

CDC's HIV Laboratory: Saves Lives. Saves Money.

Mission: CDC's HIV Laboratory supports the goal of **No New HIV Infections** by developing tools and biomedical interventions to prevent, rapidly detect, and improve treatment of HIV.

CDC's HIV Laboratory:

- Advances** state-of-the-art testing technologies so more people can know their HIV status.
- Develops** sensitive tests for drug resistance to identify hidden anti-viral resistance.
- Creates** analytical tools to aid in HIV cluster detection, investigation, and response.
- Evaluates** novel pre-exposure prophylaxis strategies so people have more ways to prevent HIV infection.

The Challenge:



~40,000
diagnoses
each year



people in the US are living with HIV, and 1 in 7 of them don't know it.



\$466,000
lifetime
treatment cost
for HIV



Recent Successes:

18% decrease in HIV cases from 2008-2014



\$14.9 billion
saved

**NO
NEW
HIV
INFECTIONS**

Improved Pre-Exposure Prophylaxis

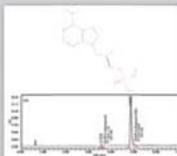


PrEP

Long-acting and on-demand products



Intravaginal ring



Analytic methods to measure protective levels of antiretroviral drugs

State-of-the-Art Testing Technologies



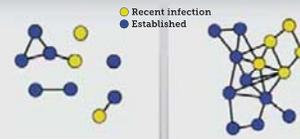
Bioinformatics Tools



**Cluster Detection,
Investigation, and Response**

HIV genetic sequence + epidemiologic data

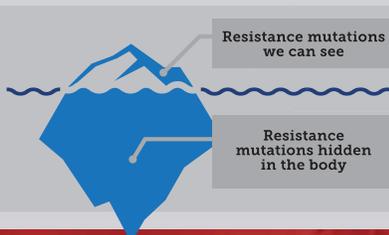
HIV transmission networks



Slow growth
Lower priority

Rapid growth
High priority

Viral Suppression



Resistance mutations we can see

Resistance mutations hidden in the body

Simple tests to uncover hidden drug resistance



Increase Knowledge of HIV Status

Rapid HIV testing



Point-of-care testing to reach more people



Increasing Knowledge of HIV Status

HIV Testing

HIV testing is the cornerstone of HIV prevention. Accurate and rapid test results help individuals learn of their infection sooner, so they can get treatment to protect their health and to prevent further transmission of HIV.



Improved HIV testing and expanded access to tests are vital.

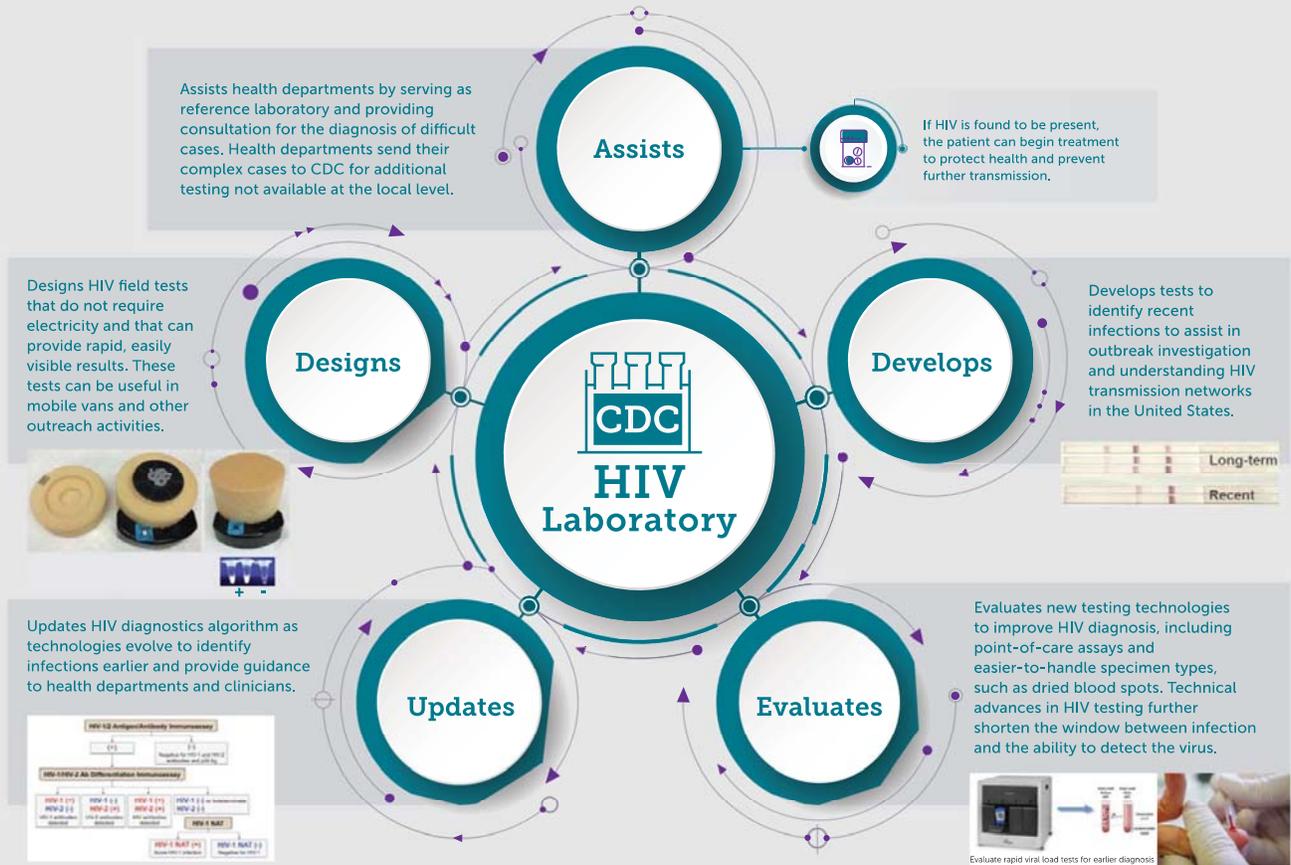
 Research shows that:

 **1 in 2** people with HIV have had the virus at least **3 years** before diagnosis.



About **40%** of new HIV infections are transmitted by people who **don't know they have HIV.**

Continually improving HIV tests to make them more accurate and easier to use means more people can learn their HIV status and more infections can be prevented.



Viral Suppression

Once HIV is diagnosed, an individual needs to get on treatment as soon as possible. Besides preserving the individual's health, effective treatment that leads to viral suppression greatly reduces the chance of further transmission.



CDC developed rapid and sensitive molecular tests to detect drug-resistant HIV. These tests are being demonstrated in the field to reach more at-risk people at lower cost.

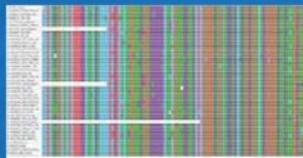


Creating Tools to Aid in HIV Cluster Detection, Investigation, and Response

CDC's HIV Laboratory helps identify high-priority HIV transmission networks to aid in resource distribution and provides laboratory support to assist health departments with outbreak investigations and unusual cases of HIV transmission.



MicrobeTrace, a CDC-developed software system, allows the HIV Laboratory to combine multiple sources of data to identify high-priority HIV transmission networks.



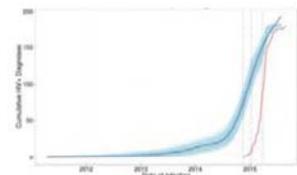
Sequence Data

	A	B	C	D	E
1	SourceID	ContactID	Year	Risk Factor	Location
2	8	0	2015	MSM	Atlanta
3	8	3	2015	MSM	Atlanta
4	8	1	2016	MSM	Decatur
5	7	1	2016	IDU	Atlanta

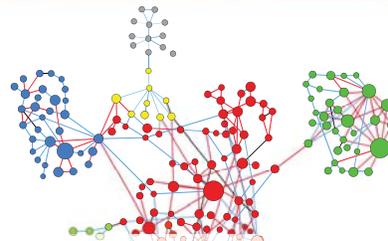
Epidemiological or Contact Tracing

The HIV Laboratory combines two sources of information — HIV genomic sequence data and epidemiologic data — through a data pipeline that results in information about HIV transmission networks, including mapping transmissions.

Observed vs Inferred Epidemiological Curve



Explosive rise of HIV infections in the Indiana outbreak

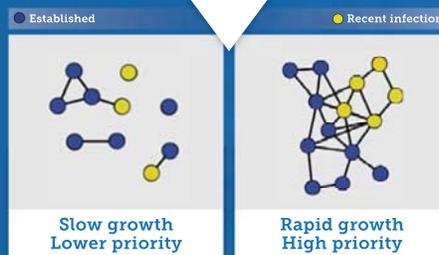


Interactive Exploration of Transmission Networks (sequence- and contact-tracing-based)



Maps

CDC's HIV Laboratory trains state partners on the CDC-developed data integration and analysis software so they can visualize HIV spread in their jurisdictions in near-real time.



The resulting interactive information shows if the transmission networks are slow growing, and therefore lower priority, or if they are rapidly growing, and therefore high priority for outbreak investigation and resource allocation. The information also shows whether the infections were recently acquired or if they were already established.



CDC's HIV Laboratory assists health departments with unusual cases of HIV transmission and outbreak investigations.

HIV infection linked to injection use of oxymorphone in Indiana, 2014-2015



CDC's HIV Laboratory used contact tracing and genetic sequence data to determine that the large outbreak of HIV fueled by injection drug use was limited to a small geographic area, thus allowing resources to be focused on that area.

Likely female-to-female sexual transmission of HIV — Texas, 2012



CDC's HIV Laboratory performed genetic analysis to determine a rare case of female-to-female sexual transmission of HIV. Laboratory testing confirmed that the woman with newly diagnosed HIV infection had a virus virtually identical to that of her female partner, who was diagnosed previously with HIV.

HIV transmitted from a living organ donor — New York City, 2009



CDC's HIV Laboratory performed genetic analysis on blood specimens from an organ donor to determine that the donor acquired HIV after being evaluated to be an organ donor and before the actual organ donation. The HIV Laboratory analyzed the HIV DNA from the donor and the organ recipient to show that the two viruses were highly related, thus providing evidence that the organ recipient's HIV infection was transmitted through organ donation.



Developing New Tools to Prevent HIV Infections

Recent years have ushered in exciting advances in HIV prevention. For the first time, individuals can take medicines to prevent becoming infected with HIV. This is called pre-exposure prophylaxis, or PrEP. CDC's HIV Laboratory played important roles in reaching that milestone and continues to expand the field of HIV prevention.

The Past

CDC's HIV Laboratory was instrumental in laying the groundwork for PrEP.

The HIV Laboratory:

- ▶ Pioneered preclinical modeling of PrEP interventions.
- ▶ Improved research models of rectal, penile, and vaginal HIV acquisition to better understand how HIV takes hold in the body.
- ▶ Informed human PrEP trials that led to FDA approval of the only antiretroviral drugs currently available to prevent HIV infections.



The Present

CDC's HIV Laboratory continues to research ways to make HIV prevention easier and more effective.

The HIV Laboratory:

- ▶ Partners with academia and biotech companies to advance HIV prevention by testing next-generation PrEP products.
- ▶ Researches new technologies, such as:
 - ▶ Rapid-dissolving inserts and intravaginal rings that release HIV medicines the laboratory has shown to be protective.
 - ▶ Implants and injectables to release HIV medicines over time.
- ▶ Tests new PrEP products that could be used around the time of HIV exposure.



Intravaginal rings and rapid-dissolving inserts that release HIV medicines are methods (in place of a pill) the HIV Laboratory is researching to prevent acquisition of HIV.



HIV prevention antiretroviral drugs that can be injected or implanted (and that will release the medicines over time) are other areas of research.

The Future

CDC's HIV Laboratory has been instrumental in furthering our understanding of how HIV interacts with a person's immune system. This information could lead to a vaccine that could safely and reliably prevent HIV infection. To date, a vaccine against HIV has been difficult to engineer – HIV's high mutation rate makes it a moving target compared to a more stable virus, such as measles. Working toward that goal, the HIV Laboratory is researching vaccines with broadly neutralizing antibodies for preventing HIV. These antibodies are capable of neutralizing a wide range of HIV strains.





Preventing New HIV Infections: Clinical Support

CDC's HIV Laboratory is involved in clinical research, in addition to its basic science research. For example, it develops tools to:



- Understand the process of HIV infection and how it can vary from person to person.
- Measure levels of antiretroviral drugs (ARVs) in individuals for clinical and prevention research.
- Support surveillance work so CDC has an accurate profile of the populations infected with HIV in the United States.

Public Health Problems

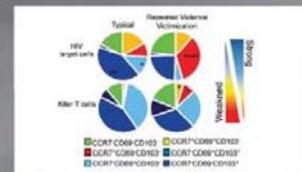


CDC's HIV Laboratory's Solution

Need to identify factors that make people more susceptible to HIV and other sexually transmitted infections



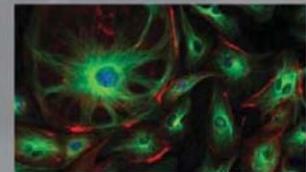
Measure immune defenses at body barrier sites



Need to identify cells that are susceptible to HIV infection and correlate that knowledge with protection strategies



Use live cell imaging techniques



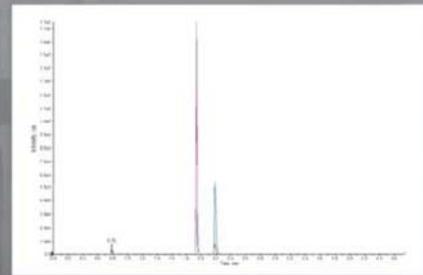
Need to measure ARVs and relevant compounds in biological specimens

Need to assess product adherence during clinical trials

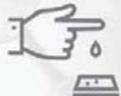
Need to collaborate in clinical studies of new ARVs as pre- and post-exposure prophylaxis to inform HIV prevention



Develop quantitative methods to precisely measure drug levels



Need to accurately measure use of ARVs in surveillance activities



Develop non-clinical outreach dried blood spot testing from the CDC National HIV Behavioral Surveillance System field studies



CDC's HIV Laboratory partners with epidemiologists, clinicians, and academia to study HIV infection risk and methods for reducing transmission.