IVD

HUMAN IMMUNODEFICIENCY VIRUSES（HIV 1/2） ANTIBODIES COLLOIDAL GOLD ASSAY

Catalog No. C0103

20 or 50 tests

INTENDED USE

The Autobio human immunodeficiency viruses（HIV1/2）antibodies (anti-HIV 1/2) colloidal gold assay is intended for the qualitative determination of anti-HIV 1/2 in human serum, plasma and whole blood.

INTRODUCTION

Acquired immune deficiency syndrome (AIDS), characterized by the progressive loss of T-helper cell immune functions, is associated with human immunodeficiency viruses (HIV). HIV-1 is prevalent in the Americas, Europe, Central African nations and other countries to which it spreads. HIV-2, prevalent in West African nations, is now reported in India. Because HIV is not an endogenous retrovirus in humans, the presence of antibodies to HIV is an acceptable evidence of infection or previous exposure to this virus. The HIV 1/2 multi-epitope protein contains all relevant antigenic epitopes of env and gag common to both HIV-1 and HIV-2.

PRINCIPLE OF THE ASSAY

ANTI-HIV assay is a rapid direct binding test for the visual detection of anti-HIV in serum、plasma and whole blood as an aid in the diagnosis of HIV infection. It is based on the principle of double antigen sandwich immunoassay for determination of anti-HIV(1+2) in serum、plasma and whole blood. Purified recombinant HIV antigens were employed to specifically identify anti-HIV with high sensitivity. This one step test only takes about 5 to 20 minutes. Test results are read visually without any instrument.

MATERIALS PROVIDED

1. Test Devices: wrapped in individual foil pouches (20/50 pouches).
2. Assay Buffer: only used in whole blood specimen collection (1 bottle).
3. Sterile Minilet Lancet: (20/50).
4. Alcohol Swab: (20/50).

MATERIALS NOT PROVIDED

The following materials are required but not provided in the kit:

1. Specimen collection container
2. Timer
3. centrifuge to process a plasma specimen
4. Protective gloves

STORAGE OF ASSAY KIT AND INSTRUMENTATION

The kit can be stored at room temperature or refrigerated (4～30°C). The test strip is stable throughout the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The anti-HIV 1/2 colloidal gold assay can be performed on either serum, plasma or whole blood specimens.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Assay should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum, plasma Specimens may be stored at 2～8 °C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. fingerprick whole blood specimen could be collected by first using an aseptic wipe to clean the finger of the person being tested, then puncturing the center of the finger pad skin with a sterile lancet , holding

the finger downward, the blood drips into the test device's sample well.

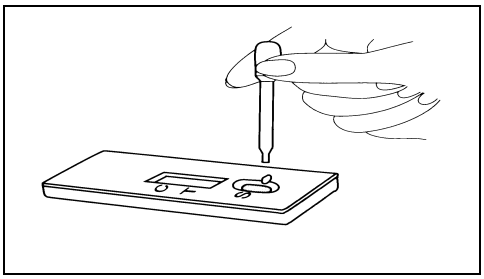
5. venipuncture whole blood specimen could be collected in accordance with the standard practices for collecting human blood specimens with anticoagulants. Validated anticoagulants include EDTA, sodium heparin and sodium citrate. other anticoagulants have not been tested and may give an incorrect result. If the specimen cannot be tested immediately, it may be stored at 2～8 ℃ for up to six days. prior to testing, mix the blood tube gently several times to ensure a homogenous sample.
6. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
7. If specimens are to be shipped, they should be packed in compliance with federal or corresponding national regulations covering the transportation of etiologic agents.

PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use only.
2. Handling of reagents, specimens should be in accordance with local safety procedures.
3. Do not smoke, drink, eat or apply cosmetics in the working area. Do not pipette by mouth. Use protective clothing and disposable gloves.
4. Wash hands after operations.
5. wipe and wash the splashed specimen with highly effective disinfectant.
6. Used specimens, Test Devices and materials that may be contaminated should be disposed of
7. Avoid splashing and the formation of smog.
8. Do not reuse expired assays.
9. Use unpakced Test Devices as soon as possible to avoid being humidified.

ASSAY PROCEDURE

1. Bring all reagents, specimens and Test Devices to room temperature before performing the assay. (Allow some time, approximately 30 minutes, for solutions to be completely recovered to room temperature before proceeding to the next step).
2. Remove the Test Device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Label the device with patient specimen's number.
3. When serum or plasma is collected, dispense 2 drops (approximately 80 l) of the serum, plasma specimen or control into the sample well. For each sample or control, use a separate dropper and device (see picture 1) .

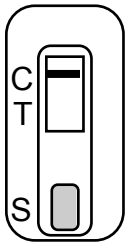


4. When whole blood is collected, dispense 2 drops (approximately 80 l) of the fingerprick whole blood specimen or venipuncture whole blood specimen, Then Dispense 1 drop (approximately 30μl) of the Assay Buffer. For each specimen, use a separate dropper and device (refer to the figure above).
5. Wait for 5～20 minutes before reading the result. Do not read the result after 30 minutes.

RESULT READING

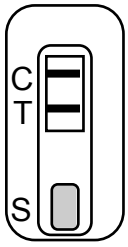
Observe the two colored lines (bands): the control line in the control ("C") region of the test membrane, and the test line in the test ("T") region of the membrane. (refer to the following figure）

Note: Please note that HIV 1/2 flow-through assay is a screening assays and any positive result should be confirmed by Western Blot Method or other confirmatory methods.



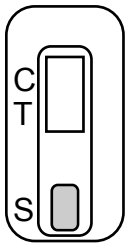
NEGITIVE

Only one colored band appears on the control region (C). No apparent band on the test region (T).



POSITIVE

A pink-rose line (band) is visible in the control ("C") and test ("T") areas of the test window, respectively.



INVALID

The assay is invalid if the control line is not visible. The assay failed, or the assay procedure was not followed properly. Verify the assay procedure and repeat the assay with a new Test Device.

CLINICAL PERFORMANCE

A total of 2534 specimens were collected from high-risk groups and low-risk populations. The Autobio human immunodeficiency viruses（HIV 1/2）antibodies colloidal gold assay was compared to Abbott® ELISA kits for detection of antibodies to HIV 1/2. Positive specimens were confirmed with Genlabs Diagnostic HIV Western Blot. From these studies, speificity was determined to be 99.9% and sensitivity was 99.4%.The results are summarized in the following table:

		Autobio assay(HIV 1/2, colloidal gold)	
		Positive	**Negative**
Reference Assay	**Positive**	**175**	**1**
	Negative	**0**	**2358**

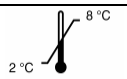
LIMITATIONS

1. The Autobio human immunodeficiency viruses (HIV1/2) antibodies colloidal gold test kit is for the detection of HIV (1/2) antibodies in serum, plasma or whole blood specimens. This test is for *in vitro* diagnostic use only. Neither the quantitative value nor the rate of increase in HIV antibodies can be determined by this qualitative test.
2. As with all diagnostic assays, all results must be interpreted together with other clinical information available to the physician.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HIV 1/2 infection.

QUALITY CONTROL

Good laboratory practice requires that quality control specimens be run to verify assay performance. To assure proper performance, a statistically significant number of controls should be assayed.

SYMBOLS

	**BATCH CODE**
	**USE BY**
	**MANUFACTURER**
	**CONTAINS SUFFICIENT FOR <n> TESTS**
	**IN VITRO DIAGNOSTIC MEDICAL DEVICE**
	**TEMPERATURE LIMITATION**
	**CATALOGUE NUMBER**
	**CONSULT INSTRUCTIONS FOR USE**

REFERENCES:

1. Rosenberg ZF and Fauci AS. The immunopathogenesis of HIV infection. Frank J. Dixon,
2. CDC. Recommendations for prevention of HIV transmission in health-care settings.
3. CDC. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. MMWR 1989; 38(S-6):3-37.
4. Mylonakis E.Paliou M.Lally M Laboratory testing for infection with human immunodeficiency virus:established and noval approaches 2000(7).
5. Weber B.Gurtler L.Thorstensson R Multicenter evaluation of a new automated fourth generation human immunodeficiency virus screening assay with a sensitive antigen detection module and high specificity 2002 (6).

For orders and inquires, please contact

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