



Knowing now matters.™



Alere Determine™ HIV-1/2 Ag/Ab Combo

Enables detection of HIV earlier at the point-of-care.

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

Breaking the HIV Infection Cycle

Identifying HIV infection early, during the most infectious stage offers significant benefits, particularly in high risk populations such as men who have sex with men and injecting drug users.

- Rapid detection also helps to get patients into effective care and treatment earlier.
- Individuals who are unaware of their infection are 3.5 times more likely to transmit the virus to someone else.¹
- By detecting HIV earlier, further transmission can be prevented during this highly infectious stage.

Next generation point-of-care HIV testing

Alere Determine™ HIV-1/2 Ag/Ab Combo is a 4th generation test that has the ability to detect HIV earlier than 2nd and 3rd generation antibody-only tests.² This enables health care providers to diagnose HIV infection earlier allowing individuals to seek medical care sooner.

- CLIA waived for fingerstick whole blood.
- Requires minimal training.
- Test in three easy steps.
- Receive results in just 20 minutes.
- Test using whole blood, serum, or plasma.
- Proved 99.9% overall clinical sensitivity for all sample types.



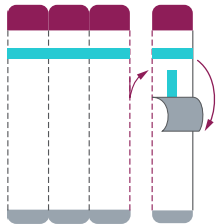
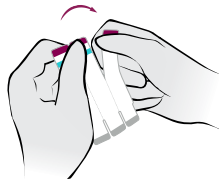
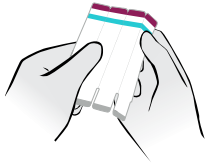
Now CLIA Waived
for Fingerstick
Whole Blood

To learn more contact your local Account Executive **1.877.441.7440** | AlereHIV.com/US

Test in 3 Easy Steps

1 Prepare Test

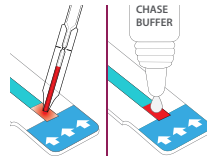
Bend along the perforation, then tear one strip from the right and remove cover.



2 Add Sample

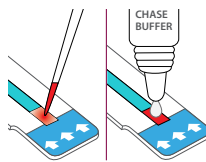
Fingerstick Whole Blood

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



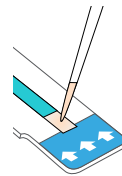
Venous Whole Blood

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

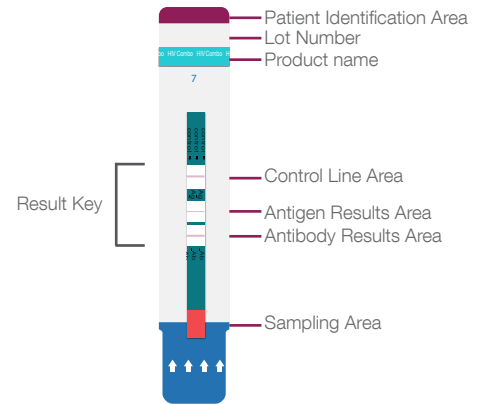
Apply 50 µL of sample by touching the tip of the precision pipette to the Sample Pad.



3 Read Results

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

Line	Reactive	Nonreactive	Invalid
Control	[Red line]	[Red line]	[Red line]
Ag	[Red line]	[No line]	[Red line]
Ab	[Red line]	[No line]	[Red line]



Please refer to the package insert for complete instructions.

Product Information

Information Type	Product Detail
Method	Lateral Flow
Time to results	20 minutes
Storage conditions	2-30°C (36-86°F)
Test shelf life	12 months*
External controls shelf life	24 months**

- Marks G, Crepez N, Janssen RS. Estimating sexual transmission of HIV from persons aware and unaware that they are infected with the virus in the USA. *AIDS*. 2006 Jun 26;20:1447-50.
- 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](http://www.journalofclinicalvirology.com/article/S1386-6532(13)00277-1/abstract)

*Average shelf life received by customer (product has a 15 month shelf life from date of manufacture)
**From date of manufacture

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Product Clinical Performance

Information 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	Order Number
Alere Determine™ HIV-1/2 Ag/Ab Combo (25 Tests)	7D2648
Alere Determine™ HIV-1/2 Ag/Ab Combo (100 Tests)	7D2649
External Controls	7D2628
Fingerstick Sample Collection Kit 100 lancets, 100 bandages, 100 Ethanol Swabs, 100 Gauze Pads	2604US199
Verification Panel	KZMC030



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