HIV Ag/Ab Rapid Test Kit

Instruction for use

【Product Name】HIV Ag/Ab Rapid Test Kit

REF A10018001B, A10018001C, A10018001D, A10018001E

【Specification】1 test/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit

【Intended Use】

The HIV Ag/Ab Rapid Test Kit Test is a colloidal gold immunochromatography intended for the qualitative detection of antigen/antibodies to Human Immunodeficiency Virus(HIV) in human whole blood,serum or plasma.This test is a rapid test used as an aid for diagnosis and all positive results must be confirmed using an appropriate test such as immunoblot assay or equivalent. This test is intended for healthcare professionals and trained healthcare workers use.

【Summary】

Human immunodeficiency virus, also known as AIDS virus, is a retrovirus that causes defects in the human immune system. This virus will attack and gradually destroy the human immune system, causing the host to be unprotected when infected. People infected with the human immunodeficiency virus and dying often die of secondary infection or cancer. AIDS is the final stage of human immunodeficiency virus infection.

Human immunodeficiency virus can be divided into two types: HIV-1 and HIV-2. The diameter of the virus is about 80-140 nm, which is round or oval. The outer membrane of the virus is a lipid envelope, which comes from the host cell and is embedded with virus proteins gp120 and gp41. Gp41 is a transmembrane protein, gp120 is located on the surface and binds to gp41 through non covalent interaction. Inwards are the spherical matrix formed by protein p17 and the semi conical capsid formed by protein p24. The capsid shows high electron density under the electron microscope. The capsid contains the RNA genome of the virus, enzymes (reverse transcriptase, integrase, protease) and other components from the host cell (such as tRNAlys3, as a primer for reverse transcription).

【Test Principle】

The test is a sandwich immunoassay of double antibodies or antigens. If there are HIVAg/Ab in the sample, it will be combined with colloidal gold labeled mouse anti-HIV p24 monoclonal antibody or HIV antigen, form a complex. Under the action of chromatography, the complex flows on the nitrocellulose membrane. Then, the complex will bind to another HIV p24 monoclonal antibody or HIV antigen encapsulated on a nitrocellulose membrane.If the specimen contains HIVAg/Ab one or two colored line will appear in test line region. If the specimen does not contain HIVAg/Ab, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line (‘C’ line) will always appear in the control line region,indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【Main Components】

Materials Provided:

Material \ Specification	1 test/kit	5 tests/kit	10 tests/kit	25 tests/kit
Test Cassette	1	5	10	25
Whole Blood Buffer	1	1	1	1
Disposable Pipettes	1	5	10	25
Instruction for Use	1	1	1	1

Materials Optioned:

1. Alcohol pad
2. Safety lancet

Materials Required but Not Provided:

1.Timer
2.Tube rack for specimens
3.Any necessary personal protective equipment

【Storage Conditions and Validity】

1.This product should be stored in a dark and dry place at 2~30℃.The validity period of the kit is 24 months.
2.The Test Cassette should be used immediately after opening the pouch.
3.Please see label for the information about the date of manufacture and shelf life.

【Samples Collection Handing】

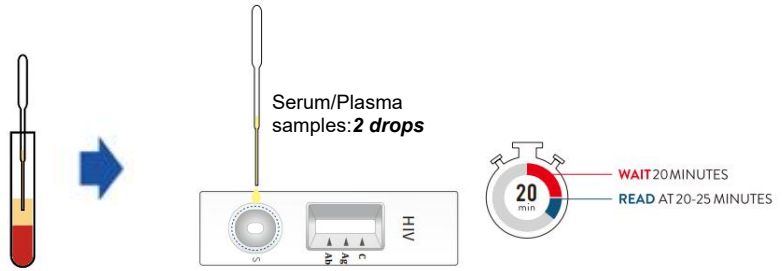
1. This kit is used to detect human serum/plasma/whole blood samples.The plasma and whole blood samples are recommended to use EDTA,heparin or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results.
2. After the blood samples are collected,if they cannot be tested in time, the serum/plasma should be stored at 2-8°C for 7 days.The sample can be stored for 30 days under -20°C.The whole blood samples should not be frozen and can be stored for 3 days at 2-8°C.

【Test Method】

1. Read the instructions for use completely before testing.
2. Before use, take out the reagents and specimens, places the reagent on a flat table and balance them to room temperature (18-25°C).
3. The operators take the test cassette out of the packaging bag and place it on the platform table.
4. Add the specimens.

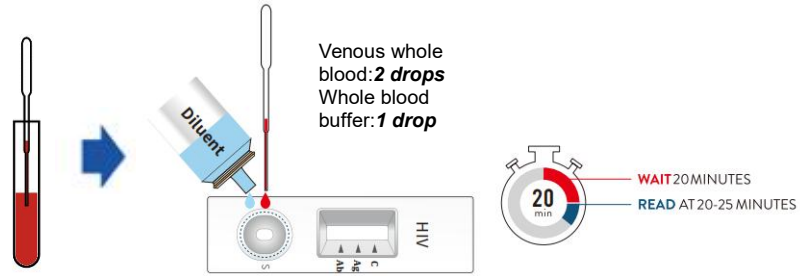
For serum or plasma samples

a.Collect and process blood samples according to standard operating procedures to obtain serum/plasma samples.
b.The operator uses a disposable pipette to absorb 2 drops (60 μL) of the serum or plasma sample,add it to the sample well.After finish adding sample,the operators start timing and keep it react for 20 minutes.



For venous whole blood samples

a.Collect and process blood samples according to standard operating procedures to obtain venous whole blood samples.
b.The operator uses a disposable pipette to absorb 2 drops (60 μL) of the venous whole blood sample, add it to the sample well. Immediately add 1 drop of whole blood buffer to the sample well.After finish adding sample,the operators start timing and keep it react for 20 minutes.

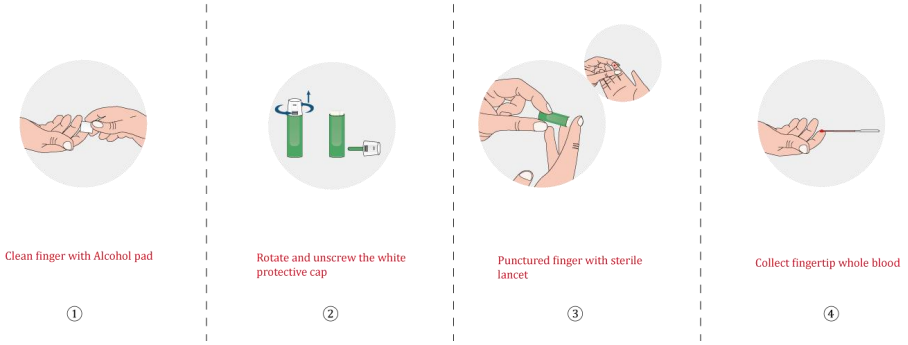


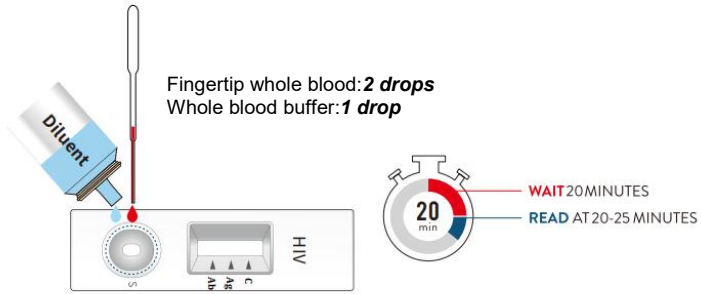
For fingertip whole blood samples

a.Clean the puncture site with the alcohol pad
b.After the alcohol is dried, the fingertips are punctured with safety lancet to form blood droplets

c.The operator uses a disposable pipette to absorb 2 drops (60 μL) of the fingertip whole blood sample,add it to the sample well. Immediately add 1 drop of whole blood buffer to the sample well.After finish adding sample,the operators start timing and keep it react for 20 minutes.

NOTE：After the formation of blood drops, should wipe the first drop of blood before using a disposable pipette dropper to take fingertip blood samples.



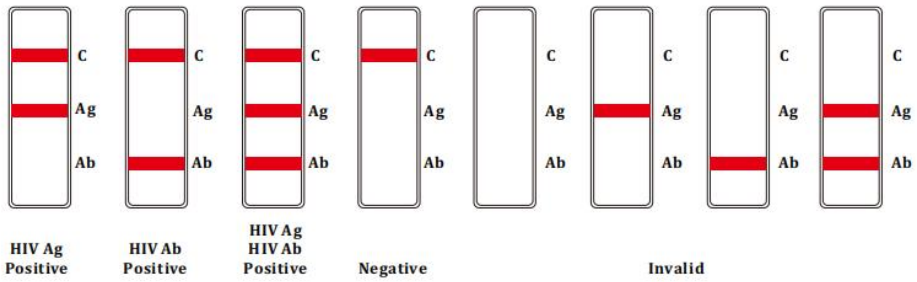


Fingertip whole blood:***2 drops***
Whole blood buffer:***1 drop***

【Interpretation of Test Results】

Positive(+): Control line and at least one test line appear on the membrane. The appearing of Ag test line indicates HIV p24 antigen positive result, the appearing of Ab test line indicates HIV antibodies positive result, the appearing of both Ag and Ab test lines indicates both HIV p24 antigen and HIV antibodies positive result. The lower the antigen concentration is, the weaker the test line is.

Negative(-):Only line C is colored (see figure below), which indicates that the sample does not contain any HIV p24 antigen and HIV antibodies.
Invalid: No coloration can be seen on line C (see figure below). The test is invalid or an error in operation occurred. Repeat the test with a new test cassette.



【Reporting of Results】

Positive： If any Positive, there is currently a suspicion HIV infection. Please carefully compare the above test results and contact your doctor or local health department immediately.
Negative: Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with HIV infection. It is recommended that these results be confirmed by other methods, if necessary, for patient management Control.
Invalid:If the control line (C-line) is failed to appeared that there is an incorrect operation process or the deterioration of the reagents.Please take a new test cassette and perform the test again.If the same problem still occurs, stop using the batch of products immediately and contact the manufacturer.

【Limitation of The Test】

1. The kit can be used for the detection of human serum,plasma or whole blood samples.The reliability of the determination of this substance in other types of samples has not been fully confirmed.
2. The result of this kit is only one of the indicators for the clinician to diagnose the patient and it needs to be judged based on the clinical symptoms.
3. If the results are inconsistent with the clinical symptoms,please retest and confirm the test results with the clinical symptoms.
4. In the early stage of infection, the HIV p24 antigen and HIV antibody is not produced or the titer is lower than the detection limit which will lead to a negative result. For suspected negative results, other methods with higher sensitivity are recommended for review. Samples with positive test results should be retested or confirmed using different methodologies. The confirmation of viral infection should be combined with the patient's clinical history, symptoms and other diagnostic results.
5. The test results of this product and other different methodological reagents are not equivalent.

【Performance Characteristics】

1. The clinical performance of HIV Ag/Ab Rapid Test Kit was evaluated in comparison to a commercial HIV Ag/Ab test using clinical specimens. The results are shown in the following tables.

For serum samples

HIV (HIV Ab)

HIV Ag/Ab Rapid Test Kit	Commercial HIV (HIV Ab) test		
	Positive	Negative	Total
Positive	300(a)	1(b)	301(a+b)
Negative	0(c)	1399(d)	1399(c+d)
Total	300(a+c)	1400(b+d)	1700(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	100%	98.78%~100.00%	
Clinical specificity	99.93%	99.60%~100.00%	
Total coincidence rate	99.94%	99.67%~100.00%	

HIV (HIV Ag)

HIV Ag/Ab Rapid Test Kit	Commercial HIV (HIV Ag) test		
	Positive	Negative	Total
Positive	299(a)	1(b)	300(a+b)
Negative	1(c)	1399(d)	1400(c+d)
Total	300(a+c)	1400(b+d)	1700(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	99.67%	98.16%~99.99%	
Clinical specificity	99.93%	99.60%~100.00%	
Total coincidence rate	99.88%	99.58%~99.99%	

For plasma samples

HIV (HIV Ab)

HIV Ag/Ab Rapid Test Kit	Commercial HIV (HIV Ab) test		
	Positive	Negative	Total
Positive	210(a)	1(b)	211(a+b)

Negative	0(c)	1295(d)	1295(c+d)
Total	210(a+c)	1296(b+d)	1506(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	100.00%	98.26%~100.00%	
Clinical specificity	99.92%	99.57%~100.00%	
Total coincidence rate	99.94%	99.63%~100.00%	

HIV (HIV Ag)

HIV Ag/Ab Rapid Test Kit	**Commercial HIV (HIV Ag) test**		
	Positive	Negative	Total
Positive	156(a)	1(b)	157(a+b)
Negative	1(c)	1348(d)	1349(c+d)
Total	157(a+c)	1349(b+d)	1506(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	99.36%	96.50%~99.98%	
Clinical specificity	99.93%	99.59%~100.00%	
Total coincidence rate	99.87%	99.52%~99.98%	

For whole blood samples

HIV (HIV Ab)

HIV Ag/Ab Rapid Test Kit	**Commercial HIV (HIV Ab) test**		
	Positive	Negative	Total
Positive	156(a)	1(b)	157(a+b)
Negative	0(c)	1229(d)	1229(c+d)
Total	156(a+c)	1201(b+d)	1386(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	100.00%	97.66%~100.00%	
Clinical specificity	99.92%	99.55%~100.00%	
Total coincidence rate	99.93%	99.60%~100.00%	

HIV (HIV Ag)

HIV Ag/Ab Rapid Test Kit	**Commercial HIV (HIV Ag) test**		
	Positive	Negative	Total
Positive	165(a)	1(b)	166(a+b)
Negative	1(c)	1219(d)	1220(c+d)
Total	166(a+c)	1220(b+d)	1386(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	99.40%	96.69%~99.98%	
Clinical specificity	99.92%	99.54%~100.00%	
Total coincidence rate	99.86%	99.48%~99.98%	

2. Performance on reference panel

A study was performed using China national Reference Panel for Rapidly Testing Antibodies to Human Immune-deficiency Virus,which from China national Institutes for Food and Drug Control.

Tab1 HIV reference panel results

No.	Test items	Standard	Result
1	Positive reference coincidence rate(HIV-1)	+/+,18/18	+/+,18/18
2	Positive reference coincidence rate(HIV-2)	+/+,2/2	+/+,2/2
3	Negative reference coincidence rate	-/-,≥18/20	-/-,20/20
4	Limit of detection(LoD)	S1:- S2:+ S3:+	S1:- S2:+ S3:+
5	Repeatability	CV test results should all be positive, and there is no difference in color rendering	CV test results should all be positive, and there is no difference in color rendering

Tab2 HIV p24 antigen reference panel results

No.	Test items	Standard	Result
1	Positive reference coincidence rate(HIV-1 p24 antigen)	+/+,10/10	+/+,10/10
2	Negative reference coincidence rate	-/-,20/20	-/-,20/20
3	Limit of detection(LoD)	≤2.5 IU/mL	1.25 IU/mL
4	Repeatability	CV test results should all be positive, and there is no difference in color rendering	CV test results should all be positive, and there is no difference in color rendering

3. Performance on specimen types

The plasma samples of different anticoagulants, serum samples, venous whole blood and fingertip blood collected by the same subject at the same time are compared and tested

Tab3 Analysis table of HIV positive specimens results

	EDTA plasma	Heparin plasma	sodium citrate plasma	serum	whole blood	fingertip blood
Confirmed result	25	25	25	25	25	25
HIV Ag/Ab Rapid Test	25	25	25	25	25	25
Sensitivity	100%	100%	100%	100%	100%	100%

Tab4 Analysis table of HIV negative specimens results

	EDTA plasma	Heparin plasma	sodium citrate plasma	serum	whole blood	fingertip blood
Confirmed result	25	25	25	25	25	25
HIV Ag/Ab Rapid Test	25	25	25	25	25	25
Specificity	100%	100%	100%	100%	100%	100%

4. Cross-reactivity: There was no cross-reactivity with specimens meeting the disease state shown below. No IgM or IgG false positive results were observed with the following potential cross-reactants:

No.	Potential cross material
1	anti-HCV +
2	anti-HBs +
3	anti-HBe +
4	anti-HBc +
5	anti-HTLV 1/2 +
6	Anti-HEV +
7	Anti-TP +
8	ANA +

5. Interfering substances:The Concentrations of triglycerides 40mmol/L,hemoglobin 2g/L,rheumatoid factor 1000IU/mL,bilirubin 350μmol/L and HAMA 600ng/mL have no effect on the test results.

【Precautions】

1. After opening the package, the kit should be ready for use as soon as possible and avoid placing it in a high temperature (over 30°C) and high humidity(over 90%) environment for a long time.

2. All samples (whole blood, serum and plasma) and test cassettes after use should be considered potentially dangerous and should be treated as infectious materials, and the waste should be disposed of in accordance with the regulations of the hospital or environmental protection department.
3. The test strips with any color lines before the test should not be used and the reagents with damaged packaging bags or invalid seals should not be used.
4. The kit is for in vitro diagnostic use only. The kit is for single-use,please do not use the product after it expires.

【Index of Symbols】

	In vitro diagnostic medical device		Do not re-use
	Do not use if package is damaged and consult instructions for use		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
	Temperature limit		Batch code
	Use-by date		Keep dry
	Keep away from sunlight		Catalog number
	Date of manufacture		Contains sufficient for <n> tests

【Basic Information】

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