

## CLIA Complexity: Waived for Fingerstick Whole Blood

- These instructions are only a Reference Guide. For complete information, refer to the Alere Determine™ HIV-1/2 Ag/Ab Combo Assay Package Insert.
- Read the Package Insert completely before using the product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate Test Results.
- Before performing testing, all operators MUST read and become familiar with Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other blood borne pathogens in Health-Care Settings.
- Non-clinical testing sites using this test must hold a CLIA Certificate of Waiver or have an agreement to work under the CLIA Certificate of an existing laboratory.
- Alere Determine™ HIV-1/2 Ag/Ab Combo has not been evaluated for newborn screening or for use with cord blood specimens or for use with specimens from individuals less than 12 years of age.

### Storage Conditions

Alere Determine™ HIV-1/2 Ag/Ab Combo Test Cards and Chase Buffer must be stored at 2-30°C (36-86°F) until expiration date.

### For ordering and technical assistance please contact:

Ordering: (877) 441-7440

Technical Service: (877) 866-9335 or ts.scr@alere.com

[www.alere.com](http://www.alere.com)

Alere Determine™ HIV-1/2 Ag/Ab Combo (25 Tests, Catalog #7D2648)

Alere Determine™ HIV-1/2 Ag/Ab Combo (100 Tests, Catalog #7D2649)

Alere Determine™ HIV-1/2 Ag/Ab Combo Controls (Catalog # 7D2628)

Fingerstick Sample Collection Kit (Catalog #2604US199)

## External Quality Control:

Alere Determine™ HIV-1/2 Ag/Ab Combo Controls are available separately and are for use only with Alere Determine™ HIV-1/2 Ag/Ab. The Controls are used to verify your ability to perform the test and interpret the results. Refer to the Alere Determine™ HIV-1/2 Ag/Ab Combo Controls Package Insert for complete instructions.

### Run the Kit Controls under the following circumstances:

- With each new untrained operator prior to performing tests on patient specimens,
- When opening a new test Kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test storage area falls outside of 2 to 30°C (36 to 86°F),
- If the temperature of the testing area falls outside of 15 to 30°C (59 to 86°F),
- At periodic intervals as indicated by the user facility.

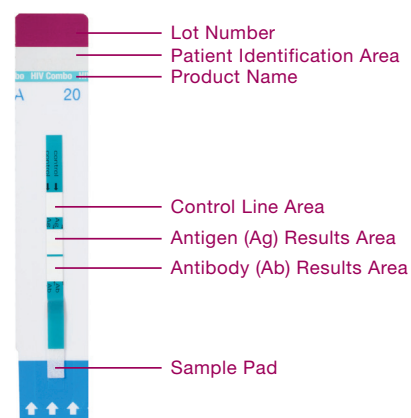
### External Controls Test Procedure

1. Using the disposable pipette provided in the kit or a precision pipette capable of delivering 50µL of sample, apply 50µL of Control Reagent to the Sample Pad. Use a new pipette tip or disposable pipette with each new Control tested.  
*NOTE: Do not add Chase Buffer when running External Controls.*
2. Read the test result between 20 and 30 minutes after the addition of the Control Reagent. Follow Step 6 of the Test Procedure Section of this Quick Reference Card.

## Before you begin:

- Please read the Package Insert in its entirety, prior to use.
- Gather materials you will need.
- Cover your work space with a clean, disposable absorbent workspace cover.
- Put on your disposable gloves.
- All components must be brought to room temperature (between 15-30°C, 59-86°F) prior to testing.

## Product Information

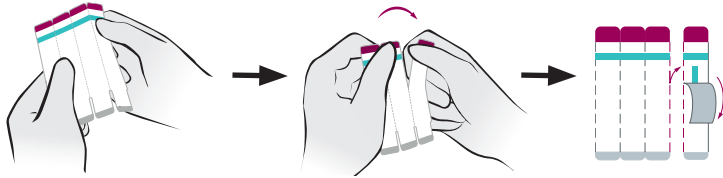


**Test Procedure: Refer to the Package Insert for Complete Instructions**

**1 Prepare Test**

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

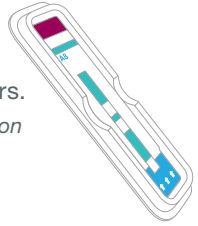
Assay should be initiated within 2 hours after removing the protective foil cover from each test.



**2 Place Test**

Place one strip inside the workstation. Do NOT touch the Sample Pad with your fingers.

NOTE: Use of the workstation is optional. If workstation is not used, place test strip on a clean flat surface.



**Optimize Bloodflow Prior to Collection:**

- Warm the hand by washing in warm water (or holding it in a heating pad or hand warmer).
- Lower the hand below the heart level before collecting a drop of blood.
- Massage the finger with a downward motion several times before performing the fingerstick.

**Fingerstick Whole Blood**

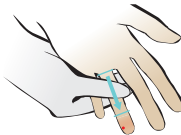
**3 Collect Fingerstick Sample**

CAUTION: The capillary tube must be used to collect the fingerstick sample.

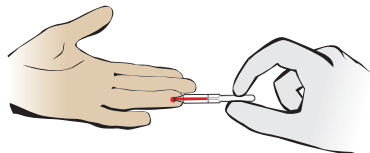
Clean the finger of the person being tested with an antiseptic wipe. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Using a sterile lancet capable of producing 50µL of blood, puncture the skin just off the center of the finger pad and wipe away the first drop with sterile gauze.

**To collect an adequate sample volume:**

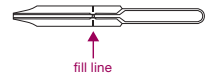
- Quickly express blood down the fingertip by gently squeezing across the entire finger, to the last joint (not to the end of the fingertip).
- Do not squeeze or “milk” the fingertip to accelerate bleeding.



Collect the second drop of blood by holding the capillary tube **HORIZONTALLY**, and touch the tip of the capillary tube to the blood sample.



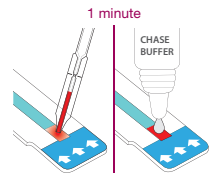
NOTE: Filling of the capillary is automatic – do NOT squeeze the bulb while sampling. Maintain this position until the flow of the sample has reached the fill line and stopped.



**4 Add Sample**

Touch the tip of the Capillary Tube containing the blood sample to the Sample Pad and expel all of the contents by gently squeezing the bulb.

When all of the blood is transferred to the Sample Pad, wait 1 minute to ensure the Chase Buffer does not overflow the Sample Pad.



**5 Add Chase Buffer**

Add one drop of Chase Buffer 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.

NOTE: Only the liquid provided in the Chase Buffer bottle should be used. Do not use water or other liquids.

**6 Read Results**

Read the Test Result between 20 and 30 minutes after the addition of the Chase Buffer. Do not read Test Results after 30 minutes.

A **PINK/RED** Control Line AND a **PINK/RED** Test Line **must** appear in order for the test to be considered Reactive. If a **PINK/RED** Control Line is visible AND a **PINK/RED** Test Line does not appear, the test is Nonreactive. If the Control Line does not appear, the results are invalid and should be repeated using a new test strip.



Result Key			
Line	Reactive	Nonreactive	Invalid
Control			
Ag			
Ab			