



Human Immunodeficiency Virus

Disease Plan

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Last updated: 04/04/2019, by Luke Edvalson

Questions about this disease plan?

Contact the Utah Department of Health Bureau of Epidemiology: 801-538-6191.

✓ **CRITICAL CLINICIAN INFORMATION**

Clinical Evidence
<p>Signs/Symptoms</p> <ul style="list-style-type: none"> • Acute illness may include flu-like symptoms including <ul style="list-style-type: none"> ○ 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
<p>Period of Communicability</p> <ul style="list-style-type: none"> • Indefinite
<p>Incubation Period</p> <ul style="list-style-type: none"> • Generally between 2 – 6 weeks from exposure to acute illness • Generally between 7 – 12 years from exposure to Stage 3 infection (AIDS)
<p>Mode of Transmission</p> <ul style="list-style-type: none"> • Sexual • Blood-borne Pathogen • Perinatal (mother-to-child)
Laboratory Testing
<p>Type of Lab Test/Timing of Specimen Collection</p> <ul style="list-style-type: none"> • 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
<p>Type of Specimens</p> <ul style="list-style-type: none"> • Serum or Plasma • Whole blood may be used for Type-Differentiating Immunoassays, but not Ag/Abs or NATs
Treatment Recommendations
<p>Type of Treatment</p> <ul style="list-style-type: none"> • 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: https://aidsinfo.nih.gov/guidelines

<p>Time Period to Treat</p> <ul style="list-style-type: none"> From diagnosis until death unless clinically contraindicated
<p>Prophylaxis</p> <ul style="list-style-type: none"> Post Exposure Prophylaxis (PEP) <ul style="list-style-type: none"> Must begin within 72 hours of exposure and should run for 28 days Preferred regimen for otherwise healthy adults and adolescents: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> tenofovir DF (300mg) with emtricitabine (FTC) (200mg) once daily plus darunavir (DRV) (800mg) and ritonavir (RTV) (100mg) once daily Health care providers prescribing PEP should avoid use of dolutegravir (DTG) for: <ul style="list-style-type: none"> Non-pregnant women of childbearing potential who are sexually active or have been sexually assaulted and who are not using an effective birth control method Pregnant women early in pregnancy (especially the first 28 days) Regimens for children, persons with decreased renal function, and pregnant women as well as the full PEP guidelines are available here: https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf Pre-exposure Prophylaxis (PrEP) <ul style="list-style-type: none"> For use in people at very high risk for HIV infection (a more complete treatment of PrEP can be found in the Treatment section of “Disease and Epidemiology”) tenofovir disoproxil fumarate (tenofovir DF or TDF) (300mg) with emtricitabine (200mg) once daily TDF alone has shown substantial efficacy and safety in trials with PWID and heterosexually active adults and can be considered as an alternative regimen for these populations, but not for men who have sex with men (MSM), among whom its efficacy has not been studied The use of other antiretroviral medications for PrEP, either in place of or in addition to TDF/FTC (or TDF) is not recommended The prescription of oral PrEP for coitally-timed or other non-continuous daily use is not recommended
<p>Contact Management</p>
<p>Isolation of Case</p> <ul style="list-style-type: none"> Universal Precautions
<p>Quarantine of Contacts</p> <ul style="list-style-type: none"> Not Applicable
<p>Infection Control Procedures</p>
<ul style="list-style-type: none"> Universal Precautions

✓ WHY IS HIV IMPORTANT TO PUBLIC HEALTH?

Human immunodeficiency virus (HIV) is a retrovirus that affects the cellular immunity of those 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 health care 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 being affected through public health surveillance and research. Prevention efforts, such as education, prophylaxis, and antiretroviral treatment are essential for reducing the spread of HIV.

✓ 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:

- Some people have a flu-like illness within a month or two 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 with AIDS, opportunistic infections are often severe and sometimes fatal because the immune system is so ravaged by 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, and vomiting, weight loss and extreme fatigue, and severe headaches.

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 seven subtypes. 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 that 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.

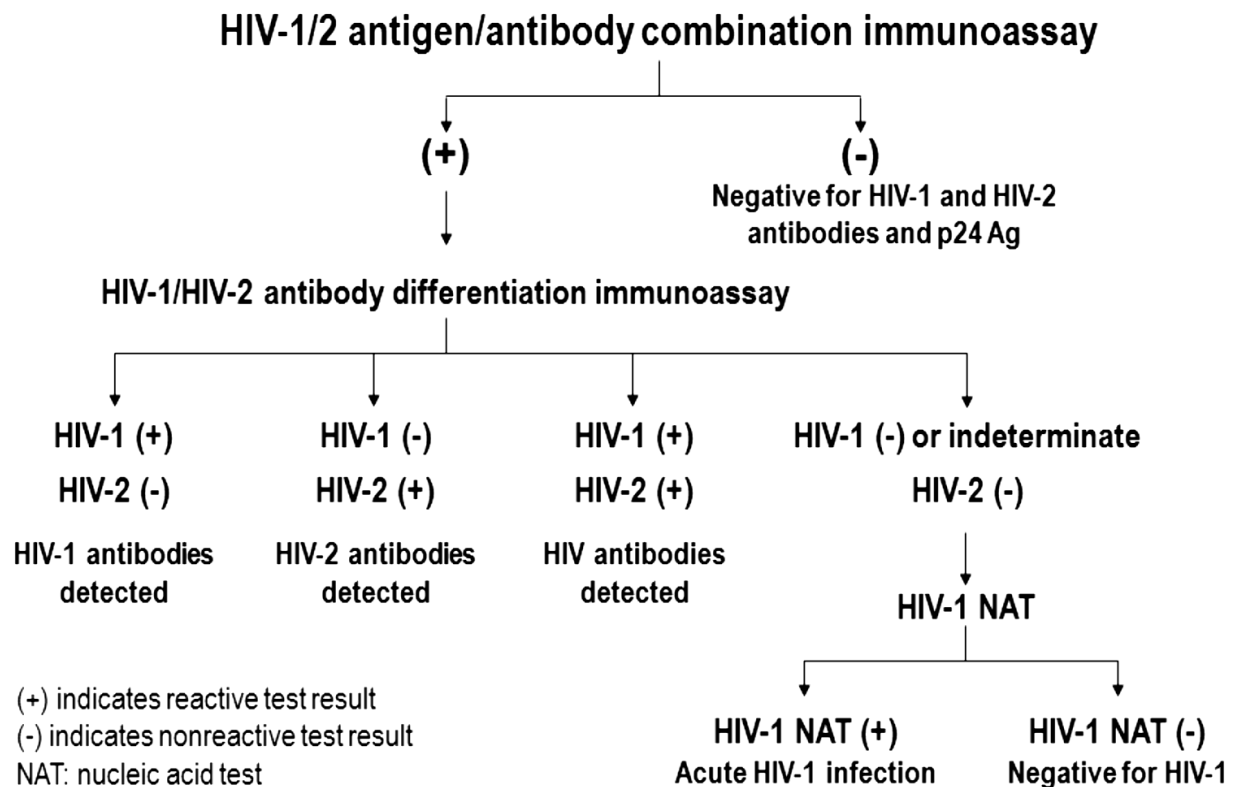
Specimens that are reactive on the initial antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 nucleic acid test (NAT). Currently, there is only one such test approved for the diagnosis 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 that 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.



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, please visit <https://aidsinfo.nih.gov/guidelines> or <https://hab.hrsa.gov/clinical-quality-management/clinical-care-guidelines-and-resources>.

Case Fatality

The proportion of HIV-infected persons who, in the absence of anti-HIV treatment, will ultimately develop AIDS has been estimated at over 90%. In the absence of effective treatment, the AIDS case-fatality rate is very high. Survival time in many developing countries is often under one 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 12,333 people with an AIDS diagnosis died in 2014.

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.

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 that circumcision of males is protective against infection.

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 one 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 have progressed to AIDS within the first 2–3 years following infection, while up to 5% of individuals in studies have stable CD4+ T cell counts and no symptoms even after 12 or more years.

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 zero) 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 over two decades, according to the latest available data – a testament to the impact of the world's efforts to vanquish the global HIV epidemic. The estimated 2.1 million [1.8–2.4 million] people globally who acquired HIV for the first time in 2015 were 15% fewer than the 2.5 million [2.3–2.7 million] who acquired the virus in 2009. In addition, the 1.1 million [940,000 – 1.3 million] who died of HIV-related causes in 2015 were 43% fewer than 2003; the year that targets for treatment with antiretrovirals were first set. (WHO, Global Health Sector Strategy on HIV, 2016-2021, 2016).

CDC estimates that 973,846 people were living with diagnosed HIV infection in the United States at the end of 2015. An estimated additional 162,500 persons over 13 years of age (15%) were unaware of their infection. 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 remained stable overall in recent years, at about 40,000 new HIV infections per year. 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, African Americans continue to be disproportionately affected.

HIV Diagnoses (new diagnoses, regardless of when infection occurred or stage of disease at diagnosis): In 2016, an estimated 39,782 people were diagnosed with HIV infection in the United States. In that same year, an estimated 18,409 people were diagnosed with AIDS. Overall, an estimated 1,268,595 people in the United States have been diagnosed with AIDS between 2011 and 2016.

In Utah, there were 3,169 HIV-infected individuals assumed to be alive and residing in Utah as of December 31, 2016. Males, accounting for 85% of the infections, continue to be primarily affected by HIV in Utah. The majority (56%) of individuals with HIV are MSM, followed by MSM/IDU (injection drug use) at 13% and IDU at 9%. Individuals reporting heterosexual risk account for 9%, however, roughly 13% 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 decreased over the last decade from 5.0 infections per 100,000 in 2005 to 3.7 per 100,000 in 2017.

✓ 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 of 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 of HIV infection.
- The specific needs of minorities; persons with different primary languages and those with visual, hearing or other impairments must be addressed.
- 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 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 for treating 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 raising awareness of HIV status, promoting behavioral change and diagnosing HIV infection.
- Pregnant women should be counseled about HIV early in pregnancy and where culturally and socially appropriate, encourage a 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 woman to her baby is significantly reduced if the mother takes zidovudine, or other anti-retroviral agents during pregnancy, labor, and delivery, and if her baby is treated for the first six weeks of life.

Chemoprophylaxis

There are two 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 of infection.

PEP: Must begin within 72 hours of the suspected exposure. Persons beginning PEP should be prescribed a 28 day course. A full set of PEP guidelines can be found here:

<https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>

Care must be taken to **avoid prescribing dolutegravir (DTG) to the following populations:**

- Non-pregnant women of childbearing potential who are sexually active or have been sexually assaulted and who are not using an effective birth control method
- Pregnant women early in pregnancy, since the risk of an unborn infant developing a neural tube defect is during the first 28 days

The official statement regarding dolutegravir (DTG) and women is available here:

<https://www.cdc.gov/hiv/pdf/basics/cdc-hiv-dolutegravir-alert.pdf>

The following is a reproduced table of HIV PEP regimens recommended by CDC

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 <i>with</i> raltegravir 400mg twice daily <i>or</i> dolutegravir 50mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300mg and fixed dose combination emtricitabine 200mg (Truvada) once daily <i>with</i> darunavir 800mg (as 2, 400mg tablets) once daily <i>and</i> 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 <i>with</i> raltegravir 400mg twice daily <i>or</i> dolutegravir 50mg once daily
	Alternative	A 3-drug regimen consisting of zidovudine and lamivudine, with both doses adjusted to degree of renal function <i>with</i> darunavir 800mg (as 2, 400mg tablets) once daily <i>and</i> 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 <i>with</i> raltegravir <i>or</i> 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 ^f –≤ 2 years	Preferred	A 3-drug regimen consisting of zidovudine oral solution and lamivudine oral solution <i>with</i> raltegravir <i>or</i> lopinavir/ritonavir ^b oral solution (Kaletra ^g), with each drug dosed to age and weight ^d
		A 3-drug regimen consisting of zidovudine oral solution and emtricitabine oral solution

	Alternative	<p style="text-align: center;">with</p> <p>raltegravir</p> <p style="text-align: center;">or</p> <p>lopinavir/ritonavir^b solution (Kaletra), with each drug adjusted to age and weight^d</p>
Children aged birth–27 days	Consult a pediatric HIV specialist	
<p>^a These recommendations do not reflect current Food and Drug Administration-approved labeling for antiretroviral medications listed in this table</p> <p>^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 against HIV in the above “3-drug” regimens</p> <p>^c Gilead Sciences, Inc., Foster City, California</p> <p>^d See also Table 6 in https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf</p> <p>^e Darunavir only FDA-approved for use among children aged ≥3 years</p> <p>^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</p> <p>^g AbbVie, Inc., North Chicago, Illinois</p>		

PrEP: There is currently only one FDA-approved PrEP regimen: tenofovir DF 300mg and fixed-dose combination emtricitabine 200mg (Truvada). By taking this one pill daily, persons at high risk of HIV infection from sexual practices or injection drug use can significantly reduce their chances of acquiring HIV. It is up to 92% effective in preventing sexual transmission and more than 70% effective in preventing HIV transmission from injection drug use. The drug is not nearly as effective when not taken consistently.

The full set of PrEP guidelines can be found here:

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

The clinical provider’s supplement can be found here: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>

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 every day and seeing their healthcare provider for follow-up every three months.

Vaccine

None.

Isolation and Quarantine Requirements

Isolation: None

Hospital: Standard body substance precautions.

Quarantine: Not applicable.

✓ CASE INVESTIGATION

Reporting

HIV infections (including AIDS) are required by Utah law to be reported to public health within three working days after identification. R386-702-4 (b). Reporting. Reporting of HIV-related test results and specific patient information are also required. R386-702-9. Special Measures for the Control of HIV/AIDS.

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

Criterion	Potential HIV Infection
<i>Laboratory Evidence</i>	
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
<i>Clinical Evidence</i>	
HIV diagnosis documented in medical record or death certificate	S
<i>Epidemiological Evidence</i>	
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 Prevention, Treatment and Care Program (PTCP) of the Utah Department of Health 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 with preliminary positive results to medical care, partner services and HIV Prevention Services.

The PTCP 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 less 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:

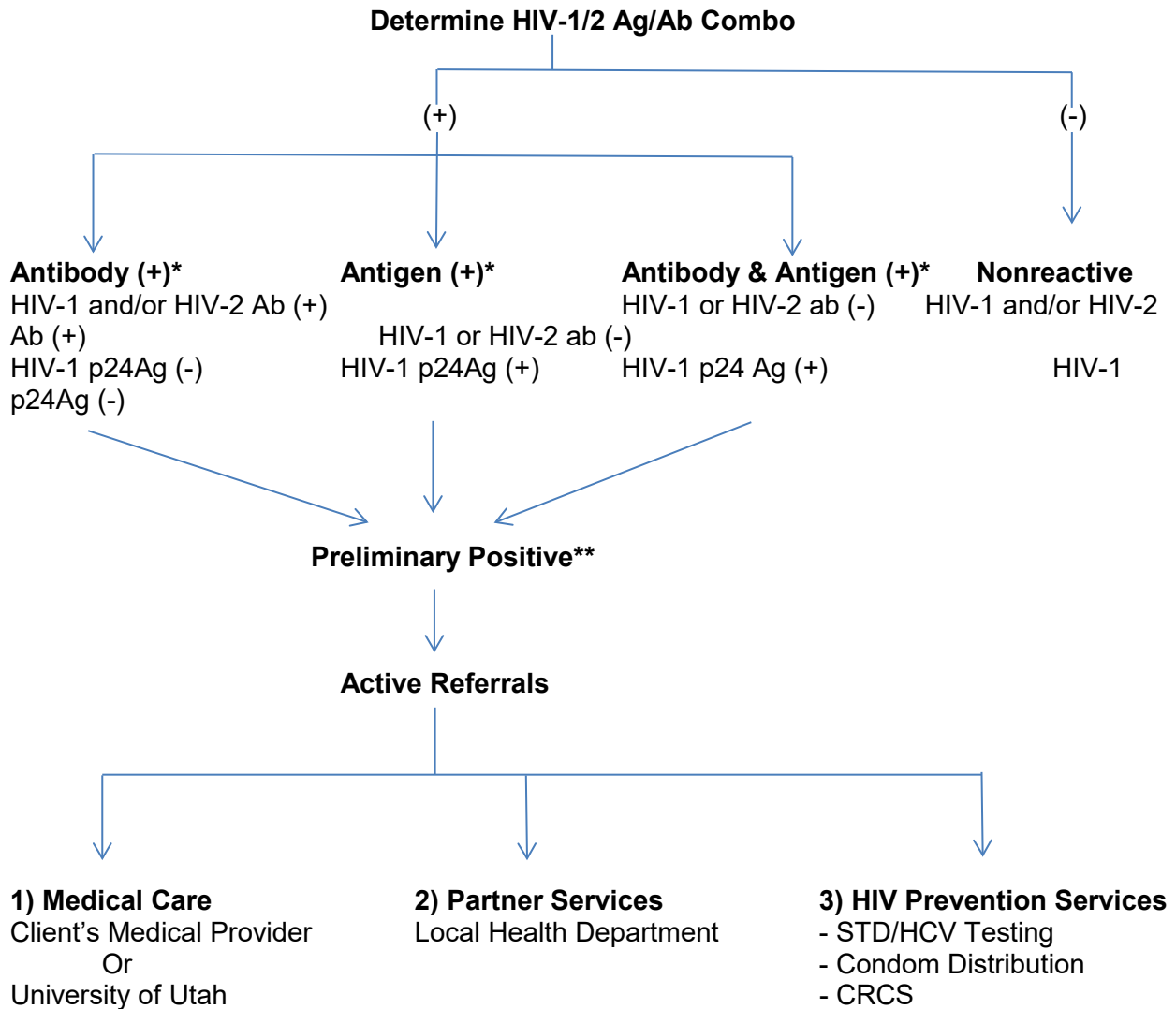
- CLIA-waived for finger stick whole blood
- It is a 4th generation rapid point-of-care that detects both HIV-1/2 antibodies and free HIV-p24 antigen on a single test strip
- Detects HIV earlier than 3rd generation antibody-only tests
- Allows for speedy and seamless linkage to care
- Reduces referral 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 PRELIMINARY 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. Please see the Updated Recommendations for Laboratory Testing for the Diagnosis of HIV Infection at: <https://stacks.cdc.gov/view/cdc/23447>.

For specific information on the above test and pertinent guidance on how to use rapid testing technology, please refer to the Utah Department of Health, Prevention, Treatment and Care Program [Rapid HIV and HCV Testing Guidance](#).

Figure 1: 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 & 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 Case Definitions for HIV Infection Among Adults, Adolescents, and Children <18 months and for HIV Infection and AIDS Among Children Aged 18 Months to <13 Years ---United States, 2008" (MMWR 2008;57 (No. RR10). 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 (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 that:

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

- A positive result of a 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 that the patient has HIV infection, **AND**
- One or both of the following:
 - The laboratory criteria for a case were met based on tests done after the physician’s note was written (validating the note retrospectively),
 - Presumptive evidence of HIV infection (e.g., receipt of HIV antiretroviral therapy or prophylaxis for an opportunistic infection), an otherwise unexplained low CD4+ T-lymphocyte count, or an otherwise unexplained diagnosis of an opportunistic illness (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 one specimen (not including cord blood) from any of following HIV virologic tests:
 - HIV-1 NAT (DNA or RNA)
 - HIV-1 p24 antigen test, including neutralization assay for a child aged >1 month
 - HIV isolation (viral culture)
 - HIV nucleotide sequence (genotype)
- The test date (at least the month and year) is known
- One or both of the following:
 - Confirmation of the first positive result by another positive result on one of the above virologic tests from a specimen obtained on a different date,
 - 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 three 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 two 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 for classifying 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, one or more of the following laboratory criteria are necessary and sufficient:

- FDA-approved HIV1/2 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 three 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 one of the following criteria:
 - At least two negative HIV NATs from specimens obtained on different dates, both of which were at age ≥ 1 month and one of which was at age ≥ 4 months
 - At least two negative HIV antibody tests from specimens obtained on different dates at age ≥ 6 months

Presumptively Uninfected

- Criteria for definitively uninfected with HIV are not met and at least one of the following four laboratory criteria are met:
 - At least two negative NATs from specimens obtained on different dates, both of which were at age ≥ 2 weeks and one of which was at age ≥ 4 weeks
 - One negative NAT (RNA or DNA) from a specimen obtained at age ≥ 8 weeks
 - One negative HIV antibody test from a specimen obtained at age ≥ 6 months
 - If criteria for HIV infection had initially been met by one positive HIV NAT test, then it must have been followed by at least two negative test results from specimens obtained on different dates, one of which is:
 - A NAT test from a specimen obtained at age ≥ 8 weeks, **OR**
 - An HIV antibody test from a specimen obtained at age ≥ 6 months 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 one of five 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 three 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

Table 1. 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
<i>Laboratory Evidence</i>						
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 two 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 one specimen					O	
No subsequent negative results on HIV virologic or HIV antibody tests					N	

<i>Clinical Evidence</i>							
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 two separate specimens (excluding cord blood) for one or more of the tests marked by an "N." "Presumptive" diagnosis requires a positive result from only one specimen for the test.

Table 2. 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 Necessary to classify the HIV type as HIV-2.

O = At least one of these "O" (Optional) 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.

Table 3. 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 two negative HIV DNA or RNA tests from separate specimens, both of which were obtained at age >1 month and one of which was obtained at age >4 months	O			
At least two negative HIV antibody tests from separate specimens obtained at age >6 months	O			
Criteria for definitively uninfected with HIV not met		N		
At least two 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 one positive HIV NAT: At least two negative tests from separate specimens, one of which is a NAT from a specimen obtained at age >8 weeks		O		

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If criteria for presumptive HIV infection were initially met by one positive HIV NAT: At least two negative tests from separate specimens, one 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 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 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.

Table 4. 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	N	N

opportunistic illness indicative of Stage 3 HIV infection (see Appendix).		
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 Necessary 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)

Table 5. 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 one 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 are rarely observed. CDC has provided guidance regarding detection of molecular and time-space clusters. UDOH 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 six 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 three months (window period), these contacts need to be re-tested after three months of their last contact.

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).
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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 testing algorithm. Updated Minimum Data Set to reflect CDC mandated changes. Updated references to reflect new information.

✓ UT-NEDSS Minimum/Required Fields by Tab

Morbidity

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
- Type of Diagnostic Facility for current event
- 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

- 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

Contacts

Demographic

- State
- Postal ZIP Code
- Date of Birth
- Birth Sex
- Ethnicity
- Race
- Contact disposition
- Contact disposition date
- Contact Type
- Partner Type

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?

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

Laboratory

- Test Type
- Test Result
- Collection Date

Investigation

- Initiation Date
- Was Contact Located?
 - (if no) Reason for Unsuccessful Attempt
 - (if Other) Please specify
- Partner Notifiability
- Actual Notification Method

Referral Basis

- Was this Contact screened for HIV?
 - Date of HIV screening test
 - HIV test result
 - Has the contact been notified of the results?
- Was this Contact screened for Syphilis?
 - (if yes) Syphilis screening test result
- Is Contact currently taking PrEP?
 - (if no) Was client referred to a PrEP provider?

✓ 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. These rules have been developed for the automated processing of electronic laboratory reports, although they apply to manual data entry, as well.

Test-Specific Rules

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

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.