Determine™

HIV-1/2

This package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are deviations from the instructions in this package insert.

NAME AND INTENDED USE

The Abbott Determine ™ HIV-1/2 is an in Vitro, visually read, qualitative immunoassay for the detection of antibodies to HIV-1 and HIV-2 in human serum, plasma or whole blood. The test is intended as an aid to detect antibodies to HIV-1/HIV-2 from infected individuals.

SUMMARY AND EXPLANATION OF THE TEST

AIDS (Acquired immunodeficiency Syndrome) is characterized by changes in the population of T-cell lymphocytes. In an infected individual, the virus causes depletion of helper T-cells, which leaves the person susceptible to opportunistic infections and some malignancies. The virus that causes AIDS exists as two related types known as HIV-1 and HIV-2. The presence of the AIDS virus elicits the production of specific antibodies to either HIV-1 or HIV-2. [1,2,3]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

Determine HIV-1/2 is an immunochromatographic test for the qualitative detection of antibodies to HIV-1 and HIV-2. Sample is added to the sample pad. As the sample migrates through the conjugate pad, it reconstitutes and mixes with the selenium colloid-antigen conjugate. This mixture continues to migrate through the solid phase to the immobilized recombinant antigens and synthetic peptides at the patient window site.

If antibodies to HIV-1 and/or HIV-2 are present in the antibodies bind to the antigen-selenium colloid and to the antigen at the patient window, forming a red line at the patient window site.

If antibodies to HIV-1 and/or HIV-2 are absent, antigen-selenium colloid flows past the patient window, and no red line is formed at the patient window site.

To insure assay validity, a procedural control bar is incorporated in the assay device.

CONTENTS

Abbott Determine HIV-1/2 Serum/Plasma Assay (List No.7D23-13), 100 Tests

- Determine HIV-1/2 Test Card, 10 cards (10 tests/card), HIV-1/2 recombinant antigen and synthetic peptide coated.

Abbott Determine HIV-1/2 Whole Blood Assay (List No.7D23-33), 100 Tests

- Determine HIV-1/2 Test Card, 10 cards (10 tests/card), HIV-1/2 recombinant antigen and synthetic peptide coated.
- 1 Bottle (2.5mL) Chase Buffer (List No.7D22-11) prepared in phosphate buffer. Preservatives: Antimicrobial Agents.

ACCESSORIES (required but not provided)

Serum/Plasma or Whole Blood (venipuncture assay)		Whole Blood (fingerstick assay)	
Pipette	No. 7D22-51	Lancets	No. 7D22-31
Pipette Tips	No. 7D22-61	EDTA Capillary Tubes	No. 7D22-21

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use.

CAUTION:

Appropriate biosafety practices [4,5] should be used for materials that contain or are suspected of containing infectious agents. These precautions include, but are not limited to the following:

- Wear gloves when handling specimens or reagents.
- Do not pipette by mouth.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses in areas where these materials are handled.
- Clean and disinfect all spills of specimens or reagents using a tuberculocidal disinfectant, such as 0.5% sodium hypochlorite, or other suitable disinfectant.[6,7]
- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials in accordance with local regulations [8,9]
- Kit components are stable until expiration date when handled and stored as directed. Do not use kit components beyond expiration date.

STORAGE

The Abbott Determine HIV-1/2 Test Cards and Chase Buffer must be stored at 2-30 °C until expiration date.

SPECIMEN COLLECTION

Serum, Plasma, and Whole Blood Collection by Venipuncture

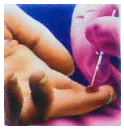
Human serum, plasma, and whole blood collected by venipuncture should be collected aseptically in such a way as to avoid hemolysis.

NOTE: For whole blood and plasma specimens, EDTA collection tubes must be used.

Whole Blood Collection by Fingerstick[10]

Before collecting a fingerstick specimen, place an EDTA capillary tube on a clean dry surface.

1. Choose the fingertip of the middle, ring, or index finger (whichever is the least callused) for adults and children older than one year. Warm the hand as needed with a warm, moist towel or warm water to increase blood flow.
2. Clean fingertip with alcohol; allow to air dry. Position the hand palm-side up
3. Use a new lancet for each person. Place the lancet off-center on the fingertip. Firmly press the lancet against the finger and puncture the skin. Dispose of the lancet in an appropriate biohazard sharps container.
4. Wipe away the first drop of blood with a sterile gauze pad.
5. Hold the finger lower than the elbow and apply gentle, intermittent pressure to the base of the punctured finger several times. Touch the tip of the EDTA Capillary Tube to the drop of blood *. Avoid air bubbles.



*If EDTA Capillary Tubes (No.7D22-21) will be used, fill the tube with blood between the 2 marked lines.

SPECIMEN STORAGE

- Serum and plasma specimens should be stored at 2-8 °C if the test is to be run within 7 days of collection. If testing is delayed more than 7 days, the specimen should be frozen (-20 °C or colder).
- Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 7 days of collection. Do not freeze whole blood specimens.
- Whole blood collected by fingerstick should be tested immediately.

TEST PROCEDURE

The desired number of test units from the 10-test card can be removed by bending and tearing at the perforation.

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

1. Remove the protective foil cover from each test.
2. For serum of plasma samples:
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait a minimum of 15 minutes (up to 60 minutes) and read result.
3. For whole blood (venipuncture) samples:
   a. Apply 50 µL of sample (precision pipette) to the sample pad (marked by the arrow symbol).
   b. Wait one minute, then apply one drop of Chase Buffer to the sample pad.
   c. Wait a minimum of 15 minutes (up to 60 minutes) and read result.
4. For whole blood (fingerstick) samples:
   a. Apply 50 µL of sample (by EDTA capillary tube) to the sample pad (marked by the arrow symbol).
   b. Wait until blood is absorbed into the sample pad, then apply one drop of Chase Buffer to the sample pad.
   c. Wait a minimum of 15 minutes (up to 60 hours) and read result.

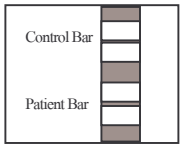
QUALITY CONTROL

To insure assay validity, a procedural control is incorporated in the device and is labeled "Control". If the control bar does not turn red by assay completion, the test result is invalid and the sample should be retested.

INTERPRETATION OF RESULTS

POSITIVE (Two Bars)

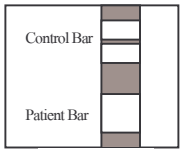
Red bars appear in both the control window (labeled "Control") and the Patient window (labeled "Patient") of the strip. Any visible red color in the patient window should be interpreted as positive.



Positive

NEGATIVE (One Bar)

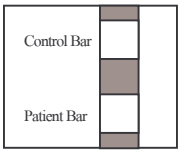
One red bar appears in the control window of the strip (labeled "Control"), and no red bar appears in the patient window of the strip (labeled "Patient").



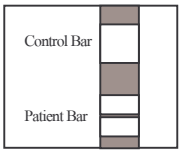
Negative

INVALID (No Bar)

If there is no red bar in the control window of the strip, and even if a red bar appears in the patient window of the strip, the result is invalid and should be repeated. If the problem persists, contact your local Abbott Customer Service and Support Center.



Invalid



Invalid

NOTES:

- The test result is positive even if the patient bar appears lighter or darker than the control bar.
- If an invalid test result occurs repeatedly, or for technical assistance, contact your local Abbott Customer Service and Support Center.

LIMITATIONS OF THE PROCEDURE

- The Abbott Determine HIV-1/2 test is designed to detect antibodies to HIV-1 and HIV-2 in human serum, plasma, and whole blood. Other body fluids or pooled specimens may not give accurate results.
- The intensity of the patient bar does not necessarily correlate to the titer of antigen in the specimen.
- No test provides absolute assurance that a sample does not contain low levels of antibodies to HIV-1 and HIV-2 such as those present at a very early stage of infection. Therefore, a negative result at any time does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.
- Positive specimens should be retested using another method and the results should be evaluated in light of the overall clinical evaluation before a diagnosis is made.
- Whole blood or plasma specimens containing anticoagulants other than EDTA may give incorrect results.

PERFORMANCE CHARACTERISTICS

SPECIFICITY

A total of 1,594 serum and plasma specimens from Asia, West Africa, and North America were tested by Abbott Determine HIV1-2 and a commercially available test (Table I).

Table I

Specificity of Abbott Determine HIV-1/2

Population	Number of Specimens Tested	Negative by Abbott Determine HIV-1/2	Negative by Commercially Available Test
Seronegatives			
Serum	908	907/908 (99.89%)	908/908(100.00%)
Plasma	403	403/403(100.00%)	403/403(100.00%)
Pregnant Females	58*	57/57 (100.00%)	57/57 (100.00%)
West Africans	49	48/49 (97.96%)	48/49 (97.96%)
Disease States Other than And Potentially Interfering Substances	176*	173/175 (98.86%)	174/175 (99.45%)
Total	1,594	1,588/1,592(99.95%)	1,590/1,592 (99.87%)

**One specimen from a pregnant female and an HCV positive patient were positive by both Abbott Determine and the commercially available test. Both specimens confirmed positive by HIV-1 Western Blot.

A total of 368 seronegative whole blood specimens from Thailand were tested with paired serum and plasma by Abbott Determine HIV-1/2 Thirty-nine of the whole blood specimens were collected by both venipuncture and fingerstick (Table II).

Table II

A Comparison of Abbott Determine HIV-1/2 Specificity in Soronegative Whole Blood and Paired Serum and Plasma Specimens

Specimen Type	Number of Specimens Tested	Negative by Abbott Determine HIV-1/2
Serum	368	368/368 (100.00%)
Plasma	368	368/368 (100.00%)
Whole Blood (venipuncture)	368	368/368 (100.00%)
Whole Blood (fingerstick)	39	39/39 (100.00%)

SENSITIVITY

A total of 869 HIV-1 and HIV-2 antibody positive serum and plasma specimens from Asia, Africa, North and South America were tested by Abbott Determine HIV-1/2 and a commercially available test (Table III).

Table III

Sensitivity of Abbott Determine HIV–1/2

Population	Number of Specimens Tested	Positive by Abbott Determine HIV-1/2	Positive by a Commercially Available Test
HIV-1 Positive	521	521/521(100.00%)	521/521 (100.00%)
HIV-2 Positive	114	114/114(100.00%)	114/114
HIV-1 Subtypes A-G	222	222/222(100.00%)	222
HIV-1 Group O	12	12/12 (100.00%)	Not Tested Not Tested
Total	869	869/869(100.00%)	635/635 (100.00%)

A total of 102 seropositive whole blood specimens from Thailand were tested with paired serum and plasma by Abbott Determine HIV-1/2. Thirty two of the whole blood specimens were collected by both venipuncture and fingerstick (Table IV).

Table IV

A Comparison of Abbott Determine HIV-1/2 Specificity in Seropositive Whole Blood and Paired Serum and Plasma Specimens

Specimen Type	Number of Specimens Tested	Positive by Abbott Determine HIV-1/2
Serum	102	102/102 (100.00%)
Plasma	102	102/102 (100.00%)
Whole Blood (venipuncture)	102	102/102 (100.00%)
Whole Blood (fingerstick)	32	32/32 (100.00%)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