Attachment E. Form Instructions in *Technical Guidance for HIV/AIDS Surveillance Programs Volume II: Data Collection Resources and Reporting*. Centers for Disease Control and Prevention; 2006

Technical Guidance for HIV/AIDS Surveillance Programs

Volume II: Data Collection Resources and Reporting

HIV Incidence and Case Surveillance Branch
Atlanta, Georgia

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The document is available at http://www2a.cdc.gov/hicsb/.

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Technical Guidance for HIV/AIDS Surveillance Programs

Adult HIV/AIDS Confidential Case Report

HIV Incidence and Case Surveillance Branch
Atlanta, Georgia

Contents — Adult HIV/AIDS Confidential Case Report

Technical Guidance for HIV/AIDS Surveillance Programs — Adult HIV/AIDS Confidential Case Report

Instructions for Completion

Purpose of case report form

The Adult HIV/AIDS Confidential Case Report (CDC 50.42A/CDC 50.42C) form is designed to collect information that promotes understanding of HIV infection and AIDS morbidity and mortality among United States residents **greater than or equal to 13 years of age** at time of diagnosis. This form reflects data that should be collected; this guidance applies to this data collection even if surveillance sites use a different form or medium for HIV/AIDS case surveillance.

The case report form in the context of document-based surveillance

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

Patients for whom form is indicated

- Each person with an HIV (not AIDS) diagnosis.
- Each person with an AIDS diagnosis.
- When a previously reported HIV (not AIDS) patient progresses to AIDS or an HIV-infected/AIDS patient dies, use this form to report the new information.

Definition of variable designators

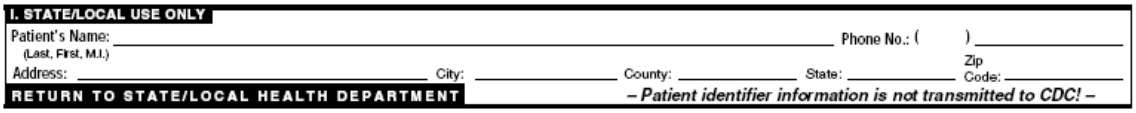
- **Required**: Variables that are required to meet the case definitions of HIV or AIDS, to identify and track cases, and to do meaningful statistical analysis.
- **Recommended**: Information that is useful for analysis but not essential for core surveillance.
- **Optional**: Information that should be ascertained if readily available.

Disposition of form

- The completed form is for state or local health agency use and is not to be sent to the Centers for Disease Control and Prevention (CDC) with patient identifiers. Some sites send forms to CDC for data entry.
- Data obtained from these forms are entered into compatible or standardized computer software provided by the Division of HIV/AIDS Prevention, National

Center for HIV, STD, and TB Prevention, CDC, and then transferred without identifiers to CDC electronically by encrypted computer diskette or electronic transfer via secure data network.

Section I, State/local use only (patient identifier information)



Patient identifier information is for state/local health department use only and is not transmitted to CDC. Enter the data below for all AIDS cases and, where consistent with statutory requirements, HIV (not AIDS) cases. Consult with your state/local health department in jurisdictions with alternatives to name-based reporting.

1.1 *PATIENT'S NAME* (**Required**, applies to Health Dept & Health Care Providers)

- Enter patient's last name, first name, and middle initial.
- If available, write in a.k.a.s, aliases, etc. for later data entry. Record these names in Section X, Comments.

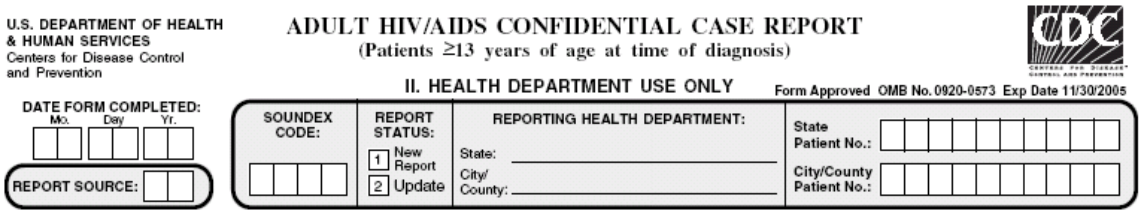
1.2 *PHONE NO.* (**Required** if patient has a telephone, applies to Health Dept & Health Care Providers)

- Enter patient's current home area code and telephone number.

1.3–1.7 *ADDRESS* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter patient's current street number and name, city, county, state, and ZIP code.

Section II, Health department use only



- Nonhealth department staff only need to complete *DATE FORM COMPLETED* and *REPORT STATUS* fields.

2.1 *DATE FORM COMPLETED* (**Required**, applies to Health Dept & Health Care Providers)

- Enter date in *mmddyy* format.

2.2 *REPORT SOURCE* (**Required**, applies to Health Dept)

- Enter the code for reporting source that provided the information for this report.
- To clearly identify multiple data sources for a given HIV/AIDS case, use a separate case report form for each source.
- Since legal values now exceed two digits, enter code immediately below this box.
- If coding proves difficult, write in report source for later coding.
- Refer to Appendix 2.2 for code information.

2.3 *SOUNDEX CODE* (**Required** in accordance with state/local law, applies to Health Dept)

- After patient name is recorded, CDC-supplied software generates this variable by using the patient's last name entered in Section I. Because this code is automatically generated, health department staff may leave this field blank 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.

2.4 *REPORT STATUS* (**Required**, applies to Health Dept and Health Care Providers). This variable does not exist in eHARS.

- Select applicable response.
- Select "New Report" if the patient is not already in the state registry with the condition reported—HIV or AIDS.
- Select "Update" for patients previously reported to the registry with either condition—HIV or AIDS.
- Health department staff establishes report status by searching the HIV/AIDS registry for previous reports on a particular patient. Public providers without access to the registry may request a record search from their jurisdiction's surveillance program.
- Providers from the public and private sectors unable to establish status may assume "New Report." As the report is processed by surveillance staff, status entered can be confirmed or corrected.
- When additional information on a previously reported case of HIV infection (not AIDS) becomes available, select "Update."
- When a patient has been previously reported with HIV infection (not AIDS) and later receives an AIDS diagnosis, select "New Report." From a surveillance perspective, the occurrence of AIDS is reportable in all US jurisdictions as an event independent of the occurrence of HIV infection (not

AIDS). Progression to AIDS among previously reported HIV case patients represents new reports of AIDS rather than an update of previously reported HIV cases.

2.5 REPORTING HEALTH DEPARTMENT

2.5.1–2.5.2 *STATE, CITY/COUNTY* (each element **Required**, applies to Health Dept)

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

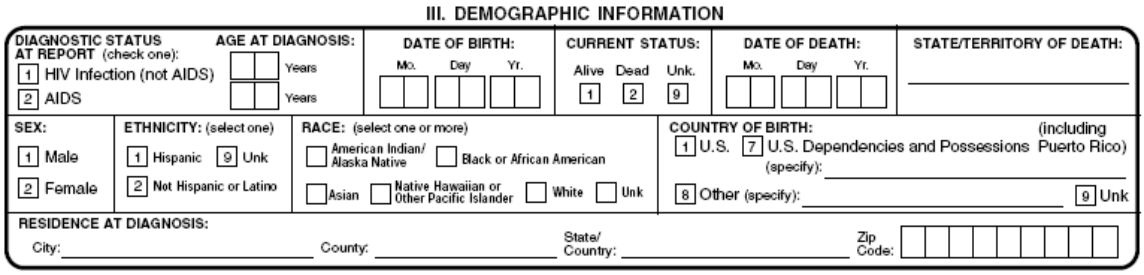
2.6 *STATE PATIENT NO.* (**Required** where state numbers are used, applies to Health Dept)

- Enter the assigned state patient number.
- Each patient should have a unique state number throughout the course of HIV disease. An exception to this is when a case is transferred to another state, where another state number may be assigned.
- Assigned numbers **should not** be reused, even if the case is later deleted.
- The precise format of this 10-digit character variable is unique to each state.
- This variable is used, along with the state of report, to uniquely identify cases reported to CDC and to merge the state datasets without duplication.

2.7 *CITY/COUNTY NUMBER* (**Required** where city numbers are used, applies to Health Dept)

- Enter the assigned city/county patient number.
- Each patient should have a unique city/county number throughout the course of HIV disease. An exception to this is when a case is transferred to another city/county and/or state, where another city number may be assigned.
- Assigned numbers **should not** be reused, even if the case is later deleted.

Section III, Demographic information



3.1 *DIAGNOSTIC STATUS AT REPORT* (**Required**, applies to Health Dept & Health Care Providers)

- Select "HIV Infection (not AIDS)" if the patient meets the case definition for HIV infection and does not meet the 1993 CDC AIDS surveillance case definition.
- Select "AIDS" if patient does meet the 1993 CDC AIDS surveillance case definition.
- A patient may meet the case definition for HIV infection only, the case definition for AIDS only, or both. These diagnostic criteria may be met simultaneously or sequentially.
- Irrespective of the interval between HIV and AIDS diagnosis dates, and even where the same source of these data reported both events, use one form to capture each event. Fill out two case report forms:
  - Fill out the first form completely for the first diagnosis.
  - Fill out the second partially, capturing additional or updated data absent from the first form.
- This second form, referred to in preceding bulleted item, must include at least the following data: *DIAGNOSTIC STATUS AT REPORT*; *RESIDENCE AT DIAGNOSIS* (see 3.11, below); and Facility of diagnosis (see Section IV, below).
- Refer to Appendix 3.1 for details.

3.2 *AGE AT DIAGNOSIS* (**Optional**, applies to Health Dept & Health Care Providers)

- Enter two-digit age at diagnosis in years.
- Where this age is unknown and therefore cannot be entered, CDC-supplied software calculates it automatically from other required entries (date of birth at 3.3 below, and a variety of laboratory and clinical fields at Section VI and Section VIII below).
- The investigator must know if the patient was at least 13 years old when HIV or AIDS was diagnosed to determine whether to use the Adult case report form (CDC 50.42A or CDC 50.42C).

3.3 *DATE OF BIRTH* (**Required**, applies to Health Dept & Health Care Providers)

- Enter patient's month, day, and year of birth.

3.4 *CURRENT STATUS* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- For further guidance on death ascertainment, see CDC's *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Death Ascertainment*.

3.5 *DATE OF DEATH* (**Required** if applicable, applies to Health Dept & Health Care Providers)

- If patient is deceased, enter date of death.
- For further guidance on death ascertainment, see CDC's *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Death Ascertainment*.

3.6 *STATE/TERRITORY OF DEATH* (**Recommended** if applicable, applies to Health Dept & Health Care Providers)

- If patient is deceased, enter the state/territory where death occurred.

3.7 *SEX* (**Required**, applies to Health Dept & Health Care Providers)

- Select patient's sex at birth.
- "CURRENT_GENDER" and "CURRENT_SEX" are optional fields appearing in new CDC-supplied software but not on the case report form.
- Refer to Appendix 3.7 for further details.

3.8 *ETHNICITY* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If no ethnicity information is available, select "Unk."
- Do not choose "Unk." unless search for this datum was unsuccessful.
- Refer to Appendix 3.8 for further details.

3.9 *RACE* (**Required**, applies to Health Dept & 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 "Unk."
- Refer to Appendix 3.9 for further details.

3.10 *COUNTRY OF BIRTH* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response from boxes provided.
- Refer to Appendix 3.10 for legal values when dependency or country is to be specified.

3.11 *RESIDENCE AT DIAGNOSIS* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter city, county, state/country, and ZIP code of patient's residence at first diagnosis with HIV or AIDS-defining clinical condition.

- The home address given by the patient at the time of HIV and/or AIDS diagnosis usually populates these fields.
- Refer to Appendix 3.11 for further details.

Section IV, Facility of diagnosis


IV. FACILITY OF DIAGNOSIS

Facility Name

City

State/Country

FACILITY SETTING (check one)

[1] Public [2] Private [3] Federal [9] Unk.

FACILITY TYPE (check one)

[01] Physician, HMO [31] Hospital, Inpatient

[88] Other (specify):

This report to the Centers for Disease Control and Prevention (CDC) is authorized by law (Sections 304 and 306 of the Public Health Service Act, 42 USC 242b and 242k). Response in this case is voluntary for federal government purposes, but may be mandatory under state and local statutes. Your cooperation is necessary for the understanding and control of HIV/AIDS. Information in CDC's HIV/AIDS surveillance system that would permit identification of any individual on whom a record is maintained, is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in the assurance on file at the local health department, and will not otherwise be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m).

The facility of diagnosis in this section should be for the diagnosis selected in the *DIAGNOSTIC STATUS AT REPORT* box in Section III (3.1).

4.1 *FACILITY NAME* (**Required**, applies to Health Dept & Health Care Providers)

- Enter name of the facility where patient *first received a diagnosis* of HIV or AIDS.
- If HIV and AIDS diagnoses occurred at different facilities, enter name of each on separate forms, specifying which diagnosis occurred at which facility.
- Refer to Appendix 4.1 for further details.

4.2 *CITY* (**Required**, applies to Health Dept & Health Care Providers)

- Enter city name where facility of diagnosis is located.

4.3 *STATE/COUNTRY* (**Required**, applies to Health Dept & Health Care Providers)

- Enter state and country name where facility of diagnosis is located.

4.4 *FACILITY SETTING* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select setting of patient's HIV or AIDS diagnosis.
- "Private" typically includes doctor's offices or clinics not affiliated with a health department.
- "Public" includes public clinics, hospitals, or county/state correctional institutions.
- "Federal" includes Department of Veterans' Affairs medical centers, military clinics, and federal correctional institutions.
- Refer to Appendix 4.4 for further details.

4.5 *FACILITY TYPE* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response corresponding to the type of facility where patient received HIV/AIDS diagnosis.
- Refer to Appendix 4.5 for further details.

Section V, Patient history

V. PATIENT HISTORY

AFTER 1977 AND PRECEDING THE FIRST POSITIVE HIV ANTIBODY TEST OR AIDS DIAGNOSIS, THIS PATIENT HAD (Respond to ALL Categories):

	Yes	No	Unk.
• Sex with male	1	0	9
• Sex with female	1	0	9
• Injected nonprescription drugs	1	0	9
• Received clotting factor for hemophilia/coagulation disorder	1	0	9
Specify disorder: 1 Factor VIII (Hemophilia A) 2 Factor IX (Hemophilia B) 8 Other (specify): _____			
• *HETEROSEXUAL* relations with any of the following:			
• Intravenous/injection drug user	1	0	9
• Bisexual male	1	0	9
• Person with hemophilia/coagulation disorder	1	0	9
• Transfusion recipient with documented HIV infection	1	0	9
• Transplant recipient with documented HIV infection	1	0	9
• Person with AIDS or documented HIV infection, risk not specified	1	0	9
• Received transfusion of blood/blood components (other than clotting factor)	1	0	9
First Mo. Yr. Last Mo. Yr.			
• Received transplant of tissue/organs or artificial insemination	1	0	9
• Worked in a health-care or clinical laboratory setting	1	0	9
(specify occupation): _____			

- The form's direction to limit recording of risk factors to those occurring after 1977 is obsolete. Collect data about the risk factors that occurred before the first positive HIV test or AIDS diagnosis. See *Technical Guidance for HIV/AIDS Surveillance Programs, Volume 1: Policies and Procedures, Risk Factor Ascertainment, Epidemiologic follow-up*.

- These data yield information about how patients may have acquired their infections.
- Respond to each risk factor, selecting "Yes" for all factors that apply; "No" for those that do not apply, i.e., only select "No" if medical record specifically states this is not a risk factor; and "Unk." for those for which investigation failed to yield an answer.
- Record updates as additional risk factor information is obtained. For example, if the patient received a blood transfusion after the documentation of HIV infection, do not enter that information on the form.
- If brief instructions in 5.1–5.8 are insufficient, see Appendix Section V for further guidance about how to ascertain risk factor information. See *Technical Guidance for HIV/AIDS Surveillance Programs, Volume 1: Policies and Procedures, Risk Factor Ascertainment* for further guidance on HIV risk factor ascertainment, relevant definitions, and clarification of risk factors.

5.1 *SEX WITH MALE* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Abstractor may presume "Yes" for this risk factor among males as anatomical site of sexually transmitted disease (STD) infection suggests. For example, the presence of rectal gonorrhea in a male patient suggests a history of receptive anal intercourse.

5.2 *SEX WITH FEMALE* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.

5.3 *INJECTED NONPRESCRIPTION DRUGS* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.

5.4 *RECEIVED CLOTTING FACTOR* (**Required**, applies to Health Dept & 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).
- Select applicable response.
- This risk factor is generally documented in the history and physical section of the patient's medical chart.
- If "Yes" to "Other" disorder, specify the disorder.

5.5 *HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING*: This section, addressed at 5.5.1–5.5.6, relates to ascertainment of risk among heterosexual sex partners of the case patient.

5.5.1 *INTRAVENOUS/INJECTION DRUG USER* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.

5.5.2 *BISEXUAL MALE* (**Required**, applies to Health Dept & Health Care Providers)

- Applies only to **female** cases.
- Select applicable response.

5.5.3 *PERSON WITH HEMOPHILIA/COAGULATION DISORDER* (**Required**, applies to Health Dept & 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).
- 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."
- Select "Yes" for the field labeled 5.5.4 about transfusion recipient if the partner was also known to be HIV infected.
- Refer to *Protocol for Evaluation of Identification and Follow-up of Cases of Public Health Importance* at http://www2a.cdc.gov/hicsb/docs/COPHI_Protocol.pdf for more information.

5.5.4–5.5.5 *TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION—TRANSPLANT RECIPIENT WITH DOCUMENTED HIV INFECTION* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Consider documenting the reason for transfusion/transplant in the Comments section.
- Refer to Appendix 5.5.3 for further details.

5.5.6 *PERSON WITH AIDS OR DOCUMENTED HIV INFECTION, RISK NOT SPECIFIED* (**Required**, applies to Health Dept & Health Care Providers)

- Select "Yes" only if HETEROSEXUAL sex partner is known to be HIV positive and that partner's risk factor for HIV is unknown.

5.6 *RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR)* (**Required**, applies to Health Dept & Health Care Providers)

- 'Blood,' according to http://cancerweb.ncl.ac.uk/cgi-bin/omd?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, according to http://cancerweb.ncl.ac.uk/cgi-bin/omd?blood, include erythrocytes, leukocytes, platelets, and plasma.
- If "Yes," specify month and year of first and last transfusions before occurrence of patient's HIV diagnosis.
- It is often helpful to document the reason for the transfusion in the Comments section.

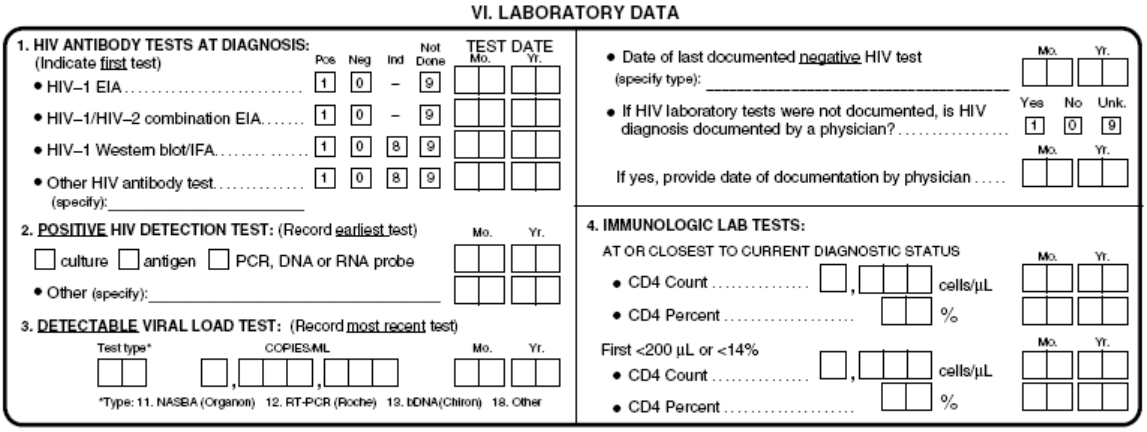
5.7 *RECEIVED TRANSPLANT OF TISSUE/ORGANS OR ARTIFICIAL INSEMINATION* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Alert the state/local cases of public health importance (COPHI) coordinator.

5.8 *WORKED IN HEALTH CARE OR CLINICAL LABORATORY SETTING* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes," specify setting.
- Investigate apparent occupational exposures to determine if this was the only risk factor present.

Section VI, Laboratory data



VI. LABORATORY DATA

1. HIV ANTIBODY TESTS AT DIAGNOSIS: (Indicate first test) — Pos / Neg / Ind / Not Done — TEST DATE Mo. Yr.
- HIV–1 EIA ..... 1 0 – 9
- HIV–1/HIV–2 combination EIA ..... 1 0 – 9
- HIV–1 Western blot/IFA 1 0 8 9
- Other HIV antibody test 1 0 8 9
  (specify): _____

2. POSITIVE HIV DETECTION TEST: (Record earliest test) — Mo. Yr.
☐ culture ☐ antigen ☐ PCR, DNA or RNA probe
- Other (specify): _____

3. DETECTABLE VIRAL LOAD TEST: (Record most recent test)
Test type* — COPIES/ML — Mo. Yr.
*Type: 11. NASBA (Organon) 12. RT-PCR (Roche) 13. bDNA(Chiron) 18. Other

- Date of last documented negative HIV test (specify type): _____ — Mo. Yr.
- If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician? ..... — Yes 1 / No 0 / Unk. 9
  If yes, provide date of documentation by physician ..... — Mo. Yr.

4. IMMUNOLOGIC LAB TESTS:
AT OR CLOSEST TO CURRENT DIAGNOSTIC STATUS — Mo. Yr.
- CD4 Count ..... ☐,☐☐☐ cells/µL
- CD4 Percent ..... ☐☐ %

First <200 µL or <14% — Mo. Yr.
- CD4 Count ..... ☐,☐☐☐ cells/µL
- CD4 Percent ..... ☐☐ %

- "TEST DATE" refers to the specimen collection date rather than the analysis or report date.
- If search for either or both of these data was unsuccessful, then enter ".." for unknown month or year of "TEST DATE."
- In the presence of lab tests, record them all.
- Include all diagnostic and CD4 tests where possible. Where number of tests exceeds the number of fields available on the form, record such results in the Comments section for later data entry.
- In the absence of lab tests, record HIV or AIDS diagnostic evidence documented in the chart by a physician.
- If the following brief instructions for recording HIV-related tests are insufficient, see *Technical Guidance for HIV /AIDS Surveillance Programs, Volume I: Policies and Procedures, Electronic Reporting, HIV and HIV-associated Laboratory Tests.*

6.1 HIV ANTIBODY TESTS AT DIAGNOSIS

- Enter results and test dates for first positive HIV antibody tests.
- Assuming active case finding, review patient's chart and lab reports for the earliest date of documented HIV positivity.
- "Ind." refers to *Indeterminate* HIV antibody test results.

6.1.1 *HIV-1 EIA* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter result and date of first HIV-1 EIA, including rapid tests.
- "Positive EIA" means repeatedly reactive tests on a single sample.

6.1.2 *HIV-1/HIV-2 COMBINATION EIA* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter result and collection date of first HIV-1/HIV-2 combination EIA test.
- If tests indicate HIV-1 or HIV-2 results separately, please specify the results as given in the laboratory report.

6.1.3 *HIV-1 WESTERN BLOT/IFA* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter result and collection date of first HIV-1 Western blot/IFA.

6.1.4 *OTHER HIV-1 ANTIBODY TEST* (each element **Required**, applies to Health Dept & Health Care Providers)

- If HIV-1 tests other than those at 6.1.1–6.1.3 were employed, specify the type of test performed.
- Enter result and collection date.

6.2 *POSITIVE HIV DETECTION TEST* (each element **Required**, applies to Health Dept & Health Care Providers)

- Select applicable response corresponding to earliest positive detection test.
- These are all qualitative tests.
- All varieties of such tests establish the presence of the pathogen, HIV. By contrast, HIV tests such as the EIA or Western blot establish the presence of our immune systems' response to the pathogen—HIV antibodies.

6.2.1 *CULTURE* (**Required**, applies to Health Dept & Health Care Providers)

- Enter result and collection date of earliest test by culture.
- HIV culture tests cannot distinguish between HIV-1 and HIV-2.

6.2.2 *ANTIGEN* (**Required**, applies to Health Dept & Health Care Providers)

- Enter result and collection date of earliest antigen test. Antigens are the virus's own proteins; such tests are specific for these proteins.
- HIV antigen detection tests include Abbott HIVAG-1 Monoclonal and Coulter HIV-1 p24 Antigen ELISA Test System.

6.2.3 *PCR, DNA, OR RNA PROBE* (**Required**, applies to Health Dept & Health Care Providers)

- Enter result and date of earliest test by these methods.
- The most commonly used DNA PCR test is Amplicor/COBAS HIV-1 DNA.

- The most commonly used RNA PCR test is Procliex RNA test.
- Enter type of HIV detection test in the space provided, and result and date by this other method.

6.2.4 *OTHER (SPECIFY)* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter type of HIV detection test in the space provided, and result and date by this other method.
- Other assays and their equivalents are any in-house HIV virus detection tests that are not FDA approved.

6.3 *DETECTABLE VIRAL LOAD*

- These are all quantitative tests.
- Enter results in units of copies per milliliter (mL).
- Enter the month and year test was performed.
- Viral load tests with undetectable results should also be entered here. See 6.3.2, below.

6.3.1 *TEST TYPE* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter test type.
- Two-digit codes are "11" = NASBA; "12" = RT-PCR; "13" = bDNA; "18" = other.
- Enter "19" for unspecified test type.

6.3.2 *COPIES/ML* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter result in units of viral copies per milliliter.
- Where detectable results are reported with log data only, enter "greater than detection limits for this assay" under the copies/mL field.
- Because undetectable results are typically reported as *below the detection limits of the assay* rather than by a specific quantitative value, enter "fewer than detectable by this assay" under the copies/mL field.

6.3.3 *TEST DATE* (**Required**, applies to Health Dept & Health Care Providers)

- Enter the date the specimen was collected.
- Do not confuse this date with the date the test was run or reported.

6.4 *DATE OF LAST DOCUMENTED HIV-NEGATIVE TEST (SPECIFY TYPE)* (**Required** if available, applies to Health Dept & Health Care Providers)

- Enter type of test and specimen collection date.
- A negative HIV test result does not necessarily represent absence of infection. Because antibody tests such as the HIV-ELISA are the standard means of screening for HIV infection, the test type specified in this field is typically an antibody test. Additionally, HIV-2 infection would be missed by assays specific to detection of HIV-1 antibodies; such case reports could include a previous HIV-1 negative antibody test result here. By contrast, other HIV tests, such as those measuring viral load, are typically ordered for patients already known to be infected; so these are not included here.
- Patient self report of last negative test is not considered "documented" and thus should not be entered in this field.

6.5 *IF HIV LABORATORY TESTS WERE NOT DOCUMENTED, IS HIV DIAGNOSIS DOCUMENTED BY A PHYSICIAN?* (**Required** if applicable, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If laboratory evidence of an HIV test is unavailable in the patient's medical or other record *and* written documentation of lab evidence of HIV infection consistent with the HIV case definition is noted by the physician, enter "Yes"; otherwise enter "No" or "Unk."

6.5.1 *IF "YES" (TO 6.5) PROVIDE DATE OF DOCUMENTATION BY PHYSICIAN* (**Required** in the absence of lab results, applies to Health Dept & Health Care Providers)

- If antibody tests are not available in chart, enter date that physician diagnosed or first knew about patient's HIV infection.
- Record the date on which physician accepts and notes patient's diagnosis of HIV infection. Do not record earlier date stated by the patient.

6.6 IMMUNOLOGIC LAB TESTS

- If both CD4 count and percent are available, *record both*.
- Enter test date corresponding to the reported CD4 test result. Test date = specimen collection date.

6.6.1 *CD4 COUNT AT OR CLOSEST TO CURRENT DIAGNOSTIC STATUS*

6.6.1.1 *CD4 COUNT* (**Required**, applies to Health Dept & Health Care Providers)

- For HIV reports, record the CD4 count closest to the time patient was determined to be HIV infected.
- If this information is not available when the initial case report is completed, it may be entered later.
- For AIDS reports, record the CD4 count with date at or closest to the date of AIDS diagnosis. This AIDS diagnosis date is typically the date on which an AIDS-defining illness is diagnosed or the specimen collection date of a CD4 count < 200 cells/µL.

6.6.1.2 *CD4 PERCENT* (**Required**, applies to Health Dept & Health Care Providers)

- For HIV reports, record the CD4 percent with date at or closest to the date of HIV diagnosis.
- For AIDS reports, record the CD4 percent at or closest to the time that an AIDS-defining clinical condition was first diagnosed. This AIDS diagnosis date is typically the date on which an AIDS-defining illness is diagnosed or the specimen collection date of a CD4 count < 200 cells/µL.

6.6.2 *CD4 COUNT (FIRST < 200 cells/µL or < 14%)*

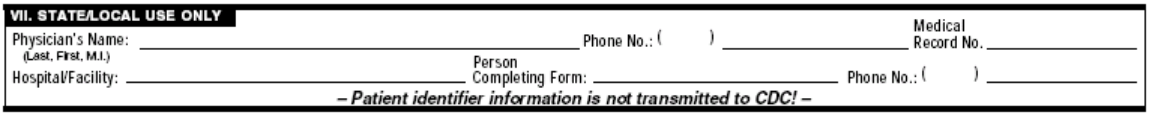
6.6.2.1 *CD4 COUNT* (**Required** if available, applies to Health Dept & Health Care Providers)

- Enter results and specimen collection date of first CD4 < 200 cells/µL.

6.6.2.2 *CD4 PERCENT* (**Required** if available, applies to Health Dept & Health Care Providers)

- Record results and specimen collection date of first CD4 < 14%.

Section VII, State/local use only



Physician identifier information is supplied in this section.

7.1 *PHYSICIAN'S NAME* (**Required**, applies to Health Dept & Health Care Providers)

- For HIV infection reports, enter name of physician who ordered the test.
- For AIDS case reports, enter name of physician medically managing patient.
- Refer to Appendix 7.1 for further guidance.

7.2 *PHONE NUMBER* (**Required**, applies to Health Dept & Health Care Providers)

- Enter phone number of physician named at 7.1, above.
- If no physician is named, enter phone number of the facility of diagnosis.

7.3 *MEDICAL RECORD NUMBER* (**Required**, applies to Health Dept & Health Care Providers)

- Enter medical record number of the patient if available.
- Refer to Appendix 7.3 for further guidance.

7.4 *HOSPITAL/FACILITY* (**Required**, applies to Health Dept & Health Care Providers)

- Enter the name of the facility where the report originated.
- If this report is generated from a laboratory report of HIV infection, the laboratory slip should contain the name of the facility where the specimen was collected.

7.5 *PERSON COMPLETING FORM* (**Required**, applies to Health Dept & Health Care Providers)

- Enter the name of the person completing the form who can be contacted to clarify entries and supply additional information.

7.6 *PHONE NUMBER* (**Required**, applies to Health Dept & Health Care Providers)

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

Section VIII, Clinical status

VIII. CLINICAL STATUS

CLINICAL RECORD REVIEWED: Yes [1] No [0]

ENTER DATE PATIENT WAS DIAGNOSED AS: Asymptomatic (including acute retroviral syndrome and persistent generalized lymphadenopathy): Mo. Yr. Symptomatic (not AIDS): Mo. Yr.

AIDS INDICATOR DISEASES	Initial Diagnosis Def.	Initial Diagnosis Pres.	Initial Date Mo. Yr.	AIDS INDICATOR DISEASES	Initial Diagnosis Def.	Initial Diagnosis Pres.	Initial Date Mo. Yr.
Candidiasis, bronchi, trachea, or lungs	1	NA		Lymphoma, Burkitt's (or equivalent term)	1	NA	
Candidiasis, esophageal	1	2		Lymphoma, immunoblastic (or equivalent term)	1	NA	
Carcinoma, invasive cervical	1	NA		Lymphoma, primary in brain	1	NA	
Coccidioidomycosis, disseminated or extrapulmonary	1	NA		*Mycobacterium avium* complex or *M.kansasii*, disseminated or extrapulmonary	1	2	
Cryptococcosis, extrapulmonary	1	NA		*M. tuberculosis*, pulmonary*	1	2	
Cryptosporidiosis, chronic intestinal (>1 mo. duration)	1	NA		*M. tuberculosis*, disseminated or extrapulmonary*	1	2	
Cytomegalovirus disease (other than in liver, spleen, or nodes)	1	NA		*Mycobacterium*, of other species or unidentified species, disseminated or extrapulmonary	1	2	
Cytomegalovirus retinitis (with loss of vision)	1	2		*Pneumocystis carinii* pneumonia	1	2	
HIV encephalopathy	1	NA		Pneumonia, recurrent, in 12 mo. period	1	2	
Herpes simplex: chronic ulcer(s) (>1 mo. duration); or bronchitis, pneumonitis or esophagitis	1	NA		Progressive multifocal leukoencephalopathy	1	NA	
Histoplasmosis, disseminated or extrapulmonary	1	NA		Salmonella septicemia, recurrent	1	NA	
Isosporiasis, chronic intestinal (>1 mo. duration)	1	NA		Toxoplasmosis of brain	1	2	
Kaposi's sarcoma	1	2		Wasting syndrome due to HIV	1	NA	

Def. = definitive diagnosis Pres. = presumptive diagnosis

* RVCT CASE NO.:

• If HIV tests were not positive or were not done, does this patient have an immunodeficiency that would disqualify him/her from the AIDS case definition? [1] Yes [0] No [9] Unknown

8.1 *CLINICAL RECORD REVIEWED* (**Recommended**, applies to Health Dept & Health Care Providers)

- The person recording data in the form's *Clinical status* section either reviewed the patient's medical chart or they did not do so. Select applicable response.

8.2 *ENTER DATE PATIENT WAS DIAGNOSED AS* (**Recommended**, applies to Health Dept & Health Care Providers)

- If a year is present but search for month was unsuccessful, then enter ".." for the unknown month, followed by the documented year.

8.2.1 *ASYMPTOMATIC (including acute retroviral syndrome)* (**Recommended**, applies to Health Dept & Health Care Providers)

- This category includes HIV-positive patients with no HIV-related symptoms, with acute retroviral illnesses, or with persistent generalized lymphadenopathy (PGL).
- Enter date of patient's evaluation.
- Refer to Appendix 8.2.1 for further guidance.

8.2.2 *SYMPTOMATIC (not AIDS)* (**Recommended**, applies to Health Dept & Health Care Providers)

- This category includes HIV-positive patients with symptoms attributable to HIV infection other than acute illness or persistent generalized lymphadenopathy (PGL).
- Enter date of evaluation.
- Refer to Appendix 8.2.2 for a list of conditions in this category.

8.3 *AIDS INDICATOR DISEASES*

8.3.1–8.3.26 (**Recommended**, applies to Health Dept & Health Care Providers)

- Select all that apply and enter diagnosis dates.
- If search for month of "Initial Date" was unsuccessful, then enter ".." for unknown month.
- Definitive diagnoses are based on specific laboratory methods such as histology or culture.
- Presumptive diagnoses are made by the clinician based on history/observations.
- Refer to Appendix 8.3.1–8.3.26 for further details.

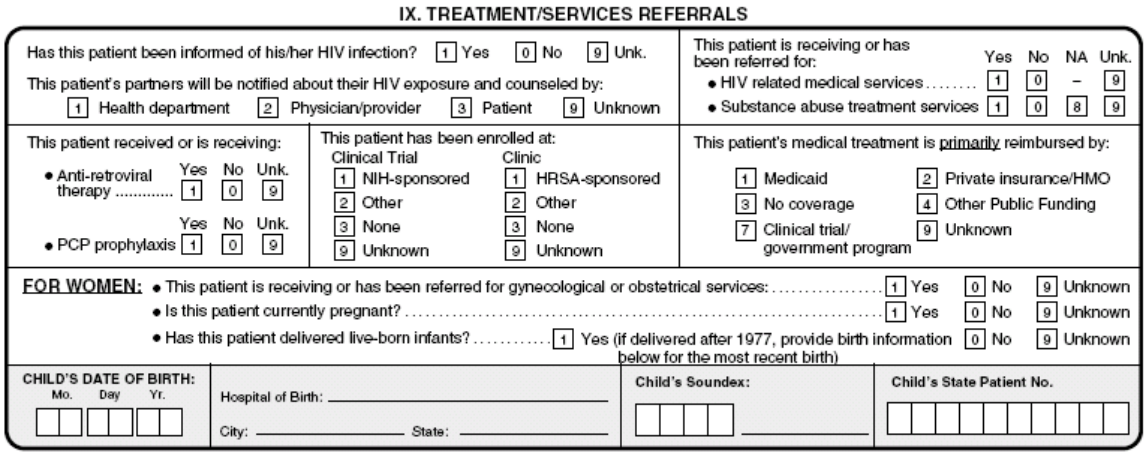
8.3.27 *RVCT CASE NUMBER* (**Recommended** if applicable, applies to Health Dept)

- 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 AIDS patients may get this number from TB surveillance staff.

8.4 *IF TESTS WERE NOT POSITIVE OR WERE NOT DONE, DOES THIS PATIENT HAVE AN IMMUNODEFICIENCY THAT WOULD DISQUALIFY HIM/HER FROM THE AIDS CASE DEFINITION?* (**Required** if applicable, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Refer to Appendix 8.4 for causes of disqualifying immunodeficiency.

Section IX, Treatment/services referrals



IX. TREATMENT/SERVICES REFERRALS

Has this patient been informed of his/her HIV infection? [1] Yes [0] No [9] Unk.

This patient's partners will be notified about their HIV exposure and counseled by:
[1] Health department [2] Physician/provider [3] Patient [9] Unknown

This patient is receiving or has been referred for:

	Yes	No	NA	Unk.
• HIV related medical services	1	0	–	9
• Substance abuse treatment services	1	0	8	9

This patient received or is receiving:

	Yes	No	Unk.
• Anti-retroviral therapy	1	0	9
• PCP prophylaxis	1	0	9

This patient has been enrolled at:

Clinical Trial	Clinic
[1] NIH-sponsored	[1] HRSA-sponsored
[2] Other	[2] Other
[3] None	[3] None
[9] Unknown	[9] Unknown

This patient's medical treatment is primarily reimbursed by:
[1] Medicaid [2] Private insurance/HMO
[3] No coverage [4] Other Public Funding
[7] Clinical trial/ government program [9] Unknown

FOR WOMEN:
• This patient is receiving or has been referred for gynecological or obstetrical services: [1] Yes [0] No [9] Unknown
• Is this patient currently pregnant? [1] Yes [0] No [9] Unknown
• Has this patient delivered live-born infants? [1] Yes (if delivered after 1977, provide birth information below for the most recent birth) [0] No [9] Unknown

CHILD'S DATE OF BIRTH: Mo. Day Yr.
Hospital of Birth:
City: State:
Child's Soundex:
Child's State Patient No.

This section should be completed by the person initially notifying the health department of the HIV/AIDS case. Where health department staff populated fields in the *Treatment/Services Referrals* section through chart abstraction, providers of surveillance data may defer this task to public health workers.

9.1 *HAS THIS PATIENT BEEN INFORMED OF HIS/HER HIV INFECTION?* (**Optional**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If notification is not documented, select "Unk." unless the person completing the form knows with certainty that the patient is aware of the infection.

9.2 *THIS PATIENT'S PARTNERS WILL BE NOTIFIED ABOUT THEIR HIV EXPOSURE AND COUNSELED BY* (**Optional**, applies to Health Dept & Health Care Providers)

- Select applicable response.

9.3 THIS PATIENT IS RECEIVING OR HAS BEEN REFERRED FOR

- Select "Yes" even if patient has yet to actually receive such services.

9.3.1 *HIV-RELATED MEDICAL SERVICES* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.

9.3.2 *SUBSTANCE ABUSE TREATMENT SERVICES* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.

9.4 THE PATIENT RECEIVED OR IS RECEIVING

9.4.1 *ANTIRETROVIRAL THERAPY* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- For list of antiretroviral therapies currently available and link to treatment guidelines, refer to Appendix 9.4.1.

9.4.2 *PCP PROPHYLAXIS* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Examples of PCP prophylaxis include Trimethoprim/sulfamethoxazole (TMP/SMX, Bactrim, Septra), Pentamidine, and Dapsone.

9.5 THIS PATIENT HAS BEEN ENROLLED AT

9.5.1 *CLINICAL TRIAL* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response, according to whether patient is enrolled in a clinical trial that is sponsored by the National Institutes of Health (NIH) or enrolled in a clinical trial sponsored by another organization.

9.5.2 *CLINIC* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response according to whether patient is enrolled at a clinic, particularly if that clinic is sponsored by the Health Resources and Services Administration (HRSA).

9.6 *THIS PATIENT'S MEDICAL TREATMENT IS PRIMARILY REIMBURSED THROUGH* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Look for this information on the face sheet of patient's chart.

9.7 FOR WOMEN

9.7.1 *THIS PATIENT IS RECEIVING OR HAS BEEN REFERRED FOR GYNECOLOGICAL OR OBSTETRICAL SERVICES* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.

9.7.2 *IS THIS PATIENT CURRENTLY PREGNANT?* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response. Response is dependent on which date was selected for populating the field described at 2.1 above, *Date form completed*. If patient was pregnant on that date, select "Yes."

9.7.3 *HAS THIS PATIENT DELIVERED LIVE-BORN INFANTS?* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes" (disregard reference to delivery after 1977), provide birth information *for the most recent birth* as described at 9.8, below.
- Information on additional or multiple births can be recorded in Section X, Comments.

9.8 *CHILD'S DATE OF BIRTH* (**Recommended**, applies to Health Dept & Health Care Providers)

- Enter child's month, day, and year of birth.
- Child to whom field refers is from *the most recent birth* (disregard reference to delivery after 1977) as discussed at 9.7.3, above.

9.9–9.11 *HOSPITAL OF BIRTH* (**Recommended**, applies to Health Dept & Health Care Providers)

- Enter the name, city, and state of the hospital where the child described at 9.7–9.8 above was born.
- If the child was born at home, enter "home birth."

9.12 *CHILD'S SOUNDEX* (**Recommended**, applies to Health Dept)

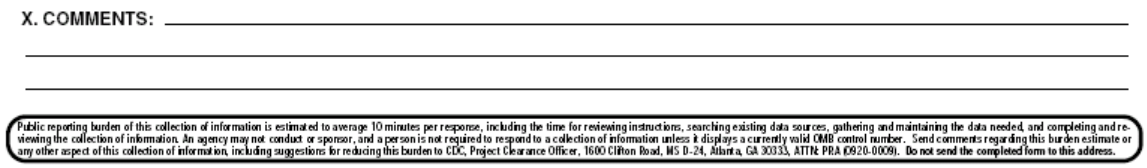
- To be completed by state/local health department personnel.
- Refers to child described at 9.7–9.11, above.
- Retrieve soundex from the HIV/AIDS registry (database) and enter here if child's name was previously entered in your database and a *State No.* exists.
- If child's name has not been entered yet, enter name and date of birth information in the CDC-provided software. This software will convert child's surname to a soundex code.

9.13 *CHILD'S STATE PATIENT NO.* (**Optional**, applies to Health Dept)

- To be completed by state/local health department personnel.
- Refers to child described at 9.7–9.12, above.
- This number is typically assigned by state/local health department personnel if the child is known to have received a diagnosis of "confirmed HIV

infection (not AIDS)" or "AIDS." Some states also assign numbers for children classified as "Perinatally HIV Exposed" or "Seroreverter."

Section X, Comments


X. COMMENTS:

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0009). Do not send the completed form to this address.

- This section can be used for information not requested on the form. For example, surveillance staff may document investigative progress toward ascertainment of risk factor information.
- If city or facility of treatment in another state is known, record these data on as many case report forms (CRFs) as there are facilities. Each facility represents a separate information source.

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

Instructions for Completion

Section I, State/local use only (patient identifier information)

Although Social Security number is not a field appearing on the 50.42A/50.42C, it is useful as a patient identifier.

Section II, Health department use only

2.2 *REPORT SOURCE*

- If "Other database," "Other Clinic," "Other," or "Out of state" is selected, specify source in Section X, Comments.
- Two-level codes for report source are shown below. The first level of source code is required, and the second level is recommended.

Report Source Codes for HIV/AIDS Reporting

First level source <Source 1>	**Second (more detailed) level source <Source 2>**
A01. = Inpatient	A01.01 = IP/Acute care facility A01.01.02 = IP/ACF/OBGYN records A01.01.03 = IP/ACF/Pediatric records A01.01.04 = IP/ACF/Birth records A01.02 = IP/VA A01.03 = IP/Military hospital A01.03.02 = IP/Military/OBGYN records A01.03.03 = IP/Military/Pediatric records A01.04 = IP/Long-term care facility A01.04.03 = IP/LTCF/Drug TX program A01.05 = IP/Hospice

First level source <Source 1>	**Second (more detailed) level source <Source 2>**
A02. = Outpatient	A02.01 = OP/HMO A02.02 = OP/VA A02.03 = OP/Private physician A02.04 = OP/Adult HIV Clinic A02.05 = OP/Infect. Dis. Clinic A02.06 = OP/County HD clinic A02.07 = OP/Maternal HIV clinic A02.08 = OP/Prenatal clinic or records A02.09 = OP/Pediatric HIV clinic A02.10 = OP/OBGYN clinic (not HIV related) A02.11 = OP/Pediatric clinic A02.12 = OP/TB clinic A02.14 = OP/IHS clinic A02.15 = OP/Early intervention nurse A02.16 = OP/Visiting nurse service A02.17 = OP/Hemophilia TX clinic A02.18 = OP/Hospice A02.19 = OP/Drug TX center A02.20 = OP/Rehab center A02.25 = OP/Other clinic
A03. = Emergency room	A03 = Emergency room
A04. = Screening, diagnosis, and referral agencies	A04.01 = Scr, Dx, Ref/Blood bank A04.02 = Scr, Dx, Ref/Drug TX program A04.03 = Scr, Dx, Ref/Family planning clinic A04.04 = Scr, Dx, Ref/HIV case management agency A04.05 = Scr, Dx, Ref/HIV counseling & testing site A04.06 = Scr, Dx, Ref/Immigration report A04.07 = Scr, Dx, Ref/Insurance report A04.08 = Scr, Dx, Ref/Job Corps A04.09 = Scr, Dx, Ref/Military A04.10 = Scr, Dx, Ref/Partner referral & counseling service A04.11 = Scr, Dx, Ref/STD clinic

First level source <Source 1>	Second (more detailed) level source <Source 2>
A05. = Laboratory	A05.01 = Lab/hosp. A05.02 = Lab/state A05.03 = Lab/private
A06. = Other databases	A06.01 = Other DB/ADAP A06.02 = Other DB/ASD A06.03 = Other DB/Birth certificate A06.04 = Other DB/Birth defects registry A06.05 = Other DB/Cancer registry A06.06 = Other DB/Database from coroner A06.07 = Other DB/Death certificate review A06.08 = Other DB/EHRAP database A06.09 = Other DB/EPS database A06.10 = Other DB/HARS database A06.11 = Other DB/Health department records A06.12 = Other DB/Hepatitis registry A06.13 = Other DB/Hosp billing summary or discharge data A06.14 = Other DB/HRSA HIV Care database A06.15 = Other DB/Immunization registry A06.16 = Other DB/Medicaid records A06.17 = Other DB/NDI A06.18 = Other DB/Out-of-state report A06.19 = Other DB/Prison, jail, or other correctional facility database A06.20 = Other DB/PSD A06.21 = Other DB/State disease registry A06.22 = Other DB/SHAS A06.23 = Other DB/SHDC database A06.24 = Other DB/STD registry A06.25 = Other DB/TB registry A06.50 = Other DB/Other database or report
A07. = Other facility records	A07.01 = Oth facility records/Prison, jail, or other correctional facility A07.02 = Oth facility records/Coroner, not associated with IP facility

First level source <Source 1>	Second (more detailed) level source <Source 2>
A10 = Other source	A10 = Other source (specify)_____
Unknown	

Section III, Demographic information

3.1 *DIAGNOSTIC STATUS AT REPORT*

The following three text boxes are provided to help determine if patients meet HIV/AIDS diagnostic criteria; criteria were current as of January 2005.

BOX 1. Quick Reference Guide for HIV/AIDS Case Definitions

Necessary for HIV infection (not AIDS)

- Documentation of +EIA plus +WB with date ***or***
- Detectable viral load with date ***or***
- Positive p24 antigen test with date ***or***
- Positive viral culture with date ***or***
- Physician documentation of HIV with date

Necessary for AIDS

- Documentation of HIV (one or more of the above)

  And

- CD4 < 200 or < 14% with date ***or***
- Any presumptively or definitively diagnosed opportunistic infection (See box 2, below)

OR

- Selected definitively diagnosed opportunistic infection with date (See box 3, below)

BOX 2. Adult AIDS indicator diseases—one or more sufficient

if definitively diagnosed in the absence of positive HIV test results

- Candidiasis of bronchi, trachea, or lungs
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (greater than 1 month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes)
- Herpes simplex: chronic ulcer(s) (greater than 1 month's duration); or bronchitis, pneumonitis, or esophagitis
- Kaposi's sarcoma (among patients < 60 years of age)
- Lymphoma, primary, of brain (among patients < 60 years of age)
- Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Pneumocystis carinii pneumonia
- Progressive multifocal leukoencephalopathy
- Toxoplasmosis of brain

If HIV tests were not positive or were not done, does patient have an immunodeficiency that would preclude an AIDS diagnosis?

BOX 3. Adult AIDS indicator diseases—one or more sufficient

if diagnosed presumptively or definitively in the presence of positive HIV test results

- Candidiasis of bronchi, trachea, or lungs
- Candidiasis, esophageal
- Cervical cancer, invasive
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (greater than 1 month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes)
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy, HIV-related
- Herpes simplex: chronic ulcer(s) (greater than 1 month's duration); or bronchitis, pneumonitis, or esophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (greater than 1 month's duration)
- Kaposi's sarcoma (among patients < 60 years of age)
- Lymphoma, Burkitt's (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain (among patients < 60 years of age)
- Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary
- Mycobacterium tuberculosis, any site (pulmonary or extrapulmonary)
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Pneumocystis carinii pneumonia
- Pneumonia, recurrent
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain
- Wasting syndrome due to HIV

- For further guidance on current *HIV* case definition, see http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a2.htm.
- For further guidance on current adult *AIDS* case definition, see http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm.
- For further guidance on the distinction between presumptive and definitive diagnoses of opportunistic infections (OIs), see Appendix 8.3.1–8.3.26.

3.7 *SEX*

- In addition to "male" or "female" sex at birth, CDC-supplied software includes a third choice of "Unk." While "current sex" is not a variable appearing on the case report form, the person completing the form may record current sex in Section X (ten) or in the form's margin next to Section III—particularly if current sex differs from sex at birth.
- Selections and legal values for "CURRENT_SEX" from eHARS Lookup Codes are as follows:

CURRENT_SEX = F = Female Person's current sex
CURRENT_SEX = I = Intersexed Person's current sex
CURRENT_SEX = M = Male Person's current sex

- Additionally, the current form does not include fields for patient gender but eHARS optionally does. A variety of genders may be recorded either in the margin of the case report form at Section III or in Section X, Comments. Note that "current gender" adds behavioral, biological, and iatrogenic selections to those of "current sex."
- Selections and legal values for "CURRENT GENDER" from eHARS Lookup Codes are as follows:

CURRENT_GENDER = CD = Cross Dresser Person's current gender
CURRENT_GENDER = DQ = Drag Queen Person's current gender
CURRENT_GENDER = F = Female Person's current gender
CURRENT_GENDER = FM = Female to Male Person's current gender
CURRENT_GENDER = I = Intersexed Person's current gender
CURRENT_GENDER = M = Male Person's current gender
CURRENT_GENDER = MF = Male to Female Person's current gender
CURRENT_GENDER = SM = She Male Person's current gender

3.8 *ETHNICITY*

- Regardless of the presence of race or absence of any information, collect data on ethnicity.
- As of January 2003, the US Office of Management and Budget (OMB) required that race and ethnicity (Hispanic, non-Hispanic) for a person be collected as separate variables.

- A wide variety of ethnicities may be selected from legal values available in CDC-supplied software. These ethnicities and codes are documented in the *eHARS Technical Reference Guide*.

3.9 *RACE*

- 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 categories:
  - American Indian or Alaska Native
  - Asian
  - Black or African American
  - Native Hawaiian or Other Pacific Islander
  - White
- A wide variety of race categories may be selected from legal values available in CDC-supplied software. These races and codes are documented in the *eHARS Technical Reference Guide*.

3.10 *COUNTRY OF BIRTH*

- Select first from boxes provided:

  United States

  US dependency, specify

  Other, specify

  Unknown

- For patients born in US dependencies, specify from the following table:

US dependencies	
American Samoa	Pacific Trust Terr.
Guam	Palau
Johnston Atoll	Puerto Rico
Mariana Islands	Ryukyu Islands
Marshall Islands	Swan Islands
Micronesia	US Virgin Islands
Midway Islands	Wake Island
Navassa Island	

3.11 *RESIDENCE AT DIAGNOSIS*

- Residence may be identical to that listed above in Section I, unless otherwise noted in the chart.
- For HIV case reports, enter residence at the time of the first positive confirmatory test for HIV infection.
- If a diagnostic test result is not available, enter patient's residence at the date of *physician diagnosis* of HIV infection.
- For AIDS case reports, enter patient's residence at the date of the first AIDS-defining clinical condition **or** the date of the first immunologic marker that reaches AIDS-defining thresholds.

Residence assignment can be problematic for patients who:

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

3.12.1 *RESIDENCE, INCARCERATED*

- Enter home of record for sites of relatively brief incarceration such as county jails.
- For patients who are incarcerated in state or federal correctional facilities at the time of diagnosis, record the correctional facility's address.
- For patients incarcerated in city or county jails, record home address; enter jail address only after unsuccessful search for address of patient's home of record.

3.12.2 *RESIDENCE, HOMELESS*

- For homeless patients, enter the address that most accurately describes where they stay—including a shelter address if applicable.
- People without a usual residence should be reported by the jurisdiction where they were staying at the time of diagnosis.

For further guidance about residency assignment, see *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Case Residency Assignment*.

Section IV, Facility of diagnosis

4.1 *FACILITY NAME*

- For HIV case reports, enter the name of the facility where the patient first had blood drawn and was given a diagnosis of HIV infection.
- If test results are not in the medical record, enter the name of the facility where the patient's HIV infection was diagnosed and documented by the health care provider.
- For AIDS case reports, enter the name of the facility where the patient's AIDS-defining clinical condition was first diagnosed, or a CD4 count below 200 cells/μL or a CD4 percentage below 14 was documented, whichever came first.
- Enter facility/physician name uniformly to prevent the occurrence of multiple names for a given facility.
- If a physician name is listed without a facility name, enter physician name.

4.4 *FACILITY SETTING*

- State/local surveillance program staff may create tables of settings by facilities in their jurisdictions to prevent misclassification.

4.5 *FACILITY TYPE*

- Select "Physician, HMO" where diagnosis was made at a private, outpatient care site not associated with a hospital. Examples of "other" include publicly or privately operated facilities such as HIV counseling and testing sites, STD clinics, drug treatment facilities, family planning clinics, prenatal/obstetrics clinics, tuberculosis clinics, and correctional facilities.

Section V, Patient history

- Surveillance staff has found such information within charts at discharge summary, history and physical, social service notes, counseling and testing notes, and STD diagnosis notes.
- Where not explicitly annotated, contact patient's provider about risk factor information.
- See *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Risk Factor Ascertainment, Risk Factor Ascertainment Procedures, Epidemiologic Follow-Up* 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.

5.5 *HETEROSEXUAL CONTACT WITH ANY OF THE FOLLOWING:*

5.5.3 *PERSON WITH HEMOPHILIA/COAGULATION DISORDER*

- 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."
- Select "Yes" for the field labeled 5.5.4 about transfusion recipient if the partner was also known to be HIV infected.
- Refer to *Protocol for Evaluation of Identification and Follow-up of Cases of Public Health Importance* at http://www2a.cdc.gov/hicsb/docs/COPHI_Protocol.pdf for more information. COPHI is also covered in *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Risk Factor Ascertainment, Cases of Public Health Importance (COPHI)*.

Section VII, State/local use only

7.1 *PHYSICIAN'S NAME*

- If the test was provided as part of a visit to a health department, an STD clinic, an HIV counseling and testing site, or other facility where no single individual is responsible for medical management of the patient, leave this space blank and complete the "FACILITY OF DIAGNOSIS" section (Section IV of the CRF), appropriately.

7.3 *MEDICAL RECORD NUMBER*

- This field may be left blank unless patient was hospitalized as an inpatient or treated as an outpatient in a hospital, community health center, or health department clinic.
- If the patient has more than one medical record number, enter the number of the primary record that has HIV/AIDS documentation. Additional numbers can be noted in the Comments section, clearly annotating which facility is associated with which record number.

Section VIII, Clinical status

8.2.1 *ASYMPTOMATIC (including acute retroviral syndrome and persistent generalized lymphadenopathy)*

- Populate this field if there is documentation of asymptomatic infection (Group A1 and A2). For further guidance, see the 1993 CDC Revised Classification System for HIV Infection and Expanded

Surveillance Case Definition for AIDS among Adolescents and Adults at http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm.

8.2.2 *SYMPTOMATIC (not AIDS)*

- Populate this field if there is documentation of symptomatic (Group B1 and B2) infection as outlined in the 1993 CDC Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS among Adolescents and Adults, or if the conditions are documented to be related to HIV infection. Examples of conditions in clinical Category B include, but are not limited to:

- Bacillary angiomatosis
- Candidiasis, oropharyngeal (thrush)
- Candidiasis, vulvovaginal; persistent, frequent, or poorly responsive to therapy
- Cervical dysplasia (moderate or severe)/cervical carcinoma in situ
- Constitutional symptoms, such as fever (38.5 C) or diarrhea lasting greater than 1 month
- Hairy leukoplakia, oral
- Herpes zoster (shingles), involving at least two distinct episodes or more than one dermatome
- Idiopathic thrombocytopenic purpura
- Listeriosis
- Pelvic inflammatory disease, particularly if complicated by tubo-ovarian abscess
- Peripheral neuropathy

- For further guidance, see the 1993 CDC Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS among Adolescents and Adults at http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm.

8.3.1–8.3.26 *AIDS INDICATOR DISEASES*

- Definitive diagnostic methods are detailed in the 1987 and 1993 *MMWR* case definition supplement and recommendations (1987;36:1 15S and 1992;41:1 17RR). Guidance on diagnosis of these diseases in the context of all nationally notifiable diseases is available at http://www.cdc.gov/epo/dphsi/casedef/case_definitions.htm.
- For another view of this distinction in the context of treatment of opportunistic infections, see Treating Opportunistic Infections Among HIV-Infected Adults and Adolescents, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5315a1.htm.

The following box is an excerpt from the 1993 case definition, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm:

Definitive diagnostic methods for diseases indicative of AIDS

Cryptosporidiosis, Isosporiasis, Kaposi's sarcoma, Lymphoma, Pneumocystis carinii pneumonia, Progressive multifocal leukoencephalopathy, Toxoplasmosis, Cervical cancer: Microscopy (histology or cytology).

Candidiasis: Gross inspection by endoscopy or autopsy or by microscopy (histology or cytology) on a specimen obtained directly from the tissues affected (including scrapings from the mucosal surface), not from a culture.

Coccidioidomycosis, Cryptococcosis, Cytomegalovirus, Herpes simplex virus, Histoplasmosis: Microscopy (histology or cytology), culture, or detection of antigen in a specimen obtained directly from the tissues affected or a fluid from those tissues.

Tuberculosis, Other mycobacteriosis, Salmonellosis: Culture.

HIV encephalopathy (dementia): Clinical findings of disabling cognitive or motor dysfunction interfering with occupation or activities of daily living, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection that could explain the findings. Methods to rule out such concurrent illness and conditions must include cerebrospinal fluid examination and either brain imaging (computed tomography or magnetic resonance) or autopsy.

HIV wasting syndrome: Findings of profound involuntary weight loss of greater than 10% of baseline body weight plus either chronic diarrhea (at least two loose stools per day for greater than or equal to 30 days), or chronic weakness and documented fever (for greater than or equal to 30 days, intermittent or constant) in the absence of a concurrent illness or condition other than HIV infection that could explain the findings (e.g., cancer, tuberculosis, cryptosporidiosis, or other specific enteritis).

Pneumonia, recurrent (more than one episode in a 1-year period), acute (new x-ray evidence not present earlier) pneumonia diagnosed by both: **a**) culture (or other organism—specific diagnostic method) obtained from a clinically reliable specimen of a pathogen that typically causes pneumonia (other than Pneumocystis carinii or Mycobacterium tuberculosis), and **b**) radiologic evidence of pneumonia; cases that do not have laboratory confirmation of a causative organism for one of the episodes of pneumonia will be considered to be presumptively diagnosed.

- Methods for the presumptive diagnosis of diseases indicative of AIDS listed in the case definition supplement are simply suggested guidelines, not requirements. Among illnesses that can be presumptively diagnosed and if a method does not meet the requirements for definitive diagnosis, then it meets the requirements for presumptive diagnosis. Accept any method that the clinician considers diagnostic.

8.4 *IF HIV TESTS WERE NOT POSITIVE OR WERE NOT DONE, DOES THIS PATIENT HAVE AN IMMUNODEFICIENCY THAT WOULD DISQUALIFY HIM/HER FROM THE AIDS CASE DEFINITION?*

- Causes of immunodeficiency that disqualify clinical conditions as indicators of AIDS *in the absence of laboratory evidence for HIV* infection are:

- High-dose or long-term systemic corticosteroid therapy or other immunosuppressive/cytotoxic therapy within 3 months before the onset of the AIDS-defining clinical condition.
- Any of the following diseases diagnosed before or within 3 months after the AIDS-defining clinical condition was diagnosed:
    - Hodgkin's disease
    - non-Hodgkin's lymphoma (other than primary brain lymphoma)
    - lymphocytic leukemia
    - multiple myeloma
    - any other cancer of lymphoreticular or histiocytic tissue
    - angioimmunoblastic lymphadenopathy
- A genetic (congenital) immunodeficiency syndrome or an acquired immunodeficiency syndrome atypical of HIV infection, such as one involving hypogammaglobulinemia.

Section IX, Treatment/services referrals

9.4.1 *ANTIRETROVIRAL THERAPY*

A single drug formulation often has multiple names; trade names are in bold. Drug names include the following, which serves only as a guide as of January 2005; and the reference indicated below gives an updated guideline for treatment:

Drug type among antiretroviral class				
Nucleoside/ Nucleotide Reverse Transcriptase Inhibitors (NRTIs)	*Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)*	*Protease Inhibitors*	*Fusion Inhibitors*	*NRTI Combination Drugs*
Drug name				
Abacavir—ABC, **Ziagen**	Delavirdine—**Rescriptor**	Amprenavir—**Agenerase**	Enfuvirtide—**Fuzeon**	**Combivir**
Didanosine—ddI, **Videx**, **Videx EC**	Efavirenz—**Sustiva**	Atazanavir—**Reyataz**		**Trizivir**
Emtricitabine—FTC, **Emtriva**	Nevirapine—**Viramune**	Indinavir—**Crixivan**		**Truvada**
Lamivudine—3TC, **Epivir**		Lopinavir + Ritonavir—**Kaletra**		**Abacavir combo**
Stavudine—D4T, **Zerit**		Nelfinavir—**Viracept**		
Tenofovir—Disoproxil, Fumarate, **Viread**		Ritonavir—**Norvir**		
Zalcitabine—ddC, **HIVID**		Saquinavir (hard gel capsule)—**Invirase**		
Zidovudine—AZT, ZDV, **Retrovir**		Saquinavir (soft gel capsule)—**Fortovase**		

- For *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, see http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.

Technical Guidance for HIV/AIDS Surveillance Programs

Pediatric HIV/AIDS Confidential Case Report

HIV Incidence and Case Surveillance Branch
Atlanta, Georgia

Contents — Pediatric HIV/AIDS Confidential Case Report

Technical Guidance for HIV/AIDS Surveillance Programs — Pediatric HIV/AIDS Confidential Case Report

Instructions for Completion

Purpose of case report form

- The Pediatric HIV/AIDS Confidential Case Report (CDC 50.42B) form is designed to collect information that promotes understanding of HIV/AIDS morbidity and mortality among patients **less than 13 years of age** at time of diagnosis. This form reflects data that should be collected; these guidelines apply to this data collection even if surveillance sites use a different form or medium for HIV/AIDS case surveillance.
- See Appendix for further details.

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 given reported case, fill out the applicable part of the form for each data source contributing to that case.

Patients for whom form is indicated

- Each child who meets the pediatric AIDS case definition, and for those with confirmed HIV infection in areas where HIV reporting is required by law.
- In areas with confidential perinatal exposure HIV reporting, all children born to HIV-infected mothers.
    - Includes children whose infection status has not yet been determined, seroreverters, and those exposed but determined not to be infected with HIV; inclusion of such patients is for public health surveillance purposes only.
    - A federal assurance of confidentiality applies to information on children exposed perinatally with or without consequent infection.

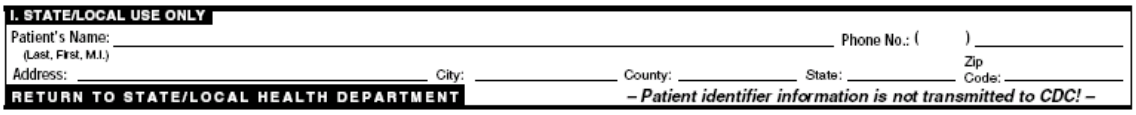
Definition of variable designators

- **Required**: Variables that are required to meet the case definitions of HIV or AIDS, to identify and track cases, and to do meaningful statistical analysis.
- **Recommended**: Information that is useful for analysis but not essential for core surveillance.
- **Optional**: Information that should be ascertained if readily available.

Disposition of form

- The completed form is for state or local health agency use and is not to be sent to the Centers for Disease Control and Prevention (CDC) with patient identifiers. Some sites send forms to CDC for data entry.
- Data obtained from these forms are entered into compatible or standardized computer software provided by the Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, CDC, and then transferred without identifiers to CDC electronically by encrypted computer diskette or electronic transfer via secure data network.

Section I, State/local use only (patient identifier information)


I. STATE/LOCAL USE ONLY
Patient's Name: (Last, First, M.I.) Phone No.: ( )
Address: City: County: State: Zip Code:
RETURN TO STATE/LOCAL HEALTH DEPARTMENT – Patient identifier information is not transmitted to CDC! –

Patient identifier information is for state/local health department use only and is not transmitted to CDC. Enter the data below for all AIDS cases and, where consistent with statutory requirements, HIV (not AIDS) cases. Consult with your state/local health department in jurisdictions with alternatives to name-based reporting.

1.1 *PATIENT'S NAME* (**Required**, applies to Health Dept & Health Care Providers)

- Enter patient's last name, first name, and middle initial.
- If available, write in a.k.a.s, aliases, etc. for later data entry. Record these names in Section XI, Comments.

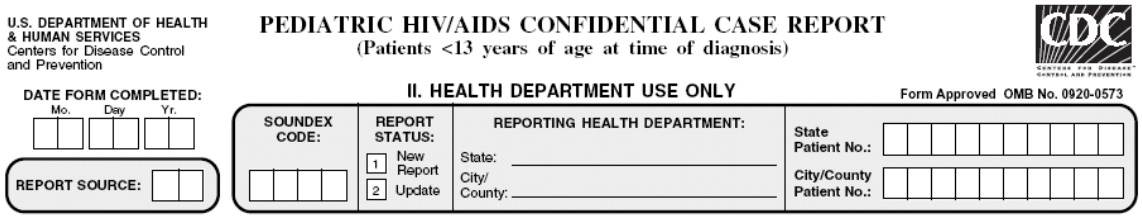
1.2 *PHONE NO.* (**Required** if patient has a telephone, applies to Health Dept & Health Care Providers)

- Enter patient's current home area code and telephone number.

1.3–1.7 *ADDRESS* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter patient's current street number and name, city, county, state, and ZIP code.

Section II, Health department use only


U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention
PEDIATRIC HIV/AIDS CONFIDENTIAL CASE REPORT
(Patients <13 years of age at time of diagnosis)
CDC
II. HEALTH DEPARTMENT USE ONLY
Form Approved OMB No. 0920-0573
DATE FORM COMPLETED: Mo. Day Yr.
REPORT SOURCE:
SOUNDEX CODE:
REPORT STATUS: 1 New Report 2 Update
REPORTING HEALTH DEPARTMENT: State: City/ County:
State Patient No.:
City/County Patient No.:

- Nonhealth department staff only need to complete *DATE FORM COMPLETED* and *REPORT STATUS* fields.

2.1 *DATE FORM COMPLETED* (**Required**, applies to Health Dept & Health Care Providers)

- Enter date in *mmddyy* format.

2.2 *REPORT SOURCE* (**Required**, applies to Health Dept)

- Enter the code for reporting source that provided the information for this report.
- To clearly identify multiple data sources for a given HIV/AIDS case, use a separate case report form for each source.
- Since legal values now exceed two digits, enter code immediately below this box.
- If coding proves difficult, write in report source for later coding.
- Refer to Appendix 2.2 for code information.

2.3 *SOUNDEX CODE* (**Required** in accordance with state/local law, applies to Health Dept)

- After patient name is recorded, CDC-supplied software generates this variable by using the patient's last name entered in Section I. Because this code is automatically generated, health department staff may leave this field blank 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.

2.4 *REPORT STATUS* (**Required**, applies to Health Dept and Health Care Providers). This variable does not exist in eHARS.

- Select applicable response.
- Select "New Report" if the patient is not already in the state registry with the condition reported—HIV or AIDS.
- Select "Update" for patients previously reported to the registry with either condition—HIV or AIDS.
- Health department staff establishes report status by searching the HIV/AIDS registry for previous reports on a particular patient. Public providers without access to the registry may request a record search from their jurisdiction's surveillance program.
- Providers from the public and private sectors unable to establish status may assume "New Report." As the report is processed by surveillance staff, status entered can be confirmed or corrected.

- When additional information on a previously reported case of HIV infection (not AIDS) becomes available, select "Update."
- When a patient has been previously reported with HIV infection (not AIDS) and later receives an AIDS diagnosis, select "New Report." From a surveillance perspective, the occurrence of AIDS is reportable in all US jurisdictions as an event independent of the occurrence of HIV infection (not AIDS). Progression to AIDS among previously reported HIV case patients represents new reports of AIDS rather than an update of previously reported HIV cases.

2.5 REPORTING HEALTH DEPARTMENT

2.5.1–2.5.2 *STATE, CITY/COUNTY* (each element **Required**, applies to Health Dept)

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

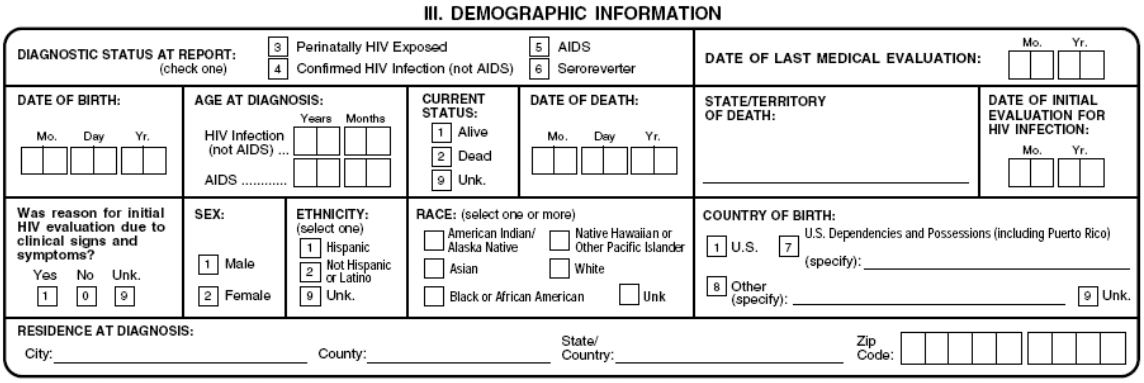
2.6 *STATE PATIENT NO.* (**Required** where state numbers are used, applies to Health Dept)

- Enter the assigned state patient number.
- Each patient should have a unique state number throughout the course of HIV disease. An exception to this is when a case is transferred to another state, where another state number may be assigned.
- Assigned numbers **should not** be reused, even if the case is later deleted.
- The precise format of this 10-digit character variable is unique to each state.
- This variable is used, along with the state of report, to uniquely identify cases reported to CDC and to merge the state datasets without duplication.

2.7 *CITY/COUNTY NUMBER* (**Required** where city numbers are used, applies to Health Dept)

- Enter the assigned city/county patient number.
- Each patient should have a unique city/county number throughout the course of HIV disease. An exception to this is when a case is transferred to another city/county and/or state, where another city number may be assigned.
- Assigned numbers **should not** be reused, even if the case is later deleted.

Section III, Demographic information



III. DEMOGRAPHIC INFORMATION

DIAGNOSTIC STATUS AT REPORT: (check one) 3 Perinatally HIV Exposed; 4 Confirmed HIV Infection (not AIDS); 5 AIDS; 6 Seroreverter

DATE OF LAST MEDICAL EVALUATION: Mo. Yr.

DATE OF BIRTH: Mo. Day Yr.

AGE AT DIAGNOSIS: Years Months — HIV Infection (not AIDS) ... ; AIDS .....

CURRENT STATUS: 1 Alive; 2 Dead; 9 Unk.

DATE OF DEATH: Mo. Day Yr.

STATE/TERRITORY OF DEATH:

DATE OF INITIAL EVALUATION FOR HIV INFECTION: Mo. Yr.

Was reason for initial HIV evaluation due to clinical signs and symptoms? Yes 1 No 0 Unk. 9

SEX: 1 Male; 2 Female

ETHNICITY: (select one) 1 Hispanic; 2 Not Hispanic or Latino; 9 Unk.

RACE: (select one or more) American Indian/ Alaska Native; Native Hawaiian or Other Pacific Islander; Asian; White; Black or African American; Unk

COUNTRY OF BIRTH: 1 U.S.; 7 U.S. Dependencies and Possessions (including Puerto Rico) (specify): ; 8 Other (specify): ; 9 Unk.

RESIDENCE AT DIAGNOSIS: City: County: State/ Country: Zip Code:

3.1 *DIAGNOSTIC STATUS AT REPORT* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Irrespective of the interval between diagnostic status dates, and even where the same source of these data reported more than one event, use one form to capture each event. Fill out suitable number of case report forms:
  - Fill out the first form completely for the first diagnosis.
  - Fill out subsequent forms partially, capturing additional or updated data absent from the first form.
- Forms referred to at preceding bulleted item must include at least the following data: *DIAGNOSTIC STATUS AT REPORT*; *RESIDENCE AT DIAGNOSIS* (see 3.14, below); and Facility of Diagnosis (see Section IV, below).
- Status depends on child's age, clinical profile, and laboratory findings. Refer to Appendix 3.1.1–3.1.4 for further details.

3.1.1 *PERINATALLY HIV EXPOSED*

- Select "Perinatally HIV Exposed" if the patient is aged less than 18 months, was born to an HIV-infected mother, and does not meet the criteria for HIV infection or the criteria for "Not Infected with HIV."
- Refer to Appendix 3.1.1 for elaboration.

3.1.2 *CONFIRMED HIV INFECTION (NOT AIDS)*

- Select "Confirmed HIV Infection (not AIDS)" if the patient meets criteria specified in the *Revised Surveillance Case Definition for HIV Infection* and does not meet the current CDC pediatric AIDS case definition.
- Refer to Appendix 3.1.2 for elaboration.

3.1.3 AIDS

- Select "AIDS" if patient meets the current AIDS case definition for children < 13 years of age.
- Refer to Appendix 3.1.3 for elaboration.

3.1.4 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 3.1.4.
- With respect to the four diagnostic status categories available on the case report form (CRF), "Seroreverter" is synonymous with "Not Infected with HIV."

3.2 *DATE OF LAST MEDICAL EVALUATION* (**Required**, applies to Health Dept & Health Care Providers)

- Enter the year and month of the child's last medical evaluation, regardless of reason for exam. This includes emergency room visits.

3.3 *DATE OF BIRTH* (**Required**, applies to Health Dept & Health Care Providers)

- Enter patient's month, day, and year of birth.

3.4 *AGE AT DIAGNOSIS* (**Optional**, applies to Health Dept & Health Care Providers)

- Enter age in months if child is less than 18 months of age, or enter age in years if child is greater than 18 months and less than 13 years of age.
- If precise age is not known, investigator must know if the patient is less than 13 years old at time of diagnosis to determine whether to use the Pediatric case report form (CDC 50.42B).

3.5 *CURRENT STATUS* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Refer to Appendix 3.5 for further guidance.

3.6 *DATE OF DEATH* (**Required** if applicable, applies to Health Dept & Health Care Providers)

- If child is deceased, enter date of death.
- For further guidance on death ascertainment, see *Technical Guidance for HIV/AIDS Surveillance Programs, Volume 1: Policies and Procedures, Death Ascertainment*.

3.7 *STATE/TERRITORY OF DEATH* (**Recommended** if applicable, applies to Health Dept & Health Care Providers)

- If child is deceased, enter the state/territory of death.

3.8 *DATE OF INITIAL EVALUATION FOR HIV INFECTION* (**Required**, applies to Health Dept & Health Care Providers)

- Enter the date of initial evaluation for HIV infection. This is the date when HIV infection was first considered, either clinically or through laboratory evaluation.
- For a child whose mother 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.
- Refer to Appendix 3.8 for further details.

3.9 *REASON FOR INITIAL HIV EVALUATION* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.

3.10 *SEX* (**Required**, applies to Health Dept & Health Care Providers)

- Select patient's sex at birth.
- "CURRENT_GENDER" and "CURRENT_SEX" are optional fields appearing in new CDC-supplied software but not on the case report form.
- Refer to Appendix 3.10 for further details.

3.11 *ETHNICITY* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If no ethnicity information is available but was searched for, select "Unk."
- Refer to Appendix 3.11 for further details.

3.12 *RACE* (**Required**, applies to Health Dept & 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 "Unk."
- Refer to Appendix 3.12 for further details.

3.13 COUNTRY OF BIRTH (Recommended, applies to Health Dept & Health Care Providers)

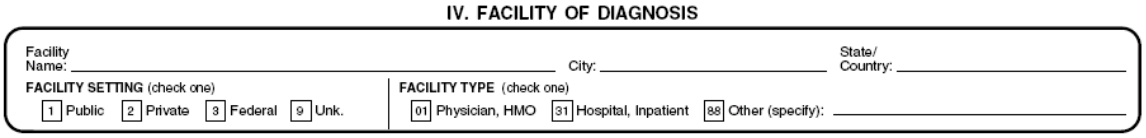
- Select applicable response from boxes provided.

- Refer to Appendix 3.13 for legal values when dependency or country is to be specified.

3.14 *RESIDENCE AT DIAGNOSIS* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter city, county, state/country, and ZIP code of patient's residence at first diagnosis with HIV or AIDS-defining clinical condition (or remaining pediatric diagnostic status categories at 3.1, above).
- The home address as given by the parent/guardian of the patient at the time of HIV and/or AIDS diagnosis usually populates these fields.
- Refer to Appendix 3.14 for further details.

Section IV, Facility of diagnosis


IV. FACILITY OF DIAGNOSIS

Facility Name: _____ City: _____ State/ Country: _____

FACILITY SETTING (check one)
1 Public 2 Private 3 Federal 9 Unk.

FACILITY TYPE (check one)
01 Physician, HMO 31 Hospital, Inpatient 88 Other (specify): _____

4.1 *FACILITY NAME* (**Required**, applies to Health Dept & Health Care Providers)

- Enter name of the facility where patient *first received a diagnosis* of HIV or AIDS. This may or may not be the facility where infant was born.
- For occurrences of seroreversion or perinatal exposure pending investigative closure, enter name of the facility where child received initial evaluation for HIV infection.
- When these diagnoses or events occurred at different facilities, enter name of each and specify which diagnosis occurred at which facility.
- Refer to Appendix 4.1 for further details.

4.2 *CITY* (**Required**, applies to Health Dept & Health Care Providers)

- Enter city name where facility of diagnosis is located.

4.3 *STATE/COUNTRY* (**Required**, applies to Health Dept & Health Care Providers)

- Enter state and country name where the facility of diagnosis is located.

4.4 *FACILITY SETTING* (**Recommended**, applies to Health Dept & Health Care Providers)

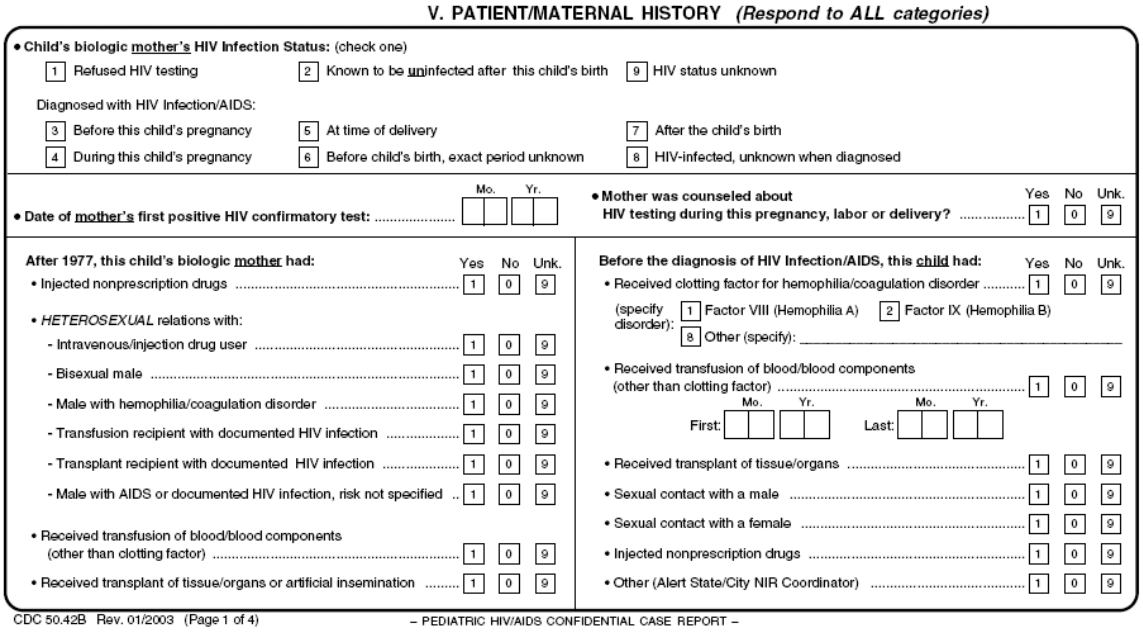
- Select applicable response.
- "Private" typically includes doctor's offices or clinics not affiliated with a health department.
- "Public" includes public clinics, hospitals, or county/state correctional institutions.

- "Federal" includes Department of Veterans' Affairs medical centers, military clinics, and federal correctional institutions.
- Refer to Appendix 4.4 for further details.

4.5 *FACILITY TYPE* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response corresponding to the type of facility where patient received HIV/AIDS diagnosis.
- Refer to Appendix 4.5 for further details.

Section V, Patient/maternal history



V. PATIENT/MATERNAL HISTORY *(Respond to ALL categories)*

• Child's biologic mother's HIV Infection Status: (check one)

[1] Refused HIV testing [2] Known to be uninfected after this child's birth [9] HIV status unknown

Diagnosed with HIV Infection/AIDS:

[3] Before this child's pregnancy [5] At time of delivery [7] After the child's birth

[4] During this child's pregnancy [6] Before child's birth, exact period unknown [8] HIV-infected, unknown when diagnosed

• Date of mother's first positive HIV confirmatory test: ..... Mo. Yr.

• Mother was counseled about HIV testing during this pregnancy, labor or delivery? ..... Yes [1] No [0] Unk. [9]

After 1977, this child's biologic mother had:	Yes	No	Unk.
• Injected nonprescription drugs	1	0	9
• *HETEROSEXUAL* relations with:			
- Intravenous/injection drug user	1	0	9
- Bisexual male	1	0	9
- Male with hemophilia/coagulation disorder	1	0	9
- Transfusion recipient with documented HIV infection	1	0	9
- Transplant recipient with documented HIV infection	1	0	9
- Male with AIDS or documented HIV infection, risk not specified	1	0	9
• Received transfusion of blood/blood components (other than clotting factor)	1	0	9
• Received transplant of tissue/organs or artificial insemination	1	0	9

Before the diagnosis of HIV Infection/AIDS, this child had:	Yes	No	Unk.
• Received clotting factor for hemophilia/coagulation disorder	1	0	9
(specify disorder): [1] Factor VIII (Hemophilia A) [2] Factor IX (Hemophilia B) [8] Other (specify):			
• Received transfusion of blood/blood components (other than clotting factor)	1	0	9
First: Mo. Yr. Last: Mo. Yr.			
• Received transplant of tissue/organs	1	0	9
• Sexual contact with a male	1	0	9
• Sexual contact with a female	1	0	9
• Injected nonprescription drugs	1	0	9
• Other (Alert State/City NIR Coordinator)	1	0	9

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- Maternal perinatal exposure is the predominant risk factor for pediatric HIV cases.
- Respond to each risk factor, selecting "Yes" for all factors that apply, "No" for those that do not apply, and "Unk." for those for which investigation failed to yield an answer. See Appendix Section V for more general guidance or further information about how to ascertain risk factor information.
- The form's direction to limit recording maternal risk factors to those occurring after 1977 is obsolete (see 5.5, below). Collect data about the risk factors that occurred before the first positive HIV test or AIDS diagnosis. See *Technical Guidance for HIV/AIDS Surveillance Programs, Volume 1: Policies and Procedures, Risk Factor Ascertainment, Epidemiologic follow-up*. Risk factor information on the mother refers to behaviors that started before the child's birth.
- 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 information on Cases of Public Health Importance, refer to this password-protected site: http://www2a.cdc.gov/hicsb/docs/COPHI_Protocol.pdf. Consult your local HIV/AIDS Surveillance Coordinator for access. COPHI is also covered in *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Risk Factor Ascertainment, Cases of Public Health Importance*.

5.1 *CHILD'S BIOLOGIC MOTHER'S HIV INFECTION STATUS* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Refer to Appendix 5.1 for further details.

5.2 (MOTHER) DIAGNOSED WITH HIV INFECTION/AIDS (Required, applies to Health Dept & Health Care Providers)

- If mother was diagnosed with HIV infection/AIDS, select from boxes 3–8, depending on information available to determine the timing of her diagnosis. Where date of mother's first positive HIV confirmatory test is available, establish which box to select by comparing to the date of birth and then selecting the appropriate box.
- Refer to Appendix 5.2 for further details.

5.3 *DATE OF MOTHER'S FIRST POSITIVE HIV CONFIRMATORY TEST* (**Required**, applies to Health Dept & Health Care Providers)

- Where mother is known to be HIV infected, enter month and year of the first positive HIV confirmatory test.
- If year is present and search for month was unsuccessful, then enter ".." for the unknown month followed by the documented year.
- Refer to Appendix 5.3 for further details.

5.4 *MOTHER WAS COUNSELED ABOUT HIV TESTING DURING THIS PREGNANCY, LABOR, OR DELIVERY?* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Select "Yes" if mother was counseled at anytime during this pregnancy, labor, or delivery by a health care provider (private or public) about the risks of HIV in pregnancy and the risks, benefits, and meaning of HIV testing.
- Refer to Appendix 5.4 for further details.

5.5 *AFTER 1977, THIS CHILD'S BIOLOGIC MOTHER HAD*

5.5.1 *INJECTED NONPRESCRIPTION DRUGS* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.

5.5.2 *HETEROSEXUAL RELATIONS WITH ANY OF THE FOLLOWING:*

- This section, addressed at 5.5.2–5.5.2.6, relates to ascertainment of risk among heterosexual sex partners of the biologic mother of the case patient.
- Verification of sex partner's HIV infection status is not necessary.

5.5.2.1 *INTRAVENOUS/INJECTION DRUG USER* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.

5.5.2.2 *BISEXUAL MALE* (**Required**, applies to Health Dept & Health Care Providers)

- Applies only to **female** case patients.
- Select applicable response.

5.5.2.3 *PERSON WITH HEMOPHILIA/COAGULATION DISORDER* (**Required**, applies to Health Dept & 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).
- Refer to Appendix 5.5.2.3 for further details.

5.5.2.4 *TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Consider documenting the reason for transfusion in the Comments section.
- Refer to Appendix 5.5.2.4 for further details.

5.5.2.5 *TRANSPLANT RECIPIENT WITH DOCUMENTED HIV INFECTION* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Consider recording documentation available about the transplant in the Comments section.
- Alert state/local COPHI coordinator.

5.5.2.6 *MALE WITH AIDS OR DOCUMENTED HIV INFECTION, RISK NOT SPECIFIED* (**Required**, applies to Health Dept & Health Care Providers)

- Select "Yes" only if male partner is known to be HIV positive *and* that partner's risk for HIV is unknown.

5.5.3 *RECEIVED TRANSFUSION OF BLOOD/BLOOD COMPONENTS* (each element **Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes," specify the month and year of the first and last transfusion before the child's biologic mother received a diagnosis of HIV or AIDS.
- If the last transfusion was after March 1985, then alert state/local COPHI coordinator.

5.5.4 *RECEIVED TRANSPLANT OF TISSUES/ORGANS OR ARTIFICIAL INSEMINATION* (each element **Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If this is the only risk factor present and the biologic mother did not have a diagnosis of HIV infection 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; then alert state/local COPHI coordinator.
- If the biologic mother is known to be HIV infected and this is the only maternal risk, then the case patient will initially be classified as "mother has HIV infection, risk not specified."

5.6 *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.

5.6.1 *RECEIVED CLOTTING FACTOR FOR COAGULATION DISORDER* (**Required**, applies to Health Dept & 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).
- Select applicable response.
- If "Yes" to "Other" disorder, specify.
- Alert state/local COPHI coordinator if child was born after March 1998 and receipt of clotting factor is the suspected mode of HIV transmission.
- Refer to Appendix 5.6.1 for further details.

5.6.1.1 *SPECIFY DISORDER* (**Required**, applies to Health Dept & Health Care Providers)

- If "Yes" to 5.6.1, above, then enter the specific disorder.

5.6.2 *TRANSFUSION OF BLOOD/BLOOD COMPONENTS (OTHER THAN CLOTTING FACTOR)* (**Required**, applies to Health Dept & Health Care Providers)

- If child received a transfusion of blood cells (red cells, white cells, and platelets) or plasma, specify month and year of first and last transfusion before the patient was infected with HIV or received a diagnosis of AIDS.
- It is often helpful to document the reason for the transfusion in the Comments section.

5.6.3 *TRANSPLANT OF TISSUE/ORGANS* (**Required**, applies to Health Dept & Health Care Providers)

- The case will be initially classified as "risk not reported/identified" pending outcome of the no identified risk (NIR) investigation.
- Alert the state/local COPHI coordinator.

5.6.4 *SEXUAL CONTACT WITH A MALE* (**Required**, applies to Health Dept & Health Care Providers)

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

- Alert state/local COPHI coordinator.

5.6.5 *SEXUAL CONTACT WITH A FEMALE* (**Required**, applies to Health Dept & Health Care Providers)

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

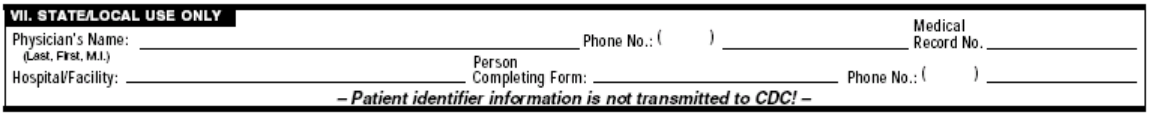
5.6.6 *INJECTED NONPRESCRIPTION DRUGS* (**Required**, applies to Health Dept & Health Care Providers)

- Mark the appropriate box.
- If this is the only risk history, the case will be initially classified as "risk not reported/identified" pending outcome of the NIR investigation.
- Alert state/local COPHI coordinator.

5.6.7 *OTHER (Alert State/Local NIR Coordinator)* (**Required**, applies to Health Dept & Health Care Providers)

- Select this response only if directed to do so by the state/local NIR coordinator.

Section VI, State/local use only



Physician identifier information is for state/local health department use only and is not transferred to CDC.

6.1 *PHYSICIAN'S NAME* (**Required**, applies to Health Dept & Health Care Providers)

- For HIV infection reports, enter name of physician who ordered the test.
- For AIDS case reports, enter name of physician medically managing patient.
- Refer to Appendix 6.1 for further guidance.

6.2 *PHONE NUMBER* (**Required**, applies to Health Dept & Health Care Providers)

- Enter phone number of physician named at 6.1, above.
- If no physician is named, enter phone number of the facility of diagnosis.

6.3 *MEDICAL RECORD NUMBER* (**Required**, applies to Health Dept & Health Care Providers)

- Enter medical record number of the patient if inpatient or outpatient services were received.
- Refer to Appendix 6.3 for further guidance.

6.4 *HOSPITAL/FACILITY* (**Required**, applies to Health Dept & Health Care Providers)

- Enter the name of the hospital or clinic where the report originated.
- If this report is generated from a laboratory report of HIV infection, the laboratory slip should contain the name of the facility where the specimen was collected.
- If this report is generated from a laboratory report of an HIV counseling and testing site or other facility where no single individual is responsible for medical management of the patient, leave the space blank and complete the CRF's Section IV, Facility of diagnosis, appropriately.

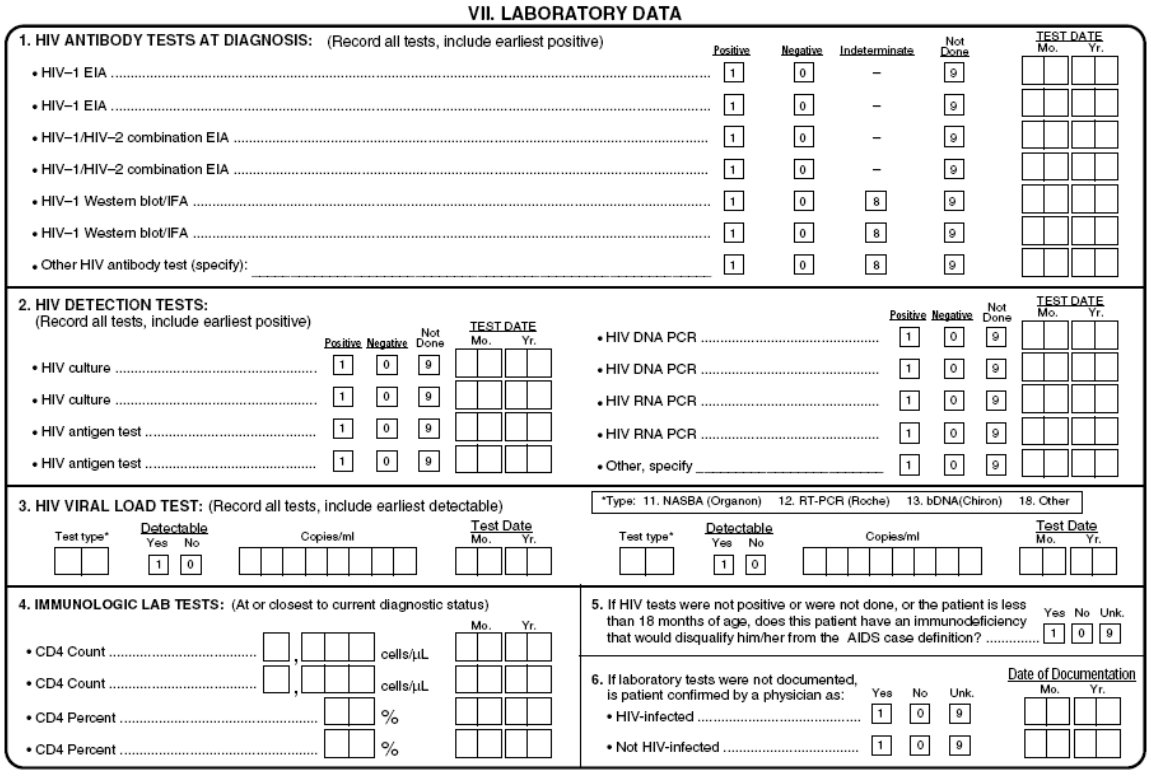
6.5 *PERSON COMPLETING FORM* (**Required**, applies to Health Dept & Health Care Providers)

- Enter the name of the person completing the form who can be contacted to clarify entries and supply additional information.

6.6 *PHONE NUMBER* (**Required**, applies to Health Dept & Health Care Providers)

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

Section VII, Laboratory data



VII. LABORATORY DATA

1. HIV ANTIBODY TESTS AT DIAGNOSIS: (Record all tests, include earliest positive)

	Positive	Negative	Indeterminate	Not Done	TEST DATE Mo.	TEST DATE Yr.
• HIV–1 EIA	1	0	–	9		
• HIV–1 EIA	1	0	–	9		
• HIV–1/HIV–2 combination EIA	1	0	–	9		
• HIV–1/HIV–2 combination EIA	1	0	–	9		
• HIV–1 Western blot/IFA	1	0	8	9		
• HIV–1 Western blot/IFA	1	0	8	9		
• Other HIV antibody test (specify): _____	1	0	8	9		

2. HIV DETECTION TESTS: (Record all tests, include earliest positive)

	Positive	Negative	Not Done	TEST DATE Mo.	TEST DATE Yr.
• HIV culture	1	0	9		
• HIV culture	1	0	9		
• HIV antigen test	1	0	9		
• HIV antigen test	1	0	9		
• HIV DNA PCR	1	0	9		
• HIV DNA PCR	1	0	9		
• HIV RNA PCR	1	0	9		
• HIV RNA PCR	1	0	9		
• Other, specify _____	1	0	9		

3. HIV VIRAL LOAD TEST: (Record all tests, include earliest detectable)

*Type: 11. NASBA (Organon) 12. RT-PCR (Roche) 13. bDNA(Chiron) 18. Other

Test type*	Detectable Yes	Detectable No	Copies/ml	Test Date Mo.	Test Date Yr.
	1	0			
	1	0			

4. IMMUNOLOGIC LAB TESTS: (At or closest to current diagnostic status)

	Mo.	Yr.
• CD4 Count ____,___ cells/µL		
• CD4 Count ____,___ cells/µL		
• CD4 Percent ____ %		
• CD4 Percent ____ %		

5. If HIV tests were not positive or were not done, or the patient is less than 18 months of age, does this patient have an immunodeficiency that would disqualify him/her from the AIDS case definition? Yes 1 No 0 Unk. 9

6. If laboratory tests were not documented, is patient confirmed by a physician as:

	Yes	No	Unk.	Date of Documentation Mo.	Date of Documentation Yr.
• HIV-infected	1	0	9		
• Not HIV-infected	1	0	9		

- "Test date" refers to the specimen collection date rather than the analysis or report date.
- If search for either or both of these data was unsuccessful, then enter ".." for unknown month or year of "TEST DATE."
- In the presence of lab tests, record them all.
- Include all diagnostic and CD4 tests where possible. Where number of tests exceeds the number of fields available on the form, record such results in the Comments section for later data entry.
- For children not infected with HIV (seroreverter), include all negative viral detection and negative antibody tests.
- All "Confirmed HIV infection (not AIDS)" or AIDS case reports must include documentation of all children having tested positive for HIV.
- If "Perinatally HIV Exposed," include all test results regardless of result.
- In the absence of lab tests, record HIV or AIDS diagnostic evidence documented in the medical chart by a physician.
- See also *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Electronic Laboratory Reporting*.

7.1 HIV ANTIBODY TESTS AT DIAGNOSIS

- Enter results and test dates for positive HIV antibody tests.
- "Ind." means *Indeterminate* HIV antibody test results.

7.1.1 *HIV-1 EIA* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter results and dates of HIV-1 EIA tests, including rapid tests.
- "Positive EIA" designates repeatedly reactive tests on a single sample.

7.1.2 *HIV-1/HIV-2 COMBINATION EIA* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter results and collection dates of HIV-1/HIV-2 combination EIA tests.
- If tests indicate HIV-1 or HIV-2 results separately, please specify the results as given in the laboratory report.

7.1.3 *HIV-1 WESTERN BLOT/IFA* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter results and collection dates of HIV-1 Western blot/IFA tests.
- Refer to Appendix 7.1.3 for further guidance.

7.1.4 *OTHER HIV ANTIBODY TEST, SPECIFY* (each element **Required**, applies to Health Dept & Health Care Providers)

- If HIV-1 antibody tests other than those at 7.1.1–7.1.3 were employed, specify types of tests performed.
- Enter results and dates of collection.

7.2 *POSITIVE HIV DETECTION TESTS*

- Record all tests, including earliest positive.
- Select applicable response.
- These are all qualitative tests.
- All varieties of such tests establish the presence of the pathogen, HIV. By contrast, HIV tests such as the EIA or Western blot establish the presence of our immune systems' response to the pathogen—HIV antibodies.

7.2.1 *HIV CULTURE* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter results and collection dates of tests by culture.

7.2.2 *HIV ANTIGEN TEST* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter results and collection dates of antigen tests. Antigens are the virus's own proteins; such tests are specific for these proteins.
- HIV antigen detection tests include Abbott HIVAG-1 Monoclonal and Coulter HIV-1 p24 Antigen ELISA Test System.

7.2.3 *HIV DNA PCR* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter results and dates of DNA PCR tests, including most recent negative tests.
- The most commonly used DNA PCR test is Amplicor/COBAS HIV-1 DNA test.

7.2.4 *HIV RNA PCR* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter results and dates of RNA PCR tests, including most recent negative tests.
- The most commonly used RNA PCR test is Procliex RNA test.

7.2.5 *OTHER (SPECIFY)* (each element **Required**, applies to Health Dept & Health Care Providers)

- Enter type of HIV detection test in the space provided, result and date by this other method.
- Other assays and their equivalents are any in-house HIV virus detection tests that are not FDA approved.

7.3 *HIV VIRAL LOAD TEST*

7.3.1 *TEST TYPE* (**Required**, applies to Health Dept & Health Care Providers)

- Enter test type.
- Two-digit codes are "11" = NASBA; "12" = RT-PCR; "13" = bDNA; "18" = other.
- Enter "19" for unspecified test type.

7.3.2 *DETECTABLE* (**Required**, applies to Health Dept & Health Care Providers)

- Enter whether HIV viral load was detectable.

7.3.3 *COPIES/ML* (**Required**, applies to Health Dept & Health Care Providers)

- If viral load was detectable, enter test result in copies per milliliter.

7.3.4 *TEST DATE* (**Required**, applies to Health Dept & Health Care Providers)

- Enter date of specimen collection.

7.4 IMMUNOLOGIC LAB TESTS (AT OR CLOSEST TO CURRENT DIAGNOSTIC STATUS)

- If both CD4 count and percent are available, *record both*.
- For all tests, indicate the results and enter the month and year of the test.
- In the presence of more than two test results for CD4 count or percent, record additional test information in Section XI, Comments, for later data entry.

7.4.1 *CD4 COUNT* (each element **Required**, applies to Health Dept & Health Care Providers)

- Record the first CD4 count, the CD4 count at or closest to current diagnostic status (Section 3.1), and the most recent CD4 counts.
- For AIDS cases, record the CD4 count closest to an AIDS-defining clinical condition.
- Enter month and year of the test.

7.4.2 *CD4 PERCENT* (each element **Required**, applies to Health Dept & Health Care Providers)

- Record the CD4 percent that corresponds with the CD4 count, as described at 7.4.1, above.
- If no CD4 count is available, record first CD4 percent, CD4 percent at or closest to current diagnostic status (Section 3.1), and most recent CD4 percent values.
- For AIDS cases, record the CD4 percent closest to an AIDS-defining clinical condition.
- Enter month and year of the test.

7.5 *IF HIV TESTS WERE NOT POSITIVE OR WERE NOT DONE, OR THE PATIENT IS LESS THAN 18 MONTHS OF AGE, DOES THIS PATIENT HAVE AN IMMUNODEFICIENCY THAT WOULD DISQUALIFY HIM/HER FROM THE AIDS CASE DEFINITION?* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.

- Refer to Appendix 7.5 for causes of disqualifying immunodeficiency.

7.6 IF HIV LABORATORY TESTS WERE NOT DOCUMENTED, IS HIV INFECTION CONFIRMED BY A PHYSICIAN AS

- Documentation by a physician of a patient/parent history or patient self report is not considered a "physician diagnosis."

7.6.1 *HIV-INFECTED* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If laboratory evidence of an HIV test is unavailable in the patient's medical or other record *and* written documentation of positive HIV test is noted by the physician, enter "Yes"; otherwise enter "No" or "Unk."

7.6.1.1 *DATE OF DOCUMENTATION* (**Required**, applies to Health Dept & Health Care Providers)

7.6.2 *NOT HIV-INFECTED* (**Required**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If laboratory evidence of negative HIV tests is not available in the patient's medical or other record and there is written documentation by a physician of a diagnosis of seroreverter, based on evidence of negative HIV laboratory tests noted in the patient medical record, enter a physician diagnosis of "not infected with HIV" or "Seroreverter."

7.6.2.1 *DATE OF DOCUMENTATION* (**Required**, applies to Health Dept & Health Care Providers)

Section VIII, Clinical status

VIII. CLINICAL STATUS

AIDS INDICATOR DISEASES	Initial Diagnosis Def.	Initial Diagnosis Pres.	Initial Date Mo.	Initial Date Yr.
Bacterial infections, multiple or recurrent (including Salmonella septicemia)	1	NA		
Candidiasis, bronchi, trachea, or lungs	1	NA		
Candidiasis, esophageal	1	2		
Coccidioidomycosis, disseminated or extrapulmonary	1	NA		
Cryptococcosis, extrapulmonary	1	NA		
Cryptosporidiosis, chronic intestinal (>1 mo. duration)	1	NA		
Cytomegalovirus disease (other than in liver, spleen, or nodes) onset at >1 mo. of age	1	NA		
Cytomegalovirus retinitis (with loss of vision)	1	2		
HIV encephalopathy	1	NA		
Herpes simplex: chronic ulcer(s) (>1 mo. duration); or bronchitis, pneumonitis or esophagitis, onset at >1 mo. of age	1	NA		
Histoplasmosis, disseminated or extrapulmonary	1	NA		
Isosporiasis, chronic intestinal (>1 mo. duration)	1	NA		

AIDS INDICATOR DISEASES	Initial Diagnosis Def.	Initial Diagnosis Pres.	Initial Date Mo.	Initial Date Yr.
Kaposi's sarcoma	1	2		
Lymphoid interstitial pneumonia and/or pulmonary lymphoid hyperplasia	1	2		
Lymphoma, Burkitt's (or equivalent term)	1	NA		
Lymphoma, immunoblastic (or equivalent term)	1	NA		
Lymphoma, primary in brain	1	NA		
Mycobacterium avium complex or *M.kansasii*, disseminated or extrapulmonary	1	2		
M. tuberculosis, disseminated or extrapulmonary*	1	2		
Mycobacterium, of other species or unidentified species, disseminated or extrapulmonary	1	2		
Pneumocystis carinii pneumonia	1	2		
Progressive multifocal leukoencephalopathy	1	NA		
Toxoplasmosis of brain, onset at >1 mo. of age	1	2		
Wasting syndrome due to HIV	1	NA		

Def. = definitive diagnosis Pres. = presumptive diagnosis

Has this child been diagnosed with pulmonary tuberculosis?* 1 Yes 0 No 9 Unk. If yes, initial diagnosis and date: 1 Definitive 2 Presumptive Mo. Yr. *RVCT CASE NO.:

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8.1.1–8.1.24 *AIDS INDICATOR DISEASES* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select all that apply and enter diagnosis dates.
- Where search for this datum was unsuccessful, enter ".." where month is unknown for "Initial Date."
- *Definitive diagnoses* are based on specific laboratory methods such as histology or culture.
- *Presumptive diagnoses* are made by the clinician based on history/observations.
- Refer to Appendix 8.1.1–8.1.24 for further guidance.

8.2 *HAS THIS CHILD BEEN DIAGNOSED WITH PULMONARY TUBERCULOSIS?* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes," provide the month and year of diagnosis.
- The definitive diagnostic method for tuberculosis is culture.
- For presumptive diagnosis when bacteriologic confirmation is not available, other reports may be considered to be verified cases of pulmonary

tuberculosis if the criteria of the Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention, CDC, are used.

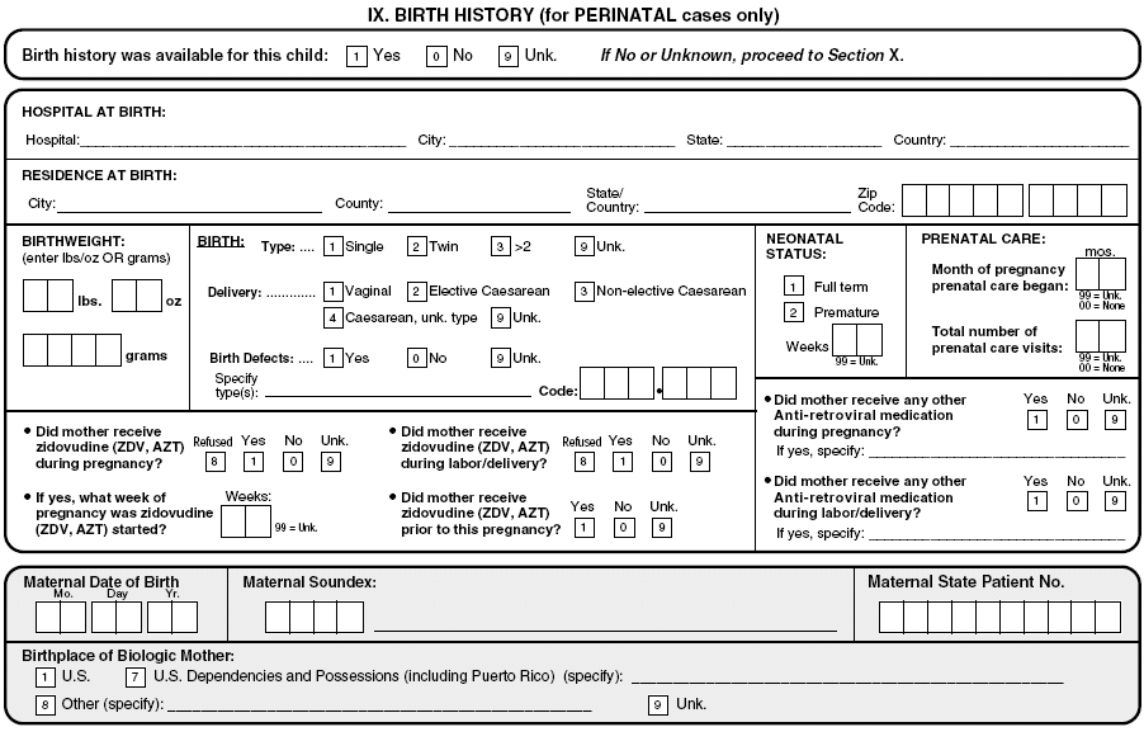
8.2.1 *IF "YES," INITIAL DIAGNOSIS AND DATE* (**Recommended** if applicable, applies to Health Dept & Health Care Providers)

- Select applicable response and enter month and year of diagnosis.
- If search for this datum was unsuccessful, enter ".." for month of initial diagnosis followed by the documented year.

8.2.2 *RVCT CASE NO.* (**Recommended** if applicable, applies to Health Dept)

- 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 AIDS patients may get this number from TB surveillance staff.

Section IX, Birth history (Required for perinatal cases only)



9.1 *BIRTH HISTORY WAS AVAILABLE FOR THIS CHILD* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If birth history is not available, proceed to Section X.

9.2 *HOSPITAL OF BIRTH* (**Recommended**, applies to Health Dept & Health Care Providers)

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

9.3 *RESIDENCE AT BIRTH* (**Recommended**, applies to Health Dept & Health Care Providers)

- Enter name of city, county, state, country, and ZIP code of residence of the patient at birth.
- Use mother's residence at time of infant's birth.
- After an unsuccessful search for these data, enter "Unk."

9.4 *BIRTH WEIGHT* (**Recommended**, applies to Health Dept & Health Care Providers)

- Enter the birth weight in pounds or grams as requested on the form.
- If recorded in pounds and ounces, convert to grams.

9.5 *BIRTH*

9.5.1 *TYPE* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response. If unknown, select "9."

9.5.2 *DELIVERY* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response. If unknown, select "9."
- Notes in the child's records are acceptable even if no birth records are available.
- Refer to Appendix 9.5.2 for further details.

9.5.3 *BIRTH DEFECTS* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes," specify type.
- Refer to Appendix 9.5.3 for further details and an abbreviated list of birth defects.

9.5.3.1 *CODE* (**Recommended**, applies to Health Dept & Health Care Providers)

- Record all codes.
- Refer to Appendix 9.5.3.1 for further details and list of birth defect codes.

9.6 *NEONATAL STATUS* (**Recommended**, applies to Health Dept & 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 ".." for unknown number of weeks.
- Post mature neonatal status (after 40 weeks) should be recorded as full term.

9.7 *PRENATAL CARE* (**Recommended**, applies to Health Dept & Health Care Providers)

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

9.7.1 *MONTH OF PREGNANCY PRENATAL CARE BEGAN* (**Recommended**, applies to Health Dept & Health Care Providers)

- Record the month of pregnancy (01 to 09) that the mother began her prenatal care.
- If any fraction of a month is reported, round to the next whole month.
- In the absence of prenatal care, enter "00."
- Refer to Appendix 9.7.1 for further details.
- If search for this datum was unsuccessful, then enter ".." for month of first visit.

9.7.2 *TOTAL NUMBER OF PRENATAL CARE VISITS* (**Recommended**, applies to Health Dept & Health Care Providers)

- Record the total number of times the mother went to the clinic or doctor for her 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 ".." for number of prenatal visits.

- Where data source reports a range of visits (e.g., "10–13"), enter the lowest number (e.g., "10").

9.8.1 *DID MOTHER RECEIVE ZIDOVUDINE (ZDV, AZT) DURING PREGNANCY?* (**Recommended**, applies to Health Dept & 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.'
- If a woman did not receive zidovudine, do not assume it was because she refused it.
- Select "Refused" only if explicit documentation in the medical record indicates that the patient was offered the drug, but the patient declined.
- In the absence of evidence of the patient having taken the drug, select "No."
- Select "Unk." after an unsuccessful search for this datum.

9.8.2 *IF "YES," WHAT WEEK OF PREGNANCY WAS ZIDOVUDINE (ZDV, AZT) STARTED?* (**Recommended**, applies to Health Dept & Health Care Providers)

- Enter the time of the start of ZDV, AZT.

9.8.3 *DID MOTHER RECEIVE ZIDOVUDINE (ZDV, AZT) DURING LABOR/DELIVERY?* (**Recommended**, applies to Health Dept & Health Care Providers)

- If a woman did not receive zidovudine, do not assume it was because she refused it.
- Select "Refused" only if specific documentation in the record clearly states that she was offered the drug but she declined.
- In the absence of evidence of the patient having taken the drug, select "No."
- "Unk." should be used only if the labor/delivery records are not available.

9.8.4 *DID MOTHER RECEIVE ZIDOVUDINE (ZDV, AZT) PRIOR TO THIS PREGNANCY?* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select "Yes" if information is available that states that the mother used ZDV anytime before this pregnancy.

- Select "No" if mother never used this antiretroviral.
- Select "Unk." if it is unknown whether the mother ever used ZDV before this pregnancy.

9.9.1 *DID MOTHER RECEIVE ANY OTHER ANTIRETROVIRAL MEDICATION DURING PREGNANCY?* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes," enter type of medication received.
- For a list of antiretroviral therapies currently available and link to treatment guidelines, refer to Appendix 9.9.1.

9.9.2 *DID MOTHER RECEIVE ANY OTHER ANTIRETROVIRAL MEDICATION DURING LABOR/DELIVERY?* (**Recommended**, applies to Health Dept & Health Care Providers)

- If "Yes," write in the type of medication received.
- Examples of other antiretrovirals are listed in Appendix 9.9.1.

9.10 State/local health department to complete shaded area appearing above section X

9.10.1 *MATERNAL DATE OF BIRTH* (**Recommended**, applies to Health Dept)

- Enter the biologic mother's month, day, and year of birth.

9.10.2 *MATERNAL SOUNDEX* (**Recommended**, applies to Health Dept)

- Enter maternal soundex here.
- Refer to Appendix 9.10.2 for further details.

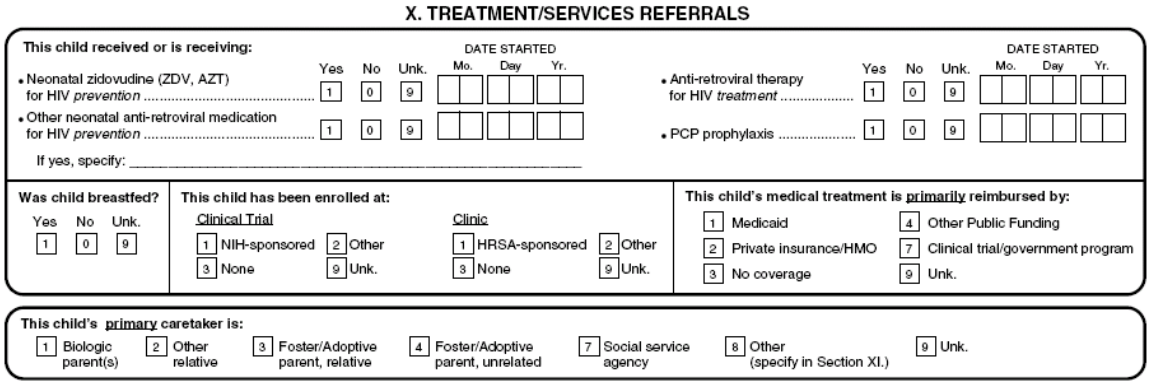
9.10.3 *MATERNAL STATE PATIENT NO.* (**Recommended**, applies to Health Dept)

- Enter assigned state patient number if the biologic mother is known to be HIV infected.
- State patient numbers should not be reused.

9.10.4 *BIRTHPLACE OF BIOLOGIC MOTHER* (**Recommended**, applies to Health Dept)

- Mark the box corresponding to the biologic mother's country of birth.
- If this information is not available in the child's records, it can be left blank and updated on follow-up.
- Refer to Appendix 9.10.4 for further details.

Section X, Treatment/services referrals



X. TREATMENT/SERVICES REFERRALS

This child received or is receiving:

	Yes	No	Unk.	DATE STARTED Mo.	Day	Yr.
• Neonatal zidovudine (ZDV, AZT) for HIV *prevention*	1	0	9			
• Other neonatal anti-retroviral medication for HIV *prevention*	1	0	9			
• Anti-retroviral therapy for HIV *treatment*	1	0	9			
• PCP prophylaxis	1	0	9			

If yes, specify: _____

Was child breastfed? Yes 1 No 0 Unk. 9

This child has been enrolled at:

Clinical Trial: 1 NIH-sponsored 2 Other 3 None 9 Unk.

Clinic: 1 HRSA-sponsored 2 Other 3 None 9 Unk.

This child's medical treatment is primarily reimbursed by:

1 Medicaid 4 Other Public Funding 2 Private insurance/HMO 7 Clinical trial/government program 3 No coverage 9 Unk.

This child's primary caretaker is:

1 Biologic parent(s) 2 Other relative 3 Foster/Adoptive parent, relative 4 Foster/Adoptive parent, unrelated 7 Social service agency 8 Other (specify in Section XI.) 9 Unk.

- This section should be completed by the person initially notifying the health department of the HIV/AIDS case. Where health department staff populated fields in the Treatment/Services Referrals section through chart abstraction, providers of surveillance data may defer this task to public health workers.
- This information should be updated for each child when there is a change in diagnostic status, whenever possible.

10.1 THIS CHILD RECEIVED OR IS RECEIVING

10.1.1 *NEONATAL ZIDOVUDINE (ZDV, AZT) FOR HIV PREVENTION* (**Recommended**, applies to Health Dept & Health Care Providers)

- Record whether child received any neonatal (first 6 weeks of life) zidovudine to prevent perinatal HIV infection.
- Refer to Appendix 10.1.1 for further details.

10.1.2 *DID NEONATE RECEIVE ANY OTHER ANTIRETROVIRAL MEDICATION DURING THE NEONATAL PERIOD FOR HIV PREVENTION?* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes," record the day, month, and year the child was started on other antiretrovirals as prophylaxis *during the first 6 weeks of life*.
- If the year and month are present but search for day was unsuccessful, then enter ".." for the day followed by the documented year and month.

10.1.2.1 *IF "YES," SPECIFY* (**Recommended**, applies to Health Dept & Health Care Providers)

- If "Yes," write in the type of medication received.
- Refer to Appendix 10.1.2.1 for examples.

10.1.3 *ANTIRETROVIRAL THERAPY FOR HIV TREATMENT* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes," record day, month, and year the child started on any antiretroviral therapy for treatment of confirmed HIV infection.
- Refer to Appendix 10.1.3 for further details.

10.1.4 PCP PROPHYLAXIS (Recommended, applies to Health Dept & Health Care Providers)

- Select applicable response.
- If "Yes," enter the month, day, and year the child was started on therapy to prevent the occurrence of PCP.
- If the year and month are present without a designated day, ".." should be entered for the day followed by the documented year and month.
- Refer to Appendix 10.1.4 for further details.
- 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."
- "Unk." is used if treatment information in the medical chart is unclear or was unavailable.

10.2 *WAS CHILD BREASTFED?* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response.
- Refer to Appendix 10.2 for further details.
- If there is suspicion that the child's only exposure to HIV was through breast milk, the local/state NIR coordinator should be alerted.

10.3 THIS CHILD HAS BEEN ENROLLED AT

10.3.1 *CLINICAL TRIAL* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response according to whether patient is enrolled in a clinical trial, particularly if that trial is sponsored by the National Institutes of Health (NIH).
- Children treated under the AIDS Clinical Trials Group (ACTG) protocols or enrolled in the Women and Infants Transmission Study (WITS) are participating in NIH-sponsored clinical trials.

10.3.2 *CLINIC* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select applicable response according to whether patient is enrolled at a clinic, particularly if that clinic is sponsored by the Health Resources and Services Administration (HRSA).

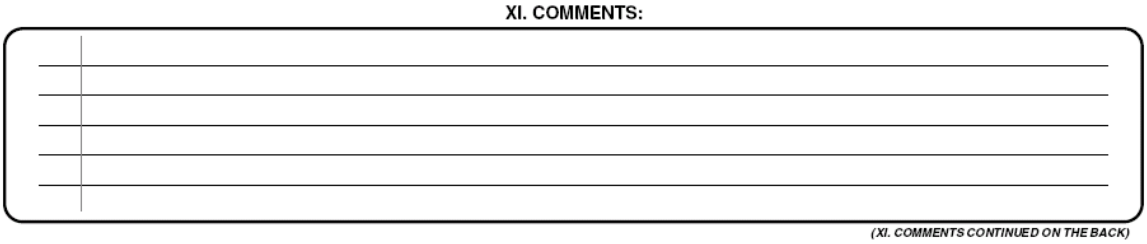
10.4 *THIS CHILD'S MEDICAL TREATMENT IS PRIMARILY REIMBURSED BY* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select the most appropriate response for primary source of reimbursement for this child's clinical care.
- Refer to Appendix 10.4 for further details.

10.5 *THIS CHILD'S PRIMARY CARETAKER IS* (**Recommended**, applies to Health Dept & Health Care Providers)

- Select the response corresponding to the persons who give the majority of care for the child.
- For children living with two biologic parents or just one, "Biologic parent(s)" should be selected.
- Refer to Appendix 10.5 for further details.

Section XI, Comments



- This section can be used for information not requested on the form. For example, surveillance staff may document investigative progress toward ascertainment of risk factor information.
- If city or facility of treatment in another state is known, record these data on as many CRFs as there are facilities. Each facility represents a separate information source.

Appendix: Pediatric HIV/AIDS Confidential Case Report (CDC 50.42B)

Instructions for Completion

Purpose

- Information captured on the form 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 their prevention activities.
- CDC's Division of HIV/AIDS Prevention (DHAP) needs reports and updates to reflect the earliest dates that children meet each reporting criteria (i.e., perinatal exposure, HIV infection, AIDS, seroreverter), as well as changes in diagnostic or vital status.
- When a child who was previously reported as HIV infected has progressed to AIDS or has died, state/reporting area personnel update the database 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 form can accommodate updated information including immunologic markers and diagnoses of opportunistic infections.
- CDC updated the HIV/AIDS reporting form 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 mother 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 ZDV during pregnancy and labor/delivery and neonatal ZDV.
- Maternal HIV counseling and testing, prenatal care, and refusal of ZDV treatment were added in 1996.
- Viral load tests, receipt of additional antiretroviral (ARV) therapy during labor/delivery or to 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 ZDV and receipt of other antiretroviral therapy can be collected for all children born to HIV-infected women. 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

Pediatric Cases of Public Health Importance (COPHI)

- **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, mother-to-infant transmission due to breast feeding, transfusions after March 1985, or any unusual transmission circumstances. This direct communication will ensure the timeliest technical support. COPHI is covered in *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures for HIV/AIDS Surveillance* under risk factor ascertainment.

Section I, State/local use only (patient identifier information)

- Although Social Security number is not a field appearing on the 50.42B, it is useful as a patient identifier.

Section II, Health department use only

2.2 *REPORT SOURCE*

- If "Other database," "Other Clinic," "Other," or "Out of state" is selected, specify source in Section X, Comments.
- Two-level codes for report source are shown below. The first level of source code is required, and the second level is recommended.

Report Source Codes for HIV/AIDS Reporting

First level source <Source 1>	Second (more detailed) level source <Source 2>
A01. = Inpatient	A01.01 = IP/Acute care facility A01.01.02 = IP/ACF/OBGYN records A01.01.03 = IP/ACF/Pediatric records A01.01.04 = IP/ACF/Birth records A01.02 = IP/VA A01.03 = IP/Military hospital A01.03.02 = IP/Military/OBGYN records A01.03.03 = IP/Military/Pediatric records A01.04 = IP/Long-term care facility A01.04.03 = IP/LTCF/Drug TX program A01.05 = IP/Hospice
A02. = Outpatient	A02.01 = OP/HMO A02.02 = OP/VA A02.03 = OP/Private physician A02.04 = OP/Adult HIV Clinic A02.05 = OP/Infect. Dis. Clinic A02.06 = OP/County HD clinic A02.07 = OP/Maternal HIV clinic A02.08 = OP/Prenatal clinic or records A02.09 = OP/Pediatric HIV clinic A02.10 = OP/OBGYN clinic (not HIV related) A02.11 = OP/Pediatric clinic A02.12 = OP/TB clinic A02.14 = OP/IHS clinic A02.15 = OP/Early intervention nurse A02.16 = OP/Visiting nurse service A02.17 = OP/Hemophilia TX clinic A02.18 = OP/Hospice A02.19 = OP/Drug TX center A02.20 = OP/Rehab center A02.25 = OP/Other clinic
A03. = Emergency room	A03 = Emergency room

First level source <Source 1>	**Second (more detailed) level source <Source 2>**
A04. = Screening, diagnosis, and referral agencies	A04.01 = Scr, Dx, Ref/Blood bank A04.02 = Scr, Dx, Ref/Drug TX program A04.03 = Scr, Dx, Ref/Family planning clinic A04.04 = Scr, Dx, Ref/HIV case management agency A04.05 = Scr, Dx, Ref/HIV counseling & testing site A04.06 = Scr, Dx, Ref/Immigration report A04.07 = Scr, Dx, Ref/Insurance report A04.08 = Scr, Dx, Ref/Job Corps A04.09 = Scr, Dx, Ref/Military A04.10 = Scr, Dx, Ref/Partner referral & counseling service A04.11 = Scr, Dx, Ref/STD clinic
A05. = Laboratory	A05.01 = Lab/hosp. A05.02 = Lab/state A05.03 = Lab/private

First level source <Source 1>	**Second (more detailed) level source <Source 2>**
A06. = Other databases	A06.01 = Other DB/ADAP A06.02 = Other DB/ASD A06.03 = Other DB/Birth certificate A06.04 = Other DB/Birth defects registry A06.05 = Other DB/Cancer registry A06.06 = Other DB/Database from coroner A06.07 = Other DB/Death certificate review A06.08 = Other DB/EHRAP database A06.09 = Other DB/EPS database A06.10 = Other DB/HARS database A06.11 = Other DB/Health department records A06.12 = Other DB/Hepatitis registry A06.13 = Other DB/Hosp billing summary or discharge data A06.14 = Other DB/HRSA HIV Care database A06.15 = Other DB/Immunization registry A06.16 = Other DB/Medicaid records A06.17 = Other DB/NDI A06.18 = Other DB/Out-of-state report A06.19 = Other DB/Prison, jail, or other correctional facility database A06.20 = Other DB/PSD A06.21 = Other DB/State disease registry A06.22 = Other DB/SHAS A06.23 = Other DB/SHDC database A06.24 = Other DB/STD registry A06.25 = Other DB/TB registry A06.50 = Other DB/Other database or report
A07. = Other facility records	A07.01 = Oth facility records/Prison, jail, or other correctional facility A07.02 = Oth facility records/Coroner, not associated with IP facility
A10 = Other source	A10 = Other source (specify)_____
Unknown	

Section III, Demographic information

3.1 *DIAGNOSTIC STATUS AT REPORT*

- See 3.1.1–3.1.4, below.

3.1.1 *PERINATALLY HIV EXPOSED*

- The "Perinatally HIV Exposed" category is composed of "Presumptively Not Infected," "Definitively Not Infected," and "Indeterminate."
- A child aged less than 18 months born to an HIV-infected mother will be categorized as having perinatal exposure to HIV infection if the child does not meet the criteria for HIV infection or the criteria for "not infected with HIV."

3.1.2 CONFIRMED HIV INFECTION (NOT AIDS)

- Among children aged greater than or equal to 18 months and less than 13 years, a reportable case of HIV infection must meet at least one of the following criteria:

Laboratory Criteria

- Positive result on a screening test for HIV antibody (e.g., repeatedly reactive enzyme immunoassay), followed by a positive result on a confirmatory (sensitive and more specific) test for HIV antibody (e.g., Western blot or immunofluorescence antibody test) **or**
- Positive result or report of a detectable quantity on any of the following HIV virologic (nonantibody) tests:
  - HIV nucleic acid (DNA or RNA) detection (e.g., DNA polymerase chain reaction [PCR] or plasma HIV-1 RNA)
  - HIV p24 antigen test, including neutralization assay
  - HIV isolation (viral culture)

OR

Clinical or Other Criteria (if the above laboratory criteria are not met)

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician **or**
- Conditions that meet criteria included in the case definition for AIDS

- Among children aged less than 18 months, a reportable case of HIV infection must meet at least one of the following criteria:

Laboratory Criteria

Definitive

- Positive results on two separate specimens (excluding cord blood) using one or more of the following HIV virologic (nonantibody) tests:
  - HIV nucleic acid (DNA or RNA) detection
  - HIV p24 antigen test, including neutralization assay, in a child greater than or equal to 1 month of age
  - HIV isolation (viral culture)

OR

Presumptive

A child who does not meet the criteria for definitive HIV infection but who has:

- Positive results on only one specimen (excluding cord blood) using the above HIV virologic tests and no subsequent negative HIV virologic or negative HIV antibody test

OR

Clinical or Other Criteria (if the above definitive or presumptive laboratory criteria are not met)

- Diagnosis of HIV infection, based on the laboratory criteria above, that is documented in a medical record by a physician**OR**
- Conditions that meet criteria included in the 1987 pediatric surveillance case definition for AIDS (http://www.cdc.gov/mmwr/pdf/other/mmsu3601.pdf)— see next page for detailed listing

- In the absence of laboratory evidence of HIV infection in the child, that child meets the HIV case definition if diagnosed with conditions that meet the criteria in the 1987 pediatric case definition for AIDS if born to a mother known to be infected at the time of birth.
- The current HIV case definition for children less than 13 years of age, and persons of all ages, is available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a2.htm.

3.1.3 *AIDS*

- The current pediatric AIDS case definition is available at http://www.cdc.gov/mmwr/pdf/other/mmsu3601.pdf. The 1994 revised classification system for HIV infection in children less than 13 years of age is available at http://www.cdc.gov/mmwr/preview/mmwrhtml/00032890.htm.
- Children who are HIV infected and exhibit any of the following AIDS-defining clinical conditions should be reported as presumptive AIDS cases; although most of these conditions appear among adult AIDS diagnostic criteria, asterisked conditions apply only to pediatric cases.
- For children with an AIDS-defining condition that requires laboratory evidence of HIV infection, a single positive HIV-detection test (i.e., HIV culture, HIV PCR, or HIV p24 antigen) is sufficient for a reportable AIDS diagnosis if the diagnosis is confirmed by a clinician.

- Candidiasis, esophageal
- Cervical cancer, invasive
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1 month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes)
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy, HIV related
- Herpes simplex: chronic ulcer(s) (>1 month's duration); or bronchitis, pneumonitis, or esophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (>1 month's duration)
- Kaposi's sarcoma
- Lymphoid interstitial pneumonia*
- Lymphoma, Burkitt's (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- Multiple recurrent bacterial infections*
- Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- Pneumocystis carinii pneumonia
- Progressive multifocal leukoencephalopathy
- Salmonella septicemia, recurrent
- Toxoplasmosis of brain
- Wasting syndrome due to HIV

3.1.4 *SEROREVERTER*

- Virtually all children less than 18 months of age born to HIV-infected mothers are antibody positive at birth.
- A child aged < 18 months born to an HIV-infected mother 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:

Laboratory Criteria

Definitive

- At least two negative HIV antibody tests from separate specimens obtained at ≥ 6 months of age
- At least two negative HIV virologic tests* from separate specimens, both of which were performed at ≥ 1 month of age and one of which was performed at ≥ 4 months of age

AND

No other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition)

OR

Presumptive

A child who does not meet the above criteria for definitive "not infected" status but who has:

- One negative EIA HIV antibody test performed at ≥ 6 months of age and NO positive HIV virologic tests, if performed ***OR***
- One negative HIV virologic test* performed at ≥ 4 months of age and NO positive HIV virologic tests, if performed ***OR***
- One positive HIV virologic test with at least two subsequent negative virologic tests*, at least one of which is at ≥ 4 months of age; or negative HIV antibody test results, at least one of which is at ≥ 6 months of age

AND

No other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition).

OR

Clinical or Other Criteria (if the above definitive or presumptive laboratory criteria are not met)

Determined by a physician to be "not infected," and a physician has noted the results of the preceding HIV diagnostic tests in the medical record

AND

NO other laboratory or clinical evidence of HIV infection (i.e., has not had any positive virologic tests, if performed, and has not had an AIDS-defining condition)

* HIV nucleic acid (DNA or RNA) detection tests are the virologic methods of choice to exclude infection in children aged < 18 months. Although HIV culture can be used for this purpose, it is more complex and expensive to perform and is less well standardized than nucleic acid detection tests. The use of p24 antigen testing to exclude infection in children aged < 18 months is not recommended because of its lack of sensitivity.

3.5 *CURRENT STATUS*

- For further guidance on death ascertainment, see *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Death Ascertainment*.

3.8 *DATE OF INITIAL EVALUATION FOR HIV INFECTION*

- Enter the date of initial evaluation for HIV infection.
- Evidence of HIV infection in a child **must be obtained on or after the birth date**.

3.10 *SEX*

- In addition to "Male" or "Female" sex at birth, CDC-supplied software includes a third choice of "Unk." Although "CURRENT_SEX" is not a variable appearing on the case report form, the person completing the form may record current sex in Section XI or in the form's margin next to Section III—particularly if current sex differs from sex at birth.
- Selections and legal values for "CURRENT_SEX" from eHARS Lookup Codes are as follows:

CURRENT_SEX = F = Female Person's current sex
CURRENT_SEX = I = Intersexed Person's current sex
CURRENT_SEX = M = Male Person's current sex

- Additionally, the current form does not include fields for patient gender, but eHARS optionally does. A variety of genders may be recorded either in the margin of the case report form at Section III or in the Comments section. Note that "CURRENT_GENDER" adds behavioral, biological, and iatrogenic selections to those of "current sex."

- Selections and legal values for "CURRENT GENDER" from eHARS Lookup Codes are as follows:

CURRENT_GENDER = CD = Cross Dresser Person's current gender
CURRENT_GENDER = DQ = Drag Queen Person's current gender
CURRENT_GENDER = F = Female Person's current gender
CURRENT_GENDER = FM = Female to Male Person's current gender
CURRENT_GENDER = I = Intersexed Person's current gender
CURRENT_GENDER = M = Male Person's current gender
CURRENT_GENDER = MF = Male to Female Person's current gender
CURRENT_GENDER = SM = She Male Person's current gender

3.11 *ETHNICITY*

- Regardless of the presence of race or absence of any information, collect data on ethnicity.
- As of January 2003, the US Office of Management and Budget (OMB) required that race and ethnicity (Hispanic, non-Hispanic) for a person be collected as separate variables.
- A wide variety of ethnicities may be selected from legal values available in CDC-supplied software. These ethnicities and codes are documented in the *eHARS Technical Reference Guide*.

3.12 *RACE*

- 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 categories:
    - American Indian or Alaska Native
    - Asian
    - Black or African American
    - Native Hawaiian or Other Pacific Islander
    - White
- A wide variety of race categories may be selected from legal values available in CDC-supplied software. These races and codes are documented in the *eHARS Technical Reference Guide*.

3.13 *COUNTRY OF BIRTH*

- Select first from boxes provided:

  United States

  US dependency, specify

  Other, specify

  Unknown

- For patients born in US dependencies, specify from the following table:

US dependencies	
American Samoa	Pacific Trust Terr.
Guam	Palau
Johnston Atoll	Puerto Rico
Mariana Islands	Ryukyu Islands
Marshall Islands	Swan Islands
Micronesia	US Virgin Islands
Midway Islands	Wake Island
Navassa Island	

3.14 *RESIDENCE AT DIAGNOSIS*

- For reports of HIV infection or perinatal HIV exposure, enter the patient's city, county, state/country, and ZIP code of residence at the time of the first confirmatory test for HIV infection or when HIV infection was first considered, either clinically or through laboratory evaluation.
- Documentation of an HIV test is often the earliest evidence that HIV diagnosis was considered; however, an HIV test may not have been ordered at that time.
- 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 AIDS case reports, enter the patient's residence at the date of the first AIDS-defining clinical condition or the date of the first immunologic marker that reaches AIDS-defining thresholds.

3.14.1 *RESIDENCE, HOMELESS*

- For homeless patients, enter the address that most accurately describes where they stay—including a shelter address if applicable.
- People without a usual residence should be reported by the jurisdiction where they were staying at the time of diagnosis.

For further guidance about residency assignment, see *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Case Residency Assignment*.

Section IV, Facility of diagnosis

4.1 *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 mother 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 where the child was confirmed to be HIV-infected.
- 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.
- If a facility name is not documented but a physician's name is listed, enter "Private Physician" or a numeric code for each physician; enter the name of the physician under Physician Identifier Information (Section VI).
- For reports of AIDS, enter the name of the facility where the patient's AIDS-defining clinical condition was first diagnosed.
- If a physician name is listed without facility name, enter physician name.
- These fields strictly apply to facility where HIV or AIDS was diagnosed. Where chart abstraction is accomplished at a facility other than the Facility of Diagnosis (Section IV), document report source at "report source" field; refer to 2.2 for further details.

4.4 *FACILITY SETTING*

- State/local surveillance program staff may create tables of settings by facilities in their jurisdictions to prevent misclassification.

4.5 *FACILITY TYPE*

- Select "Physician, HMO" where diagnosis was made at a private, outpatient care site not associated with a hospital.
- Examples of "Other" include HIV counseling and testing sites, STD clinics, drug treatment facilities, family planning clinics, prenatal/obstetrics clinics, tuberculosis clinics, and correctional facilities. Select "Other" for any public outpatient setting.

Section V, Patient/maternal history

- Surveillance staff have found such information within mother's chart at discharge summary, history and physical, social service notes, counseling and testing notes, and STD diagnosis notes.
- Where not explicitly annotated, contact child's provider about maternal/child risk factor information.
- Definition of 'Risk factors': The collective term for the individual routes of exposure/transmission on which data are routinely collected for surveillance of HIV/AIDS cases. "Yes," "No," or "Unk." must be selected.
- See *Technical Guidance for HIV/AIDS Surveillance Programs, Volume I: Policies and Procedures, Risk Factor Ascertainment* for further guidance on risk factor data collection. States should have risk factor ascertainment procedures tailored to their jurisdictions as well.

5.1 *CHILD'S BIOLOGIC MOTHER'S HIV INFECTION STATUS*

- "Refused HIV testing" should be selected if mother's refusal is documented in the medical chart.
- If the biologic mother 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, however, mother-to-infant transmission through breast-feeding is considered as the only mode of transmission, please alert the state or local NIR coordinator and enter in the field labeled "other" in the patient/maternal history section.

5.2. *(MOTHER) DIAGNOSED WITH HIV INFECTION/AIDS*

- If dates are not available, please review medical charts to determine when maternal HIV diagnosis occurred in relationship to the child's birth and select:

  3) before this child's pregnancy;

  4) during this child's pregnancy;

5) at time of delivery (i.e., when admitted for labor/delivery and before discharge from the birth hospital or within 7 days of birth;

6) before child's birth, exact period unknown;

7) after the child's birth (i.e., anytime after discharge from birth hospital or after 7 days of birth); or

8) HIV-infected, unknown when diagnosed.

- If no information is available regarding maternal HIV status, please select:

  9) HIV status unknown.

5.3 *DATE OF MOTHER'S FIRST POSITIVE HIV CONFIRMATORY TEST*

The following is adapted from an excerpt of the adult/adolescent HIV surveillance case definition, accessible at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a2.htm:

Necessary for HIV infection (not AIDS)

- Documentation of +EIA plus +WB/IFA with date ***or***
- Detectable viral load with date ***or***
- Positive p24 antigen test with date ***or***
- Positive viral culture with date ***or***
- Physician documentation of HIV with date

5.4 *MOTHER WAS COUNSELED ABOUT HIV TESTING DURING THIS PREGNANCY, LABOR, OR DELIVERY?*

- Complete this question for all mothers regardless of whether they were diagnosed with HIV infection before this pregnancy.
- If not, then select "No."
- If no information in the medical chart is available regarding counseling, then select "Unk."

5.5 *AFTER 1977, THIS CHILD'S BIOLOGIC MOTHER HAD*

5.5.2.3 *HETEROSEXUAL RELATIONS WITH PERSON WITH HEMOPHILIA/COAGULATION DISORDER*

- 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 the correct answer to this question is "No"; and the question below about transfusion recipient should be answered "Yes" if the partner was also known to be HIV infected.

- Refer to *Protocol for Evaluation of Identification and Follow-up of Cases of Public Health Importance* at http://www2a.cdc.gov/hicsb/docs/COPHI_Protocol.pdf for more information.

5.5.2.4 *HETEROSEXUAL RELATIONS WITH TRANSFUSION RECIPIENT WITH DOCUMENTED HIV INFECTION*

- This refers to someone with documented HIV infection who received a transfusion of blood cells (red cells, white cells, platelets) or plasma.

5.6.1 *RECEIVED CLOTTING FACTOR FOR COAGULATION DISORDER*

- 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, then the correct answer to this question is "No"; and the question below about blood transfusion should be answered "Yes." If "Yes," please specify disorder.
- If child was born after March 1985 and receipt of clotting factor is the suspected mode of HIV transmission, alert the state/local NIR coordinator.

Section VI, State/local use only

6.1 *PHYSICIAN'S NAME*

- If the test was provided as part of a visit to a health department, an STD clinic, an HIV counseling and testing site, or other facility where no single individual is responsible for medical management of the patient, leave this space blank and complete the "Facility of Diagnosis" section appropriately.

6.3 *MEDICAL RECORD NUMBER*

- This field may be left blank unless patient was hospitalized as an inpatient or treated as an outpatient in a hospital, community health center, or health department clinic.
- If the patient has more than one medical record number, enter the number of the primary record that has HIV/AIDS documentation. Additional numbers can be noted in the Comments section, clearly annotating which facility is associated with which record number.

Section VII, Laboratory data

7.1.3 *HIV-1 Western blot/IFA*

- Western blot banding patterns should be interpreted according to the CDC/Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) recommendations "Human Immunodeficiency Virus Type 1 Infections" (MMWR, 1989:38:No.S-7).

7.5 *IF HIV TESTS WERE NOT POSITIVE OR WERE NOT DONE, OR THE PATIENT IS LESS THAN 18 MONTHS OF AGE, DOES THIS PATIENT HAVE AN IMMUNODEFICIENCY THAT WOULD DISQUALIFY HIM/HER FROM THE AIDS CASE DEFINITION?*

Causes of immunodeficiency that disqualify clinical conditions as indicators of AIDS *in the absence of laboratory evidence for HIV* infection are:

- High-dose or long-term systemic corticosteroid therapy or other immunosuppressive/cytotoxic therapy within 3 months before the onset of the AIDS-defining clinical condition.
- Any of the following diseases diagnosed before or within 3 months after the AIDS-defining clinical condition was diagnosed:
  - Hodgkin's disease
  - non Hodgkin's lymphoma (other than primary brain lymphoma)
  - lymphocytic leukemia
  - multiple myeloma
  - any other cancer of lymphoreticular or histiocytic tissue
  - angioimmunoblastic lymphadenopathy
- A genetic (congenital) immunodeficiency syndrome or an acquired immunodeficiency syndrome atypical of HIV infection, such as one involving hypogammaglobulinemia.

Section VIII, Clinical status

8.1.1–8.1.24 *AIDS INDICATOR DISEASES*

- Enter the dates of initial diagnosis of each indicator disease.
- If at all possible, it is important to include both month and year for future trend analysis.
- In rare circumstances, both month and year may not be available. However, if after further searches the investigator finds that the only documentation of the diagnosis date is the year, without a designated month, ".." should be entered for the unknown month followed by the documented year.
- Choosing an arbitrary month is not recommended.

- Definitive diagnoses are based on specific laboratory evidence such as histology or culture.
- Methods for the presumptive diagnosis of diseases indicative of AIDS listed in the case definition supplement are simply suggested guidelines, not requirements. If a method does not meet the requirements for definitive diagnosis, it meets the requirements for presumptive diagnosis for those conditions that may be diagnosed presumptively. Accept any method that the clinician considers diagnostic.

Section IX, Birth history (for perinatal cases only)

9.5.2 *DELIVERY*

- Elective cesarean section refers to a cesarean section that occurs before rupture of membranes and before the onset of labor.
- Elective cesarean section has been demonstrated to reduce perinatal transmission of HIV, if performed before the onset of labor.
- It will be important to monitor the trends in the use of elective cesarean section for the prevention of perinatal HIV.

9.5.3 *DEFECTS*

- 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 (i.e., neural tube defects, congenital heart defects, esophageal atresia, cleft lip/palate, etc.).
- 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 and used in the Metropolitan Atlanta Congenital Defects Program and 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.
- 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 psychologic 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 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 lab 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 call the CDC HIV Incidence and Case Surveillance Branch (HICSB) at (404) 639-2050. For reference, you may request the full copy of the Metropolitan Atlanta Congenital Defects Program Procedure Manual from HICSB at (404) 639-2050.

9.5.3.1 *CODE*

- The 6-digit defect code is based on 3- or 5-digit ICD-9 codes. The ICD-9 code, which may be available in the child's medical record, can be used in place of the 6-digit code. If defects exist, list all on the case report form and enter in the Comments section. Call CDC's DHAP Help Desk by phone at (877) 659-7725 for assistance with coding.
- The following is an abbreviated reference list for birth defect coding:

System	Condition	6-digit Codes	3-digit Codes
Central Nervous System	Spina Bifida (meningocele)	741.000–741.990	A04
	Anencephaly	740.000–740.100	A01
	Encephalocele	742.000–742.090	A13
Cardiovascular	Atrial septal defects	745.510–745.590	D06
	Ventricular septal defects	745.400–745.490	D05
	Pulmonary valve anomalies	746.000–746.090	D12
	Coarctation of the aorta	747.100–747.190	D26
	Aortic valve anomalies	746.300–746.490	D14
	Transposition of the Great Arteries	745.100–745.190	D02
	Tetralogy of Fallot	745.200–742.210	D03
	Hypoplastic left heart syndrome	746.700	D18
Orofacial	Cleft palate without cleft lip	749.000–749.090	F01
	Cleft lip with and without cleft palate	749.100–749.290	F02
Musculoskeletal	Clubfoot	754.730	J05
	Reduction defect of upper limb	755.200–755.290	K01
	Reduction defect of lower limb	755.300–755.390	K02
Chromosomal	Down syndrome	758.000–758.098	R01
	Trisomy 13 (Patau Syndrome)	758.100–758.198	R02
	Trisomy 18 (Edwards Syndrome)	758.200–758.298	R03
	22q11.2 deletion	758.370	R04
Eye	Cataract	743.320–743.326	B04
	Anophthalmos and microphthalmus	743.000–743.100	B01
Genitourinary	Hypospadius	752.600–752.607	G02
	Anomalies of renal pelvis and ureter	753.200–753.290	H06
	Ambiguous genitalia	752.700–752.790	G04
Abdominal Wall Anomalies	Gastrochisis	756.710	N04
	Omphalocele	756.700	N02
Diaphragmatic Anomalies	Diaphragmatic hernia	756.600–756.616	N01

Note: To add a birth defect that is not in this abbreviated list, please refer to the codes from the *Metropolitan Atlanta Congenital Defects Program Procedure Manual*.

9.7.1 *MONTH OF PREGNANCY PRENATAL CARE BEGAN*

- Enter "09" if care began in the ninth month or later.
- If entry is reported in weeks, convert to appropriate months as follows:

Weeks	Months	Weeks	Months
1–4	1	23–26	6
5–9	2	27–30	7
0–13	3	31–35	8
14–17	4	36+	9
18–22	5		

9.9.1 *DID MOTHER RECEIVE ANY OTHER ANTIRETROVIRAL MEDICATION DURING PREGNANCY?*

- A single drug formulation often has multiple names; trade names are in bold. Drug names include the following, which serves only as a guide. This guide is current as of January 2005:

Drug type among antiretroviral class				
Nucleoside/ Nucleotide Reverse Transcriptase Inhibitors (NRTIs)	*Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)*	*Protease Inhibitors*	*Fusion Inhibitors*	*NRTI Combination Drugs*
Drug name				
Abacavir—ABC, **Ziagen**	Delavirdine—**Rescriptor**	Amprenavir—**Agenerase**	Enfuvirtide—**Fuzeon**	**Combivir**
Didanosine—ddI, **Videx**, **Videx EC**	Efavirenz—**Sustiva**	Atazanavir—**Reyataz**		**Trizivir**
Emtricitabine—FTC, **Emtriva**	Nevirapine—**Viramune**	Indinavir—**Crixivan**		**Truvada**
Lamivudine—3TC, **Epivir**		Lopinavir + Ritonavir—**Kaletra**		**Abacavir combo**
Stavudine—D4T, **Zerit**		Nelfinavir—**Viracept**		
Tenofovir—Disoproxil, Fumarate, **Viread**		Ritonavir—**Norvir**		
Zalcitabine—ddC, **HIVID**		Saquinavir (hard gel capsule)—**Invirase**		
Zidovudine—AZT, ZDV, **Retrovir**		Saquinavir (soft gel capsule)—**Fortovase**		

- Clinicians initiating antiretroviral regimens in the HIV-1-infected pregnant patient should refer to *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States* at http://www.aidsinfo.nih.gov/guidelines/.

9.10.2 *MATERNAL SOUNDEX*

- If name of the patient's biologic mother has not been entered in the database, enter name and date of birth in the CDC-supplied software.
- The biologic mother's surname will be converted to a *SOUNDEX CODE* when entered into the CDC-supplied software.
- If name of the biologic mother has been entered in your database and a "stateno" exists, retrieve the soundex code from the database and enter here.
- Consult with your state/local health department in jurisdictions with alternatives to name-based reporting.

9.10.4 *BIRTHPLACE OF BIOLOGIC MOTHER*

- Select first from boxes provided:

  United States

  US dependency, specify

  Other, specify

  Unknown

- For patients born in US dependencies, specify from the following table:

US dependencies	
American Samoa	Pacific Trust Terr.
Guam	Palau
Johnston Atoll	Puerto Rico
Mariana Islands	Ryukyu Islands
Marshall Islands	Swan Islands
Micronesia	US Virgin Islands
Midway Islands	Wake Island
Navassa Island	

Section X, Treatment/services referrals

10.1.1 *NEONATAL ZIDOVUDINE (ZDV, AZT) FOR HIV PREVENTION*

- The neonatal component of the ACTG protocol 076 consisting of 6 weeks of neonatal prophylactic ZDV therapy should begin within 24 hours of birth. Therefore, to monitor implementation and impact, we

collect the day, month, and year the child was first started on ZDV for prophylaxis.

- If "Yes," record the day, month, and year the child was started on AZT or ZDV as prophylaxis *during the first 6 weeks of life*.
- If search for day was unsuccessful and year and month are present, then enter ".." for the unknown day followed by the documented year and month.

10.1.2 *DID NEONATE RECEIVE ANY OTHER ANTIRETROVIRAL MEDICATION DURING THE NEONATAL PERIOD FOR HIV PREVENTION?*

10.1.2.1 *IF "YES," SPECIFY*

- Examples of other antiretrovirals are as follows: Didanosine (ddI, dideoxyinosine, Videx), Dideoxycytidine (ddC, HIVID, Zalcitabine), Lamivudine (3TC, Epivir), Stavudine (d4t, Zerit), Nevirapine, Indinavir (Crixivan), Ritonavir, and Saquinavir (Invirase).

10.1.3 ANTIRETROVIRAL THERAPY FOR HIV TREATMENT

- Please refer to the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection (MMWR 1998;47(RR-4):1–43). Examples of antiretroviral therapies include Zidovudine (ZDV, AZT, Retrovir), Didanosine (ddI, dideoxyinosine, Videx), Dideoxycytidine (ddC, HIVID, Zalcitabine), Lamivudine (3TC, Epivir), Stavudine (d4T, Zerit), Nevirapine, Indinavir (Crixivan), Ritonavir, and Saquinavir (Invirase).

10.1.4 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.

10.2 *WAS CHILD BREASTFED?*

- Avoidance of breast-feeding to prevent postpartum transmission of HIV has been recommended for HIV-infected mothers in the United States.

10.4 *THIS CHILD'S MEDICAL TREATMENT IS PRIMARILY REIMBURSED BY*

- Medicaid reimbursement means specifically Medicaid and includes Medicaid HMOs.
- For clinical trial or government program, please select the applicable trial or program. For example, State Crippled Children's services would be "other public funding." HRSA clinic would be "Clinical trial/government program."

10.5 *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 dead 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 dead 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 section XI.