



HIV

HUMAN IMMUNODEFICIENCY VIRUS

The Evolution of HIV Diagnostics & Treatment

1ST OFFICIAL HIV REPORTING

The first official reporting of the AIDS epidemic. A CDC report describes a rare lung infection in five previously healthy, gay men in Los Angeles — 270 cases are reported by the end of the year. ^[1]

100,000 reported cases of AIDS in the U.S. ^[3]

1981

1983

U.S. Congress approves \$12 million in funding for AIDS research and treatment. ^[2]



1989



Roche Diagnostics organizes consortium of HIV experts to develop the First HIV viral load monitoring test.

1992

1992

#1 CAUSE OF DEATH

AIDS becomes the number one cause of death for U.S. men ages 25 to 44. ^[4]

1ST PROTEASE INHIBITOR

FDA approves the first protease inhibitor (Nevirapine) for highly active antiretroviral therapy (HAART). ^[5]

1995

1995

1ST COMMERCIAL HIV TEST

Roche launches the first commercial test to reliably quantitate HIV viral loads — FDA approval comes the following year for the Amplicor HIV-1 Monitor. ^[11]

GLOBAL SURVEILLANCE

Roche initiates the Global Surveillance Program to monitor changes in the HIV-1 genomic sequence. ^[11]

1998

1998

1ST IN DONOR SCREENING

In response to the FDA, Roche launches the first IND HIV nucleic acid test for use in donor screening. ^[11]



HIV/AIDS becomes the fourth leading cause of death in the world, and the number one cause of death in Africa. ^[6]

1999

1999

MOST SENSITIVE HIV-1 TEST

Roche launches the Amplicor Monitor Ultrasensitive — the most sensitive test available at the time, lowering test sensitivity to 200 copies/mL. ^[11]

775,000

AIDS cases reported in the U.S. ^[7]

2000

2002

IMPROVED GENETIC DIVERSITY

Leveraging the Global Surveillance Program, Roche launches the Cobas® Amplicor HIV-1 Monitor 1.5 — an updated test design that adds multiple primer sets and increases the genetic diversity captured.

1ST FULLY AUTOMATED REAL-TIME TEST

Roche launches the Cobas® Ampliprep/Cobas® TaqMan HIV-1 Test — the first fully automated real-time PCR test for monitoring HIV-1. ^[11]

2007

2007

INCREASING DRUG RESISTANCE

Raltegravir is approved as the first integrase inhibitor. Within two years, publications detail 42 mutations associated with resistance to Raltegravir. ^[8, 9]

1ST DUAL TARGET ASSAY

Roche launches the Cobas® Ampliprep/Cobas® TaqMan HIV-1 Test v2.0 — the first dual target HIV assay to deal with highly mutagenic nature of HIV.

2010

2010

MOST SENSITIVE HIV-1 TEST, AGAIN

Roche's new generation test — the Cobas® Ampliprep / Cobas® TaqMan HIV-1 Test v2.0 — reliably detects down to 20 copies/mL. Still today, it's the most sensitive HIV-1 viral load test available. ^[11]



FDA approves the use of Truvada® for pre-exposure prophylaxis (PrEP). ^[10]

2012

2012

HIV-1 CONTINUES TO MUTATE

Roche's Global Surveillance Program maps 26,000 HIV-1 genomic sequences. ^[11]



UNAIDS reports that global AIDS-related deaths have fallen 30% since peaking in 2005. ^[12]

2013

2014

Roche launches the Global Access Program to help meet the UNAIDS 90:90:90 initiative by providing sustainable access to diagnostics. ^[11]



8TH GENERATION HIV TEST

With the experience of 52 million viral loads ^[11] and 40 clinical drug trials ^[13], Roche launches its 8th generation HIV test on the cobas® 6800/8800 analyzer, still the most sensitive and clinically validated test available.

2015

A VIRUS ON THE MOVE

2018+

HIV-1, either from polymorphic ^[14] or drug pressure ^[15], continues to mutate; yet you can test with confidence, knowing that Roche will continue to improve testing and keep you a step ahead of this highly mutagenic virus.

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- [1] http://www.cdc.gov/mmwr/preview/mmwrhtml/june_5.htm
- [2] <https://www.aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline/>
- [3] <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001442.htm>
- [4] <http://www.cdc.gov/mmwr/preview/mmwrhtml/00022174.htm>
- [5] <https://www.aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline/>
- [6] <https://www.aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline/>
- [7] <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5021a2.htm>
- [8] Ceccherini-Silberstein F et al. Characterization and structural analysis of HIV-1 integrase conservation. *AIDS Rev.* 2009 Jan-Mar; 11: 17-29.
- [9] Latallaide M et al. Natural polymorphism of the HIV-1 integrase gene and mutations associated with integrase inhibitor resistance. *Antivir Ther.* 2007; 12: 563-570.
- [10] <https://www.poz.com/article/milestones-era-effective-hiv-treatment>
- [11] Roche Data on File.
- [12] <https://www.poz.com/article/milestones-era-effective-hiv-treatment>
- [13] Reference Drug Manufacturer Package Inserts
- [14] Loeb LA et al. Lethal mutagenesis of HIV with mutagenic nucleoside analogs. *Proc Natl Acad Sci U S A.* 1999; 96: 1492-1497.
- [15] Wainberg MA et al. The development of novel HIV integrase inhibitors and the problem of drug resistance. *Curr Opin Virol.* 2012; 2: 656-662.