

HIV TESTING CAN CHANGE EVERYTHING

Determine⁻ HIV-1/2 Ag/Ab Combo

"Every time someone gets tested for HIV, we are one step closer to ending the AIDS epidemic. Learning your HIV status opens the door to powerful HIV prevention and treatment options that could save your life or the life of someone you love."

–Jonathan Mermin, MD, MPH

Dr. Mermin is the Director of the National Center for HIV/ AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), and a Rear Admiral in the U.S. Public Health Service.

HIV INCIDENCE AND DISTRIBUTION

According to HIV.gov, there are approximately **1.2 million** people living with HIV in the U.S. and **and 13%** are unaware they are infected.1

In 2019, there were **36,801** new HIV diagnoses.² Approximately 80% of new HIV transmissions are from individuals who do not know they have HIV infection and/or are not receiving regular care.³

GLOBAL NUMBER OF AIDS-RELATED DEATHS. NEW HIV INFECTIONS, AND PEOPLE LIVING WITH HIV, 1990-2019⁴ (IN MILLIONS)



A NEW CHALLENGE -**OPIOID USE AND HIV INCIDENCE**

People who inject drugs accounted for 10% (3,864) of the 37,968 new HIV diagnoses in the United States in 2018.5 Up to **32%** of new users share needles.⁵ The prescription opioid and heroin epidemic has led to increased numbers of injection drug users, placing new populations at increased risk for HIV. Historically, urban areas have

The prevention and treatment of people with HIV is of primary concern as this will result in decreasing the number contracting the virus and developing AIDS.



high rates of HIV due to injection drug use, however the opioid epidemic has disproportionately affected nonurban areas. While prevalence rates are normally low in these communities, there are limited services for HIV detection, prevention and treatment.5

TYPES OF HIV TESTING AND TIME TO RESULTS

HIV tests can be conventional or rapid.⁶⁻⁷

CONVENTIONAL		
CONVENTIONAL BLOOD TEST	-	< HOUR TO SEVERAL DAYS ⁷
CONVENTIONAL ORAL FLUID TEST	➡	A FEW DAYS TO TWO WEEKS7
RAPID		
RAPID TEST POINT OF CARE	➡	≤20 MINUTES ⁶⁻⁷
NEGATIVE	➡	NO FURTHER TESTING NEEDED
POSITIVE	➡	LABORATORY CONFIRMATION NEEDED
HOME		
HOME TEST	-	20 MINUTES TO THREE DAYS ⁷



Picture from 1985 of Abbott scientists with the first HIV test kit, the Abbott HTLV-III.

HIV ANTIGEN AND ANTIBODY TESTING

Antibody-only tests were developed in the 1980s and improved the specificity and positive predictive value of the screening procedures by adding recombinant antigens, specifically HIV-1 p24, HIV-2, and HIV-1 group O. Antibody-only assays reduced the antibody-negative window to 4-6 weeks after exposure. With the addition of HIV-2, confirmatory testing of that protein was added to the developing CDC algorithm for HIV testing.⁸

IgM detection was added to assays to produce a new type of HIV test. The IgM/IgG combination reduced the antibody-negative window to approximately 3 weeks. The development of a **p24 antigen** detection ELISA could detect the virus as early as two weeks.⁸

Detection of HIV after becoming infected has been difficult to ascertain, especially if tests are performed during the window period (the period of time between becoming infected with HIV and the ability of a test to detect HIV) which increases the likelihood of a false negative.



The probability of a false negative decreases with the use of an antibody-antigen test.

FALSE NEGATIVES IN ANTIBODY-ONLY AND ANTIBODY/ANTIGEN HIV TESTS⁹

TIME SINCE EXPOSURE	ANTIBODY TEST (CHANCE OF A FALSE NEGATIVE TEST RESULT)	ANTIBODY/ ANTIGEN TEST (CHANCE OF A FALSE NEGATIVE TEST RESULT)
0-9 DAYS	100% CHANCE	100% CHANCE
10-15 DAYS	95-99%	79-99%
16-20 DAYS	56-80%	35-51%
21-28 DAYS	13-46%	8-31%
29-50 DAYS	5-9%	0-8%
51-80 DAYS	3-4%	0%
MORE THAN 80 DAYS	5 0-1%	0%



CDC SCREENING RECOMMENDATIONS

SCREENING METHOD

In 2014, the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) published recommendations for the laboratory diagnosis of HIV infection.¹⁰

In 2017, a technical update provided information on the use of Determine[™] HIV 1/2 Ag/Ab Combo single use rapid test in laboratories where it is not feasible to conduct an instrumented antigen/antibody test as the initial test in the algorithm when using serum/plasma. Determine[™] HIV-1/2 Ag/Ab Combo is the first and only rapid point-of-care test recommended in the algorithm.¹¹

The CDC and APHL continue to recommend that laboratories use an instrumented, laboratory-based antigen/antibody HIV screening immunoassay, followed by an HIV-1/HIV-2 antibody differentiation immunoassay when reactive. However, for laboratories in which instrumented antigen/antibody testing is not feasible, Determine can be used with serum/plasma as the first step in the laboratory algorithm.¹¹

SCREENING FREQUENCY

RIS

The CDC recommends everyone between the ages of 13 and 64 should be tested for HIV at least once in their lifetime.¹³ Individuals with high risk should be screened annually and in some cases, every 3 to 6 months.¹³ Additional guidelines from the American Academy of Pediatrics (AAP) suggest adolescents should be screened for HIV at least once between the ages of 15 and 18.14

CDC ADULT SCREENING RECOMMENDATIONS

K LEVEL	RISK BEHAVIORS ^{5,15}
LOW	NONE
HIGH	INTRAVENOUS DRUG USE AND/OR NEEDLE SHARING
	UNPROTECTED SEX
	PREVIOUS STI
	PREVIOUS SEX WITH AN HIV-POSITIVE PARTNER
	MSM
	SEX WITH ANYONE WHO MAY POSITIVE FOR ANY OF THE ABOVE

AAP ADOLESCENT SCREENING RECOMMENDATIONS

ADOLESCENT AGE	11	12	13
HIV TEST ¹⁴	*	*	*

*TEST FOR HIV ONLY IF ADOLESCENT IS AT AN INCREASED RISK.

USPSTF SCREENING RECOMMENDATIONS

THE U.S. PREVENTIVE SERVICES TASK FORCE (USPSTF) RECOMMENDS SCREENING FOR HIV INFECTION IN ADOLESCENTS AND ADULTS AGED 15 TO 65 YEARS. YOUNGER ADOLESCENTS AND OLDER ADULTS WHO ARE AT INCREASED RISK OF INFECTION SHOULD ALSO BE SCREENED. THE USPSTF RECOMMENDS SCREENING FOR HIV INFECTION IN ALL PREGNANT PERSONS, INCLUDING THOSE WHO PRESENT IN LABOR OR AT DELIVERY WHOSE HIV STATUS IS UNKNOWN.¹⁵

RECOMMENDED LABORATORY HIV TESTING ALGORITHM FOR SERUM OR PLASMA SPECIMENS¹²



The AAP suggests that efforts should be made to meet privately with adolescents to discuss any potential risks. Adolescents at increased risk of HIV infection, including those who are sexually active, participate in injection drug use, or who may be tested for other STIs, should also be tested for HIV and reassessed annually.14-15

CDC SCREENING RECOMMENDATION¹³

ONCE BETWEEN THE AGES OF 13 AND 64

AT LEAST ANNUALLY

DEPENDING ON FREOUENCY OF RISK BEHAVIORS, UP TO EVERY 3-6 MONTHS

RF RISKS



DETERMINE[®] HIV-1/2 AG/AB COMBO

Determine[™] HIV-1/2 Ag/Ab Combo is the first step in the CDC laboratory algorithm for HIV diagnosis when it is not feasible to conduct an instrumented antigen/ antibody test. This is the first and only rapid point-of-care test that the CDC has recommended, with serum or plasma, as the initial screen in the HIV testing algorithm.¹¹

Determine[™] HIV-1/2 Ag/Ab Combo can detect infection earlier than IgM/IgG (antibody-only) assays when used with plasma.¹⁶⁻¹⁷ If the result is non-reactive, then testing stops and the result is reported according to the Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm (aphl.org/HIV).

HIV TESTS BY GENERATION¹⁹

2ND GENERATION DETECTS IgG ANTIBODIES	3RD GENERATION DETECTS IgM AND IgG ANTIBODIES
HIV 1/2 STATPAK®	AVIOQ HIV-1 MICROELISA SYSTEM
DPP® HIV 1/2 ASSAY	VITROS ANTI-HIV 1+2
SURE CHECK® HIV 1/2 ASSAY	GS HIV-1/HIV-2 PLUS O EIA
REVEAL® G3 RAPID HIV-1 ANTIBODY TEST	ADVIA CENTAUR [®] HIV 1/O/2 ENHANCED ASSAY
	UNI-GOLD™ RECOMBIGEN® HIV-1/2
	INSTI™ HIV-1/HIV-2 ANTIBODY TEST
	ORAQUICK ADVANCE® RAPII HIV-1/2 ANTIBODY TEST

DETECTING HIV SOONER THAN CONVENTIONAL ANTIBODY-ONLY TESTS¹⁶⁻¹⁸



ECONOMIC IMPACT OF HIV

According to the CDC, the total lifetime cost of HIV per person is \$501,000.²⁰ In the U.S., the 36,801² individuals diagnosed with HIV in 2019 will have an estimated total lifetime healthcare cost of over \$18 million. Individuals who do not know they are infected with HIV are



ESTIMATED U.S. HEALTHCARE COSTS FOR HIV BASED ON PER PERSON COST FOR THE 36,801 PEOPLE DIAGNOSED IN 2019²⁰

\$18,437,301,000

\$501,000²⁰

TOTAL LIFETIME COST OF HIV PER PERSON

responsible for 38% of new transmissions.²¹ Earlier detection would lead to fewer transmissions from undiagnosed individuals, reducing both the spread of HIV and associated healthcare costs.

ID

ADVIA CENTAUR HIV AG/AB COMBO (CHIV) ASSAY

BIOPLEX 2200 HIV AG-AB

ELECSYS HIV COMBI PT

VITROS HIV COMBO TEST

GS HIV COMBO AG/AB EIA

INSTRUMENT BASED

ALINITY m HIV-1 ASSAY

DETECTS IgM AND IgG ANTIBODIES, AND HIV-1 p24 ANTIGEN

4TH GENERATION

DETECTS IgM AND IgG ANTIBODIES, AND FREE HIV-1 p24 ANTIGEN

RAPID

DETERMINE™ HIV-1/2 AG/AB COMBO

DETERMINE[™] HIV-1/2 AG/AB COMBO PRODUCT AND ORDERING INFORMATION

Test in 3 easy steps

PREPARE TEST

Bend along the perforation then tear one strip from the right and remove cover.





Apply 50 µL of sample by touching

the tip of the precision pipette to

the Sample Pad, wait 1 minute,



Serum or Plasma

Sample Pad.

Apply 50 µL of sample

by touching the tip of the

precision pipette to the

ADD SAMPLE

Fingerstick Whole Blood Apply 50 µL of sample by touching the tip of the capillary tube to the Sample Pad, wait 1 minute, then add Chase Buffer.





Venous Whole Blood

1 MIN

READ RESULTS Read the results – for both free HIV-1 p24 antigen (Ag) and HIV-1/2 antibodies (Ab) - in just 20 minutes. REACTIVE NONREACTIVE LINE INVALID





Please refer to the full instructions prior to running this test. Full instructions for the Determine™ HIV-1/2 Ag/Ab Combo test can be found in the package insert



REIMBURSEMENT CODES

- CPT[®] Codes: 87806 (Non-waived), 87806-QW (Waived)
- Medicare Screening: G0433 (Non-waived), G0433-QW (Waived) Providers operating under a CLIA waiver should use the QW modifier when appropriate

CLIA-waived for Fingerstick Whole Blood

Moderate Complexity: Venipuncture Whole Blood, Serum/Plasma

- 1. HIV Basics. https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics Accessed 18 February 2022.
- 2. Centers for Disease Control. https://www.cdc.gov/hiv/basics/statistics.html Accessed 18 February 2022.
- 3. Li Z, Purcell DW, Sansom SL, et al. Vital Signs: HIV Transmission Along the Continuum of Care – United States, 2016. MMWR Morb Mortal Wkly Rep. 2019(11);68:267-72. Available at http://dx.doi.org/10.15585/mmwr.mm6811e1. Accessed 18 February 2022.
- 4. https://ourworldindata.org/hiv-aids. Accessed 18 February 2022.
- 5. Centers for Disease Control and Prevention. https://www.cdc.gov/hiv/group/hiv-idu.html. Accessed 18 February 2022.
- 6. Greenwald JL, Burstein GR, Pincus J, et al. A rapid review of rapid HIV antibody tests. Clin Infect Dis. 2006;8(2):125-31.
- 7. HIV Testing in the United States. https://www.kff.org/hivaids/fact-sheet/hiv-testing-in-the united-states/, Accessed 18 February 2022,
- 8. Alexander TS. Human immunodeficiency virus diagnostic testing: 30 years of evolution Clin Vacc Immunol. 2016;4:249-53.
- 9. Taylor D. https://paninbc.ca/2016/03/07/smartsexresource-making-sense-of-hiv-window periods/. Accessed 18 February 2022.
- 10. Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at http://dx.doi.org/10.15620/cdc.23447. Published June 27, 2014. Accessed 18 February 2022.
- 11. Centers for Disease Control and Prevention and Association of Public Health Laboratories. Technical update: Use of the Determine HIV 1/2 Ag/Ab combo test with serum or plasma in the laboratory algorithm for HIV diagnosis. Available at https://stacks.cdc.gov/view/cdc/48472 Published October 4, 2017. Accessed 18 February 2022.
- 12. Centers for Disease Control and Prevention and Association of Public Health Laboratories. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. Available at https://stacks.cdc.gov/view/cdc/50872. Published January 2018. Accessed 18 February 2022.

PRODUCT INFORMATION		
INFORMATION TYPE	PRODUCT DETAIL	
Method	Lateral flow	
Time to results	20 minutes	
Results window	20-30 minutes after starting test	
Test lines	HIV-1 p24 antigen HIV-1/2 antibodies	
Storage conditions	2-30°C (36-86°F)	
Test shelf life	18 months*	
External controls shelf life	24 months*	
Sample type	Whole blood/serum/plasma	
Operating temperature	15-30°C (59-86°F)	

*From date of manufacture

PRODUCT CLINICAL PERFORMANCE

SAMPLE TYPE	OVERALL CLINICAL SENSITIVITY	OVERALL CLINICAL SPECIFICITY
Fingerstick Whole Blood	99.9%	99.8%
Venous Whole Blood	99.9%	99.7%
Serum	99.9%	99.6%
Plasma	99.9%	99.7%

ORDERING INFORMATION		
PRODUCT	CAT. NO.	
Determine HIV-1/2 Ag/Ab Combo (x25)	7D2648	
External Controls	7D2628	
Fingerstick Sample Collection Kit (100 Sterile Safety Lancets, 100 Adhesive Bandages, 100 Ethanol Swabs, 100 Gauze Pads)	2604US199	

- 13. Centers for Disease Control and Prevention. https://www.cdc.gov/hiv/testing/index.html Accessed 18 February 2022.
- 14. Bright Futures Guidelines Pocket Guide, American Academy of Pediatrics, https:// brightfutures.aap.org/Bright%20Futures%20Documents/BF4_POCKETGUIDE.pdf Accessed 18 February 2022.
- 15. Final Update Summary: Human Immunodeficiency Virus (HIV) Infection: Screening. U.S. Preventive Services Task Force. June 2019. https://www.uspreventiveservicestaskforce.org/ uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening. Accessed 18 February 2022.
- 16. Fiebig EW, Wright DJ, Rawal BD, et al. Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. AIDS. 2003;17(13):1871-79.

17. Patel P, Mackellar D, Simmons P, et al. Detecting acute human immunodeciency virus infection using aRNA, 2006-2008. Arch Intern Med. 2010;170(1):66-74.

18. Masciotra S, Luo W, Youngpairoj AS, et al. Performance of the Alere Determine™ HIV-1/2 Ag/ Ab Combo Rapid Test with specimens from HIV-1 seroconverters from the US and HIV-2 infected individuals from Ivory Coast. J Clin Virol. 2013;58 Suppl 1:e54-8.

19. Advantages and Disadvantages of FDA-Approved HIV Assays Used for Screening. CDC. https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf. Accessed 18 February 2022.

20. Centers for Disease Control. https://www.cdc.gov/nchhstp/budget/infographics/hiv.html. Accessed 18 February 2022.

21. Infectious Disease News. https://www.healio.com/news/infectious-disease/20190318/80-ofnew-hiv-cases-transmitted-by-undiagnosed-or-untreated-people. Accessed 21 February 2022.

22. https://www.globalpointofcare.abbott/en/product-details/determine-1-2-ag-ab-combo.html. Accessed 18 February 2022.

DETERMINE[®] HIV-1/2 AG/AB COMBO

INNOVATIVE

It's the first 4th generation rapid point-of-care test that detects both HIV-1/2 antibodies and free HIV-1 p24 antigen on a single test strip.

DEPENDABLE

Built-in quality controls to let you know the test is working.

EFFICIENT Test in three simple steps with clear results in just 20 minutes.

NEXT GENERATION¹⁷

A 4th generation test, with the ability to detect HIV earlier than 2nd and 3rd generation antibody-only tests.

FLEXIBLE

Test using whole blood, serum or plasma samples.

RELIABLE

Proved 99.9% overall clinical sensitivity for all sample types.





CLIA-WAIVED FOR FINGERSTICK WHOLE BLOOD!

ABBOTT'S WORK IN HIV DIDN'T STOP IN 1985

Since 1985, we have launched more than 20 types of tests and our global surveillance team works around the clock to monitor disease trends to stay one step ahead of HIV as new mutations and strains of this virus appear. Unlike polio, where a vaccine eradicated the disease, weapons for fighting HIV include early testing, treatment and surveillance. Voluntary HIV testing and counseling allow people who have HIV to know their status, get life-saving treatment and care, and prevent HIV transmission to others.



Please contact your local Abbott representative or visit globalpointofcare.abbott