Screening kit for Antibody to Human Immunodeficiency Virus (Colloidal Gold)

Doc. No.: Screenig kit for antibody to HIV1/2 (Cassette), A/1-20230129

For In Vitro Diagnostic Use Only

INTENDED USE

The Screening kit for Antibody to Human Immunodeficiency Virus (Colloidal Gold) is used for qualitative detection of HIV-1 antibody and HIV-2 antibody in human fingertip blood. It functions as an auxiliary method for diagnosis of human immunodeficiency virus (HIVI/2), with the characteristics of rapid, simple, accurate and high sensitivity.

INTRODUCTION

Acquired Immune Deficiency Syndrome is the full name of AIDS (HIV), an infectious disease caused by HIV infection, which is transmitted through sexual transmission, blood transmission and mother-to-child transmission. HIV is an immune cell that targets the most important immune cells in the human immune system, CD4+ T lymphocytes, and destroys the body in large numbers. HIV-1 and HIV-2 have been found. HIV-1 has 8 subtypes A-H and O subtypes, which are highly pathogenic and are the main pathogens causing the global AIDS epidemic; HIV-2 is less virulent and has an incubation period. It is mainly confined to West Africa, and causes HIV with a longer course and milder symptoms. HIV is highly dependent on etiological diagnosis of infectious diseases, because no matter in the early stage of infection or onset, or in a long incubation period, only through the pathogen test, find out the evidence of the presence of human immunodeficiency virus (HIV), can make the diagnosis of HIV infection or AIDS.

PRINCIPLE

Diagnostic kit for Antibody to Human Immunodeficiency Virus (Colloidal Gold) uses highly specific antigen-antibody reaction and colloidal gold immunochromatography technology. The polyester fiber (or non-woven fabric) was pre-coated with gold-labeled HIVI/2 recombinant antigen and rabbit monoclonal antibody, and the nitrate fiber membrane test line and control line were coated with HIVI/2 recombinant antigen and anti-rabbit IgG antibody.

When positive samples are tested, the HIVI/2 antibody in human finger blood sample combines with the HIVI/2 recombinant antigen in colloidal gold to form a complex. Due to the chromatography, the complex moves forward along the strip and binds to the HIVI/2 recombinant antigens pre-coated by the test line to form a complex. In this way, purplish red bands are displayed on the test line, while free gold rabbit monoclonal antibody is combined with anti-rabbit IgG antibody on the control line, thus purplish red bands are displayed on the control line. The negative specimens showed only purplish red bands at the control line.

REAGENTS AND MATERIALS PROVIDED

1. Each kit contains 1 test device, sealed in a foil pouch with the following items inside: 1 test cassette, 1 desiccant
2. Dropper
3. Sample diluent
4. Lancet
5. One package insert (instruction for use)

MATERIALS REQUIRED BUT NOT PROVIDED

Clock or Timer

STORAGE AND STABILITY

Store at room temperature (2-30°C) in the original package and valid for 24 months. Keep away from direct sunlight, moisture and heat, and DO NOT FREEZE.

WARNINGS AND PRECAUTIONS

1. For in vitro qualitative diagnostic use only, please read the instructions carefully before testing.
2. For single use only.
3. Use within the validity period and store in strict accordance with the instructions.
4. Do not use the test cassette if its pouch is damaged, or if there are missing components.
5. Do not drink buffer from the tube without or with swab, if accidentally drink, get medical advice/attention immediately.
6. Desiccant is in the pouch, do not take orally.
7. Do not touch test and sample zone of the test cassette directly with hands.
8. The kit is recommended to be used within 1 hour after opening.

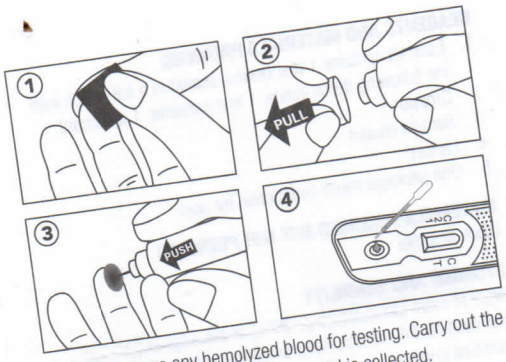
SPECIMEN COLLECTION

*Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Make sure the test components are balanced at room temperature if refrigerated. Open the aluminum pouch at the notch and remove the components.

Wash your hands and dry thoroughly. Use the lancet provided to take a blood sample as follows:

1. Twist and then pull out the lancet cover
2. Put the lancet to your finger and press the button
3. In order to obtain the required amount of blood, gently press the finger near the puncture site until a large drop of blood is formed
4. Holding the dropper horizontally, touch the blood drop with the dropper and fill the dropper with blood

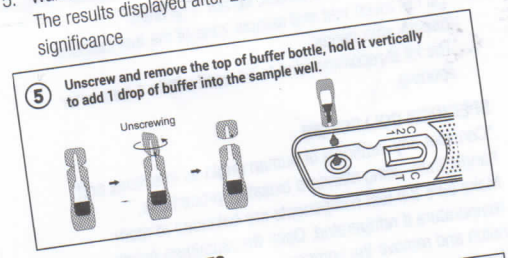


Note: Do not use any hemolyzed blood for testing. Carry out the test immediately after the fingertip blood is collected.

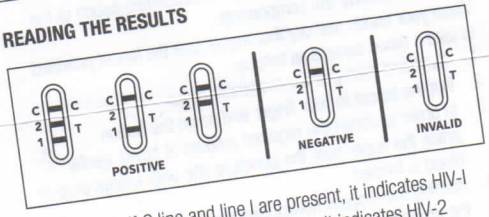
TEST PROCEDURE

*Please read the instructions for use carefully and completely before testing.

1. Return the test cassette and the sample to room temperature (2-30°C).
2. Tear open the aluminum foil pouch and take out the test cassette, place it on a smooth surface.
3. Add l drop of finger blood to the sample well.
4. Then add l drop of sample diluent to the sample well.
5. Wait 15 minutes to interpret and record the test result. The results displayed after 20 minutes have no clinical significance



READING THE RESULTS



Positive (+): If C line and line l are present, it indicates HIV-l positive; If C line and line 2 are present, it indicates HIV-2 positive; If C line, line l and line 2 are all present, it indicates both HIV-l and HIV-2 are positive.
Positive result means that the HIV antibody was detected in the sample.

***NOTE:** When different specimens are tested, the line l or line 2 may show different shades of color, which is due to the different concentrations of HIV antibody. However, within the specified time, regardless of the color of the band, even a very weak band should be judged as a positive result.

Negative(-): Only C line is present means the test result is negative. Negative result means that no HIV antibody was detected in the sample.

Invalid: When control C line is missing, regardless of the presence of line l and line 2, it indicates that the result is invalid. You need to take a new test cassette and test again.
Invalid results means that the test is failed or the test kit is invalid. Read the instructions carefully again and repeat the test with a new test device. If the problem persists, discontinue using the test device immediately and contact your local distributor.

LIMITATIONS

1. Positive results must be confirmed by relevant confirmatory methods or processed by other methods stipulated by the state.
2. Limited by the analytical sensitivity, negative result cannot completely exclude the possibility of HIVl/2 infection, which may be caused by the concentration in the sample being lower than the sensitivity of the product. For suspected negative results, it is suggested to use other kinds of methods with higher sensitivity for rechecking.

INDEX OF SYMBOLS

IVD	In vitro diagnostic medical		Consult instructions for use
2°C 30°C	Storage temperature 2-30°C		Do not re-use
LOT	Batch number		Use-by date
EC REP	Authorized representative		Contains sufficient for <n> test
	Keep dry		Keep away from sunlight
	Caution		Manufacturer

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