Abbott

DETERMINE™ HIV-1/2 Ag/Ab COMBO

The only rapid antigen/antibody point-of-care test that detects both acute and chronic HIV infections

1.1 MILLION

persons in the United States are currently living with HIV infection (estimated).[6]

14.5%

of individuals living with HIV infection are unaware of their positive status.[6]

80%

of new infections are transmitted by individuals who are unaware of their HIV positive status or are not receiving regular care.[6]

Innovative

The first rapid point-of-care test that simultaneously and separately detects free HIV-1 p24 antigen and HIV-1/2 antibodies on a single test strip.[1]

Next Generation

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

Reliable

Proved 99.9% overall clinical sensitivity for all sample types.[7]

Efficient

- Requires minimal training
- Test in three simple steps
- Receive results in just 20 minutes

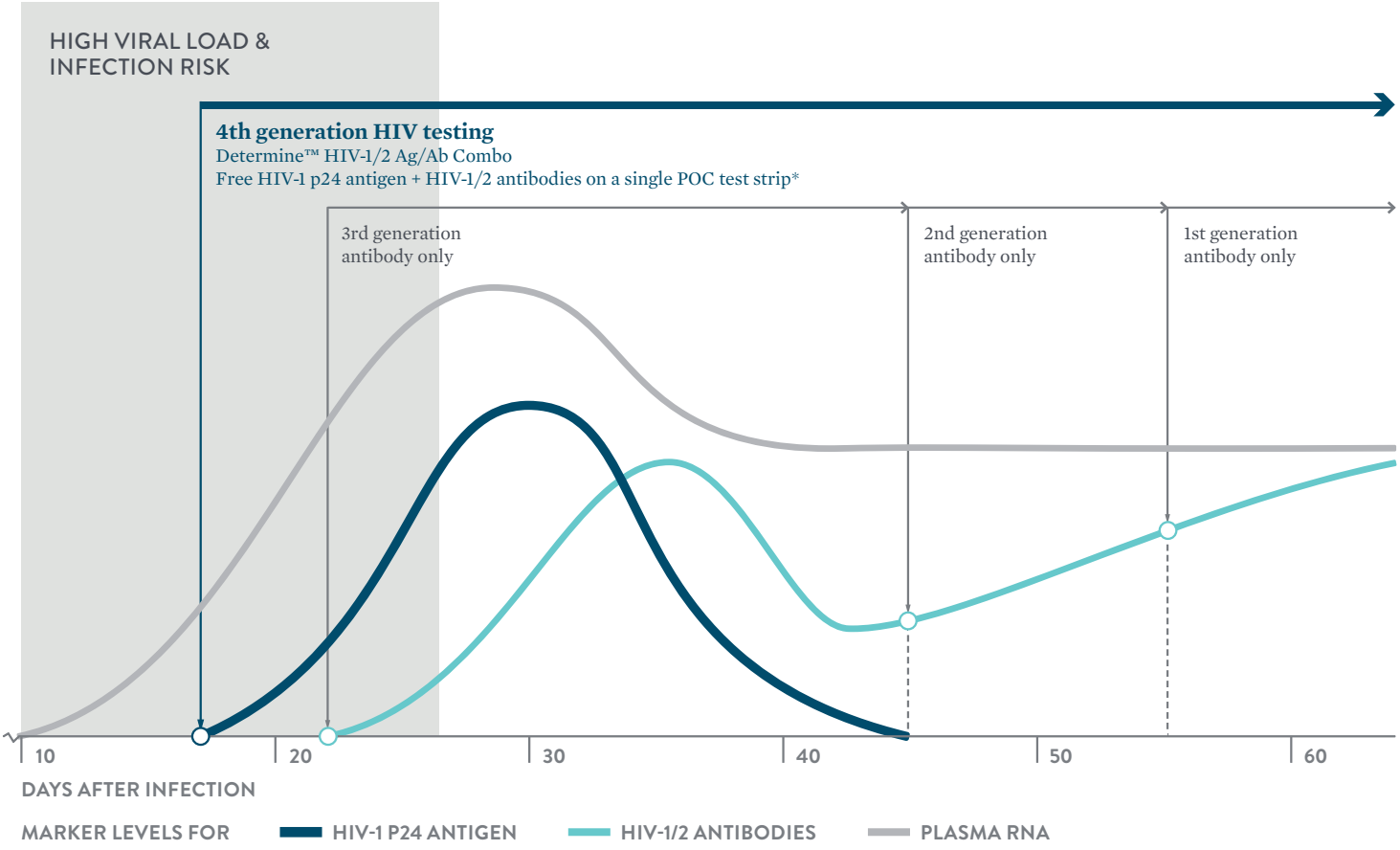
Flexible

- Test using whole blood, serum, or plasma
- CLIA-waived for fingerstick whole blood

"This test helps diagnose HIV infection at an earlier time in outreach settings, allowing individuals to seek medical care sooner."[1]

– FDA REPRESENTATIVE (PUBLISHED AUG. 8, 2013)

Detecting HIV sooner than conventional antibody-only tests[2-4]



HIV TESTS BY GENERATION[5]

4TH GENERATION INSTRUMENT BASED
Detects IgM and IgG antibodies, and HIV-1 p24 antigen

- GS HIV Combo Ag/Ab EIA
- ARCHITECT® HIV Ag/Ab Combo
- ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay
- BioPlex 2200 HIV Ag-Ab
- Elecsys HIV Combi PT
- VITROS HIV Combo Test

4TH GENERATION RAPID
Detects IgM and IgG antibodies, and free HIV-1 p24 antigen

- **Determine™ HIV-1/2 Ag/Ab Combo**

3RD GENERATION
Detects IgM and IgG antibodies

- Avioq HIV-1 Microelisa System
- VITROS Anti-HIV 1+2
- GS HIV-1/HIV-2 PLUS O EIA
- ADVIA Centaur® HIV 1/O/2 Enhanced Assay
- Uni-gold™ Recombigen® HIV-1/2
- INSTI™ HIV-1/HIV-2 Ab Test
- OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test

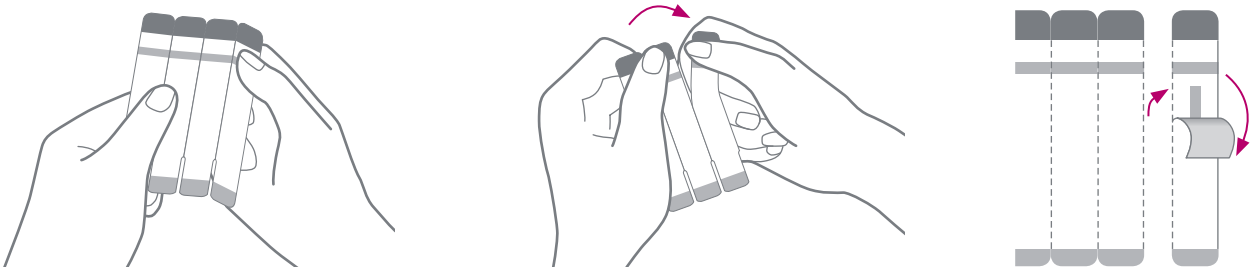
2ND GENERATION
Detects IgG antibodies

- Chembio HIV 1/2 STAT-PAK®
- Chembio DPP® HIV 1/2 Assay
- Chembio SURE CHECK® HIV 1/2 Assay
- BioRad Multispot HIV-1/HIV-2 Rapid Test
- Medmira Reveal® G3 Rapid HIV-1 Antibody Test

Test in 3 easy steps

1 PREPARE TEST

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

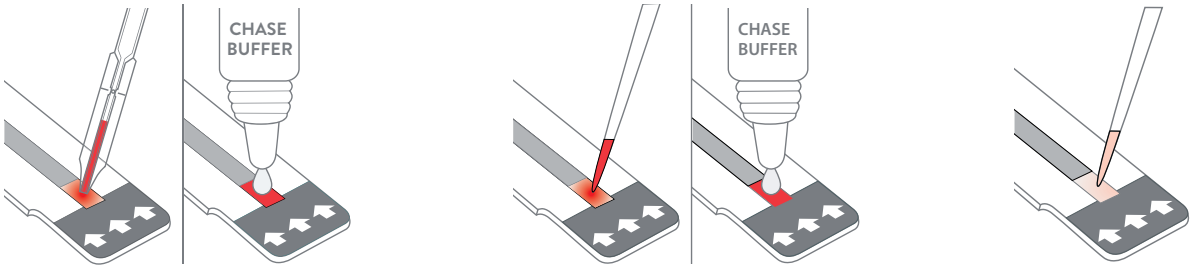


2 ADD SAMPLE

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.

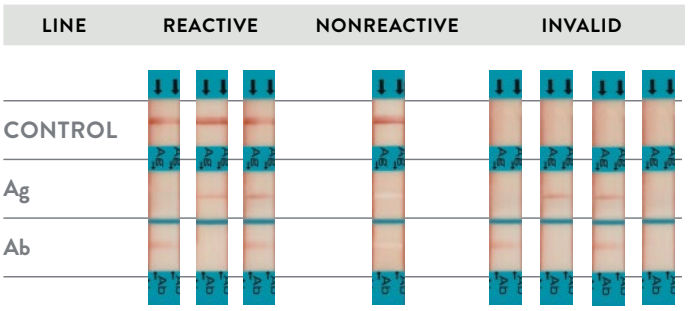
Venous Whole Blood
Apply 50 µL of sample by touching the tip of the precision pipette to the Sample Pad, wait 1 minute, then add Chase Buffer.

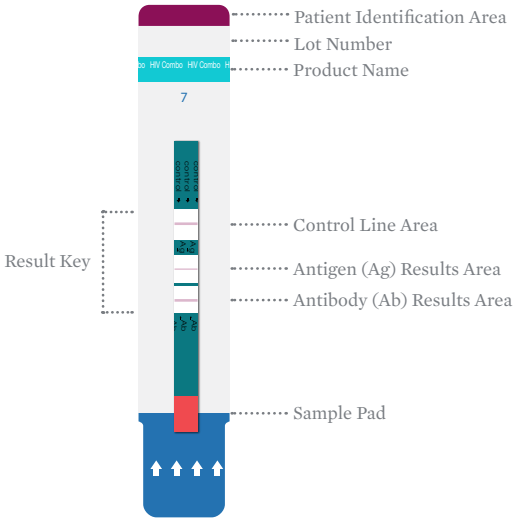
Serum or Plasma
Apply 50 µL of sample by touching the tip of the precision pipette to the Sample Pad.



3 READ RESULTS

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





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.

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

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 %

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

ORDERING INFORMATION

PRODUCT	CAT. NO.
Determine™ HIV-1/2 Ag/Ab Combo (x25)	7D2648
Determine™ HIV-1/2 Ag/Ab Combo (x100)	7D2649
External Controls	7D2628
Fingerstick Sample Collection Kit (100 Sterile Safety Lancets, 100 Adhesive Bandages, 100 Ethanol Swabs, 100 Gauze Pads)	2604US199

1. FDA approves first rapid diagnostic test to detect both HIV-1 antigen and HIV-1/2 antibodies [Press release]. (2013, August 8). Retrieved from http:// www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm364480.htm
2. Masciotra, S, 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: Published online 05 August 2013. DOI: 10.1016/j.jcv.2013.07.002 http://www.journalofclinicalvirology.com/article/ S1386-6532(13)00277-1/abstract
3. Fiebig EW, Wright DJ, Rawal BD, et al. Dynamics of HIV viremia and antibodyseroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. AIDS. 2003;17(13):1871-1879.
4. Patel P, Mackellar D, Simmons P, et al. Detecting acute human immunodeciency virus infection using 3 different screening immunoassays and nucleic acid amplication testing for human immunodeciency virus RNA, 2006-2008. Arch Intern Med. 2010;170(1):66-74. doi:10.1001/archinternmed.2009.445.
5. CDC. Advantages and disadvantages of FDA-approved HIV immunoassays used for screening by test format and CLIA complexity updated. (June 2018). Retrieved from https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf
6. CDC. Morbidity and Mortality Weekly Report, Vol. 68, March 18, 2019.
7. Determine HIV-1/2 Ag/Ab Combo Package Insert

FOR MORE INFORMATION, CALL 877.441.7440

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