



Determine™ HIV-1/2 Ag/Ab Combo Controls

Catalog # 7D2628

Storage: Store at 2 to 8°C (36 to 46°F)

Read this Package Insert and the Alere Determine™ HIV-1/2 Ag/Ab Combo 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. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other bloodborne pathogens.¹

Intended Use

The Alere Determine™ HIV-1/2 Ag/Ab Combo Controls are quality control reagents for use with the Alere Determine™ HIV-1/2 Ag/Ab Combo Assay only.

Perform the Kit Controls under the following circumstances:

- 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.

It is the responsibility of each laboratory using Alere Determine™ HIV-1/2 Ag/Ab Combo to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use.

Summary and Explanation of HIV Reactive and Nonreactive Controls

Alere Determine™ HIV-1/2 Ag/Ab Combo Controls are human, plasma-based reagents. The Controls are specifically formulated and manufactured to ensure performance of the test, and are used to verify the user's ability to properly perform the test and interpret the results. The HIV-1 and HIV-2 Reactive Controls will produce a Reactive test result and have been manufactured to produce a visible Test "Ab" line. The HIV-1 p24 Antigen Control will produce a Reactive test result and has been manufactured to produce a visible Test "Ag" line. The Nonreactive Control will produce a Nonreactive test result. Use of control reagents manufactured by another source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the Alere Determine™ HIV-1/2 Ag/Ab Combo Assay.

Materials Provided

Alere Determine™ HIV-1/2 Ag/Ab Combo Controls

Each Kit Control box contains a package insert, 40 disposable pipettes, and four vials (one HIV-1 Reactive Control, one HIV-2 Reactive Control, one HIV-1 p24 Antigen Control, and one Nonreactive Control) as described below.

Note: *The disposable pipettes provided with the Alere Determine™ HIV-1/2 Ag/Ab Combo Control Kit are for use with the external controls only and are NOT to be used for testing patient samples.*

HIV-1 Reactive Control

One red-capped vial containing 1.5 mL of heat inactivated human plasma positive for antibodies to HIV-1, diluted in normal human plasma. Negative for Hepatitis B surface antigen and Hepatitis C antibody.

HIV-2 Reactive Control

One green-capped vial containing 1.5 mL of heat inactivated human plasma positive for antibodies to HIV-2, diluted in normal human plasma. Negative for Hepatitis B surface antigen and Hepatitis C antibody.

HIV-1 p24 Antigen Control

One lavender-capped vial containing 1.5 mL of heat inactivated human plasma positive for HIV-1 p24 antigen, diluted in normal human plasma. Negative for Hepatitis B surface antigen and Hepatitis C antibody.

Nonreactive Control

One white-capped vial containing 1.5 mL of normal human plasma negative for antibodies to HIV-1 and HIV-2 and negative for HIV-1 p24 antigen. Negative for Hepatitis B surface antigen and Hepatitis C antibody.

Materials Required and Provided in the Alere Determine™ HIV-1/2 Ag/Ab Combo Assay

- Alere Determine™ HIV-1/2 Ag/Ab Combo Test Cards (5 or 10 tests/card)
- Desiccant Package
- Chase Buffer (2.5 mL)
- Disposable Capillary Tubes
- Disposable Workstations
- Subject Information Notices
- Alere Determine™ HIV-1/2 Ag/Ab Combo Package Insert
- Quick Reference Card
- Customer Letter

Materials Required but Not Provided

- Clock, watch, or other timing device
- Disposable gloves
- Protective eyeglasses
- Biohazard waste container

Optional Materials Not Provided

- Pipettor capable of delivering 50 µL of sample may be used in lieu of the disposable pipettes supplied with the Kit.

Warnings

For *IN VITRO* diagnostic use

1. Read this Package Insert and the Alere Determine™ HIV-1/2 Ag/Ab Combo Package Insert completely before using this product. Follow the instructions carefully as not doing so may result in inaccurate Test Results.
2. Users of this test should follow the CDC Universal Precautions for prevention of transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other bloodborne pathogens¹ and “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV Recommendations for Postexposure Prophylaxis”.²
3. Handle the Alere Determine™ Combo HIV-1/2 Ag/Ab Controls, and materials contacting the Controls, as if capable of transmitting infectious agents.
4. Do not eat, drink or smoke in the area where kit reagents are handled. Avoid any contact with hands, eyes or mouth during control testing.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling Kit Controls.
6. Decontaminate and dispose of all specimens, reagents, workstations, and other potentially contaminated materials in a biohazard waste container in accordance with local regulations.^{3,4} Lancets should be placed in a puncture-resistant container prior to disposal. The workstations are for single use only. The used workstation and test strip should be regarded as potentially infectious material. They should be disposed of together, without trying to remove the strip from the workstation, in a biohazard waste container as indicated above.
7. Use 10% bleach or other appropriate disinfectant to wipe all spills. The bleach solution should be made fresh each day.
8. Use of Kit Control reagents manufactured by another source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the Alere Determine™ HIV-1/2 Ag/Ab Combo Assay.
9. The disposable pipettes provided with the Alere Determine™ HIV-1/2 Ag/Ab Combo Control Kit are for use with the external controls only and are NOT to be used for testing patient samples.

Storage and Stability

Alere Determine™ HIV-1/2 Ag/Ab Combo Controls should be stored at 2 to 8°C (36 to 46°F). Do not use beyond the indicated expiration date. Open the Control Vials only when you are performing tests. Recap and store the Control Vials in their original container at 2 to 8°C (36 to 46°F) after use.

Test Procedure

All components for the Alere Determine™ HIV-1/2 Ag/Ab Combo Assay are ready to use as supplied. Instructions for use are given in the Alere Determine™ HIV-1/2 Ag/Ab Combo Assay Package Insert. Follow directions as indicated.

External control material stored at refrigerated temperatures must be brought to room temperature (15 to 30°C; 59 to 86°F) prior to testing.

Procedure for Using Controls with the Alere Determine™ HIV-1/2 Ag/Ab Combo Assay

The desired number of test units from the 5- or 10-test card can be removed by bending and tearing at the perforation. The test(s) should be initiated within 2 hours after removing the protective foil cover from each test.

1. 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.
2. Remove the protective foil cover from each test and place it on a flat surface or in the workstation.
3. Label the Test Device with Control Reagent name or identification number.
4. Open a Control Vial containing the Control Reagent.

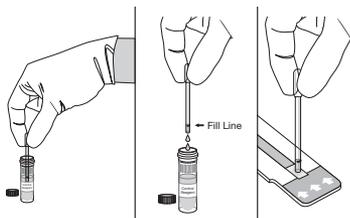
a. Squeeze the pipette bulb and place the pipette tip into the Control Reagent.

b. Gently release the bulb to bring the liquid above the fill line on the pipette.

c. Raise the pipette and gently squeeze the bulb to bring the liquid down to the fill line.

d. Touch the pipette tip to the Sample Pad and squeeze the pipette bulb to release all of the liquid.

Use a new pipette tip or disposable pipette with each new Control Reagent.



Note: Do not add Chase Buffer when running External Controls.

5. Read the Test Result between 20 and 30 minutes after the addition of the Control Reagent in a well-lit area. **Do not read Test Results after 30 minutes.**
6. Discard the used Test Device and any other test materials into a biohazard waste container.
7. Reseal the Control Reagent Vials and store them in their original container at 2 to 8°C (36 to 46°F).

Quality Control

Built-in Control Feature

To ensure assay validity, a procedural control is incorporated in the device and is labeled “Control”. Any visible line (even very faint) in the control window should be interpreted as a valid result. If the control line does not turn pink/red by assay completion, the test result is invalid and the control reagent should be retested.

Expected Results

Please refer to the Alere Determine™ HIV-1/2 Ag/Ab Combo Package Insert for pictorial examples of REACTIVE, NONREACTIVE and INVALID Test Results.

Nonreactive Control

(One Line – Control Line)

One PINK/RED line appears in the control area of the strip (labeled “Control”), and no PINK/RED line appears in either the Lower Test Area or the Upper Test Area of the strip (labeled “Ab” and “Ag”). A NONREACTIVE Test Result means that HIV-1 or HIV-2 antibodies and HIV-1 p24 antigen were not detected in the specimen.

HIV-1 p24 Antigen Control

(Two Lines - Control and Ag Line)

Two PINK/RED lines appear in both the Control Area (labeled “Control”) and the Upper Test Area (labeled “Ag”) of the strip. Line intensity of the “Ag” and “Control” line may vary. Any visible PINK/RED color in both the “Ag” and “Control” Area, regardless of intensity, is considered REACTIVE.

HIV-1 Reactive Control

(Two Lines - Control and Ab Line)

Two PINK/RED lines appear in both the Control Area (labeled “Control”) and the Lower Test Area (labeled “Ab”) of the strip. Line intensity of the “Ab” and “Control” line may vary. Any visible PINK/RED color in both the “Ab” and “Control” Area, regardless of intensity, is considered REACTIVE.

HIV-2 Reactive Control

(Two Lines - Control and Ab Line)

Two PINK/RED lines appear in both the Control Area (labeled “Control”) and the Lower Test Area (labeled “Ab”) of the strip. Line intensity of the “Ab” and “Control” line may vary. Any visible PINK/RED color in both the “Ab” and “Control” Area, regardless of intensity, is considered REACTIVE.

Note: If the Test Result for the Nonreactive Control, HIV-1 p24 Antigen Control, HIV-1 Reactive Control or HIV 2 Reactive Control does not produce the expected result, the test should be repeated using a new Test Device and Control Specimen. If the HIV Control Reagents do not produce the expected results upon repeat testing, contact Alere™ Technical Support at (877) 866-9335.

Limitations

Alere Determine™ HIV-1/2 Ag/Ab Combo Controls are quality control reagents for use ONLY with the Alere Determine™ HIV-1/2 Ag/Ab Combo Assay.

References

1. 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.
2. CDC: Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV Recommendations for Postexposure Prophylaxis. MMWR 2001; 50(RR-11):1-42.
3. National Committee for Clinical Standards Clinical Waste Management: Approved Guideline. NCCLS Document GPS-A. Villanova, PA: NCCLS, 1993; 13(22):1-18, 29-42.
4. US Environmental Protection Agency EPA Guide for Infections Waste Management: Publication No. EPA /530-SW-86-014. Washington, DC: US Environmental Protection Agency, 1986:1-1-5, R1-R3, A1-A24.

For ordering and technical assistance please contact:

Ordering: (877) 441-7440

Technical Service: (877) 866-9335

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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)



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