Status Active PolicyStat ID 16691922

Beaumont

Origination	10/19/2021
Last Approved	9/27/2024
Effective	9/27/2024
Last Revised	9/27/2024
Next Review	9/27/2026

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Area	Laboratory-Chemistry
Applicability	Taylor + Trenton + Wayne

Laboratory Abbott Determine™ HIV-1/2 Ag/Ab Combo

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The Abbott Determine™ HIV–1/2 Ag/Ab Combo test provides a mechanism for rapid HIV resulting in the urgent situations outlined below. It should be as part of a multi-test algorithm for HIV testing; if the result is negative, no additional testing is required. However, if positive (unconfirmed reactive), the result should be confirmed by another method. In the ~~Beaumont~~Corewell Lab, the Abbott Determine™ HIV–1/2 Ag/Ab Combo test is being used to determine the presence of antigen and/or antibodies in a "source patient" of an employee who has had an exposure to blood or body fluids or an assault case from the Emergency Center (EC). This test will also be used for obstetric (OB) patients with an unknown/undocumented HIV status.

II. PRINCIPLE:

A. Abbott Determine™ HIV–1/2 Ag/Ab Combo is an immunochromatographic test for the simultaneous and separate qualitative detection of free HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2. The test device is a laminated strip that consists of:

1. sample pad containing monoclonal biotinylated anti-HIV-1 p24 antibody
2. conjugate pad containing monoclonal anti-HIV-1 p24 antibody-colloidal selenium and HIV-1 and HIV-2 recombinant antigen-colloidal selenium
3. nitrocellulose membrane with an immobilized mixture of recombinant and synthetic peptide HIV-1 and HIV-2 antigens in the Lower Test Area
4. immobilized streptavidin in the Upper Test Area
5. immobilized mixture of anti-HIV-1 antibodies, HIV-1/2 antigens, and HIV-1 p24 recombinant antigen and anti-HIV-1 p24 monoclonal antibody in the Control Area

III. SPECIMEN COLLECTION AND HANDLING:

A. EDTA plasma is the specimen of choice. Specimens should be free from hemolysis, icterus and lipemia. See Limitations section below.

B. Specimens may be stored at 2-8°C for up to 7 days of collection.

C. If testing is delayed more than 7 days, the plasma should be removed from the cells and frozen (-20°C or colder).

D. Avoid repeated freeze/thaw cycles. Specimens that have been frozen and thawed more than 3 times cannot be used. All frozen specimens must be centrifuged at 10,000g for 5 minutes. If a lipid layer is formed on the surface of the liquid, ensure that the sample is taken from the clear liquid below that layer.

E. Abbott Determine™ HIV-1/2 Ag/Ab Combo is not intended for newborn screening or for use with cord blood specimens or specimens from individuals less than 12 years of age.

F. For specimens from patients less than 12 years of age, cancel the rapid test and place a new order for the HIV 1/2 Testing Algorithm.

IV. REAGENTS:

A. Each kit of Abbott Determine™ HIV–1/2 Ag/Ab Combo contains:

1. Aluminum zip-lock pouch containing Abbott Determine™ HIV-1/2 Ag/Ab Combo Cards. Each Card consists of 5 or 10 Test Units which can be separated from each other by tearing along the perforated lines. Each Test Unit has a cover that is to be removed for sample application and visualization of test results. Cards are stored at 2-30°C (36-86°F) until expiration date.
2. Quick Reference Guide
3. Disposable Workstations
4. Note: The Chase Buffer and Disposable Capillary Tubes supplied with the kits will NOT be used.

V. SUPPLIES:

A. 50µL Micropipettor

B. Timer

VI. EXTERNAL QUALITY CONTROL (QC):

A. Each package Abbott Determine™ HIV–1/2 Ag/Ab Combo Controls contains:

1. HIV-1 p24 Antigen Control: 1.5 mL HIV-1 viral lysate in defibrinated pooled normal human plasma negative for antibodies to HIV-1, HIV-2 and HCV; negative for HBsAg.
2. HIV-1 Reactive Control: 1.5 mL human plasma positive for anti-HIV-1 antibodies, diluted in defibrinated pooled normal human plasma; negative for antibodies to HIV-2 and HCV; negative for HBsAg.
3. HIV-2 Reactive Control: 1.5 mL human plasma positive for anti-HIV-2 antibodies, diluted in defibrinated pooled normal human plasma; negative for antibodies to HIV-1 and HCV;

negative for HBsAg and HIV-1 p24.

4. Nonreactive Control: 1.5 mL defibrinated normal human plasma; negative for antibodies to HIV-1, HIV-2, and HCV; negative for HBsAg and HIV-1 p24.

B. Abbott Determine™ HIV-1/2 Ag/Ab Combo Controls should be tested prior to testing patient specimens when:

1. new untrained operator performs testing
2. a new lot number of test kit is to be used
3. a new shipment of test kits is received
4. Every 30 days

C. Controls should be tested in the same manner as plasma samples in the following Procedure section.

D. An Individualized Quality Control Plan (IQCP) has been prepared and External Quality Controls were validated for ~~31~~at least 30 days.

1. For labs not utilizing an IQCP, External Quality Controls are tested each day of patient testing.

VII. PROCEDURE:

A. Kit Component Preparation

1. All components must be brought to room temperature (between 15-30˚C, 59-86˚F) prior to testing if stored at 2-8˚C.
2. Open the aluminum pouch containing the Abbott Determine™ HIV-1/2 Ag/Ab Combo Cards.
3. 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.
4. Return the unused test units to the aluminum pouch and close the pouch with the zip-lock. NOTE: Store the unused cards and test units only in the aluminum pouch containing the desiccant package. Carefully close the zip-lock, so that the cards are not exposed to ambient humidity during storage.
5. Lay the Test Unit flat in the disposable workstation and remove the protective foil cover from each Test Unit. The test should be initiated within 2 hours after 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.

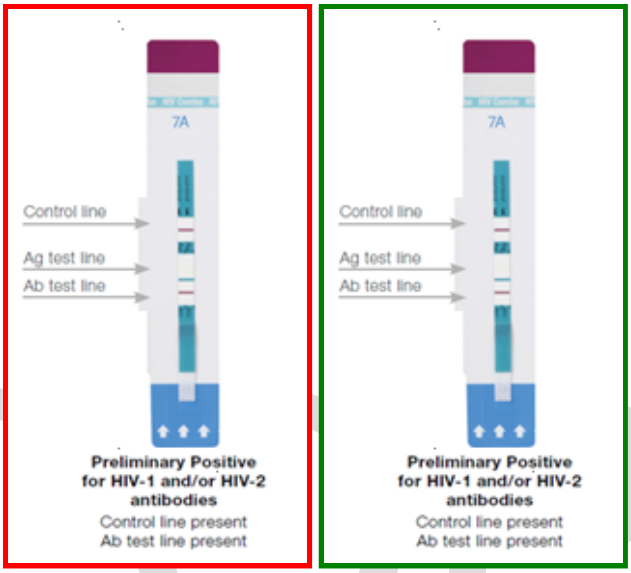
B. Testing

1. Check plasma for particulates or incomplete centrifugation; re-centrifuge if necessary.
2. Apply 50 µL of sample (precision pipette) to the Sample Pad (marked by the arrow symbol). Do not add Chase Buffer when using plasma specimens.
3. Read the test result between 20 and 30 minutes after the addition of the Sample. Do not read Test Results after 30 minutes.

VIII. INTERPRETATION:

A. **ANTIBODY REACTIVE (Two Lines - Control Line and Ab Line)**

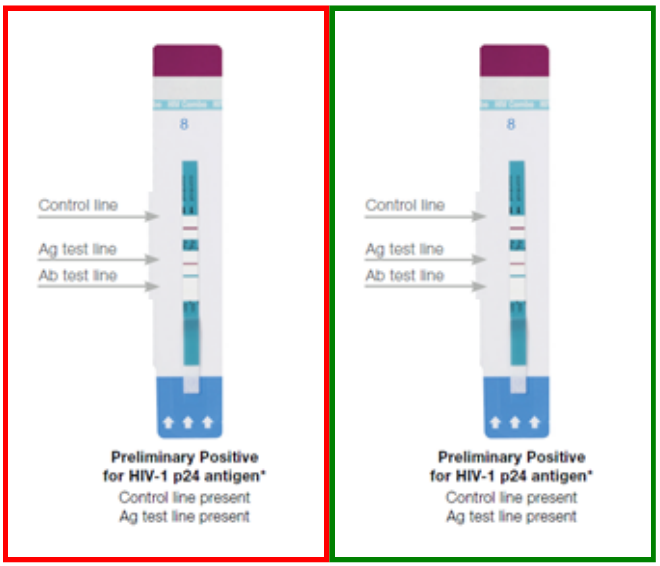
1. A pink/red Control line appears in the Control Area AND a pink/red Ab line appears in the Lower Test Area of the Test Unit. The intensity of the Ab and Control lines may vary. Any visible pink/red color in both the Control and Lower Test Areas, regardless of intensity, is considered REACTIVE. A Reactive test result means that HIV-1 and/or HIV-2 antibodies have been detected in the specimen. The Rapid test result is interpreted as UNCONFIRMED REACTIVE.



B. **ANTIGEN (HIV-1 P24) REACTIVE (Two Lines-Control Line and Ag Line)**

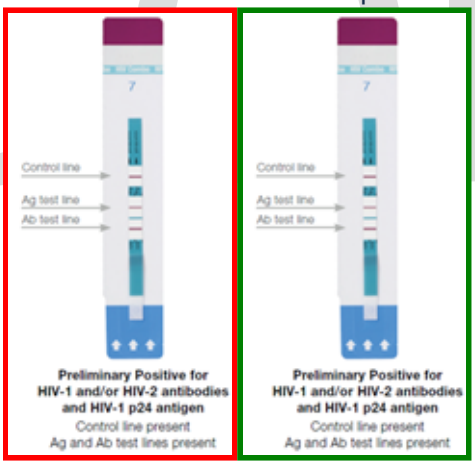
1. A pink/red Control line appears in the Control Area AND a pink/red Ag line appears in the Upper Test Area of the Test Unit. The intensity of the Ag and Control lines may vary. Any visible pink/red color in both the Control and Upper Test Areas, regardless of intensity, is considered REACTIVE. A Reactive test result means that HIV-1 p24 antigen has been detected in the specimen. The Rapid test result is interpreted as UNCONFIRMED REACTIVE.

NOTE: *A test result that is UNCONFIRMED REACTIVE 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.*



C. **ANTIBODY REACTIVE AND ANTIGEN (HIV-1 p24) REACTIVE (Three Lines- Control, Ab, and Ag Lines)**

1. A pink/red Control line appears in the Control Area AND a pink/red Ab line appears in the Lower Test Area AND a pink/red Ag line appears in the Upper Test Area of the Test Unit. The intensity of the Ab, Ag and Control lines may vary. Any visible pink/red color in the Control Area, the Lower Test Area and the Upper Test Area, regardless of intensity, is considered REACTIVE. The Rapid test result is interpreted as UNCONFIRMED REACTIVE.

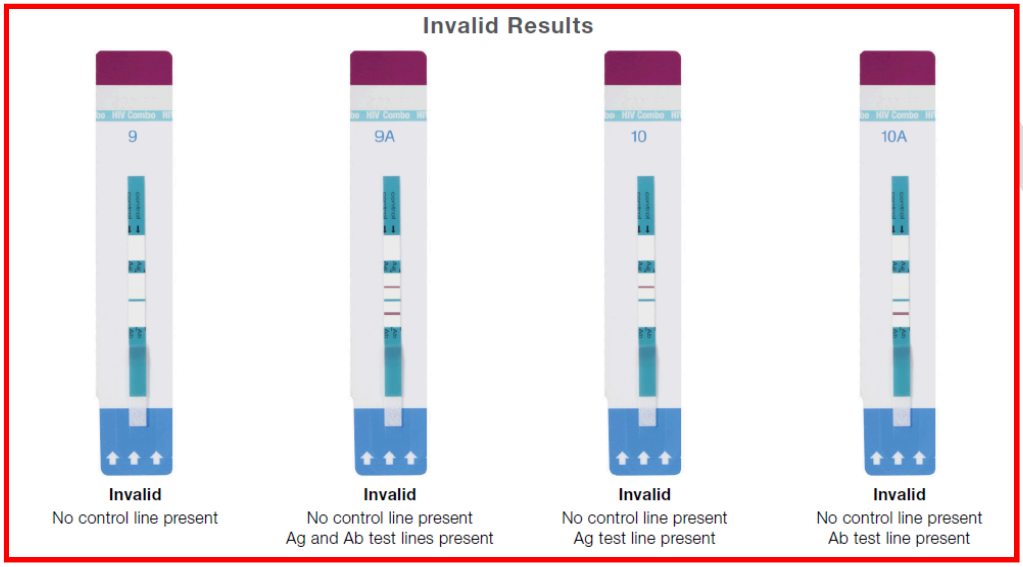


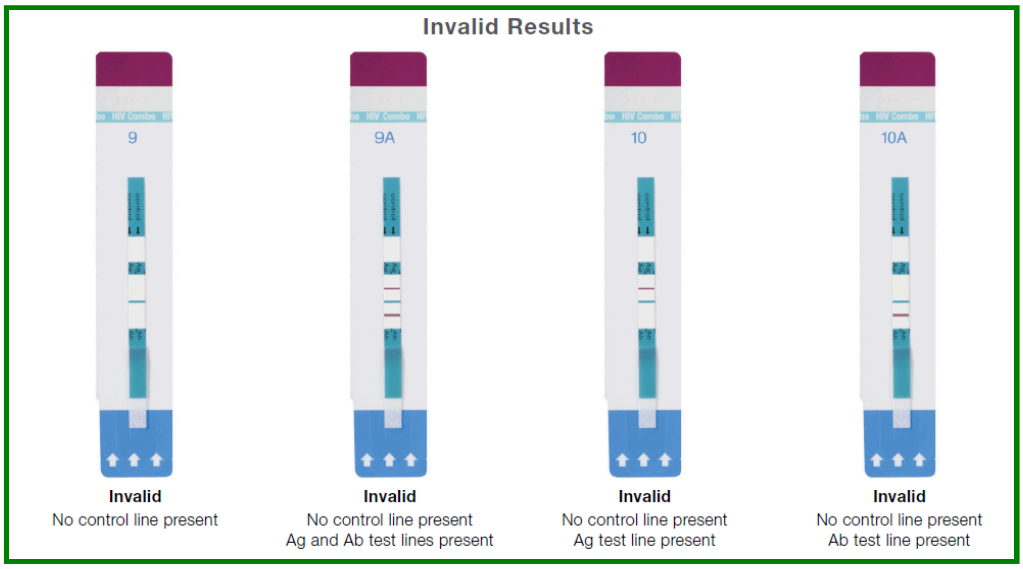
D. **NONREACTIVE (One Line – Control Line)**

1. A pink/red Control line appears in the Control Area of the Test Unit, and no pink/red Ab or Ag line appears in the Lower Test Area and the Upper Test Area of the Test Unit, respectively. A NONREACTIVE test result means that HIV-1 or HIV-2 antibodies and HIV-1 p24 antigen were not detected in the specimen. The Rapid test result is interpreted as NONREACTIVE.

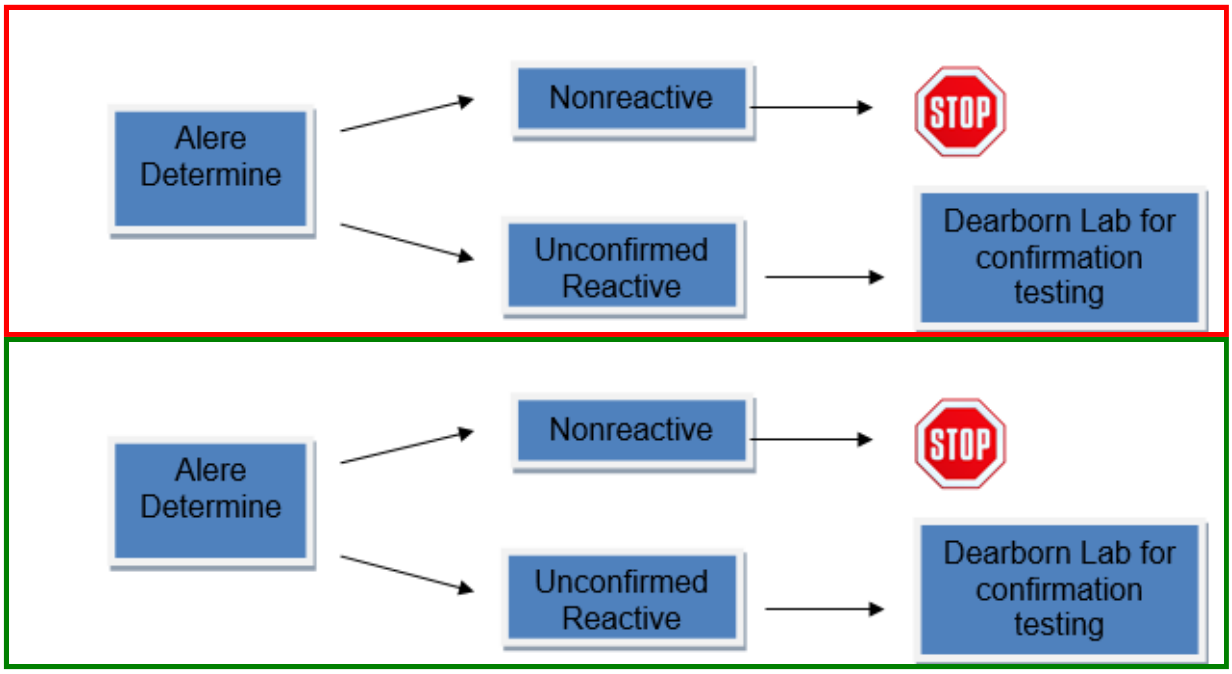
E. **INVALID (No Control Line)**

1. If there is no pink/red Control line in the Control Area of the Test Unit, even if a pink/red line appears in the Lower Test Area or the Upper Test Area of the Test Unit, the result is INVALID and the test should be repeated. If the problem persists, request a new specimen. Contact Abbott Technical Support if the problem persists and do not perform patient testing until valid external QC has been achieved.





IX. TESTING ALGORITHM:



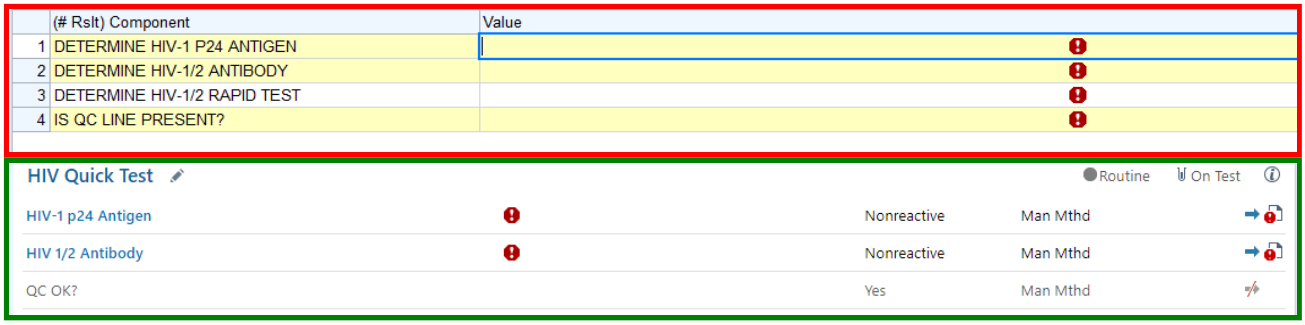
X. RESULTING:

A. Results, along with internal QC results, should be manually entered into the Laboratory Information System (LIS).
    1. If both the Antigen and Antibody are Nonreactive, report the rapid test (3) as Nonreactive.
    2. If either the Antigen or Antibody (1 or 2) is Reactive, report the rapid test (3) as Unconfirmed Reactive.
    3. Unconfirmed Reactive results will reflex to the HIV 1/2 Testing Algorithm.

B. All Unconfirmed Reactive Rapid results on source patients should be called to the charge nurse.

C. All Unconfirmed Reactive Rapid results on OB patients should be called to the patient's caregiver.

D. All Unconfirmed Reactive Rapid results on assault victims should be called to the charge nurse.



	(# Rslt) Component	Value
1	DETERMINE HIV-1 P24 ANTIGEN	
2	DETERMINE HIV-1/2 ANTIBODY	
3	DETERMINE HIV-1/2 RAPID TEST	
4	IS QC LINE PRESENT?	

XI. LIMITATIONS:

A. Testing may only be performed on patients 12 years of age and older.

1. For patients <12 years of age, cancel the Rapid test code and place a new order for the HIV 1/2 Testing Algorithm test code.

B. Specimens from individuals with elevated triglycerides (>600 mg/dL), may give false positive results.

1. Lipemic specimens should be recollected as a fasting sample.
2. If lipemia persists, cancel the Rapid test code and place a new order for the HIV 1/2 Testing Algorithm test code.

C. Hemolyzed or icteric samples should be recollected.

1. If the recollected samples are hemolyzed or icteric, the technologist will run the sample and assess the test strip for clarity of results.
    a. If results are in question, cancel the Rapid test code and place a new order for the HIV 1/2 Testing Algorithm test code.

XII. INTERFERING SUBSTANCES:

A. Biotin, also known as Vitamin B7, is a water soluble and essential B-vitamin. It can be found in a wide range of foods that are high in proteins, multivitamins, prenatal vitamins and dietary substances used for hair, skin and nail growth. Biotin is also a substance that is often used in the manufacturing of immunoassay diagnostic tests. Biotin technology is used due to its ability to bond with specific proteins which can be measured to detect certain health conditions.

B. The Determine™ HIV-1/2 Ag/Ab Combo test is manufactured using biotin technology. Detection of p24 may be inhibited by biotin in the sample, causing false negative results in acute infection and therefore, samples from patients taking Biotin should not be tested.

C. Biotin, taken in large doses above the daily recommended allowance (30-100 mcg) has been shown to interfere with certain laboratory diagnostic tests. It is important for consumers and health care providers to have an open discussion regarding biotin interference prior to laboratory testing.

See package insert and Customer Bulletin: BIOTIN Determine™ HIV-1/2 Ag/Ab Combo

XIII. REFERENCES:

1. Abbott Determine™ HIV–1/2 Ag/Ab Combo, package insert, IN02732530 Rev. 8 2021/06
2. Abbott Determine™ HIV-1/2 Ag/Ab Combo Controls package insert 2016/5
3. CDC: Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations, 6-26-2014Abbott Customer Bulletin: BIOTIN Determine™ HIV-1/2 Ag/Ab Combo. 2019 TB000036 Rev. 1

Attachments

Abbott Determine Patient Log.pdf

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QC Log Abbott Determine HIV 1 2 Ag Ab Combo.pdf

Approval Signatures

Step Description	Approver	Date
Medical Director	Muhammad Arshad: Chief, Pathology	9/27/2024
Policy and Forms Steering Committee Approval (if needed)	Laura Bellon: Medical Technologist Lead	9/26/2024
	Christopher Ferguson: Dir, Lab Services	9/26/2024
	Kristen DiCicco: Mgr, Laboratory	9/26/2024
	Ashley Beesley: Mgr, Laboratory	9/25/2024
	Katherine Persinger: Mgr, Laboratory	9/25/2024
	Laura Bellon: Medical Technologist Lead	9/24/2024

Applicability

Taylor, Trenton, Wayne