Utah Department of Health & Human Services

Human immunodeficiency virus (HIV)

Disease plan

Quick links

Last updated: 05/26/2023, by Luke Edvalson

Questions about this disease plan?

Contact the Utah Department of Health and Human Services Office of Communicable Diseases: 801-538-6191.

HIV critical clinician information

Clinical evidence

Signs/symptoms

- Acute illness may include flu-like symptoms such as:
  - Fever
  - Chills
  - Rash
  - Night sweats
  - Muscle aches
  - Sore throat
  - Fatigue
  - Swollen lymph nodes
  - Mouth ulcers
- Chronic infection is characterized by low CD4+ lymphocyte counts
- Patients with low CD4+ lymphocyte counts may exhibit the symptoms of opportunistic infections which are secondary to HIV infection

Period of communicability

- Indefinite

Incubation period

- Generally between 2–6 weeks from exposure to acute illness
- Generally between 7–12 years from exposure to Stage 3 infection (AIDS)

Mode of transmission

- Sexual
- Blood-borne pathogen
- Perinatal (mother-to-child)

Laboratory testing

Type of lab test/timing of specimen collection

- 4th generation antigen/antibody combination (Ag/Ab) testing can begin 18 to 45 days after exposure
- A positive Ag/Ab test should reflex to a Geenius HIV 1/2 Type-Differentiating Immunoassay
- A positive type-differentiating test is confirmation of HIV infection
- **A negative or indeterminate Geenius does *not* confirm absence of HIV infection.** An FDA-approved HIV-1 nucleic acid test (NAT) test is required to rule out early infection. If a qualitative RT-PCR test is unavailable, a quantitative RT-PCR viral load will suffice
- A positive Ag/Ab with a negative or indeterminate type-differentiating test **and** negative RT-PCR is considered HIV-negative

Type of specimens

- Serum or plasma
- Whole blood may be used for type-differentiating immunoassays, but not Ag/Abs or NATs

Treatment recommendations

Type of treatment

- Treatment with antiretroviral medications is both essential and complex. Generally, treatment should be monitored by a physician who is familiar with HIV. A full set of current treatment

guidelines is available from the National Institutes of Health at this web address[1]: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/

Time period to treat

- From diagnosis until death unless clinically contraindicated

Prophylaxis

- Post-exposure prophylaxis (PEP)
  - Must **begin within 72 hours of exposure and should run for 28 days**
  - **Preferred regimen** for otherwise healthy adults and adolescents:
    - Tenofovir disoproxil fumarate (tenofovir DF or TDF) (300mg) with emtricitabine (200mg) once daily ***plus***
    - Raltegravir (RAL) 400mg twice daily or dolutegravir (DTG) 50mg daily
  - **Alternative regimen** for otherwise healthy adults and adolescents:
    - Tenofovir DF (300mg) with emtricitabine (FTC) (200mg) once daily ***plus***
    - Darunavir (DRV) (800mg) and ritonavir (RTV) (100mg) once daily
  - Healthcare providers who prescribe dolutegravir (DTG) should be careful to make sure people who are pregnant take folate supplements to avoid a potential small increase in the risk of neural tube defects.
  - Regimens for children, people who have decreased renal function, and pregnant people, as well as the full PEP guidelines, are available here[2]: https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf
- Pre-exposure prophylaxis (PrEP)
  - For use in people who have a very high risk for HIV infection (a more complete treatment for PReP can be found in the Treatment section of "Disease and epidemiology")
  - There are now 3 approved PrEP medications:
    - Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg
    - Emtricitabine 200 mg in combination with tenofovir alafenamide (TAF) 25 mg
    - Cabotegravir (CAB) 600 mg injection
  - The use of other antiretroviral medications for PrEP, either in place of or in addition to approved PrEP medications is **not recommended**
  - The prescription of oral PrEP for coitally-timed or other noncontinuous daily use is **not recommended**

Contact management

Isolation of case

- Universal Precautions

Quarantine of contacts

- Not applicable

Infection control procedures

- Universal Precautions

Why is HIV important to public health?

Human immunodeficiency virus (HIV) is a retrovirus that affects the cellular immunity of those who are infected. HIV is the cause of acquired immunodeficiency syndrome (AIDS) and may lead to other health conditions and, left untreated, death. The first AIDS diagnoses in the United States were discovered in 1981. Millions of deaths have been reported worldwide. As a result of recent advancements in antiretroviral therapy (ART) and increased access to medical care, individuals infected with the virus who can access proper healthcare are no longer dying, but they continue to have adverse health effects throughout their lives. HIV has no cure or vaccine and remains inside the human body regardless of treatment. HIV infection may not be curable but is completely preventable. Efforts must continue to understand the populations who are affected through public health surveillance and research. Prevention efforts, such as education, prophylaxis, and antiretroviral treatment are essential for reducing the spread of HIV.[3]

Disease and epidemiology

Clinical description

Infection with HIV produces a spectrum of disease that progresses from acute infection (stage 0) to clinically latent or an asymptomatic state (stage 1 or 2—depending on age and CD4 cell counts) to AIDS (stage 3). AIDS represents the most advanced stage of disease.

As the immune system weakens, a variety of complications start to appear.[3]

- Some people have a flu-like illness within a month or 2 after exposure to the virus. This illness may include fever, headache, fatigue, enlarged lymph nodes, or a rash. These symptoms usually disappear within a week to a month and are often mistaken for those of another viral infection.
- Symptoms that may be experienced months to years before the onset of acquired immunodeficiency syndrome (AIDS) include: lack of energy, weight loss, frequent fevers and sweats, persistent or frequent yeast infections (oral or vaginal), persistent skin rashes or flaky skin, pelvic inflammatory disease that does not respond to treatment (in women), and short-term memory loss.

In people who have AIDS, opportunistic infections are often severe and sometimes fatal because the immune system is so ravaged by the HIV infection that the body cannot fight off certain bacteria, viruses, fungi, parasites, and other microbes. Symptoms of opportunistic infections common in people with AIDS include: coughing and shortness of breath, seizures and lack of coordination, difficult or painful swallowing, mental symptoms such as confusion

and forgetfulness, severe diarrhea, fever, vision loss, nausea, abdominal cramps, vomiting, weight loss, extreme fatigue, and severe headaches.[3]

Causative agent

The human immunodeficiency virus (HIV) is a retrovirus. Most cases are HIV type 1 (HIV-1); HIV-2, a related virus that is extremely uncommon in the United States is more common in West Africa. Three groups of HIV-1 have been identified—M, N, and O. Group M is the most prevalent and is subdivided into 7 subtypes.[3] There may be differences between HIV-1 subtypes in rates of disease progression and possibly in transmissibility.

Differential diagnosis

The most common symptoms associated with acute infection occur 2–6 weeks after exposure, are influenza-like and include fever, malaise, lymphadenopathy, and sore throat. A rash may also develop, and the differential diagnosis includes infectious mononucleosis, pityriasis rosea, secondary syphilis, drug reaction, or toxic erythema due to another infectious cause.

Laboratory identification

Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody combination immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to screen for established infection with HIV-1 or HIV-2 and for acute HIV-1 infection. No further testing is required for specimens which are nonreactive on the initial immunoassay.

Specimens with a reactive antigen/antibody combination immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody combination immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV antibodies, undifferentiated.

Specimens that are reactive on the initial antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 nucleic acid test (NAT). Currently, there is only 1 such test approved for the diagnosis of HIV-1 available for wide-spread use: the APTIMA HIV-1 RNA qualitative assay. Should an FDA-approved NAT not be available, a quantitative RT-PCR viral load is sufficient; provided it was ordered by a medical professional for diagnostic purposes.

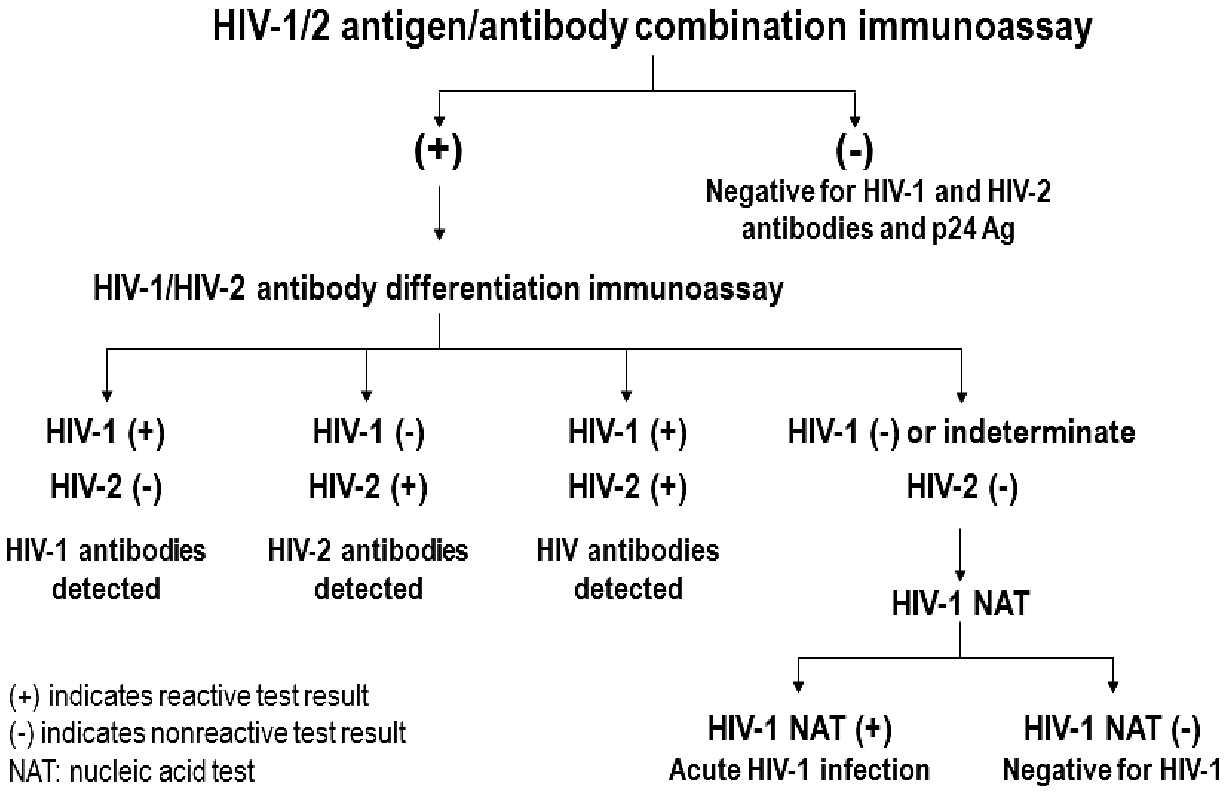
- A reactive HIV-1 NAT result and nonreactive HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence for acute HIV-1 infection.
- A reactive HIV-1 NAT result and indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates the presence of HIV-1 infection confirmed by HIV-1 NAT.

A negative HIV-1 NAT result and nonreactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates a false-positive result on the initial immunoassay.

Laboratories should use this same testing algorithm, beginning with an antigen/antibody combination immunoassay, with serum or plasma specimens submitted for testing after a reactive (preliminary positive) result from any rapid HIV test. If laboratory capacity is unavailable to perform a conventional antigen/antibody combination immunoassay, a repeatedly reactive antigen/antibody combination rapid result is sufficient to move to the next step in the HIV testing algorithm.

Figure 1

Interpretation of HIV-1/2 antigen/antibody combination immunoassay



Treatment

Primary care physicians are encouraged to participate actively in the care of HIV-infected patients in consultation with specialists who have HIV expertise. Guidelines for the treatment of HIV/AIDS are updated on a regular basis. For updated treatment guidelines, visit National Institutes of Health HIV/AIDS Treatment Guidelines[1] or HRSA clinical care guidelines.[4]

Case fatality

The proportion of HIV-infected persons who, in the absence of anti-HIV treatment, will ultimately develop AIDS has been estimated at more than 90%. In the absence of effective treatment, the AIDS case-fatality rate is very high. Survival time in many developing countries is often less than 1 year. In industrialized countries, 80–90% of untreated patients used to die within 3–5 years after diagnosis. Recent advancements in treatment and medical care have significantly postponed the development of AIDS-defining conditions and death. In the United States, an estimated 13,877 people with an AIDS diagnosis died in 2020.[5]

Reservoir

Humans are the only natural host. An infected individual may be asymptomatic for several years while continuing to be infectious.

Transmission

Person-to-person transmission through unprotected sexual contact (penile, vaginal, or anal intercourse); use of HIV-contaminated needles or syringes (primarily shared by intravenous drug users); vertical transmission from mother to infant during pregnancy, delivery, or breastfeeding; or less commonly (and now very rarely in countries where blood is screened for evidence of HIV infection), through transfusions of infected blood or blood clotting factors.[6]

Susceptibility

Susceptibility is unknown, but presumed to be general: race, gender, and pregnancy do not appear to affect susceptibility to HIV infection or AIDS. The presence of other sexually transmitted infections, especially if ulcerative, increases susceptibility. Recent data indicates male circumcision is protective against infection.[3]

Incubation period

The incubation period for HIV is variable. The presence of antibodies is typically detected within 30 days after infection occurs. Among patients enrolled in large epidemiologic studies, the time from infection with HIV to the development of AIDS-related symptoms has ranged from less than 1 year

to 15 years or longer. Factors such as the absence of antiretroviral therapy, co-infection, and general health of the individual affect this time frame. However, researchers have observed a wide variation in disease progression. Approximately 10% of HIV-infected people in these studies progressed to AIDS within the first 2–3 years following infection, while as many as 5% of individuals in studies have stable CD4+ T cell counts and no symptoms even after 12 or more years.[3]

Period of communicability

The period of communicability is not known precisely. It begins early after onset of HIV infection and presumably extends throughout life. Recent studies have solidified the relationship between the quantity of circulating virus and infectiousness. The CDC has officially stated that persons with an undetectable viral load have an extremely low (though not 0) risk of transmitting the virus to an HIV-negative sexual partner. HIV is still, however, a chronic infection and persons with HIV remain infectious indefinitely.

Epidemiology

The number of people newly infected with HIV has fallen to the lowest level in more than 2 decades, according to the latest available data—a testament to the impact of the world's efforts to end the global HIV epidemic. The estimated 1.5 million people globally who acquired HIV for the first time in 2020 were 48.3% fewer than in 2000.[7]

CDC estimates that 1,058,900 people were living with diagnosed HIV infection in the United States at the end of 2021.[8] An estimated additional 153,500 persons older than 13 years of age (12.6%) were unaware of their infection.[8] Over the past decade, the number of people living with HIV has increased, while the annual number of new HIV infections has remained relatively stable. Still, the pace of new infections continues at far too high a level—particularly among certain groups.

HIV incidence (new infections): The estimated incidence of HIV has declined slightly in recent years, with about 32,000 new HIV infections in 2021.[9] Within the overall estimates, however, some groups are affected more than others. MSM continue to bear the greatest burden of HIV infection, and, among races/ethnicities, people who are Black or African American continue to be disproportionately affected.

HIV diagnoses (new diagnoses, regardless of when infection occurred or stage of disease at diagnosis): In 2021, an estimated 35,769 people were diagnosed with HIV infection in the United States.[10]

In Utah, there were 2,911 HIV-infected individuals assumed to be alive and residing in Utah as of December 31, 2020. Males, accounting for 85% of the infections, continue to be primarily affected

by HIV in Utah. The majority (57.5%) of individuals with HIV are MSM, followed by MSM/IDU (injection drug use) at 13% and IDU at 6%. Individuals who report heterosexual risk account for 9%, however, roughly 14% of individuals with HIV reported some other historic risk or did not report a risk. While the number of people living in Utah with HIV increases each year, the rate of newly diagnosed infections has remained steady over the last decade from 4.2 infections per 100,000 in 2012 to 4.0 per 100,000 in 2021.[11]

Public health control measures

Public health responsibility

- Investigate all suspect cases of disease and fill out and submit appropriate disease investigation forms.
- Provide education to the general public, clinicians, and first responders regarding disease transmission and prevention.
- Identify clusters or outbreaks of this disease.
- Identify sources of exposure and stop further transmission.

Prevention

HIV/AIDS prevention programs can be effective only with full community and political commitment to promote proven prevention measures such as pre-exposure prophylaxis (PrEP) and antiretroviral therapy (ART) while discouraging high HIV-risk behaviors.

- The importance of adhering to antiretroviral therapy to maintain an undetectable viral load should be emphasized with HIV-positive individuals.
- Expand the availability and use of PrEP among persons at high risk for HIV infection.
- Public and school health education should stress that having multiple and especially concurrent and/or overlapping sexual partners or sharing drug paraphernalia all increase the risk for HIV infection.
- Students should be taught to avoid or reduce risky behavior.
- Programs for school-age youth should address the needs and developmental levels of both students and those who do not attend school.
- The specific needs of minorities; persons with different primary languages and those with visual, hearing or other impairments must be addressed.
- The only absolute way to avoid infection through sex is to abstain from sexual intercourse or to engage in mutually monogamous sexual intercourse only with someone known to be uninfected.
- Latex condoms must be used correctly every time a person has vaginal, anal, or oral sex. Only water-based lubricants should be used with male condoms.

- Expansion of facilities to treat drug users reduces HIV transmission. Programs that instruct needle users in decontamination methods and needle exchange have been shown to be effective.
- HIV testing and counseling is an important intervention to raise awareness of HIV status, promote behavioral change and diagnose HIV infection.
- Pregnant people should be counseled about HIV early in pregnancy and where culturally and socially appropriate, encourage an HIV test as a routine part of standard antenatal care.
- Care must be taken in handling, using, and disposing of needles or other sharp instruments.
- Healthcare workers should wear latex gloves, eye protection and other personal protective equipment in order to avoid contact with blood or other bodily fluids.
- The risk of transmission from an HIV-infected pregnant person to their baby is significantly reduced if the mother is treated with zidovudine, or other antiretroviral agents throughout pregnancy, labor, and delivery, and if their baby is treated during the first 6 weeks of life.

Chemoprophylaxis

There are 2 major divisions of prophylaxis in relation to HIV. Post-exposure prophylaxis (PEP) refers to treatment given **after** a person has been exposed to the virus. Pre-exposure prophylaxis (PrEP) refers to treatment given **before** an HIV exposure has occurred and is given to persons at highest risk for infection.

PEP: Must begin within 72 hours of the suspected exposure. Persons beginning PEP should receive a 28-day course. A full set of PEP guidelines can be found on the CDC website.[2]

Healthcare providers who prescribe dolutegravir (DTG) should be careful to make sure people who are pregnant take folate supplements to avoid a potential small increase in the risk for neural tube defects in the unborn baby.

Table 1 is a reproduced table of HIV PEP regimens recommended by CDC.

Table 1

CDC recommended HIV post-exposure prophylaxis regimens

CDC recommended HIV post-exposure prophylaxis regimens[a, b]		
Population	**Preferred/alternative**	**Treatment regimen**
Adults and adolescents aged ≥13 years, including pregnant women with normal renal function (creatinine clearance ≥ 60 mL/min)	**Preferred**	A 3-drug regimen consisting of tenofovir DF 300mg ***and*** fixed dose combination emtricitabine 200mg (Truvada[c]) once daily ***with*** raltegravir 400mg twice daily ***or*** dolutegravir 50mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300mg ***and*** fixed dose combination emtricitabine 200mg (Truvada) once daily ***with*** darunavir 800mg (as 2, 400mg tablets) once daily ***and*** ritonavir[b] 100mg once daily
Adults and adolescents aged ≥13 years with renal dysfunction (creatinine clearance ≤59 mL/min)	**Preferred**	A 3-drug regimen consisting of zidovudine ***and*** lamivudine, with both doses adjusted to degree of renal function ***with*** raltegravir 400mg twice daily ***or*** dolutegravir 50mg once daily
	Alternative	A 3-drug regimen consisting of zidovudine ***and*** lamivudine, with both doses adjusted to degree of renal function ***with*** darunavir 800mg (as 2, 400mg tablets) once daily ***and*** ritonavir[b] 100mg once daily
Children aged 2–12 years	**Preferred**	A 3-drug regimen consisting of tenofovir DF, emtricitabine, and raltegravir, with each drug dosed to age and weight[d]

	Alternative	A 3-drug regimen consisting of zidovudine ***and*** lamivudine ***with*** raltegravir ***or*** lopinavir/ritonavir[b], with raltegravir and lopinavir/ritonavir dosed to age and weight[d]
	Alternative	A 3-drug regimen consisting of tenofovir DF ***and*** emtricitabine ***and*** lopinavir/ritonavir[b] with each drug dosed to age and weight[d]
Children aged 3–12 years	Alternative	A 3-drug regimen consisting of tenofovir DF ***and*** emtricitabine ***and*** darunavir[e]/ritonavir[b], with each drug dosed to age and weight[d]
Children aged 4 weeks–≤ 2 years	**Preferred**	A 3-drug regimen consisting of zidovudine oral solution ***and*** lamivudine oral solution ***with*** raltegravir ***or*** lopinavir/ritonavir[b] oral solution (Kaletra[g]), with each drug dosed to age and weight[d]
	Alternative	A 3-drug regimen consisting of zidovudine oral solution ***and*** emtricitabine oral solution ***with*** raltegravir ***or*** lopinavir/ritonavir[b] solution (Kaletra), with each drug adjusted to age and weight[d]
Children aged birth–27 days	Consult a pediatric HIV specialist	

[a] These recommendations do not reflect current Food and Drug Administration-approved labeling for antiretroviral medications listed in this table

[b] Ritonavir is used in clinical practice as a pharmacokinetic enhancer to increase the trough concentration and prolong the half-life of darunavir, lopinavir, and other protease inhibitors. Ritonavir is not counted as a drug directly active again HIV in the above "3-drug" regimens

[c] Gilead Sciences, Inc., Foster City, California

[d] See also Table 6 in https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf

[e] Darunavir only FDA-approved for use among children aged ≥3 years

[f] Children should have attained a postnatal age of ≥ 28days and a postmenstrual age (i.e., first day of the mother's last menstrual period to birth plus the time elapsed after birth) of ≥42 weeks

[g] AbbVie, Inc., North Chicago, Illinois

PrEP: There are now 3 FDA-approved PrEP regimens:

- Tenofovir DF 300mg and fixed-dose combination emtricitabine 200mg (Truvada)
- Tenofovir AF 25mg and fixed-dose combination emtricitabine 200 mg (Descovy)
- Cabotegravir 600 mg injection (Apretude)

Daily oral PrEP with Truvada or equivalent generic is recommended to prevent HIV among all people at risk through sex or injection drug use. Daily oral PrEP with Descovy or equivalent generic is recommended to prevent HIV among people at risk through sex, **excluding people at risk through receptive vaginal sex.** Tenofovir AF with emtricitabine has not yet been studied for HIV prevention for people assigned female at birth who could get HIV through receptive vaginal sex. Injectable PrEP with Apretude or equivalent generic is recommended among all people at risk through sex. It is given as an intramuscular injection. It is started by following up the first injection with a second injection 1 month later. Injections are given every 2 months after that. These regimens are not nearly as effective when not taken consistently. The full set of PrEP guidelines can be found on the CDC website.[12, 13]

PrEP is a powerful HIV prevention tool and can be combined with condoms and other prevention methods to provide even greater protection than when used alone. But people who use PrEP must commit to taking the drug regularly and seeing their healthcare provider for follow-up every 3 months.

Vaccine

None.

Isolation and quarantine requirements

Isolation: None
Hospital: Standard body substance precautions
Quarantine: Not applicable

Case investigation

Reporting (CSTE position statement, [2012])[14]

Note: The following section is copied directly from CSTE position statement 12-ID-05.

HIV infections (including AIDS) are required by Utah law to be reported to public health within 3 working days after identification.[15] Reporting of HIV-related test results and specific patient information are also required.[15]

Criteria to determine whether a case should be reported to public health authorities.

Criterion	Potential HIV infection
Laboratory evidence	
Positive HIV antibody test	S
Positive HIV antigen test	S
Positive HIV combination antigen/antibody test	S
Positive qualitative HIV nucleic acid test	S
Quantitative HIV nucleic acid test (viral load), any result*	S
Viral isolation (culture)	S
HIV genotype test result	S
Clinical evidence	
HIV diagnosis documented in medical record or death certificate	S
Epidemiological evidence	
Child born to HIV-infected mother, documented in medical record or death certificate	S

NOTES: S = This criterion alone is **S**ufficient to report a potential case.
*****Even undetectable viral loads should be reported unless the patient is known not to have HIV infection, because they could represent potential cases or may help to monitor whether known cases are in care.

Case definition

One-rapid HIV testing case definition (2016)

The following description and algorithm describes the test method the Utah Department of Health and Human Services HIV/STD Elimination, Analysis, Response, and Treatment program (HEART) recommends for its grantees, local health departments, and other agencies, as a guide on how to use HIV rapid testing technology for the early detection of HIV infection to prevent further transmission of the disease. Additionally, this document describes how to appropriately link those individuals who have preliminary positive results to medical care, partner services, and HIV prevention services.

HEART recommends that Alere Determine™ HIV-1/2 Ag/Ab Combo be used as a point-of-care immunoassay for the simultaneous detection of HIV-1 p24 antigen (Ag) and antibodies (Ab) to HIV-1 and HIV-2 in human serum, plasma, capillary (fingerstick) whole blood or venipuncture (venous) whole blood.

Alere Determine™ HIV-1/2 Ag/Ab Combo is not intended for newborn screening or for use with cord blood specimens or specimens from individuals younger than 12 years of age.

Alere Determine™ HIV-1/2 Ag/Ab Combo is not intended for use in screening blood, plasma, cell, or tissue donors.

The recommended test device and algorithm have several advantages over previous recommendations, including:

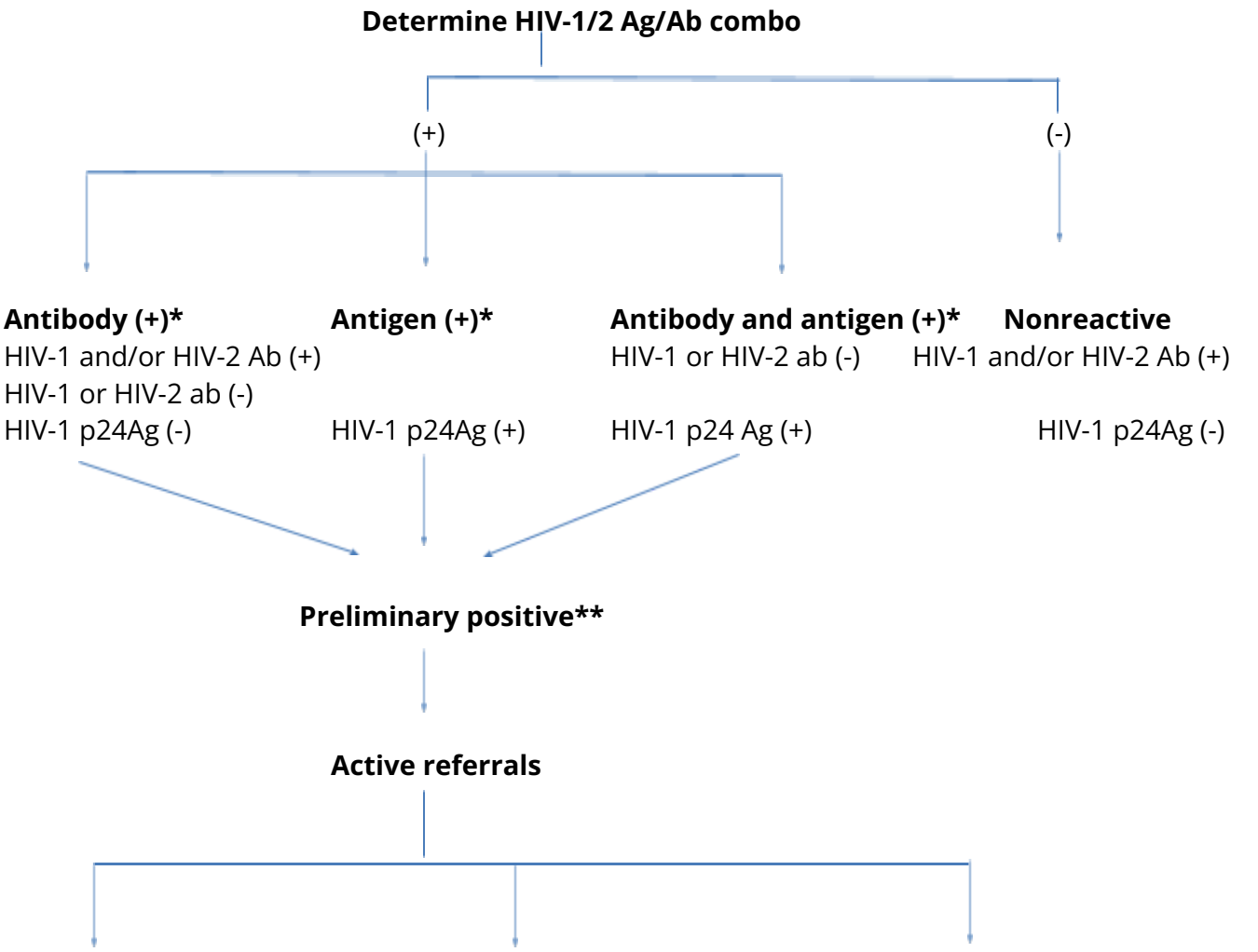
- CLIA-waived for fingerstick whole blood
- It is a 4th generation rapid point-of-care that detects both HIV-1/2 antibodies and free HIV-p24 antigen on a single test strip
- Detects HIV earlier than 3rd generation antibody–only tests
- Allows for speedy and seamless linkage to care
- Reduces referral burden for clients and counselors

A reactive test result using Alere Determine™ HIV-1/2 Ag/Ab Combo suggests the presence of HIV-1 p24 antigen and/or antibodies to HIV-1 and/or HIV-2 in the sample. The reactive result is interpreted as **preliminarily positive** for HIV-1 p24 antigen and/or antibodies to HIV-1 and/or HIV-2. Alere Determine™ HIV-1/2 Ag/Ab Combo is intended as an aid in the diagnosis of infection with HIV-1/2 and its reactive results must be confirmed by a medical provider with an FDA-approved antigen/antibody combination (4th generation) immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to screen for established infection with HIV-1 or HIV-2 and for acute HIV-1 infection. AIDS-related conditions are clinical syndromes, and their diagnosis can only be established clinically.

Medical providers should refer to the CDC Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens to confirm the preliminary positive results of the Alere Determine™ HIV-1/2 Ag/Ab Combo test.[16, 17]

Figure 2

Recommended Rapid HIV Testing Algorithm for serum, plasma, and capillary (fingerstick) whole blood or venipuncture (venous) whole blood



(+) Indicates reactive test result

(-) Indicates non-reactive test result

STD means sexually transmitted disease

HCV means hepatitis C virus

CRCS means comprehensive risk counseling and services

* Result is reportable

** Rapid reactive results must be confirmed

Surveillance case definition (2014)

Description of criteria to determine how a case should be classified

The case definition below builds on CDC's MMWR article entitled "Revised Surveillance Case Definition for HIV Infection—United States, 2014."[18] It combines the confirmation and staging criteria for different age groups into a single definition. The definition is intended for public health surveillance and prevention, not as a guide for clinical diagnosis or patient management. The definition applies to all HIV variants (e.g., HIV-1 or HIV-2). Criteria for a confirmed case of HIV infection may not be met solely by the diagnosis of a stage-3-defining opportunistic illness (see appendix).

Criteria for a confirmed case

Criteria for a confirmed case can be met by either laboratory evidence or clinical evidence, as described below. Laboratory evidence is preferred over clinical evidence.

Persons aged ≥18 months

AND

Children aged <18 months whose mothers were not infected

Laboratory evidence

Laboratory criteria require:

1. A test result specified as positive (reactive or detectable), **AND**
2. The date of specimen collection (at least the year), **AND**
3. The type of test.

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

- A multi-test algorithm consisting of:
    - A positive result from an initial HIV antibody or combination antigen/antibody test,
      AND
    - An accompanying or subsequent positive result from a supplemental HIV test different from the initial test.

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

antibody test, and HIV-2 NAT). However, the initial and supplemental tests must be "orthogonal" (e.g., have different antigenic constituents or use different principles) to minimize the possibility of concurrent nonspecific reactivity. Because the antigenic constituents and test principles are proprietary information that might not be publicly available for some tests, tests will be assumed to be orthogonal if they are of different types.

For example:

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

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

- A positive result of a multi-test HIV antibody algorithm from which only the final result was reported, including a single positive result on a test used only as a supplemental test (e.g., HIV Western blot, immunofluorescence assay) or on a test that might be used as either an initial test or a supplemental test (e.g., HIV-1/2 type-differentiating rapid antibody immunoassay) when it might reasonably be assumed to have been used as a supplemental test (e.g., because the algorithm customarily used by the reporting laboratory is known).
- A positive result or report of a detectable quantity (i.e., within the established limits of the laboratory test) from any of the following HIV virologic (e.g., non-antibody) tests:
    - Qualitative HIV NAT (DNA or RNA)
    - Quantitative HIV NAT (viral load assay)
    - HIV-1 p24 antigen test
    - HIV isolation (viral culture)
    - HIV nucleotide sequence (genotype)

Clinical (non-laboratory) evidence

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

- A note in a medical record by a physician or other qualified medical-care provider that states the patient has HIV infection, **AND**
- One or both of the following:
    - The laboratory criteria for a case were met based on tests done after the physician's note was written (validating the note retrospectively),

- Presumptive evidence of HIV infection (e.g., receipt of HIV antiretroviral therapy or prophylaxis for an opportunistic infection), an otherwise unexplained low CD4+ T-lymphocyte count, or an otherwise unexplained diagnosis of an opportunistic illness (Appendix).

Children aged <18 months born to mothers who have an unknown infection status or were known to be infected

Laboratory evidence

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

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

Clinical evidence

- The same criteria as in the section above (*persons aged ≥18 months and children aged <18 months whose mothers were **not** infected*) **OR**
- All 3 of the following alternative criteria:
  1. Evidence of perinatal exposure to HIV infection before age 18 months
     a. A mother with documented HIV infection **OR**
     b. A confirmed positive test for HIV antibody (e.g., a positive initial antibody test or antigen/antibody test, confirmed by a supplemental antibody test) and a mother whose infection status is unknown or undocumented
  2. Diagnosis of an opportunistic illness indicative of stage 3 (Appendix)
  3. No subsequent negative result on an HIV antibody test.

Definition for date of diagnosis of a confirmed case for all ages

Laboratory criteria

If the diagnosis is based on laboratory evidence, the diagnosis date is defined as the earliest date on which the specimen was obtained for a positive HIV test result.

Clinical criteria

If the diagnosis was based on clinical evidence ("physician-documented") rather than laboratory evidence, the diagnosis date is defined as the date (at least the year) of diagnosis reported in the content of the medical record or physician's note. If the diagnosis date was not reported in the note, the date when the note was written can be used as a proxy. However, both of these dates should be reported, as well as the date of the diagnosis stated by the patient, if it differs from the other 2 dates.

Criteria for classifying the HIV type as HIV-2

All HIV infections in the United States should be assumed to be type 1 (HIV-1) unless laboratory test results are sufficient to classify the infection as type 2 (HIV-2), dual HIV-1 and HIV-2 infections, or undifferentiated HIV infection, as described below. Clinical or epidemiologic evidence might lead to laboratory testing for HIV-2 but is insufficient to classify the HIV type as HIV-2.

Persons aged ≥18 months

AND

Children aged <18 months not perinatally exposed

HIV-2 infection

For HIV-2 infection, 1 or more of the following laboratory criteria are necessary and sufficient:

- FDA-approved HIV 1/2 type-differentiating antibody test result positive for HIV-2 and negative for HIV-1
- Positive HIV-2 Western blot (WB) (or immunoblot or line assay) result and negative or indeterminate HIV-1 WB result
- Positive qualitative HIV-2 NAT result
- Detectable quantitative HIV-2 NAT (viral load)
- Laboratory results interpreted as consistent with HIV-2 infection by a laboratory expert experienced in differentiating HIV-2 from HIV-1 if laboratory evidence for HIV-2 is ambiguous.

Dual infection with HIV-1 and HIV-2

The HIV type is classified as "dual" infection (both HIV-1 and HIV-2) if both an HIV-1 NAT and an HIV-2 NAT are positive.

Undifferentiated HIV type

The HIV type is classified as "undifferentiated" if there is no positive or detectable result from an HIV-1 NAT and a laboratory expert cannot resolve ambiguous evidence for HIV-2, such as:

- HIV-2 WB is positive and HIV-1 WB is HIV positive, **OR**
- HIV-1/HIV-2 type-differentiating antibody test result interpretation is "undifferentiated" (positive for both HIV-1 and HIV-2).

Difficulty of diagnosing HIV-2 infection in children aged <18 months born to mothers known to be HIV-infected or whose HIV infection status is unknown

In perinatally-exposed children aged <18 months, antibody tests are not used to diagnose HIV infection because of the expectation that they might be false indicators of infection in the child due to passive transfer of maternal antibody. The HIV-1 NAT routinely used to diagnose HIV-1 infection in children of this age is likely to be negative in an HIV-2-infected child because it is insensitive to HIV-2. A positive HIV-2 NAT result would satisfy the criteria for a case. Otherwise, the diagnosis of HIV-2 infection in a child will need to wait until the child is 18 months of age, when it can be based on antibody test results.

Criteria for uninfected and indeterminate HIV infection status of perinatally exposed children aged <18 months

Uninfected

A child <18 months of age who was born to an HIV-infected mother or had a positive HIV antibody test result is classified for surveillance purposes as not infected with HIV if all 3 of the following criteria are met:

1) Laboratory criteria for HIV infection are not met, **AND**
2) No diagnosis of a stage-3-defining opportunistic illness (Appendix) attributed to HIV infection, **AND**
3) Either laboratory or clinical evidence of absence of HIV infection as described below.

Laboratory evidence

Definitively uninfected

- No positive HIV NAT (RNA or DNA) and at least 1 of the following criteria:
    - At least 2 negative HIV NATs from specimens obtained on different dates, both of which were at age ≥1 month and 1 of which was at age ≥4 months
    - At least 2 negative HIV antibody tests from specimens obtained on different dates at age ≥6 months

Presumptively uninfected

- Criteria for definitively uninfected with HIV are not met and at least 1 of the following 4 laboratory criteria are met:
    - At least 2 negative NATs from specimens obtained on different dates, both of which were at age ≥2 weeks and 1 of which was at age ≥4 weeks
    - One negative NAT (RNA or DNA) from a specimen obtained at age ≥8 weeks
    - One negative HIV antibody test from a specimen obtained at age ≥6 months

- If criteria for HIV infection had initially been met by 1 positive HIV NAT test, then it must have been followed by at least 2 negative test results from specimens obtained on different dates, 1 of which is:
  - A NAT test from a specimen obtained at age ≥8 weeks, **OR**
  - An HIV antibody test from a specimen obtained at age ≥6 months and no subsequent positive NAT.

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

Indeterminate HIV infection status

A child <18 months of age born to an HIV-infected mother is categorized as having perinatal exposure with an indeterminate HIV infection status if neither the criteria for being HIV-infected nor the criteria for being uninfected are met.

Criteria for classifying the stage of HIV infection

The stages of HIV infection defined in this document are for surveillance staging of disease and might not be appropriate for patient care, clinical research, or other purposes.

A confirmed case that meets the criteria for diagnosis of HIV infection can be classified in 1 of 5 HIV infection stages (0, 1, 2, 3, or unknown):

- Stage 0 indicates early HIV infection, inferred from a negative or indeterminate HIV test result within 6 months of a confirmed positive result, and these criteria supersede and are independent of the criteria used for later stages.
- Stages 1, 2, and 3 are based on the CD4+ T-lymphocyte count. If the CD4+ count is missing or unknown, the CD4+ T-lymphocyte percentage of total lymphocytes can be used to assign the stage.
- Cases with no information on CD4+ T-lymphocyte count or percentage are classified as stage unknown.

If a stage-3-defining opportunistic illness has been diagnosed, then the stage is 3, regardless of CD4 T-lymphocyte test results, unless the criteria described below for stage 0 are met. CD4+ T-lymphocyte counts or percentages at the time of diagnosis allow classification of cases by stage at diagnosis. Subsequent CD4+ T-lymphocyte counts or percentages help monitor disease progression and whether the person is receiving ongoing care.

The stage characterizes the status of HIV disease at a particular point in time. Of primary interest to surveillance is the stage at initial diagnosis, but the stage can change in either direction after

diagnosis and might be defined with reference to dates of interest such as the most advanced stage recorded through a particular date. The stages are defined as follows:

Stage 0

The criteria for stage 0 consist of a sequence of discordant test results indicative of early HIV infection in which a negative or indeterminate result was within 180 days of a positive result. The criteria for stage 0 supersede and are independent of the criteria used for other stages.

Stage 0 can be established either:

- Based on testing history (previous negative/indeterminate test results):
    - A negative or indeterminate HIV test (antibody, combination antigen/antibody, or nucleic acid test) result within 180 days before the first confirmed positive HIV test result of any type. The first positive test result could be any time before the positive supplemental test result that confirms it, **OR**
- Based on a testing algorithm:
    - A sequence of tests performed as part of a laboratory testing algorithm that demonstrate the presence of HIV-specific viral markers such as p24 antigen or nucleic acid (RNA or DNA) 0-180 days before or after an antibody test that had a negative or indeterminate result.
    - Examples of algorithms that would fulfill this requirement include:
        - A positive initial HIV immunoassay result (e.g., antigen/antibody or antibody only) followed by a negative or indeterminate supplemental antibody test result (e.g., HIV-1/HIV-2 antibody differentiation assay or Western blot) and a positive NAT result. All 3 tests are usually performed as part of the same testing algorithm but time might elapse between tests if additional specimens must be obtained for definitive supplemental testing.
        - A negative initial HIV immunoassay result followed by a positive NAT result that might have been done to evaluate the presence of acute HIV infection.

Exceptions

A confirmed case of HIV infection is not in stage 0 if any of the following are true:

- The negative or indeterminate HIV test used as the criterion for it being a recent infection was preceded >60 days by evidence of HIV infection, such as a confirmed positive HIV test result, a clinical (physician-documented) diagnosis of HIV infection for which the surveillance staff have not found sufficient laboratory evidence, a CD4+ T-lymphocyte test result indicative of stage 3, or an opportunistic illness indicative of stage 3 (Appendix).
- The case definition for HIV-2 infection is met. (An HIV-1 antibody test may be nonreactive or indeterminate due to its inability to detect HIV-2 antibodies, and an HIV-1 NAT may be negative due to its inability to detect HIV-2 nucleic acid, rather than due to absence or earliness of HIV-2 infection.)

Classifying a case as stage 0 depends on documenting negative HIV antibody test results in the specific situations described above.

Progression of stage after initial diagnosis in Stage 0

Although the stage at diagnosis does not change, if >180 days have elapsed after the stage was 0 at diagnosis, the stage at the later date is classified as 1, 2, 3, or unknown, depending on CD4+ T-lymphocyte test results or whether an opportunistic illness had been diagnosed >180 days after HIV infection diagnosis.

Stages 1, 2, 3, and unknown

If the criteria for stage 0 are not met, the stage is classified as 1, 2, 3, or unknown, depending on CD4+ T-lymphocyte test results or whether an opportunistic illness was diagnosed.

Stage 1

- Criteria for stage 0 not met
- No stage-3-defining opportunistic illness (Appendix)
- CD4+ T-lymphocyte test results:
    - CD4 count of >500 cells/µL **OR**
    - If CD4 count is unknown, a CD4+ T-lymphocyte percentage of total lymphocytes of >26%.

Stage 2

- Criteria for stage 0 not met
- No stage-3-defining opportunistic illness (Appendix)
- CD4+ T-lymphocyte test results:
    - CD4 count of 200–499 cells/µL **OR**
    - If CD4 count is unknown, a CD4 percentage of 14%–26.

Stage 3

- Criteria for stage 0 not met
- One or both of the following:
    - Stage-3-defining opportunistic illness (Appendix), **OR**
    - CD4+ T-lymphocyte test results:
        - CD4 count of <200 cells/µL **OR**
        - If CD4 count is unknown, a CD4 percentage of <14%

Whatever method was used to make the diagnosis of any of the opportunistic illnesses will be accepted as sufficient (eliminating the previous requirement for some of them to be "definitively" diagnosed). These changes will be applied only to cases reported after implementation of this revision, not retroactively to previously reported cases.

Stage unknown

- Criteria for stage 0 not met.
- No information available on CD4+ T-lymphocyte count or percentage.
- No information available on stage-3-defining opportunistic illness (Appendix).

Children aged <13 years

Infection among children aged 6–12 years is staged with the same criteria as infection among adults and adolescents, including opportunistic illnesses indicative of stage 3 (Appendix) that formerly applied only to adults and adolescents (e.g., pulmonary tuberculosis, recurrent pneumonia, and cervical cancer). Multiple or recurrent bacterial infections (other than recurrent *Salmonella* septicemia), which formerly applied only to children aged <13 years, now apply only to children aged <6 years. Lymphoid interstitial pneumonia is no longer classified as indicative of stage 3 in children because it is associated with moderate rather than severe immunodeficiency. The diagnosis of any of the opportunistic illnesses, irrespective of diagnostic method used, will meet the criteria for staging, thereby eliminating the requirement in the 2008 case definition for some of them to be "definitively" diagnosed.

In addition, the criteria for stage 0 in adults/adolescents may also be applied to children if they are known not to have acquired HIV infection perinatally from their mother. For those aged <18 months, this requires previously meeting the criteria for definitive absence of HIV infection. If the criteria for stage 0 are not met or >180 days have elapsed after diagnosis in stage 0, the stage at the later date is classified as either 3 or "U" (undefined), depending on whether an opportunistic illness has been diagnosed (Appendix).

The criteria for staging in children differ from those in adults/adolescents. Stage 3 in children is based on the diagnosis of opportunistic infections, and not on CD4+ T-lymphocyte test results. Stages 1 and 2 in children are undefined because a consensus has not yet been reached on which CD4 test results should define the boundaries between stages 1, 2, and 3 in children.

Classification tables

Criteria for defining a confirmed case of HIV infection

Note: The criteria in the following table are intended to reflect the criteria for a confirmed case in the narrative description in *Criteria for a confirmed case* section above.

Criteria for a confirmed case	Age at diagnosis						
	>18 months				<18 months		
	Definitive			Clinical	Definitive*	Presumptive*	Clinical
Laboratory evidence							
HIV test date (at least the year)	N	N	N		N	N	
Positive result on initial HIV antibody test in algorithm	N						
Positive result on initial HIV combination antigen/antibody test wherein which of the 2 components (antibody or antigen) was positive cannot be differentiated		N					
Positive result on supplemental HIV antibody test that verifies result of initial test in algorithm	N	N					
Positive result on HIV antibody test used only as supplemental test (e.g., Western blot, immunofluorescence assay) or on conclusion of antibody test algorithm			O				
Positive result on HIV p24 antigen test			O		O (if age≥1 month)	O (if age≥1 month)	
Positive result on HIV nucleic acid test (DNA or RNA)			O		O	O	
Positive result on HIV isolation (viral culture)			O		O	O	
HIV genotype nucleotide sequence			O		O	O	
At least 2 such results from separate specimens					O		
Results from only 1 specimen						O	
No subsequent negative results on HIV virologic or HIV antibody tests						N	

Clinical evidence							
Physician's note stating patient has HIV infection				N			N
Retrospective validation of note by subsequent laboratory evidence as described above				O			O
Circumstantial evidence of HIV infection (e.g., antiretroviral therapy, low CD4 count, diagnosis of opportunistic illness)				O			O

Notes:

N = All "N" criteria in the same column are Necessary to classify a case as confirmed.

O = At least one of the "O" (Optional) criteria in each category in the same column—in conjunction with the "N" criterion in the same column—is required to classify a case as confirmed.

*"Definitive" diagnosis requires positive results from 2 separate specimens (excluding cord blood) for 1 or more of the tests marked by an "N." "Presumptive" diagnosis requires a positive result from only 1 specimen for the test.

Criteria for classifying the HIV type as HIV-2

Note: The laboratory criteria in the following table are intended to reflect the criteria in the narrative description in *Criteria for classifying the HIV type as HIV-2* section above. In children aged <18 months, a confirmed diagnosis of HIV infection must be established (Table 1) before the following criteria are applied to determine the HIV type.

Criteria	**Classification**	
HIV test date (at least the year)	N	N
Positive result on initial/screening HIV antibody test that can detect HIV-2 antibody (e.g., HIV-1/2 immunoassay)	N	
Positive result on initial HIV combination antigen/antibody test that can detect HIV-2 antibody		N
Positive result for HIV-2 AND negative result for HIV-1 on FDA-approved HIV-1/2 type-differentiating antibody test	O	O
Positive result on HIV-2 Western blot (or immunoblot or line assay) antibody test AND negative result on HIV-1 Western blot antibody test	O	O
Positive result on HIV-2 nucleic acid (DNA or RNA) test	O	O
Diagnosis of HIV-2 infection by CDC-recognized expert in interpretation of Western blots if HIV-2 WB is positive and HIV-1 WB is positive or indeterminate	O	O

Notes:

N = All "N" criteria in the same column are **N**ecessary to classify the HIV type as HIV-2.

O = At least 1 of these "O" (**O**ptional) criteria in each category in the same column—in conjunction with the "N" criteria in the same column—is required to classify the HIV type as HIV-2.

Criteria for classifications of HIV infection status other than definitively or presumptively infected in perinatally exposed children aged <18 months

Note: The criteria in the following table are intended to reflect the criteria in the narrative description in *Criteria for other classifications of the HIV infection status of perinatally exposed children aged <18 months* section above.

Criteria	Classification			
	Definitively uninfected based on lab evidence	Presumptively uninfected based on lab evidence	Uninfected based on clinical evidence	Indeterminate infection status
Laboratory evidence				
Laboratory criteria for definitive or presumptive HIV infection not met	N	N	N	N
No diagnosis of stage-3-defining opportunistic illness that could not be attributed to a cause of immunosuppression other than HIV	N	N		
At least 2 negative HIV DNA or RNA tests from separate specimens, both of which were obtained at age >1 month and 1 of which was obtained at age >4 months	O			
At least 2 negative HIV antibody tests from separate specimens obtained at age >6 months	O			
Criteria for definitively uninfected with HIV not met		N		
At least 2 negative nucleic acid (RNA or DNA) tests (NATs), from separate specimens, both obtained at age >2 weeks and one obtained at age >4 weeks		O		
One negative NAT from a specimen obtained at age >8 weeks		O		

If criteria for presumptive HIV infection were initially met by 1 positive HIV NAT: At least 2 negative tests from separate specimens, 1 of which is a NAT from a specimen obtained at age >8 weeks		O		
If criteria for presumptive HIV infection were initially met by 1 positive HIV NAT: At least 2 negative tests from separate specimens, 1 of which is an HIV antibody test obtained at age >6 months		O		
Laboratory criteria for definitive or presumptive HIV infection not met	N	N	N	N
Clinical evidence				
Note written by qualified medical care provider states patient is not HIV infected			N	
Combined laboratory and clinical evidence				
Above criteria in this table for being uninfected not met				N

Notes:

N = All "N" criteria in the same column are **N**ecessary to classify a case as confirmed.

O = At least 1 of these "O" (**O**ptional) criteria in each category in the same column—in conjunction with the "N" criteria in the same column—is required to classify a case as confirmed.

Note: The criteria in the following table are intended to reflect the first part of the criteria for staging in the narrative description in *Criteria for the classifying the stage of HIV infection—stage 0* section above.

Criteria for classifying the stage of HIV infection as stage 0

	Retrospective detection	**Prospective detection**
Laboratory evidence		
First positive HIV test was 1 to 180 days after negative, undetectable, or indeterminate HIV test.	N	
First positive HIV test was 0 to 30 days before negative or indeterminate HIV antibody test.		N
First positive test was confirmed by a second positive HIV test 0 to 30 days after negative/indeterminate antibody test.		N

The negative/indeterminate antibody test was less sensitive than first positive test (based on the test sensitivity ranking listed below).		N
The negative/indeterminate antibody test was less sensitive than the second positive test (based on the test sensitivity ranking listed below) if those tests were on the same date.		N
Type of HIV is not HIV-2 (See criteria for HIV-2 in Table 2)	N	N
The negative, indeterminate, or undetectable HIV test result used as the criterion for earliness of infection was not >60 days after an HIV infection diagnosis based on clinical (non-laboratory) evidence, a CD4+ T-lymphocyte count <200 cells/μL, or diagnosis of an opportunistic illness indicative of stage 3 HIV infection (see Appendix).	N	N
Combined laboratory and clinical evidence		
Criteria for confirmed case of HIV infection (Table 1) were met	N	N
≤180 days have elapsed after diagnosis	N	N
Epidemiologic evidence		
HIV infection was not acquired perinatally from biological mother	N	N

Notes:
N = All "N" criteria in the same column are **N**ecessary to classify the stage as stage 0.

HIV test sensitivity tiers, ranked in descending order of sensitivity:

1. Nucleic acid test (NAT), qualitative or quantitative (assumed most sensitive)
2. Combination antigen/antibody test
3. EIA (not rapid, not type-differentiating, assumed able to detect IgM)
4. Rapid immunoassay, including HIV-1/HIV-2 viral type-differentiating rapid tests
5. HIV-1 Western blot, immunoblot, line immunoassay, or immunofluorescence assay (assumed least sensitive)

Criteria for classifying the stage of HIV infection as stage 1, 2, 3, or unknown

Note: The criteria in the following table are intended to reflect the remaining part of the criteria for staging in the narrative description in *Criteria for the classifying the stage of HIV infection—stage 1, 2, 3, or unknown* section above.

Criteria for stage	Age					
	≥13 years				<13 years	
Stage	**1**	**2**	**3**	**Unknown**	**3**	**Unknown**
Laboratory evidence						
Criteria for stage 0 not met	N	N	N	N	N	N
CD4+ T-lymphocyte count >500 cells/μL, or, if unknown, CD4+ T lymphocyte percentage of total lymphocytes >26%	N					
CD4+ T-lymphocyte count 200–499 cells/μL, or, if unknown, CD4+ T lymphocyte percentage 14%–26%		N				
CD4+ T-lymphocyte count <200 cells/μL, or, if unknown, CD4+ T lymphocyte percentage <14%			O			
CD4+ T-lymphocyte count and percentage unknown				N		
Clinical evidence						
Diagnosis of opportunistic illness			O		N	
No diagnosis of opportunistic illness						N

Notes:

N = All "N" criteria in the same column are **N**ecessary to classify the stage as 1, 2, 3, or U (Unknown/undefined).

O = At least one of these "O" (**O**ptional) criteria in each category in the same column—in conjunction with the "N" criteria in the same column—is required to classify the stage.

Note: The stage characterizes the status of HIV infection at a particular date. The stage may be defined in alternative ways with reference to the date of interest. For example, the stage on the date of initial diagnosis (which does not change over time, and may be based on CD4+ T-lymphocyte values within a short time [e.g., 3 months] of diagnosis), the stage based on the lowest CD4+ T-lymphocyte values through a particular date (for which changes in stage are in only 1 direction–—from less to more severe), or the stage based on the most recent CD4+ T-lymphocyte test results (for which changes can be in either direction—from more to less severe, or from less to more severe). "U" means "unknown stage" for persons aged ≥13 years or "stage undefined" for persons aged <13 years.

Case investigation process

HIV cases reported to public health will be investigated to ensure linkage to medical care and ensure proper education is given to the patient. Contact tracing is performed to prevent further

spread of the virus. Important demographic and risk behavior information will be obtained during the course of the investigation to enable performance of surveillance activities which are designed to maintain situational awareness of the HIV epidemic in Utah and inform future HIV prevention strategies.

Outbreaks

HIV outbreaks of significant concern are rarely observed. However, CDC has provided guidance regarding detection of molecular and time-space clusters, which detects smaller clusters on a regular basis. As part of the Utah DHHS “Getting to Zero” plan, all clusters need to be investigated in a timely fashion. A cluster detection and response plan is available upon request. DHHS will work with local health departments to respond appropriately when clusters of cases or an HIV outbreak is observed.

Identifying case contacts

The contact investigation is an integral part of finding contacts. Patients should be instructed to identify their sex partners and needle-sharing partners for testing.

Case contact management

All contacts should be evaluated, and tested if they had sexual contact or shared a needle with the patient during the 12 months preceding the diagnosis of the patient, or 6 months from the patient’s last negative test, or if married during the past 10 years. If sexual contact or needle sharing occurred during the preceding 3 months (window period), these contacts need to be re-tested after 3 months of their last contact.

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Version control

V1.06.15: The new disease plan format was applied. All existing sections were updated with most current information. New sections were added: Why HIV is important to public health; HIV 4th generation testing algorithm; Minimum datasets.

V2.04.16: Updated the Epidemiology section with new data for Utah. Updated the Rapid testing section to reflect the current guidance and recommended testing algorithm.

V3.11.18: New disease plan format applied: Critical clinician information and electronic laboratory reporting processing rules added. Included specific PEP treatment regimens. Added information from CDC technical updates to the testing algorithm. Updated minimum data set to reflect CDC mandated changes. Updated references to reflect new information.

V3.23.23: New disease plan format applied. Updated minimum data set to reflect changes needed for effective cluster investigation. Updated PrEP guidance to reflect current CDC guidelines, and updated dolutegravir warning to reflect current research. Posted 2023 versions of case report forms for both adult and pediatric infections.

UT-NEDSS/EpiTrax minimum/required fields by tab

Morbidity event

Demographic

- Date first reported to public health
- Last name
- First name
- Middle name
- Date of birth
- Current address
  - Street
  - Unit number
  - City
  - State
  - County
  - ZIP code
- Address at diagnosis
  - Street
  - Unit number
  - City
  - State
  - County
  - ZIP code
- Area code
- Phone number
- Birth sex
- Current gender identity
- Ethnicity
- Race
- Country of birth

Clinical

- Disease
- Health facility
- Clinician last name
- Medical record number
- Died
  - (if yes) Date of death
- Pregnant
  - (if yes) Currently in prenatal care?
  - (if yes) Weeks gestation at time of first prenatal care visit?
- Has the patient delivered live-born infants prior to the previous 12 months?
- Clinician first name
- Clinician phone
- Diagnostic facility
  - Name
  - City
  - State
- Ever had antiretroviral therapy prior to interview?
  - (if yes) Reason for ARV use
  - (if yes) Treatment date
  - (if yes) Treatment stopped
  - (if yes) Treatment

Laboratory

- Performing lab
- Collection date time
- Specimen source
- Accession number
- Lab type
- Organism
- Test result
- Result value
- Units
- Lab test date time
- Previously tested negative for HIV?
  - (if yes) date of **last** negative HIV test

    - Is this test documented in EpiTrax?
- Previously tested positive for HIV?
    - (if yes) date of **first** positive HIV test
    - Is this test documented in EpiTrax?
- If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician?
    - If YES, provide date of documentation by physician

Contacts

- How many total partners has the case had during the last 12 months?
- Total number of NAMED partners in the last 12 months?
- Total number of NAMED partners with enough information to attempt investigation?

Investigation

Investigation details

- Clinical setting of first diagnostic test
- Did client recently experience (or do clinical notes indicate) signs/symptoms of acute retroviral syndrome (e.g., fever, malaise/fatigue, myalgia, pharyngitis, rash, lymphadenopathy)?
    - (if yes) Approximate date of acute symptom onset
- Attempt to locate outcome
    - (if located) Enrollment status
    - (if not located) Reason for unsuccessful attempt
        - (if Other) Specify the reason why the client was unable to be located
- Was the case interviewed?
    - (if no) Reason not interviewed
    - (if yes) Client informed of test results?
    - (if yes) Date of original interview
    - (if yes) Was client in HIV medical care at the time of the interview?
    - (if yes) Date of 1st HIV medical care appointment
    - (if yes) Was client screened for syphilis?
        - (if yes) Syphilis test result
        - (if yes) Has client ever taken PrEP?
        - (if yes) Approximate date of last PrEP use

- Is the client experiencing homelessness or would otherwise be considered unhoused?

Risk factors

- (if male) Is the patient MSM (a man who has sex with men)?
- During the last 5 years, has the patient had vaginal or anal sex with a transgender person?
- Is the patient a sex worker or often engage in transactional sex?

All other risk questions refer to the past 12 months

- (if female) Did the patient have vaginal or anal sex with a person who is known to her to be MSM (a man who has sex with men)?
- Had vaginal or anal sex with a male?
- Had vaginal or anal sex with a female?
- Had vaginal or anal sex without a condom?
- Had vaginal or anal sex with a person who is known or identified as HIV-positive?
- Had vaginal or anal sex with an IDU (injection drug user)?
- Used injection drugs
- Shared injection drug equipment
- Other risk (specify)

Administrative

- LHD cases status
- State case status
- LHD investigation/intervention started
- LHD investigation/intervention completed

Contact event

Demographic

- State
- ZIP code
- Date of birth
- Birth sex
- Ethnicity
- Race
- Contact disposition
- Contact disposition date

Laboratory

- Test type
- Test result
- Collection date

Investigation

- Cluster ID (cluster investigations only)
- Parent record number (cluster investigations only)
- Was this parent/contact pair known before cluster investigations began? (cluster investigations only)
- Initiation date
- Was contact located?
  - (if no) Reason for unsuccessful attempt
  - (if other) Please specify
- Partner notifiability
- Actual notification method
- Has this partner tested negative for HIV in the past?
- Approximate date of last negative HIV test
- Was contact screened for HIV
  - (if yes) Date of HIV screening test
  - (if yes) Result of HIV screening test
  - (if yes) Has the contact been notified of the results?
  - (if no) Why was no HIV screening test administered?
- Was the contact screened for syphilis?

    - (if yes) Syphilis screening test result
- Is contact currently taking PrEP?
- Was contact referred to a PrEP provider?
- PrEP referral outcome
- Partner type

Cluster investigation

Investigation

- Cluster ID
- Was the client located?
    - (if no) Reason for unsuccessful attempt
        - (if other) Please specify why the client was unable to be located
- Was the client enrolled/re-enrolled in partner services?
- Was the client interviewed?
    - (if no) Reason not interviewed
        - (if other) If other, please specify
- Date of interview
- (For original interviews only) Was client informed of test results?
- Is the client currently pregnant? (answer for cluster investigations only. Original investigations should use the fields available on the clinical tab)
    - (if yes) Is the client currently receiving prenatal care?
        - (if yes) Weeks gestation at first prenatal care visit
- (For original interviews only) Clinical setting of first diagnostic test?
- Was client in HIV medical care at the time of the interview?
- (Original interviews only) Date of first HIV medical care appointment
- Was client screened for syphilis?
- Syphilis test result
- (For original interviews only) Has the client ever taken PrEP?
- (For original interviews only) Approximate date of last PrEP use
- (for original interviews only) Does the client recall (or clinical notes indicate) recently experiencing signs/symptoms of acute retroviral syndrome (e.g., fever, malaise/fatigue, myalgia, pharyngitis, rash, lymphadenopathy)?
    - (if yes) Approximate date of acute symptom onset
- Is the client experiencing homelessness or would otherwise be considered unhoused?
- (if male) Is the patient MSM (a man who has sex with men)?
- During the last 5 years, has the patient had vaginal or anal sex with a transgender person?
- Is the patient a sex worker or often engage in transactional sex?

If this is an original interview, these questions apply to the last 12 months. Otherwise, answer for the period between original investigation and today:

- (if female) Did the patient have vaginal or anal sex with a person

who is known to her to be MSM (a man who has sex with men)?
- Had vaginal or anal sex with a male?
- Had vaginal or anal sex with a female?
- Had vaginal or anal sex without a condom?
- Had vaginal or anal sex with a person who is known or identified as HIV-positive?
- Had vaginal or anal sex with an IDU (injection drug user)?
- Used injection drugs
- Shared injection drug equipment

Case report form

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

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

U.S. Department of Health and Human Services

Adult HIV Confidential Case Report Form

(Patients ≥13 years of age at time of diagnosis) *Information NOT transmitted to CDC

Centers for Disease Control and Prevention (CDC)

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

Form approved OMB no. 0920-0573 Exp. 02/28/2026

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

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

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

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

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

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

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

Public reporting burden of this collection of information is estimated to average 20 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-74, Atlanta, GA 30333, ATTN: PRA (0920-0573). **Do not send the completed form to this address.**

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

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

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

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

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

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

Opportunistic Illnesses

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

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

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

HIV Immunoassays

TEST ☐ HIV-1 IA ☐ HIV-1/2 IA ☐ HIV-1/2 Ag/Ab ☐ HIV-2 IA

Test Brand Name/Manufacturer _____ **Lab Name** _____

Facility Name _____ **Provider Name** _____

Result ☐ Positive ☐ Negative ☐ Indeterminate **Collection Date** __ __/__ __/__ __ __ __

Testing Option (if applicable) ☐ Point-of-care test by provider ☐ Self-test, result directly observed by a provider[2] ☐ Lab test, self-collected sample

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

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

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

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

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

HIV Detection Tests

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

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

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

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

Drug Resistance Tests (Genotypic)

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

Immunologic Tests (CD4 count and percentage)

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

Documentation of Tests

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

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

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

[2]Results not directly observed by a provider should be recorded in HIV Testing History.

[3]Complete the overall interpretation and the analyte results.

[4]Always complete the overall interpretation. Complete the analyte results when available.

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

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

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

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

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

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

XIII. Comments

XIV. *Local/Optional Fields

This report to 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. Information in CDC's National HIV 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, 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).

CDC 50.42A Rev. 01/2023 (Page 4 of 4) —ADULT HIV CONFIDENTIAL CASE REPORT—

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

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

U.S. Department of Health and Human Services

Pediatric HIV Confidential Case Report Form

(Patients aged <13 years at time of perinatal exposure or patients aged <13 years at time of diagnosis) *Information NOT transmitted to CDC

Centers for Disease Control and Prevention (CDC)

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

Form approved OMB no. 0920-0573 Exp. 02/28/2026

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

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

Facility Name	*Phone ( )
*Street Address	
City / County / State/Country / *ZIP Code	
Facility Type — *Inpatient*: ☐ Hospital ☐ Other, specify_____ — *Outpatient*: ☐ Private physician's office ☐ Pediatric clinic ☐ Pediatric HIV clinic ☐ Other, specify_____ — *Other Facility:* ☐ Emergency room ☐ Laboratory ☐ Unknown ☐ Other, specify _____	
Date Form Completed __ __/__ __/__ __ __ __	*Person Completing Form / *Phone ( )

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

Diagnostic Status at Report ☐ 3-Perinatal HIV exposure ☐ 4-Pediatric HIV ☐ 5-Pediatric AIDS ☐ 6-Pediatric seroreverter	Sex Assigned at Birth ☐ Male ☐ Female ☐ Unknown	Country of Birth ☐ US ☐ Other/US dependency (specify) _____
Date of Birth __ __/__ __/__ __ __ __	Alias Date of Birth __ __/__ __/__ __ __ __	
Vital Status ☐ 1-Alive ☐ 2-Dead	Date of Death __ __/__ __/__ __ __ __	State of Death
Date of Last Medical Evaluation __ __/__ __/__ __ __ __	Date of Initial Evaluation for HIV __ __/__ __/__ __ __ __	
Gender Identity ☐ Boy ☐ Girl ☐ Transgender boy ☐ Transgender girl ☐ Additional gender identity (specify) _____ ☐ Declined to answer ☐ Unknown — Date Identified __ __/__ __/__ __ __ __		
Sexual Orientation ☐ Straight or heterosexual ☐ Lesbian or gay ☐ Bisexual ☐ Additional sexual orientation (specify) _____ ☐ Declined to answer ☐ Unknown — Date Identified __ __/__ __/__ __ __ __		
Ethnicity ☐ Hispanic/Latino ☐ Not Hispanic/Latino ☐ Unknown		Expanded Ethnicity
Race (check all that apply) ☐ American Indian/Alaska Native ☐ Asian ☐ Black/African American ☐ Native Hawaiian/Other Pacific Islander ☐ White ☐ Unknown		Expanded Race

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

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

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

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

VII. Patient History (respond to all questions) (record all dates as mm/dd/yyyy)

Birthing person's HIV infection status (select one): ☐ Refused HIV testing ☐ Known to be uninfected after this child's birth ☐ Known HIV+ before pregnancy ☐ Known HIV+ during pregnancy ☐ Known HIV+ sometime before birth ☐ Known HIV+ at delivery ☐ Known HIV+ after child's birth ☐ HIV+, time of diagnosis unknown ☐ HIV status unknown

Date of birthing person's first positive test result to confirm infection __ __ /__ __ /__ __ __ __	**Child breastfed/chestfed by birthing person** ☐ Yes ☐ No ☐ Unknown **Child received premasticated/pre-chewed food from birthing person** ☐ Yes ☐ No ☐ Unknown

After 1977 and before the earliest known diagnosis of HIV infection, the birthing person had:	
Perinatally acquired HIV infection	☐ Yes ☐ No ☐ Unknown
Injected nonprescription drugs	☐ Yes ☐ No ☐ Unknown
Birthing person had HETEROSEXUAL relations with any of the following:	
HETEROSEXUAL contact with person who injected drugs	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL contact with bisexual male	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL contact with person with hemophilia/coagulation disorder with documented HIV infection	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL contact with transfusion recipient with documented HIV infection	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL contact with transplant recipient with documented HIV infection	☐ Yes ☐ No ☐ Unknown
HETEROSEXUAL contact with person with documented HIV infection, risk not specified	☐ Yes ☐ No ☐ Unknown
Birthing person had:	
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments) First date received __ __ /__ __ /__ __ __ __ Last date received __ __ /__ __ /__ __ __ __	☐ Yes ☐ No ☐ Unknown
Received transplant of tissue/organs or artificial insemination	☐ Yes ☐ No ☐ Unknown
Before the diagnosis of HIV infection, this child had:	
Injected nonprescription drugs	☐ Yes ☐ No ☐ Unknown
Received clotting factor for hemophilia/coagulation disorder Specify clotting factor: Date received __ __ /__ __ /__ __ __ __	☐ Yes ☐ No ☐ Unknown
Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments) First date received __ __ /__ __ /__ __ __ __ Last date received __ __ /__ __ /__ __ __ __	☐ Yes ☐ No ☐ Unknown
Received transplant of tissue/organs	☐ Yes ☐ No ☐ Unknown
Sexual contact with male	☐ Yes ☐ No ☐ Unknown
Sexual contact with female	☐ Yes ☐ No ☐ Unknown
Been breastfed/chestfed by non-birthing person	☐ Yes ☐ No ☐ Unknown
Received premasticated/pre-chewed food from non-birthing person	☐ Yes ☐ No ☐ Unknown
Other documented risk (include detail in Comments)	☐ Yes ☐ No ☐ Unknown

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

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

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

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

HIV Immunoassays

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

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

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

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

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

HIV Detection Tests

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

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

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

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

Drug Resistance Tests (Genotypic)

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

Immunologic Tests (CD4 count and percentage)

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

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

Documentation of Tests			
Did documented laboratory test results meet approved HIV diagnostic algorithm criteria? ☐ Yes ☐ No ☐ Unknown **If YES, provide specimen collection date of earliest positive test result for this algorithm** __ __/__ __/__ __ __ __ *Complete the above only if none of the following were positive for **HIV-1**: Western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen, or nucleotide sequence.*			
Is earliest evidence of diagnosis documented by a physician rather than by laboratory test results?	**HIV-infected** ☐ Yes ☐ No ☐ Unknown	**Date of diagnosis by physician** __ __/__ __/__ __ __ __	
	Not HIV-infected ☐ Yes ☐ No ☐ Unknown	**Date of diagnosis by physician** __ __/__ __/__ __ __ __	

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

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

Birth history available? ☐ Yes ☐ No ☐ Unknown			
Residence at Birth	☐ Check if SAME as current address		
Address Type ☐ Residential ☐ Bad address ☐ Correctional facility ☐ Foster home ☐ Homeless ☐ Military ☐ Other ☐ Postal ☐ Shelter ☐ Temporary			
***Street Address**	**City**		
County	**State/Country**	***ZIP Code**	
Facility of Birth	☐ Check if SAME as facility providing information		
Facility Name of Birth (if child was born at home, enter "home birth")		***Phone** ( )	
Facility Type *Inpatient*: ☐ Hospital ☐ Other, specify_____	*Outpatient*: ☐ Other, specify_____	*Other Facility*: ☐ Emergency room ☐ Corrections ☐ Unknown ☐ Other, specify_____	
***Street Address**	**City**		
County	**State/Country**	***ZIP Code**	
Birth History	**Birth Weight** _____lbs _____oz _____grams	**Type** ☐ 1-Single ☐ 2-Twin ☐ 3-More than two ☐ 9-Unknown	

Delivery ☐ Vaginal ☐ Cesarean ☐ Unknown
If Cesarean delivery, mark all the following indications that apply.
☐ HIV indication (high viral load) ☐ Previous Cesarean (repeat) ☐ Malpresentation (breech, transverse)
☐ Prolonged labor or failure to progress ☐ Birthing person's or physician's preference ☐ Fetal distress
☐ Placenta abruptia or p. previa ☐ Other (e.g., herpes, disproportion) (Specify) _____
☐ Not specified

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

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

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

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

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

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

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

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

If YES, specify how many previous pregnancies _____

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

(Record additional pregnancy outcomes in Comments)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Record additional ARV medications in Comments)

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

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

XIII. Comments

XIV. *Local/Optional Fields

Electronic laboratory reporting processing rules

HIV rules for entering laboratory test results

The following rules describe how laboratory results reported to public health should be added to new or existing events in UT-NEDSS/EpiTrax. These rules have been developed for the automated processing of electronic laboratory reports, although they also apply to manual data entry.

Test-specific rules

Test-specific rules describe what test type and test result combinations are allowed to create new morbidity events in UT-NEDSS/EpiTrax, and what test type and test result combinations are allowed to update existing events (morbidity or contact) in UT-NEDSS/EpiTrax.

Test type	Test result	Create a new event	Update an existing event
Antigen/antibody combination	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	Yes	Yes
Antigen by EIA/ELISA	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	Yes	Yes
Culture	Positive	Yes	Yes
	Negative	Yes	Yes
	Equivocal	Yes	Yes
Genotyping	Positive	Yes	Yes
	Negative	Yes	Yes
	Equivocal	Yes	Yes
PCR/amplification	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	Yes	Yes
Rapid	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	Yes	Yes
Total antibody	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	Yes	Yes
Typing	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	Yes	Yes

Viral Load- Qualitative	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	Yes	Yes
Viral Load- Quantitative	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	Yes	Yes
Western (immune) blot	Positive	Yes	Yes
	Negative	No	Yes
	Equivocal	Yes	Yes

Whitelist rules

Whitelist rules describe how long an existing event can have new laboratory data appended to it. If a laboratory result falls outside the whitelist rules for an existing event, it should not be added to that event, and should be evaluated to determine if a new event (CMR) should be created.

HIV infection morbidity whitelist rule: Never a new case

HIV infection contact whitelist rule: Never added to a contact

Graylist rule

We often receive laboratory results through ELR that cannot create cases, but can be useful if a case is created in the future. These laboratory results go to the graylist. The graylist rule describes how long an existing event can have an old laboratory result appended to it.

HIV infection graylist rule: If the specimen collection date of the laboratory result is 18 months before to 7 days after the event date of the morbidity event, the laboratory result should be added to the morbidity event.

Other electronic laboratory processing rules

- If an existing event has a state case status of “not a case,” ELR will never add additional test results to that case. New labs will be evaluated to determine if a new CMR should be created.

Appendix

Stage 3-defining opportunistic illnesses in HIV infection

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 attributed to HIV§
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
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 (previously known as "*Pneumocystis carinii*") 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 <6 years.

† Only among adults, adolescents, and children aged ≥6 years.

§ Suggested diagnostic criteria for these illnesses, which might be particularly important for HIV encephalopathy and HIV wasting syndrome, are described in the following references:
CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43(No. RR-12).
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).