone. Any methadone use, whether legal or illegal, should be included as "Yes" to this question.
- Check "No" if it is known that a screen was not conducted.
- Select "Unknown" after unsuccessful search for this datum.

12. Treatment/Services Referrals

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

Has this child ever taken any ARVs? ☐ Yes ☐ No ☐ Unknown

ARV medication	Reason for use						Date began	Date of last use
	HIV Tx	PrEP	PEP	PMTCT	HBV Tx	Other (specify reason)		
i. _____	☐	☐	☐	☐	☐	☐_____	__/__/____	__/__/____
ii. _____	☐	☐	☐	☐	☐	☐_____	__/__/____	__/__/____
iii. _____	☐	☐	☐	☐	☐	☐_____	__/__/____	__/__/____
iv. _____	☐	☐	☐	☐	☐	☐_____	__/__/____	__/__/____
v. _____	☐	☐	☐	☐	☐	☐_____	__/__/____	__/__/____

(Record additional ARV medications in Comments)

Has this child ever taken PCP prophylaxis ☐ Yes ☐ No ☐ Unknown **Date began** __/__/____ **Date of last use** __/__/____

This child's primary caretaker is ☐ 1–Biological parent ☐ 2–Other relative ☐ 3–Foster/Adoptive parent, relative ☐ 4–Foster/Adoptive parent, unrelated ☐ 7–Social service agency ☐ 8–Other (specify in comments) ☐ 9–Unknown

- Enter the data below for all children reported as perinatally exposed with or without consequent HIV infection; the field "Has this child ever taken PCP prophylaxis" and the associated date field need to be completed only if the child is HIV infected.

12.1 HAS THIS CHILD 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.

12.2 ARV MEDICATION (**Recommended**, applies to health department & health care providers)

- List the medications taken.
- This variable is used to verify that the medication taken was actually an antiretroviral.
- Enter "unspecified" if an ARV was taken but the name is not known.
- Refer to Appendix 12.2 for further guidance.

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

- Select reason that applies for each specific ARV medication.
- "HIV Tx" indicates that the patient used the ARV medication to treat HIV infection.
- "PrEP" indicates that the patient used the ARV medication 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. Federal Drug Administration (FDA) intended usage of ARV medications for PrEP is for persons who weigh at least 35 kg and are sexually active or inject drugs.

- "PEP" indicates that the patient used the ARV medication as postexposure prophylaxis (PEP).
- "PMTCT" indicates that the patient used the ARV medication to prevent HIV birthing person-to-child-transmission.
- "HBV Tx" indicates that the patient used the ARV medication to treat hepatitis B virus infection.
- "Other" indicates that the patients used the ARV medication for a reason other than those indicated above.

12.4 DATE BEGAN (**Required,** applies to health department & health care providers)
- For each ARV medication indicated in 12.2, 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).

12.5 DATE OF LAST USE (**Required**, applies to health department & health care providers)
- For each ARV medication indicated in 12.2, 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).

12.6 HAS THIS CHILD EVER TAKE PCP PROPHYLAXIS? (**Optional**, applies to health department & health care providers)
- If nothing in the medical chart indicates the use of any of these drugs or refers to the prophylactic treatment of PCP, then select "No".
- If "Yes", enter the date the child was started on therapy to prevent the occurrence of PCP and the date of last use in *mm/dd/yyyy* format using ".." for unknown values (e.g., 03/../2011).
- "Unknown" is used if treatment information in the medical chart is unclear or was unavailable.
- Refer to Appendix 12.6 for further guidance.

12.7 THIS CHILD'S PRIMARY CARETAKER IS (**Optional**, applies to health department & health care providers)
- Select the person who provides the majority of care for the child.
- Refer to Appendix 12.7 for further guidance.

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

XIII. Comments

- 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 PCRF of eHARS.
- Information entered into the "Comments" tab on the PCRF of eHARS will not be transmitted to CDC.

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

XIV. *Local/Optional Fields

- 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. Pediatric HIV Confidential Case Report Form (CDC 50.42B)

Instructions for Completion

Purpose

- Information captured on the Pediatric HIV Confidential Case Report Form (PCRF) provides population-based data on diagnostic testing and initiation of prophylaxis and treatment, as well as HIV-related morbidity and mortality among children (*CARE Amendments [Section 2626]*) to support states with prevention activities.
- CDC's Division of HIV Prevention (DHP) needs initial reports and updates to reflect the earliest dates that children meet each reporting criteria (i.e., perinatal exposure, HIV infection, stage 3 or AIDS, seroreverter), as well as changes in diagnostic or vital status.
- When a child who was previously reported as HIV infected has progressed to stage 3 (AIDS) or has died, state/reporting area personnel update the National HIV Surveillance System (NHSS) accordingly.
- After programs receive initial reports of evidence of HIV exposure or infection among children, surveillance staff follow up to determine whether diagnostic status of the child changes. For example, staff update reports of children with perinatal exposure after 6 months of age to confirm or refute HIV infection and again at 18 months of age.
- The PCRF can accommodate updated information including immunologic markers and diagnoses of opportunistic infections.
- Prior to 2023, CDC provided a separate *Perinatal HIV Exposure Reporting* (PHER) form to facilitate collection of additional standardized data on HIV-exposed children. CDC revised the PCRF to include some additional standardized data on HIV-exposed children and retired the separate PHER form in 2023.
- CDC updated the PCRF and related software in 2000 to evaluate the implementation and impact of the Public Health Service (PHS) recommendations on the prevention of transmission of HIV from birthing person to child; accommodate surveillance requirements of the Ryan White CARE Act Amendments of 1996; and accommodate the revised 2000 HIV case definition for perinatal HIV exposure, pediatric infection, and those perinatally exposed but not infected with HIV.
- In 1995, CDC added variables on receipt of maternal ARVs during pregnancy and labor/delivery and neonatal ARV.
- Maternal HIV counseling and testing, prenatal care, and refusal of ARV treatment were added in 1996.
- Viral load tests, receipt of additional antiretroviral (ARV) therapy during labor/delivery for the newborn and elective cesarean were added to the pediatric reporting form in 1999.
- These additions enable reporting areas to identify possible reasons for failures in preventing HIV transmission related to childbirth (i.e., receipt of maternal HIV testing, prenatal care, and antiretroviral treatment).
- As states move toward pediatric HIV exposure reporting, information on receipt of prenatal, intrapartum, and neonatal ARV and receipt of other antiretroviral therapy can be collected for all children born to HIV-infected persons. Timely follow-up of these children to determine infection status will aid in evaluating the impact of these recommendations most effectively.
- For evolution of the pediatric case definition, please refer to the 1987 pediatric AIDS case definition (*MMWR* 1987;36(suppl):1–15S), the 1994 revised classification system for HIV infection in children less than 13 years of age (*MMWR* 1994;43:(No. RR-12):1–10), and the 2000 HIV case definition in the CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus

Infection and Acquired Immunodeficiency Syndrome (*MMWR* 1999;48(RR-13):1–31), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a1.htm, the 2008 case definition (MMWR 2008; 57 (RR-10) 1-12 at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a1.htm, and the Revised Surveillance Case Definition for HIV Infection — United States, 2014 (MMWR 2014;63 (RR03);1-10 at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6303a1.htm?s_cid=rr6303a1_e.

Pediatric Cases of Public Health Importance (COPHI)

- Reporting area staff should continue to discuss certain priority cases directly with CDC surveillance staff. These include HIV infection in a health care setting, HIV-2 infection, HIV infection attributed to tissue or organ transplantation, suspected transmission due to sexual contact, transmission from the birthing person to the infant due to breast feeding or pre-mastication of food , transfusions after March 1985, or any other unusual transmission circumstances. This direct communication will ensure the timeliest technical support. For further guidance, see Technical Guidance File *Risk Factor Ascertainment*.

4. Patient Demographics

4.1 DIAGNOSTIC STATUS AT REPORT

4.1.1 PERINATAL HIV EXPOSURE

- Although all children aged less than 18 months born to an HIV-infected person were perinatally exposed to HIV, the "Perinatal HIV Exposure" category on the case report form is composed of those with an undetermined HIV infection status.
- A child aged less than 18 months born to an HIV-infected person will be categorized as "Perinatal HIV Exposure" if the child does not meet the criteria for HIV infection or the criteria for presumptively or definitely uninfected.

4.1.2 PEDIATRIC HIV

- Among children <18 months old whose birthing persons were not infected and all children aged ≥18 months, a reportable case of HIV infection must meet at least one of the following criteria:

1.1: Persons Aged ≥18 Months and Children Aged <18 Months whose Birthing Persons were Not Infected

1.1.1: Laboratory Evidence

Laboratory criteria require reporting of the date of the specimen collection for positive test results in multitest algorithms or stand-alone virologic tests and enough information about the tests to determine that they meet any of the following criteria:

- A multitest algorithm consisting of
  - A positive (reactive) result from an initial HIV antibody or combination antigen/antibody test, and
  - An accompanying or subsequent positive result from a supplemental HIV test different from the initial test.

The initial HIV antibody or antigen/antibody test and the supplemental HIV test that is used to verify the result from the initial test can be of any type used as an aid to diagnose HIV infection. For surveillance purposes, supplemental tests can include some not approved by the Food and Drug Administration (FDA) for diagnosis (e.g., HIV-1 viral load test, HIV-2 western blot/immunoblot antibody test, and HIV-2 NAT). However, the initial and supplemental tests must be "orthogonal" (i.e., have different antigenic

constituents or use different principles) to minimize the possibility of concurrent nonspecific reactivity. Because the antigenic constituents and test principles are proprietary information that might not be publicly available for some tests, tests will be assumed to be orthogonal if they are of different types. For example:

- One test is a combination antigen/antibody test and the other an antibody-only test.
- One test is an antibody test and the other a NAT.
- One test is a rapid immunoassay (a single-use analytical device that produces results in <30 minutes) and the other a conventional immunoassay.
- One test is able to differentiate between HIV-1 and HIV-2 antibodies and the other is not.

Tests also will be assumed to be orthogonal if they are of the same type (e.g., two conventional immunoassays) but made by different manufacturers. The type of HIV antibody test that verifies the initial test might be one formerly used only as an initial test (e.g., conventional or rapid immunoassay, HIV-1/2 type-differentiating immunoassay), or it might be one traditionally used as a supplemental test for confirmation (e.g., western blot, immunofluorescence assay).

- A positive result of a multitest HIV antibody algorithm from which only the final result was reported, including a single positive result on a test used only as a supplemental test (e.g., HIV western blot, immunofluorescence assay) or on a test that might be used as either an initial test or a supplemental test (e.g., HIV-1/2 type-differentiating rapid antibody immunoassay) when it might reasonably be assumed to have been used as a supplemental test (e.g., because the algorithm customarily used by the reporting laboratory is known).

- A positive result or report of a detectable quantity (i.e., within the established limits of the laboratory test) from any of the following HIV virologic (i.e., non-antibody) tests:
  - Qualitative HIV NAT (DNA or RNA)
  - Quantitative HIV NAT (viral load assay)
  - HIV-1 p24 antigen test
  - HIV isolation (viral culture) or
  - HIV nucleotide sequence (genotype).

1.1.2: Clinical (Non-Laboratory) Evidence

Clinical criteria for a confirmed case (i.e., a "physician-documented" diagnosis for which the surveillance staff have not found sufficient laboratory evidence described above) are met by the combination of:

- A note in a medical record by a physician or other qualified medical-care provider that states that the patient has HIV infection, and
- One or both of the following:
  - The laboratory criteria for a case were met based on tests done after the physician's note was written (validating the note retrospectively).
  - Presumptive evidence of HIV infection (e.g., receipt of HIV antiretroviral therapy or prophylaxis for an opportunistic infection), an otherwise unexplained low CD4+ T-lymphocyte count, or an otherwise unexplained

diagnosis of an opportunistic illness.

- Among children aged less than 18 months whose birthing persons have an unknown infection status or were known to be infected a reportable case of HIV infection must meet at least one of the following criteria:

1.2: Children Aged <18 Months Born to Birthing Persons Who Have an Unknown Infection Status or were Known to be Infected

1.2.1: Laboratory Evidence

A child aged <18 months is categorized for surveillance purposes as HIV infected if all of the following criteria are met:

- Positive results on at least one specimen (not including cord blood) from any of following HIV virologic tests:
  - HIV-1 NAT (DNA or RNA)
  - HIV-1 p24 antigen test, including neutralization assay for a child aged >1 month
  - HIV isolation (viral culture) or
  - HIV nucleotide sequence (genotype).
- The test date (at least the month and year) is known.
- One or both of the following:
  - Confirmation of the first positive result by another positive result on one of the above virologic tests from a specimen obtained on a different date or
  - Both of the following:
    - No subsequent negative result on an HIV antibody test, and no subsequent negative result on an HIV NAT before age 18 months.

1.2.2: Clinical Evidence

- The same criteria as for section 1.1.2 above (1.1.2 Clinical [Non-Laboratory] Evidence for Persons Aged ≥18 Months and Children Aged <18 Months whose Birthing Persons were Not Infected) or
- All three of the following alternative criteria:
  - Evidence of perinatal exposure to HIV infection before 18 months of age:
    - A birthing person with documented HIV infection or
    - A confirmed positive test for HIV antibody (e.g., a positive initial antibody test confirmed by a supplemental antibody test) and a birthing person whose infection status is unknown or undocumented.
  - Diagnosis of a stage-3-indicative opportunistic illness.
  - No subsequent negative result on an HIV antibody test.

4.1.3 PEDIATRIC AIDS

- Children who are HIV infected and exhibit any of the following stage 3 (AIDS)-defining clinical conditions should be reported as stage 3 (AIDS) cases; although most of these conditions appear among adult stage 3 (AIDS) diagnostic criteria, asterisked conditions apply only to aged <6 years, and conditions with a dagger

footnote symbol apply only to children aged ≥6 years and adults.

- Bacterial infections, multiple or recurrent*
- Candidiasis of bronchi, trachea, or lungs
- Candidiasis of esophagus
- Cervical cancer, invasive†
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1 month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age >1 month
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy, HIV related
- Herpes simplex: chronic ulcer(s) (>1 month's duration); or bronchitis, pneumonitis, or esophagitis (onset at age >1 month)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (>1 month's duration)
- Kaposi's sarcoma
- Lymphoma, Burkitt (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- *Mycobacterium avium* complex or *M. kansasii*, disseminated or extrapulmonary
- *Mycobacterium tuberculosis* of any site, pulmonary†, disseminated, or extrapulmonary
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- *Pneumocystis jirovecii* (previously known as "*Pneumocystis carinii*") pneumonia
- Pneumonia, recurrent†
- Progressive multifocal leukoencephalopathy
- *Salmonella* septicemia, recurrent
- Toxoplasmosis of brain, onset at age >1 month
- Wasting syndrome due to HIV

† Only among adults and children aged ≥6 years.
* Only among children aged <6 years.

4.1.4 PEDIATRIC SEROREVERTER

- Virtually all children less than 18 months of age born to HIV-infected persons are antibody positive at birth.
- A child aged < 18 months born to an HIV-infected person will be categorized for surveillance purposes as "not infected with HIV" if the child does not meet the criteria for HIV infection but meets the following criteria:

3.1: Uninfected

A child aged <18 months who was born to an HIV-infected person or had a positive HIV antibody test result is classified for surveillance purposes as not infected with HIV if all three of the following criteria are met:

- Laboratory criteria for HIV infection are not met (see section 1.2.1)
- No diagnosis of a stage-3-defining opportunistic illness attributed to HIV infection and
- Either laboratory or clinical evidence as described below.

3.1.1: Laboratory Evidence

Definitively Uninfected

- No positive HIV NAT (RNA or DNA) and
- At least one of the following two criteria:
  - At least two negative HIV NATs from specimens obtained on different dates, both of which were at age ≥ 1 month and one of which was at age ≥ 4 months.
  - At least two negative HIV antibody tests from specimens obtained on different dates at age ≥ 6 months.

Presumptively Uninfected

- Criteria for definitively uninfected with HIV are not met
- At least one of the following four laboratory criteria are met:
  - At least two negative NATs from specimens obtained on different dates, both of which were at age ≥2 weeks and one of which was at age ≥4 weeks.
  - One negative NAT (RNA or DNA) from a specimen obtained at age ≥8 weeks.
  - One negative HIV antibody test from a specimen obtained at age ≥6 months.
  - If criteria for HIV infection had initially been met by one positive HIV NAT test then it must have been followed by at least two negative test results from specimens obtained on different dates, one of which is:
    - A NAT test from a specimen obtained at age ≥ 8 weeks, or
    - An HIV antibody test from a specimen obtained at age ≥ 6 months.
- No subsequent positive NAT

3.1.2: Clinical Evidence

A note in a medical record by a physician or other qualified medical-care provider states that the patient is not infected with HIV.

5. Residence at Diagnosis

- For reports of perinatal HIV exposure, enter the patient's city, county, state/country, and ZIP code of residence at the time when HIV infection was first considered, either clinically or through laboratory evaluation.

- 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.
- If the patient's residence changes between diagnosis of perinatal HIV exposure and confirmed HIV infection, record new address.
- If laboratory slips are not available, enter the 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.
- For further guidance about residency assignment, see Technical Guidance File *Date and Place of Residence*.

6. Facility of Diagnosis

6.2 FACILITY NAME

- For reports of perinatal HIV exposure, enter the name of the facility where child was first evaluated for HIV infection, either clinically or through laboratory evaluation.
- The hospital where the birthing person obtained prenatal care should not be used to answer this question unless it was also the facility where the child was born and HIV infection was considered as a diagnosis at the time of the child's birth or at the time of subsequent physician/clinic visits.
- For reports of confirmed HIV infection, 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 were not in the medical record, enter the name of the facility where the child's HIV infection was diagnosed and documented by the health care provider. Enter facility uniformly to prevent the occurrence of multiple names for a given facility.
- 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.
- These fields strictly apply to facility where HIV or HIV infection stage 3 (AIDS) was diagnosed. Where chart abstraction is conducted at a facility other than the Facility of Diagnosis document report source in the document source field in the II. Health Department Use Only section of the case report form and in III. Facility Providing Information section of the case report form, as applicable.

7. Patient History

- This information is often found in the birthing person's chart in the discharge summary, history and physical, social service notes, counseling and testing notes, and STD diagnosis notes.
- Where not explicitly annotated, contact the child's provider about birthing person and child 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.

7.1 BIRTHING PERSON'S HIV INFECTION STATUS

- "Refused HIV testing" should be selected if birthing person's refusal is documented in the medical chart.
- If the birthing person has been tested for HIV and found to be uninfected at or after the child's birth, then perinatal transmission is not the presumed mode of exposure to HIV infection.
- If birthing person-to-infant transmission through breast-feeding is considered to be the only mode of transmission, please alert the state or local NIR coordinator.
- If dates are not available, please review medical charts to determine when HIV diagnosis for the birthing person occurred in relationship to the child's birth and select:
  Known HIV+ before pregnancy;
  Known HIV+ during pregnancy;
  Known HIV+ sometime before birth;
  Known HIV+ at delivery;
  Known HIV+ after child's birth; or
  HIV+, time of diagnosis unknown.
- If no information is available regarding HIV status for the birthing person, please select: HIV status unknown.

10. Birth History (for patients exposed perinatally with or without consequent infection)

10.4 BIRTH HISTORY

10.4.6 CONGENITAL DISORDERS

- Data collected will be used to evaluate changes in incidence or other unusual patterns of serious birth defects among children exposed to zidovudine in utero compared with those who were not exposed and with the general population.
- Approximately 3%–4% of all babies will have serious birth defects (e.g., neural tube defects, congenital heart defects, esophageal atresia, and cleft lip/palate).
- The methods and definitions used were developed by the CDC National Center on Birth Defects and Developmental Disabilities and are currently used in the Metropolitan Atlanta Congenital Defects Program, an active surveillance system for birth defects in the Atlanta metropolitan area.
- Select "Yes" if the child meets the case definition for birth defects as defined by the CDC National Center on Birth Defects and Developmental Disabilities as listed below.
- Criteria for Inclusion as Reportable Birth Defect:
  - The child must have a structural or genetic birth defect or other specified birth outcome that can adversely affect his or her health and development;
  - The structural or genetic birth defect must be diagnosed or its signs or symptoms recognized within the first year of life;
  - The infant must have a gestational age of at least 20 weeks or a birth weight of at least 500 grams; and
  - A case must be abstracted by the child's sixth birthday.
- Criteria for Exclusion:
  - Defects such as normal variants or minor anomalies are considered excludable. Diagnoses that may be normal variants or minor anomalies may be included only if associated with another reportable defect.
  - Imprecise diagnoses (probable, possible, compatible with, consistent with, suspected, questionable, suggestive of, etc.) should be abstracted and coded as such and follow-up conducted to ascertain true status.
  - For children with possible birth defects, please review newborn and

hospital records including the face sheet; history and physical; discharge summary; operative, laboratory, x-ray, cardiac catheterization, and autopsy reports; and notes and consultations by physicians, nurses, and social and psychological services.
        - In addition, birth defect (i.e., congenital anomalies) information is also collected on the standard US birth certificate.
        - Hospital records should be reviewed to determine if a reportable defect is present. Each reportable condition is coded separately according to the birth defect code (see below). These codes are based on ICD-9 or ICD-10 codes but provide more specific diagnostic information.
        - If reportable birth defects are diagnosed, select "Yes" and abstract all diagnoses onto the case report form.
        - Include discrepant diagnoses. Also include diagnoses appearing in the chart that have not been ruled out by an expert or laboratory test.
        - If the infant is diagnosed with a syndrome, record the name and code of the syndrome as well as the individual defects.
        - If there is a question about whether a diagnosis is reportable or how to code any diagnosis, please contact the CDC HIV Surveillance Branch surveillance project officer assigned to the state/local HIV surveillance program.
    - BIRTH DEFECTS CODE
        - The 6-digit defect codes (https://www.cdc.gov/ncbddd/birthdefects/macdp.html) are based on 3- to 5-digit ICD-9-CM or ICD-10-CM codes from a birth certificates or medical records (or ICD-9 or ICD-10 codes from death certificates). The shorter codes may be used in place of the 6-digit codes. Enter the code for the birth defect given in the birth certificate, medical record, or death certificate. If the code is not available in those places, but the birth defect is described using medical terminology, then look up the corresponding code in the ICD-9-CM-based list (downloadable from http://www.cdc.gov/ncbddd/birthdefects/macdp.html) if the record was from before October 1, 2014, or in the ICD-10-CM-based list (downloadable from http://www.cdc.gov/nchs/icd/icd10cm.htm) if the record was from October 1, 2014 or later.
        - If defects exist, list all on the case report form and enter in the Comments section. In eHARS, if there are more than five congenital defects then enter the information on the additional congenital defects on a separate PCRF document.

11. Birthing Person History

11.13 WAS THE BIRTHING PERSON SCREENED FOR ANY OF THE FOLLOWING CONDITIONS DURING THIS PREGNANCY

- GROUP B STREP (GBS) - Group B streptococci. A major cause of perinatal bacterial infections and systemic and focal infections in infants. Invasive disease categorized into early onset (1st week of life) and late onset (usually at 3-4 weeks of life). Colonization late in pregnant persons and newborns ranges from 5% to 35%. Intrapartum chemoprophylaxis is IV Penicillin G. Two types of prevention strategies may be used:
    - Screening all pregnant persons at 35 to 37 weeks for vaginal and rectal GBS colonization and offering intrapartum chemoprophylaxis to those identified as GBS carriers; or

- Risk factor-based strategy - prophylaxis given to persons with intrapartum risk factors including gestation < 37 weeks, ≥ 18 hours since rupture of membrane, or temperature of 38° C or greater.

- HEPATITIS B (Hepatitis B surface antigen, HBsAg) - Detects acutely or chronically infected persons. Prenatal HbsAg screening of all pregnant persons is recommended. Babies of birthing persons who are HbsAg (+) must have HBIG and HBV vaccine within 12 hours of birth to prevent perinatal HBV infection. Be sure the test result is for the surface antigen rather than the antibody (anti-HBs), core antigen (HbcAg), or antibody (anti-HBc); or Hepatitis B e antigen (HbeAg) or antibody (anti-HBe). This test is usually done at the initial prenatal visit or at the time of labor and delivery for persons with risk factors for hepatitis B infection and persons whose status is unknown.
- RUBELLA - Screening is usually done at the initial prenatal visit. If 'negative' the birthing person should be immunized.
- SYPHILIS - All pregnant persons should receive serologic screening for syphilis early in pregnancy with a nontreponemal test (e.g., VDRL and RPR). In addition, screening is recommended in the third trimester for those in high prevalence areas or for persons with risk factors for syphilis infection. Nontreponemal antibody tests are used for screening purposes and presumptive diagnosis: VDRL (venereal disease research laboratory); RPR (rapid plasma reagin test; STS serologic test for syphilis, syphilis screening test); ART (automated reagin test). The nontreponemal antibody test should be confirmed with a treponemal antibody test (e.g., FTA-ABS, MHA-TP). If a pregnant person has a reactive nontreponemal test and a persistently negative treponemal test, a false positive test is inferred.(Reference: Red Book 2021- American Academy of Pediatrics).

11.14 WERE ANY OF THE FOLLOWING CONDITIONS DIAGNOSED FOR THE BIRTHING PERSON DURING THIS PREGNANCY OR AT THE TIME OF LABOR AND DELIVERY

- BACTERIAL VAGINOSIS - Clinician diagnosis of bacterial vaginosis. Sometimes abbreviated BV.
- CHLAMYDIA (*Chlamydia trachomatis*) - Record positive test for chlamydia (a positive culture, positive EIA, or detection of chlamydial antigen or nucleic acid).
    - Name of laboratory tests - *Chlamydia* cell culture (TRIC Agent Culture); direct fluorescent antibody (DFA) tests; enzyme immunoassay (EIA) tests; nucleic hybridization (DNA probe) tests; and PCR and LCR.
- GENITAL HERPES - Active (herpes genitalis) - Primary herpes (first episode of herpes) or recurrence of herpes during pregnancy or at labor and delivery.
    - Name of laboratory tests - herpes virus culture; herpes cytology (herpetic inclusion bodies, cytology, inclusion body stain, Tzanck smear, Giemsa stain viral study); rapid diagnostic tests- direct immunofluorescent AB or EIA; HSV Ag; or polymerase chain reaction (PCR).
- GONORRHEA (*Neisseria gonorrhea*) - Record if culture positive.
    - Name of laboratory tests - *Neisseria gonorrhea* culture (GC Culture, Gonorrhea Culture); Thayer-Martin medium; chocolate agar; detection of nucleic acid.

- GROUP B STREP - Group B streptococci. A major cause of perinatal bacterial infections and systemic and focal infections in infants. Invasive disease categorized as early onset (1st week of life) and late onset (usually at 3-4 weeks of life). Colonization late in pregnant persons and newborns ranges from 5% to 35%. Intrapartum chemoprophylaxis is IV Penicillin G. Two types of prevention strategies may be used:
    - Screening all pregnant persons at 35 to 37 weeks for vaginal & rectal GBS colonization, offering intrapartum chemoprophylaxis to those identified as GBS carriers; or
    - Risk factor-based strategy in which prophylaxis is given to persons with intrapartum risk factors: gestation < 37 weeks, ≥ 18 hours since rupture of membrane, or temperature 38° C or greater.
- HEPATITIS B (Hepatitis B surface antigen, HbsAg) - Detects acutely or chronically infected persons. Prenatal HbsAg screening of all pregnant persons is recommended. Babies of birthing persons who are HbsAg (+) must have HBIG & HBV vaccine within 12 hours of birth to prevent perinatal HBV infection.
    - Be sure the test result is for the surface antigen rather than the antibody (anti-HBs), core antigen (HbcAg) or antibody (anti-HBc); or Hepatitis B e antigen (HbeAg) or antibody (anti-HBe). Tests are usually done at the initial prenatal visit or at the time of labor and delivery for persons with risk factors of hepatitis B infection and persons whose status is unknown.
- HEPATITIS C - Tests do not distinguish between acute, chronic, or resolved infection. Diagnosis by antibody assays involves initial screening EIA. Repeatedly positive results are confirmed by a recombinant immunoblot assay (RIBA). Highly sensitive PCR assays for detection of HCV RNA are also available.
    - Name of laboratory test - EIA (Enzyme immunoassay) screen, confirmed by recombinant immunoblot assay (RIBA).
- PELVIC INFLAMMATORY DISEASE (PID) - Look for documentation of a clinical diagnosis of PID. A note stating ‘rule out PID’ does not indicate the person had PID.
- SYPHILIS (*Treponema pallidum*) - All pregnant persons should receive a serologic screen for syphilis early in pregnancy with a nontreponemal test (e.g., VDRL, RPR, STS, and ART) and preferably again at delivery. In addition, screening is recommended in the third trimester for those in high prevalence areas or those at high risk.
    - Nontreponemal antibody tests are used for screening. Any reactive nontreponemal test must be confirmed by a specific treponemal test (FTA-ABS and MHA-TP) to exclude false positive results which can be caused by a viral infection (e.g., infectious mononucleosis, hepatitis, varicella and measles), lymphoma, TB, malaria, endocarditis, connective tissue disease, pregnancy, or abuse of injection drugs. If a pregnant person has a reactive nontreponemal test and a persistently negative treponemal test, a false positive test is inferred. A positive FTA-ABS or MHA-TP usually remains reactive for life, even after successful therapy. Also, look for evidence of treatment for syphilis - receipt of penicillin (bicillin) 2.4 million units is the standard treatment for syphilis in the birthing person. Check whether the child was diagnosed with or treated for congenital syphilis with penicillin for 10 days. A physician diagnosis will be clearly documented in the infant's birth chart. Also check the congenital syphilis registry to confirm congenital syphilis, with consideration for confidentiality and security of an individual’s HIV or stage 3 or AIDS status.

- Name of laboratory tests - *Presumptive* diagnosis: nontreponemal tests (for screening purposes) VDRL (venereal disease research laboratory); RPR (rapid plasma reagin test, serologic test for syphilis, STS, syphilis screening test, ART-automated reagin test). *Definitive* diagnosis: treponemal tests (for diagnostic purposes) Darkfield examination (Darkfield microscopy, syphilis; *Treponema Pallidum* Darkfield examination); FTA-ABS (Fluorescent Treponemal Antibody Absorbed Test, Fluorescent Treponemal Antibody Adsorption); MHA-TP (Microhemagglutination assay for Antibody to *Treponema Pallidum*; Microhemagglutination, *Treponema Pallidum*.

- TRICHOMONAS (*Trichomonas vaginalis*) - Record clinician diagnosis of trichomonas. Trichomonas is diagnosed by finding trichomonas on a wet mount.
  - Name of laboratory tests - Trichomonas preparation (Hanging Drop Mount for Trichomonas, *Trichomonas vaginalis* wet preparation; Trich Prep; wet preparation for *Trichomonas vaginalis*.

12. Treatment/Services Referrals

12.2 ARV MEDICATION

- Please refer to the *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection* https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/PedARV_GL.pdf.

12.6 HAS THIS CHILD EVER TAKE PCP PROPHYLAXIS?

- Please refer to *MMWR* 1995;44(RR-4):1–11 for the 1995 Revised Guidelines for Prophylaxis Against Pneumocystis carinii Pneumonia (PCP) for Children Infected with or Perinatally Exposed to HIV. Examples of PCP prophylaxis include Trimethoprim/sulfamethoxazole (TMP/SMX, Bactrim, Septra), Pentamidine, and Dapsone.
- TMP/SMX (Bactrim, Septra) can be used to treat infections other than HIV but is usually used for a shorter period. For example, TMP/SMX is used for 2–3 weeks to treat otitis media and would NOT be recorded as "Yes" in this field.
- Include as PCP prophylaxis if it is clearly noted as such in the medical chart or given for a period of 2 weeks or longer.

12.7 THIS CHILD'S PRIMARY CARETAKER IS

- "Other relative" refers to children living with an aunt, grandmother, etc. in an informal arrangement, and the relative does not receive a stipend for providing care.
- If a child lives with a relative and that relative is paid a stipend for caring for the child, "Foster/Adoptive parent, relative" should be selected.
- A child is in "foster/adoptive parent, unrelated" if living with someone other than a relative.
- "Adoptive parent, relative" refers to child who has been legally adopted by a relative. This includes children with deceased parents whose legal custody has been transferred to a relative.
- If the adoptive parent is unrelated, please select "foster/adoptive parent, unrelated". This includes children with deceased parents whose legal custody has been transferred to a person who is unrelated to the child.
- "Social service agency" refers to children whose primary caretaker is a social service agency, which usually refers to children living in group home situations.
- For children being cared for in situations not described above, select "other" and specify in this section.