



Alere Determine™ HIV-1/2 Ag/Ab Combo

Clinician Training

Texas Laboratory Director's Conference
Wednesday 22nd October 2014



About Alere

World's leading provider of near-patient diagnostics that when combined with our novel health information solutions, facilitates the effective management of several chronic conditions.

Alere solutions enable:

- Earlier interventions
- Better coordination among healthcare providers
- More personalized treatment
- Fewer hospitalizations
- Reduced healthcare costs
- Better quality of life



Our global presence

Aleré solutions are available in more than 100 countries.





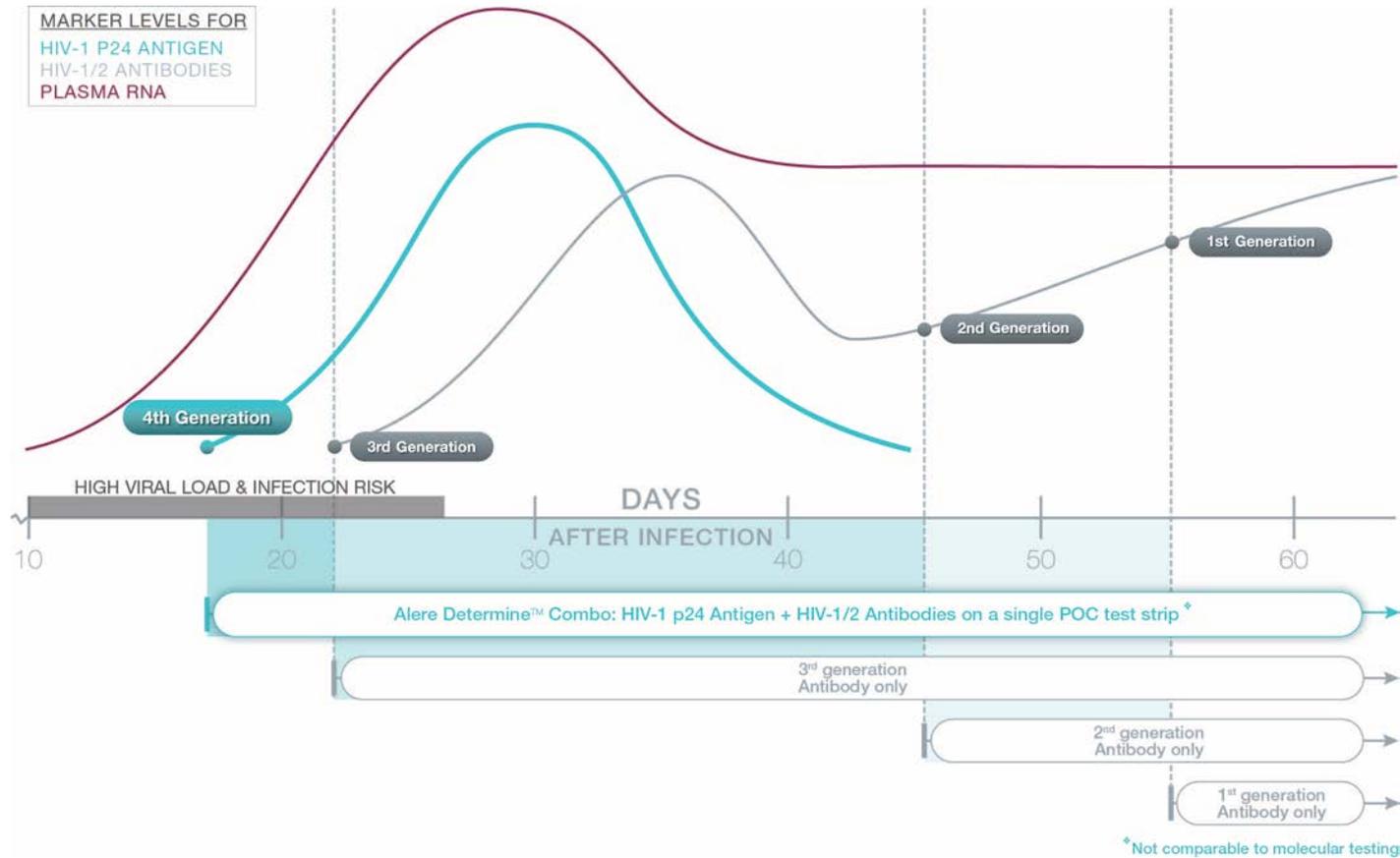
Detecting HIV earlier



- Alere Determine™ Combo is the first FDA approved rapid point-of-care test that detects both HIV-1/2 antibodies and HIV-1 p24 antigen.
- A 4th generation test that has the ability to identify HIV sooner than conventional antibody only tests.
- Enables earlier HIV diagnosis allowing individuals to seek medical care sooner.



HIV Laboratory Markers



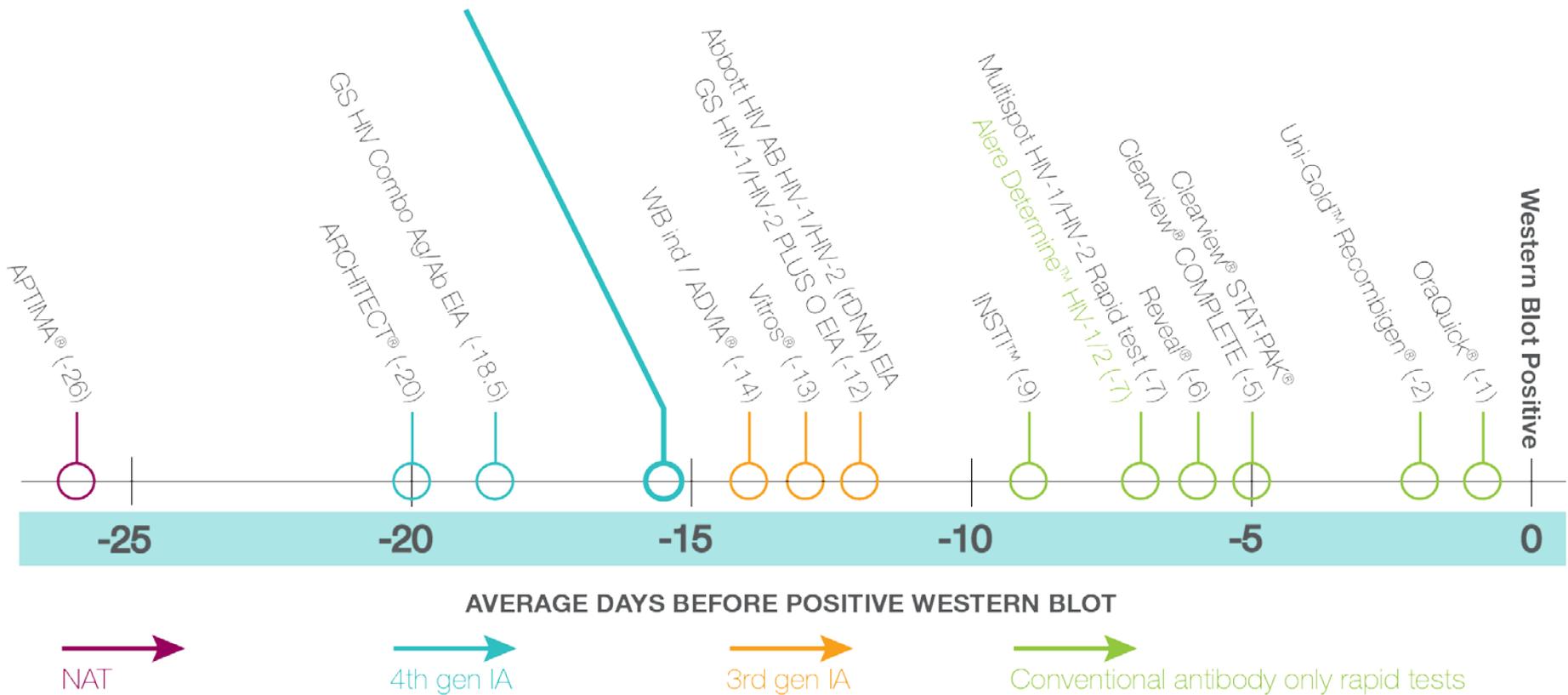
Modified from Fiebig EW, Wright DJ, Rawal BD, et al. Dynamics of HIV viremia and antibodyseroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. AIDS. 2003;17(13):1871-1879.

*Not comparable to molecular testing.



4th Generation Rapid HIV testing

Alere Determine™ HIV-1/2 Ag/Ab Combo
15.5 days before Western Blot positive



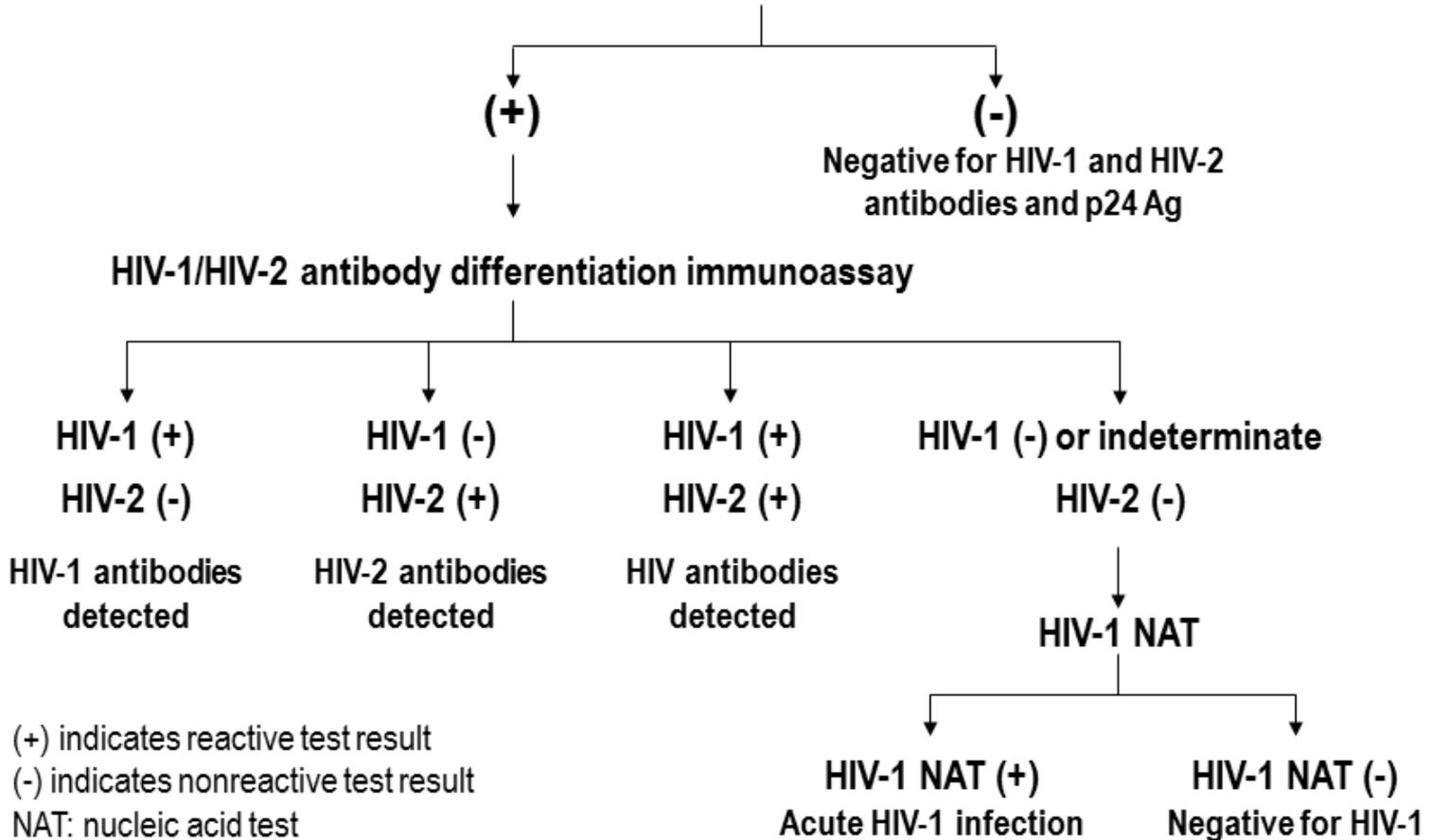
Data taken from Masciotra S, et al. Performance of the Alere Determine™ HIV-1/2 Ag/Ab Combo Rapid Test with specimens from HIV-1 seroconverters from the US and HIV-2 infected individuals from Ivory Coast. J Clin Virol 2013; Published online 05 August 2013. DOI: 10.1016/j.jcv.2013.07.002



CDC Recommended Laboratory Testing

Serum & Plasma Specimens

HIV-1/2 antigen/antibody combination immunoassay





CDC Recommended Laboratory Testing

Serum & Plasma Specimens

- Laboratories should use this same testing algorithm, beginning with an antigen/antibody combination immunoassay, with serum or plasma specimens submitted for testing after a reactive (preliminary positive) result from any rapid HIV test.
- Alere is working with thought leaders and studies are underway to provide the CDC with additional data for inclusion in the algorithm.



Alternative Testing Sequences

- Use of a 3rd generation HIV-1/2 antibody test, followed by the recommended algorithm
- Western Blot or HIV-1 IFA as the second test then HIV-1 NAT. If negative, perform HIV-2 antibody test
- Use of HIV-1 NAT as the second test. If negative or indeterminate, perform differentiating HIV-1/HIV-2 antibody test or HIV-1 antibody test. If negative, perform HIV-2 antibody test
- No diagnostic test or algorithm can be completely accurate in all cases of HIV infection
- It is the responsibility of the individual lab or testing facility to determine how they can best manage sequential testing to ensure adherence to their internal lab policies and procedures



Alere Determine™ HIV-1/2 Ag/Ab Combo

- Product Information
- Clinical Data
- Order Information & Reimbursement
- Test Procedure





Alere Determine™ HIV-1/2 Ag/Ab Combo

Information Type	Product Detail
Method	Lateral Flow
Time to results	20 minutes
Storage conditions	2-30°C (36-86°F)
Test shelf life	14 months*
Sample type	Fingerstick or Venous Whole blood/serum/plasma

- Approved for Moderate Complexity
- CLIA-Waiver Pending

*From Date of Manufacture



Clinical Data: Sensitivity & Specificity

	Sample Type	Sensitivity	Specificity
HIV-1 Sensitivity & Specificity	Serum	99.9%	99.6%
	Plasma	99.9%	99.7%
	Venipuncture Whole Blood	99.9%	99.7%
	Fingerstick Whole Blood	99.9%	99.8%

The sensitivity of Alere Determine™ HIV-1/2 Ag/Ab Combo for detection of antibodies to HIV-2 was estimated to be 250/250 = 100% (95% confidence interval 98.5 to 100.0%).



Order Information & Reimbursement

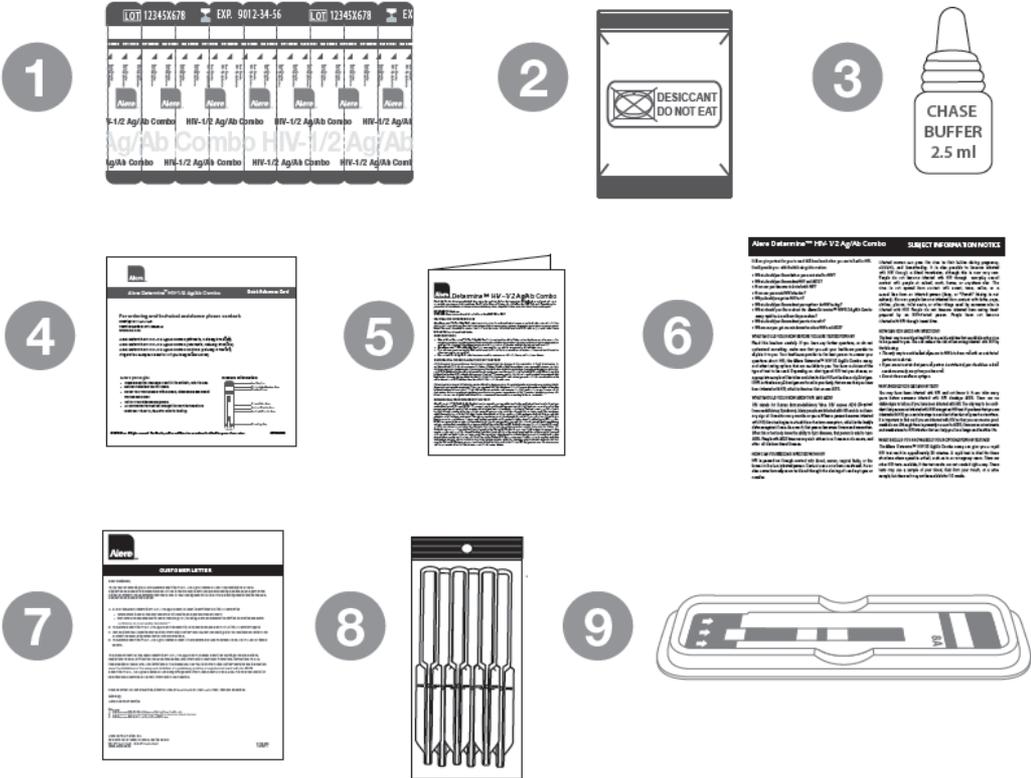
Product	Order Number	CPT® code ¹	Medicare Coverage ²	National Medicare Reimbursement ³
Alere Determine™ HIV-1/2 Ag/Ab Combo 25 tests (Diagnostic)	7D2648	86703 & 87899	NCD	\$35.06
			CCI	
Alere Determine™ HIV-1/2 Ag/Ab Combo 25 tests (Medicare Screening)	7D2648	*	Screening	\$18.70
Alere Determine™ HIV-1/2 Ag/Ab Combo 100 tests (Diagnostic)	7D2649	86703 & 87899	NCD	\$35.06
			CCI	
Alere Determine™ HIV-1/2 Ag/Ab Combo 100 tests (Medicare Screening)	7D2649	G0433	Screening	\$18.70

* Use the following CPT code to report the antibody detection portion of this test procedure: 86703 Antibody; HIV-1 and HIV-2, single result
Use the following CPT code to report the antigen detection portion of this test procedure: 87899 Infectious agent antigen detection by immunoassay with direct optical observation; not otherwise specified

1. Providers operating under a CLIA waiver should use the QW modifier when appropriate.
2. CCI, Correct Coding Initiative edits; NCD, National Coverage Determination; LCD, Local Coverage Determination
3. Centers for Medicare and Medicaid Clinical Diagnostic Laboratory Fee Schedule 2014, available at <http://www.cms.gov/apps/ama/license.asp?file=/ClinicalLabFeeSched/downloads/14CLAB.zip>



Materials Provided



1. Alere Determine™ HIV-1/2 Ag/Ab Combo Test Cards
2. Desiccant Package
3. Chase Buffer
4. Quick Reference Guide
5. Package Insert
6. Subject Information Notices
7. Customer Letter
8. Disposable Capillary Tubes
9. Disposable Workstations



Materials Required But Not Provided

- Timer or watch
- Disposable gloves
- Sterile gauze pads
- Antiseptic wipes
- Biohazard disposable container
- Disposable absorbent workspace cover
- Sterile safety lancet
- Collection devices for specimens (other than fingerstick whole blood specimens)



Prior to Testing

- **READ THE PACKAGE INSERT COMPLETELY BEFORE USING THE ASSAY**
- Remember to ***always observe*** “CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other blood borne pathogens”*

*Centers for Disease Control and Prevention (CDC) Universal Precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988; 37(24):377-388.



Begin Testing

- Gather testing materials
- Let the test materials come to the operating temperature of 15 - 30° C (59 to 86° F)
- Set up the workspace with cover and timer
- Put on gloves
- Provide the “subject information” pamphlet to the person being tested.

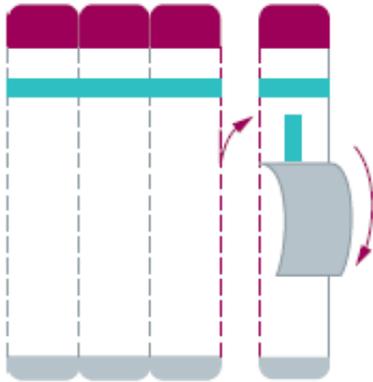


Handling Precautions

- If Desiccant Package is missing, DO NOT USE. Discard Test Cards (all Test Units) and use a new Test Card.
- Do not use any Test Units from Test Cards if the pouch has been perforated.
- Each Test Unit, lancet and Disposable Capillary Tube for collection and transfer of fingerstick samples is for single use only.
- Do not use kit components beyond the expiration date printed on the label. Always check expiration date prior to testing.
- Adequate lighting is required to read a test result.



Test Procedure

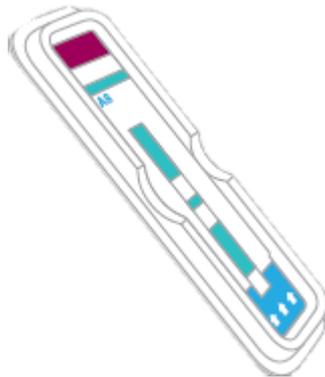


1. Open the aluminum pouch containing the Alere Determine™ HIV-1/2 Ag/Ab Combo Cards.
2. Remove the desired numbers of test units from the 5 or 10-Test Unit Card by bending and tearing at the perforation.

NOTE: Removal of the test units should start from the right side of the Card to preserve the lot number which appears on the left side of the Card.

3. Return the unused test units to the aluminum pouch and close the pouch with the ziplock.

NOTE: Store the unused cards and test units only in the aluminium pouch containing the desiccant package. Carefully close the ziplock, so that the cards are not exposed to ambient humidity during storage.

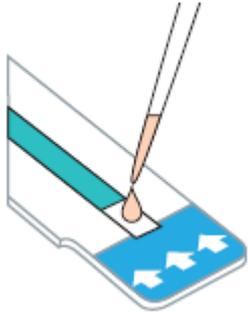


4. Lay the Test Unit Flat in the workstation and remove the protective foil cover from each Test Unit. The test should be initiated within 2 hours of removing the protective foil cover from each Test Unit.

NOTE: Use of the workstation is optional. If the workstation is not used, place the Test Unit on a flat surface.

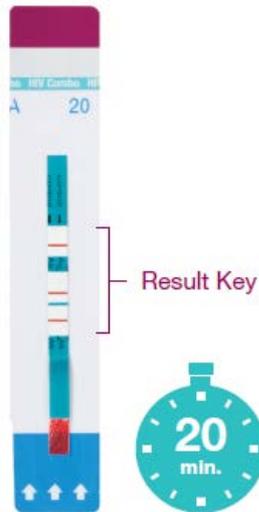


Test Procedure



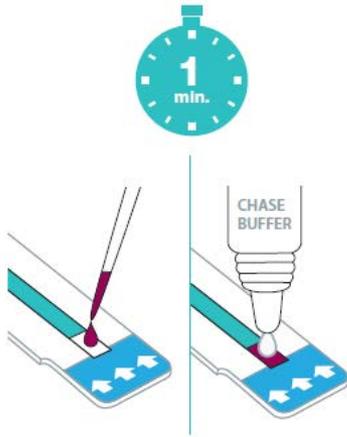
For **serum or plasma** samples:

1. Apply 50 μL of sample (precision pipette) to the Sample Pad (marked by the arrow symbol). Do not add Chase Buffer when using serum or plasma specimens.
2. Read the test result between 20 and 30 minutes after the addition of the Sample. Do not read Test Results after 30 minutes.



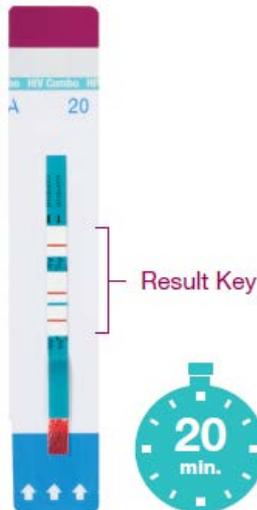


Test Procedure



For **whole blood (venipuncture)** samples

1. Using a precision pipette with a disposable tip, apply 50 µL of sample to the Sample Pad (marked by the arrow symbol).
2. Wait for one minute, then apply one drop of Chase Buffer to the Sample Pad.
3. Read the test result between 20 and 30 minutes after the addition of Chase Buffer. Do not read Test Results after 30 minutes.



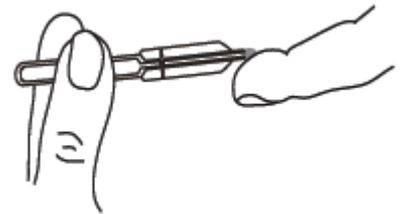


Test Procedure

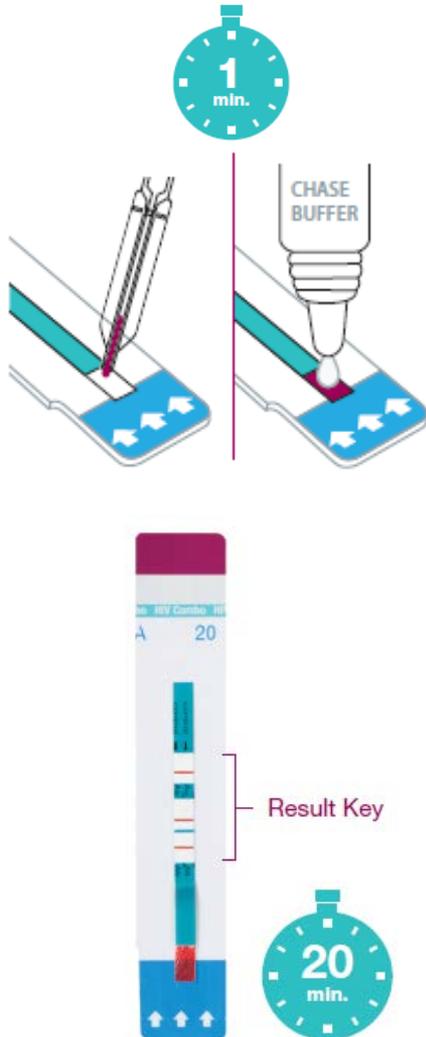
For **whole blood (fingerstick)** samples using the disposable Capillary Tube:

1. Clean the finger of the person being tested with an antiseptic wipe. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
2. Using a sterile lancet capable of producing 50 μL of blood, puncture the skin just off the center of the finger pad and wipe away the first drop with sterile gauze. Avoid squeezing the fingertip to accelerate bleeding.
3. Collect the second drop of blood by holding the capillary tube horizontally, and touch the tip of the capillary tube to the blood sample.

Note: Filling of the capillary is automatic – do NOT squeeze the bulb while sampling. Maintain this position until the flow of the sample has reached the fill line and stopped.



Test Procedure



For **whole blood (fingertstick)** samples using the disposable Capillary Tube:

1. Align the tip of the Capillary Tube containing the blood sample with the Sample Pad (marked by the arrow symbol) and gently squeeze the bulb. Avoid air bubbles. Wait until all the blood is transferred from the Capillary Tube to the Sample Pad.

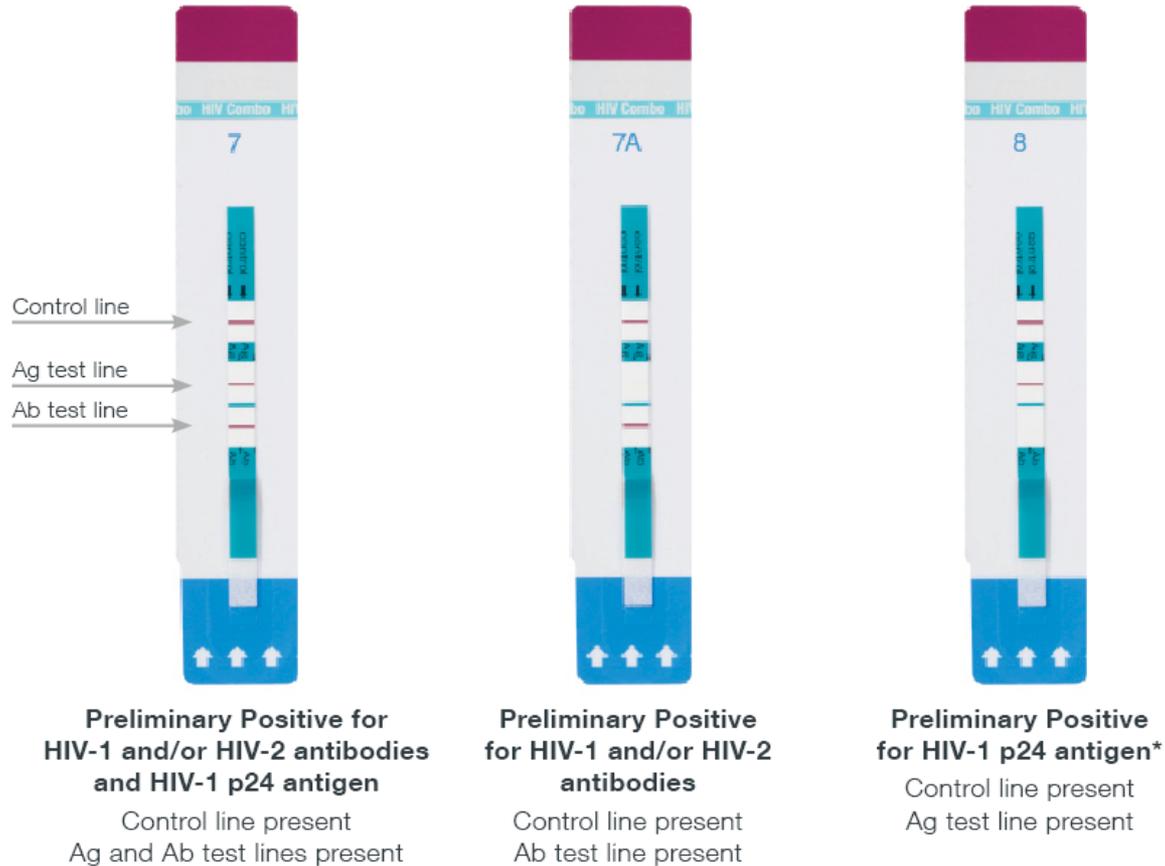
Caution: Do not lift the Capillary Tube from the Sample Pad before all the blood has been transferred – a bubble may form which will prevent the complete transfer of sample. If a sample won't expel, cover the small opening at the mark on the capillary with a gloved finger. Then squeeze the bulb until the sample is fully dispensed onto the Sample Pad.

2. Wait for one minute, then apply one drop of Chase Buffer to the Sample Pad.
3. Read the test result between 20 and 30 minutes after the addition of the Chase Buffer. Do not read Test Results after 30 minutes.



Reading the Results

Reactive / Preliminary Positive Results



*NOTE: A test result that is PRELIMINARY POSITIVE for HIV-1 p24 antigen in the absence of reactivity for HIV-1 or HIV-2 antibodies may indicate an acute HIV-1 infection in the test subject. In this case the acute HIV-1 infection is distinguished from an established HIV-1 infection in which antibodies to HIV-1 are present.



Reading the Results

Nonreactive Result



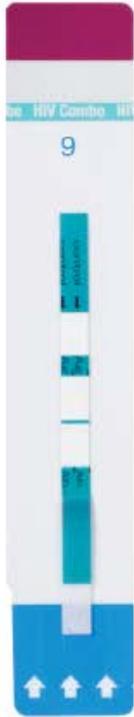
Nonreactive

Control line present
No test lines present



Reading the Results

Invalid Results



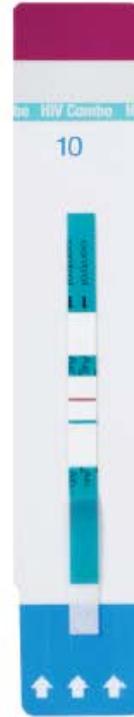
Invalid

No control line present



Invalid

No control line present
Ag and Ab test lines present



Invalid

No control line present
Ag test line present



Invalid

No control line present
Ab test line present



When to Perform Controls

- Each new operator prior to performing tests on patient specimens
- When opening a new test kit lot
- Whenever a new shipment of test kits is received
- At periodic intervals as indicated by the user facility

External control material stored at refrigerated temperatures must be brought to operating temperature (15 to 30°C; 59 to 86°F) prior to testing.
Controls must be stored at 2 to 8 °C (36 to 46 °F)



Technical Support & Training Materials

For Technical Assistance:

- Tel: 1.877.866.9335
- Email: ts.scr@alere.com

Available training materials:

- Alere Determine™ HIV-1/2 Ag/Ab Combo Package Insert
- External Controls Package Insert
- Quick Reference Guide
- Fingertick Procedure
- Results Interpretation Guide & Poster
- Training presentation



Key benefits of Alere Determine™ Combo

Innovative

- It's the first rapid point-of-care test that detects both HIV-1/2 antibodies and free HIV-1 p24 antigen

Empowering

- Enables health care providers to diagnose HIV infection earlier allowing individuals to seek medical care sooner

Reliable

- 99.9% Sensitivity for all sample types

Efficient

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

Flexible

- Multiple sample types; fingerstick and venous whole blood, serum or plasma samples



Questions?