

## 09-ID-01

**Committee:** Infectious

**Title:** Public Health Reporting and National Notification for HIV Infection\*

*\*HIV infection includes what was formerly referred to as HIV-not AIDS and AIDS*

### I. Statement of the Problem

CSTE position statement 07-EC-02 recognized the need to develop an official list of nationally notifiable conditions and a standardized reporting definition for each condition on the official list. The position statement also specified that each definition had to comply with American Health Information Community recommended standards to support “automated case reporting from electronic health records or other clinical care information systems.” In July 2008, CSTE identified sixty-eight conditions warranting inclusion on the official list, each of which now requires a standardized reporting definition.

### II. Background and Justification

HIV infection meets the following criteria for nationally and **standard** notifiable conditions, as specified in CSTE position statement 08-EC-02:

- A majority of state and territorial jurisdictions—or jurisdictions comprising a majority of the US population—have laws or regulations requiring **standard** reporting of HIV infection and AIDS (now referred to as stage 3 of HIV disease) to public health authorities
- CDC requests **standard** notification of HIV infection to federal authorities.
- CDC has condition-specific policies and practices concerning the agency’s response to, and use of, notifications.

### III. Statement of the desired action(s) to be taken

CSTE requests that CDC adopt this standardized reporting definition for HIV infection and the classification of stages of HIV disease to facilitate more timely, complete, and standardized local and national reporting of this condition. Where CSTE has identified potential changes needed in CDC’s current case definitions, such proposed changes and clarifications are noted.

CSTE recommends that implementation of the reporting standards outlined in this document be conducted in conjunction with the state or territorial HIV surveillance program to ensure consistency with local laws and regulations.

#### IV. Goals of Surveillance

To provide information on the temporal, geographic, and demographic occurrence of HIV infection along the spectrum of the disease stages to facilitate their prevention and control.

#### V. Methods for Surveillance

Surveillance for HIV infection should use the sources of data and the extent of coverage listed in Table V. In addition, the CDC’s *Technical Guidance for HIV/AIDS Surveillance Programs* outlines other potential sources for ascertaining cases (see the “Access to Source Data and Completeness” chapter of Volume I).

**Table V.** Recommended sources of data and extent of coverage for ascertaining cases of HIV infection.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician/infection control reporting	x	
laboratory reporting	x	
reporting by other entities (e.g., hospitals, pharmacies, HIV counseling and testing sites)	x	
birth certificates/registries	x	
death certificates/registries	x	
hospital discharge or outpatient records	x	
extracts from electronic medical records	x	
telephone survey		
school-based survey		
other: public health disease registries (tuberculosis STD, hepatitis, cancer); HIV-related programs (Ryan White programs, HIV Partner Services, etc.); insurance companies (health, life, disability); blood/plasma centers	x	

#### VI. Criteria for Reporting a Potential Case

Reporting refers to the process of healthcare providers or institutions (e.g., clinicians, clinical laboratories, hospitals) submitting basic information to governmental public health agencies about cases of illness that meet certain reporting requirements or criteria. Cases of illness may also be ascertained by the secondary analysis of administrative

health data or clinical data. The purpose of this section is to provide those criteria that should be used by humans and machines to determine whether a specific illness should be reported.<sup>1</sup>

**A. Narrative description of criteria to be used by humans to determine whether a potential case should be reported to public health authorities**

Report any illness to public health authorities that meets any of the criteria below for all HIV variants (e.g. HIV-1 or HIV-2). The criteria listed are for purposes of reporting and do not represent the criteria required to satisfy the case definition or for medical diagnosis. Note that the 2008 CDC case definition lists the case defining criteria in three separate age categories: <18 months; 18 months to <13 years; ≥13 years to adult. With the case defining criteria for children 18 months to <13 years the same as ≥13 years to adult, CSTE proposes that CDC collapse the case reporting and case defining criteria into two categories: <18 months and 18 months through adult.

**PERSONS AGED ≥18 MONTHS THROUGH ADULT**

Note: The criteria below include lab results or events that, when reported to the health department, may prompt an investigation of a potential case. Health departments are responsible for investigating the reports and determining whether or not the criteria for a case are met.

- Positive result from an HIV antibody screening test (e.g., reactive enzyme immunoassay [EIA]<sup>2</sup> confirmed by a positive result from a supplemental HIV antibody test (e.g., Western blot or indirect immunofluorescence assay test)

*or*

- Any result from the following tests:
  - **Quantitative** HIV nucleic acid (DNA or RNA) detection test<sup>3</sup> (e.g., polymerase chain reaction [PCR])
  - HIV genotype
  - HIV phenotype
  - Any CD4+ T-lymphocyte test result, regardless of count/percent result

*or*

- Positive result or report of a detectable quantity (i.e., within the established limits of the laboratory test) from any of the following HIV virologic (i.e., non-antibody) tests<sup>3</sup>:
  - **Qualitative** HIV nucleic acid (DNA or RNA) detection test<sup>3</sup> (e.g., polymerase chain reaction [PCR])
  - HIV p24 antigen test, including neutralization assay
  - HIV isolation (viral culture)

*or*

- HIV infection diagnosed by a physician or qualified medical-care provider<sup>4</sup> based on the laboratory criteria and documented in a medical record or death certificate.<sup>5</sup> Oral reports of prior laboratory test results are not acceptable.

*or*

- Diagnosis of an AIDS-defining condition<sup>6</sup>

### **CHILDREN AGED <18 MONTHS**

- Any result from the following tests:
  - HIV antibody screening test (e.g., reactive enzyme immunoassay [EIA]<sup>2</sup>)
  - Supplemental HIV antibody test (e.g., Western blot or indirect immunofluorescence assay test)
  - **Quantitative** HIV nucleic acid (DNA or RNA) detection test<sup>3</sup> (e.g., polymerase chain reaction [PCR])
  - HIV genotype
  - HIV phenotype
  - Any CD4+ T-lymphocyte test result, regardless of count/percent result
  - **Qualitative** HIV nucleic acid (DNA or RNA) detection test<sup>3</sup> (e.g., polymerase chain reaction [PCR])
  - HIV p24 antigen test, including neutralization assay
  - HIV isolation (viral culture)

*or*

- HIV infection diagnosed by a physician or qualified medical-care provider<sup>4</sup> based on the laboratory criteria and documented in a medical record or death certificate.<sup>5</sup> Oral reports of prior laboratory test results are not acceptable.

*or*

- HIV exposure diagnosed by a physician or qualified medical-care provider<sup>4</sup>.

*or*

- Diagnosis of an AIDS-defining condition<sup>6</sup>

**Table VI-B.** Proposed table of criteria to determine whether a case should be reported to public health authorities. Note: The following criteria are proposed for evaluation before general implementation. For purposes of currently implementing reporting the narrative description in VI-A should be used.

<b>Criteria for a reportable potential case</b>	<b>Persons aged <math>\geq</math> 18 months - adult</b>		<b>Children &lt;18 months</b>
Age at diagnosis $\geq$ 18 months	N	N	
Age at diagnosis < 18 months			N
Positive HIV antibody screening test	N		
Positive HIV antibody confirmatory test	N		
HIV antibody screening test, <u>any result</u>			O
HIV antibody confirmatory test, <u>any result</u>			O
<b>Quantitative</b> HIV nucleic acid (DNA or RNA) detection test, <u>any result</u>		O	O
HIV genotype test, <u>any result</u>		O	O
HIV phenotype test, <u>any result</u>		O	O
CD4+ T-lymphocyte test, <u>any result</u>		O	O
<b>Qualitative</b> HIV nucleic acid (DNA or RNA) detection test, <u>positive result</u>		O	
HIV p24 antigen test (including neutralization assay), <u>positive result</u>		O	
HIV isolation (viral culture), <u>pos. result</u>		O	

<b>Qualitative HIV nucleic acid (DNA or RNA) detection test, <u>any result</u></b>			O
HIV p24 antigen test (including neutralization assay), <u>any result</u>			O
HIV isolation (viral culture), <u>any result</u>			O
HIV infection diagnosed by physician		O	O
HIV infection on death certificate		O	O
Diagnosis of AIDS-defining condition <sup>6</sup>		O	O
Provider report exposed			O

N = All criteria in a column must be present to define a case

O = At least one variable in column must be present to report a case

### **C. Disease-specific data elements:**

When a case of HIV has been identified, a complete case report should be made to surveillance. In addition to the common data elements listed in the appendix, reporters should include additional data elements which can be found on the CDC's Adult HIV/AIDS Confidential Case Report form CDC 50.42C and Pediatric HIV/AIDS Confidential Case Report form CDC 50.42B.

## **VII. Case Definition for Case Classification**

### **A. Narrative description of criteria to determine whether a case should be classified as confirmed.**

The case definitions below are based on CDC's *MMWR* "Revised Case Definitions for HIV Infection Among Adults, Adolescents, and Children <18 months and for HIV Infection and AIDS Among Children Aged 18 Months to <13 Years --- United States, 2008" (*MMWR* 2008;57 (No. RR10). In this position statement, however, CSTE proposes several changes from the current case definition. Specifically:

- The 2008 CDC case definition lists the case defining criteria in three separate categories: <18 months; 18 months to <13 years;  $\geq$ 13 years to adult. With the case defining criteria for children 18 months to <13 years the same as  $\geq$ 13 years to adult, CSTE proposes that CDC collapse the case defining criteria for HIV infection into two categories: <18 months and 18 months through adult.
- For staging of disease for children 18 months to 13 years, CDC's 2008 case definition refers to the 1994 revised classification system.<sup>7</sup> CSTE recommends that CDC update definition in light of current clinical and surveillance practices.
- For determining HIV infection status among children <18 months, the 2008 case definition requires that the child be born to a woman with HIV infection. Since there are instances where a child may become infected other than through exposure to an HIV positive mother, i.e., premastication transmission from an HIV positive caregiver other than the mother, CSTE proposes to eliminate the requirement that the child be born to a mother who has HIV infection in some of the infection status categories.

The definitions are intended for public health surveillance and are not a guide for clinical diagnosis. The definition applies to all HIV variants (e.g. HIV-1 or HIV-2). HIV infection may not be confirmed through the diagnosis of an AIDS-defining condition alone.

## **PERSONS AGED 18 MONTHS THROUGH ADULT**

### **Criteria for a Case**

- Positive result from an HIV antibody screening test (e.g., reactive enzyme immunoassay [EIA]<sup>2</sup> confirmed by a positive result from a supplemental HIV antibody test (e.g., Western blot or indirect immunofluorescence assay test)

*or*

- Positive result or report of a detectable quantity (i.e., within the established limits of the laboratory test) from any of the following HIV virologic (i.e., non-antibody) tests<sup>3</sup>:
  - HIV nucleic acid (DNA or RNA) detection test (e.g., polymerase chain reaction [PCR])<sup>3</sup>
  - HIV p24 antigen test, including neutralization assay
  - HIV isolation (viral culture)

*or*

- HIV infection diagnosed by a physician or qualified medical-care provider<sup>4</sup> based on the laboratory criteria and documented in a medical record.<sup>5</sup> Oral reports of prior laboratory test results are not acceptable.

### **Case Classification**

For the purposes of surveillance, confirmed cases are staged according to severity, which includes stage 3 (AIDS) at the most advanced stage of disease. Every effort should be made to report CD4+ T-lymphocyte counts or percentages and the presence of AIDS-defining conditions upon diagnosis. In addition, CD4+T-lymphocyte counts/percentages, viral load tests, and AIDS-defining conditions are recommended to be reported for confirmed cases for the purposes of staging disease progression and to inform programmatic decisions and interventions.

### ***Staging for Persons Aged 13 Years through Adult***

A confirmed case meets the laboratory criteria for diagnosis of HIV infection and one of the four HIV infection stages (stage 1, stage 2, stage 3, or stage unknown). Although cases with no information on CD4+ T-lymphocyte count or percentage and no information on AIDS-defining conditions can be classified as stage unknown, every effort should be made to report CD4+ T-lymphocyte counts or percentages and the presence of AIDS-defining conditions at the time of diagnosis. Additional CD4+ T-lymphocyte counts or percentages and any identified AIDS-defining conditions can be reported as recommended.

### *HIV Infection, Stage 1*

- No AIDS-defining condition and either CD4+ T-lymphocyte count of  $\geq 500$  cells/ $\mu$ L or CD4+ T-lymphocyte percentage of total lymphocytes of  $\geq 29$ .

### *HIV Infection, Stage 2*

- No AIDS-defining condition and either CD4+ T-lymphocyte count of 200--499 cells/ $\mu$ L or CD4+ T-lymphocyte percentage of total lymphocytes of 14--28.

### *HIV Infection, Stage 3 (AIDS)*

- CD4+ T-lymphocyte count of  $< 200$  cells/ $\mu$ L or CD4+ T-lymphocyte percentage of total lymphocytes of  $< 14$  or documentation of an AIDS-defining condition.<sup>6</sup> Documentation of an AIDS-defining condition supersedes a CD4+ T-lymphocyte count of  $\geq 200$  cells/ $\mu$ L and a CD4+ T-lymphocyte percentage of total lymphocytes of  $\geq 14$ . Definitive diagnostic methods for these conditions are available in Appendix C of the 1993 revised HIV classification system and the expanded AIDS case definition<sup>8</sup> and from the National Notifiable Diseases Surveillance System (available at [http://www.cdc.gov/epo/dphsi/casedef/case\\_definitions.htm](http://www.cdc.gov/epo/dphsi/casedef/case_definitions.htm)).

### *HIV Infection, Stage Unknown*

- No information available on CD4+ T-lymphocyte count or percentage and no information available on AIDS-defining conditions. (Every effort should be made to report CD4+ T-lymphocyte counts or percentages and the presence of AIDS-defining conditions at the time of diagnosis.)

### ***Staging for Children Aged 18 months to <13 years***

Currently, the CDC case definition for children aged 18 months to 13 years refers to the 1994 revised classification system for HIV infection among children  $< 13$  years for staging of disease.<sup>6</sup> CSTE recommends that CDC review and update their HIV infection staging classification system in light of current surveillance system capabilities to more sensitively monitor the epidemic and progression of disease. Until such expert review is conducted, CSTE acknowledges the current staging criteria from the 1994 classification system.<sup>7</sup>

## **CHILDREN AGED <18 MONTHS**

For a child <18 months, CSTE proposes the following criteria for the purposes of surveillance in order to classify the child as definitively or presumptively HIV infected, or definitively or presumptively uninfected with HIV. These criteria largely reflect CDC's 2008 case definition, with the exception of eliminating the requirement that the child be born to an HIV infected mother as a criterion for definitive HIV infection, definitive uninfected with HIV and presumptive uninfected with HIV. Below are the criteria for health departments to confirm the status of a reported potential case.

### ***Criteria for Definitive HIV Infection***

A child aged <18 months is categorized for surveillance purposes as HIV infected if there are:

- Positive results on two separate specimens (not including cord blood) from one or more of the following HIV virologic (non-antibody) tests:
  - HIV nucleic acid (DNA or RNA) detection<sup>9</sup>
  - HIV p24 antigen test, including neutralization assay, for a child aged  $\geq 1$  month
  - HIV isolation (viral culture)

### ***Criteria for Presumptive HIV Infection***

A child aged <18 months is categorized for surveillance purposes as presumptively HIV infected if 1) born to an HIV-infected mother, 2) the criterion for definitively HIV infected is not met, and 3) the following laboratory or other criterion is met:

- Positive results on one specimen (not including cord blood) from the listed HIV virologic tests (HIV nucleic acid detection test; HIV p24 antigen test, including neutralization assay, for a child aged  $\geq 1$  month; or HIV isolation [viral culture] for definitively HIV infected) and no subsequent negative results from HIV virologic or HIV antibody tests

*or*

- HIV infection diagnosed by a physician or qualified medical-care provider<sup>4</sup> based on the laboratory criteria and documented in a medical record (oral reports of prior laboratory test results are not acceptable)

*or*

- When test results regarding HIV infection status are not available, documentation of a condition that meets the criteria in the 1987 pediatric surveillance case definition for AIDS<sup>10</sup>

### ***Criteria for Uninfected with HIV, Definitive***

A child aged <18 months is categorized for surveillance purposes as definitively uninfected with HIV if 1) the criteria for definitive or presumptive HIV infection are not met and 2) at least one of the laboratory criteria or other criteria are met.<sup>11</sup>

- At least two negative HIV DNA or RNA virologic tests from separate specimens, both of which were obtained at age  $\geq 1$  month and one of which was obtained at age  $\geq 4$  months

*or*

- At least two negative HIV antibody tests from separate specimens obtained at age  $\geq 6$  months

*and*

- No other laboratory or clinical evidence of HIV infection (i.e., no positive results from virologic tests [if tests were performed] and no current or previous AIDS-defining condition<sup>6</sup>)

### ***Criteria for Uninfected with HIV, Presumptive***

A child aged <18 months is categorized for surveillance purposes as presumptively uninfected with HIV if 1) the criteria for definitively uninfected with HIV are not met and 2) at least one of the laboratory or other criteria are met.

- Two negative RNA or DNA virologic tests, from separate specimens, both of which were obtained at age  $\geq 2$  weeks and one of which was obtained at age  $\geq 4$  weeks.<sup>12</sup>

*or*

- One negative RNA or a DNA virologic test from a specimen obtained at age  $\geq 8$  weeks

*or*

- One negative HIV antibody test from a specimen obtained at age  $\geq 6$  months

*or*

- One positive HIV virologic test followed by at least two negative tests from separate specimens, one of which is a virologic test from a specimen obtained at age  $\geq 8$  weeks or an HIV antibody test from a specimen obtained at age  $\geq 6$  months;

*and*

- No other laboratory or clinical evidence of HIV infection (i.e., no subsequent positive results from virologic tests if tests were performed, and no AIDS-defining condition for which no other underlying condition indicative of immunosuppression exists)<sup>6</sup>

*or*

- Determination of uninfected with HIV by a physician or qualified medical-care provider<sup>4</sup> based on the laboratory criteria and who has noted the HIV diagnostic test results in the medical record. Oral reports of prior laboratory test results are not acceptable;

*and*

- No other laboratory or clinical evidence of HIV infection (i.e., no positive results from virologic tests [if tests were performed] and no AIDS-defining condition for which no other underlying condition indicative of immunosuppression exists)<sup>6</sup>.

#### ***Indeterminate HIV Infection Status***

- A child aged  $< 18$  months born to an HIV infected mother is categorized as having perinatal exposure with an indeterminate HIV infection status if the criteria for infected with HIV and uninfected with HIV are not met.

**Table VII-B.** Table VII-B. Proposed table of criteria to determine whether a case is classified. Note: The following criteria are proposed for evaluation before general implementation. For purposes of current notification, the narrative description in VII-A, should be used.

Criteria for a confirmed case	Persons aged ≥ 18 months - adult		Children aged < 18 months
Age at diagnosis ≥ 18 months	N	N	N
Age at diagnosis < 18 months			
Positive HIV antibody screening test	N		
Positive HIV antibody confirmatory test	N		
HIV nucleic acid (DNA or RNA) detection test, <u>positive result</u>		O	O*
HIV p24 antigen test, including neutralization assay, <u>positive result</u>		O	O* (for a child aged ≥1 month)
HIV isolation (viral culture), <u>positive result</u>		O	O*
HIV infection diagnosis by physician or qualified medical-provider based on laboratory criteria		O	

N = All criteria in a column must be present to define a case

O = At least one variable in column must be present to report a case

\* = Positive results on two separate specimens (not including cord blood) from one or more of the following HIV virologic (non-antibody) tests

## **VIII. Period of Surveillance**

Surveillance should be on-going.

## **IX. Data sharing/release and print criteria**

It is recommended that jurisdictions notify to CDC all confirmed HIV infection cases as well as all perinatally exposed infants prior to classification.

CDC does not release case-level data. CDC does routinely release aggregate data to their partners for use in describing the epidemic (e.g., Kaiser Foundation and WHO) and funding allocations and care program planning (e.g., HRSA and the United States Congress). Additionally, CDC has a mechanism for outside parties to submit data requests for aggregate level data. If these requests are for appropriate public health purposes and meet CDC's data release policies, CDC may approve them and provide the requested data.

## **X. References**

1. Revised Surveillance Case Definitions for HIV Infection Among Adults, Adolescents, and Children Aged <18 Months and for HIV Infection and AIDS Among Children Aged 18 Months to <13 Years. MMWR 2008;57:1-8.
2. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43(No. RR-12).
3. CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41(No. RR-17).
4. CDC. Revision of the CDC surveillance case definition for acquired immunodeficiency syndrome. MMWR 1987;36(Suppl 1):1-15.
5. CSTE. Revision of Surveillance Case Definition for AIDS among adults and adolescents  $\geq$  13 years of age. 2005. <[www.cste.org](http://www.cste.org)>

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## Appendix: AIDS-Defining Conditions

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

\* Only among children aged <13 years. (CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43[No. RR-12].)

† Condition that might be diagnosed presumptively.

§ Only among adults and adolescents aged >13 years. (CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41[No. RR-17].)

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<sup>1</sup> “Human-based” criteria (described below under “A. Narrative”) can be applied by medical care providers and laboratory staff based on clinical judgment and clinical diagnosis. Machine-based criteria (described below under “B. Table”) can be applied using computerized algorithms that operate in electronic health record systems, including computerized records of laboratory test orders and laboratory test results; other clinical data systems (e.g., hospital discharge data systems serving multiple hospitals); or administrative data (e.g., healthcare provider billing data, vital records, and EMS data).

<sup>2</sup> Rapid tests are EIAs that do not have to be repeated but require a confirmatory test if reactive. Most conventional EIAs require a repeatedly reactive EIA that is confirmed by a positive result with a supplemental test for HIV antibody. Standard laboratory testing procedures should always be followed.

<sup>3</sup> For HIV screening, HIV virologic (non-antibody) tests should not be used in lieu of approved HIV antibody screening tests. A negative result (i.e., undetectable or nonreactive) from an HIV virologic test (e.g., viral RNA nucleic acid test) does not rule out the diagnosis of HIV infection.

<sup>4</sup> Qualified medical-care providers might differ by jurisdiction and might include physicians, nurse practitioners, physician assistants, or nurse midwives.

<sup>5</sup> An original or copy of the laboratory report is preferred; however, in the rare instance the laboratory report is not available, a description of the laboratory report results by a physician or qualified medical-care provider documented in the medical record is acceptable for surveillance purposes. Every effort should be made to obtain a copy of the laboratory report for documentation in the medical record.

<sup>6</sup> <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a2.htm>

<sup>7</sup> CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43(No. RR-12).

<sup>8</sup> CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41(No. RR-17).

<sup>9</sup> HIV nucleic acid (DNA or RNA) detection tests are the virologic methods of choice for the diagnosis or exclusion of infection in children aged <18 months. Although HIV culture can be used, culture is less standardized and less sensitive than nucleic acid detection tests. The use of p24 antigen testing to exclude infection in children aged <18 months is not recommended because of poor sensitivity, especially in the presence of HIV antibody. Commercial tests for RNA and DNA detection have become widely available. Quantitative RNA tests have been approved by the Food and Drug Administration (FDA) for monitoring HIV infection, and qualitative RNA tests have been approved to aid diagnosis. The quantitative and qualitative RNA tests meet FDA standards for high analytic and clinical sensitivity and specificity (14--16). All available tests detect the subtypes of group M and strains of group O. HIV-2 can be diagnosed with HIV-2 DNA PCR. HIV RNA tests sometimes do not detect HIV-2 because the viral loads in some HIV-2--infected persons are below detectable levels. Because of the possibility of mutation or recombination involving the sequences detected by a particular test, occasionally, virus might not be detected in a specimen from an HIV-2 infected individual. If HIV-2 infection seems likely but results are negative, testing with a different assay might be advisable.

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<sup>10</sup> CDC. Revision of the CDC surveillance case definition for acquired immunodeficiency syndrome. MMWR 1987;36(Suppl 1):1-15.

<sup>11</sup> Suspected cases of HIV infection among children aged <18 months who are born to a documented HIV-uninfected mother should be assessed on a case-by-case basis by the appropriate health care and public health specialists.

<sup>12</sup> If specimens for both negative RNA or DNA virologic tests are obtained at age  $\geq 4$  weeks, specimens should be obtained on separate days.