

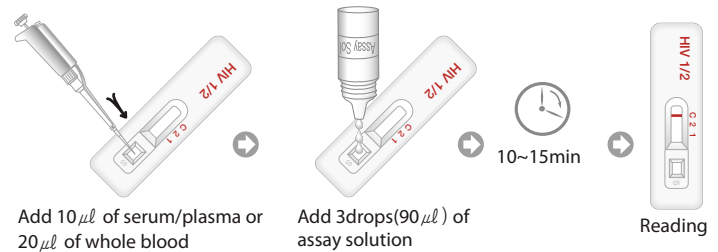


# Asan Easy Test<sup>®</sup> HIV1/2

One step kit for HIV type1 and type 2 antibodies in human serum, plasma or whole blood

IVD

Immunochromatography



## EXPLANATION OF THE TEST

Asan Easy Test<sup>®</sup> HIV1/2 is a chromatographic immunoassay kit for the rapid qualitative determination of HIV1/2 antibodies in human serum, plasma or whole blood. For diagnosis of HIV1/2 infection, recombinant HIV1/2 antigens (type 1: p24, gp41, and type 2: gp36) are used as a capture materials of the immunochromatographic test. Asan Easy Test<sup>®</sup> HIV1/2 contains the membrane, which is pre-coated with properly mixed recombinant HIV1/2 antigens (p24, gp41, and gp36) on the test band region. During test, the sample is allowed to react with the colloidal gold-rHIV1/2 conjugate, which has been pre-dried on the conjugate pad between membrane and sample pad. The mixture then moves upward on the membrane by capillary action. For positive result, a visible line with high sensitivity and specificity as forming antibody-rHIV1/2-gold complex appears in the test band region of the membrane. Regardless of the presence of HIV1/2 antibodies, the mixture continuously moves across the membrane to pre-dried control line. Therefore, the control line will always appear and verify proper performance of the test. Asan Easy Test<sup>®</sup> HIV1/2 minimizes the possibility for the false positive and places high confidence in the test result using high quality of recombinant HIV1/2 antigens (type 1: p24, gp41, and type 2: gp36).

## MATERIALS PROVIDED

Asan Easy Test<sup>®</sup> HIV1/2 contains following items to perform the assay.

1. Test device in aluminium pouch with a desiccant.
2. Assay solution.
3. Instruction manual for use.

## PRECAUTION

1. For *in vitro* diagnostic use only.
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test device and all materials should be discarded in a proper biohazard container after testing.

## SPECIMEN COLLECTION AND STORAGE

### 1. Specimen Collection and Storage

**[Whole blood]** Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture.

If blood specimens are not immediately tested, they should be refrigerated at 2~8°C and should be used within 3days or at -20°C for longer period.

**[Serum]** Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen or supernatant.

**[Plasma]** Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.

If serum or plasma specimens are not tested immediately, they should be refrigerated at 2~8°C or -20°C for longer period.

### 2. Precaution

- 1) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- 2) Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.
- 3) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous result.

## TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing the test.
2. Remove the test device from its protective pouch.
3. Load 10 µl of serum/plasma or 20 µl of whole blood into the sample well(S) of the test device.
4. Add 3 drops (about 90 µl) of assay solution into the sample well(s) of the test device.
5. Interpret the test results at 10~15 minutes. Do not interpret after 20 minutes.

## INTERPRETATION OF THE TEST

1. A color band will appear in the upper section ("C" zone) of the window to show that the test is working properly. This band is the control band.
2. The down section ("T" zone : 1 and 2) of the window indicates the test results, test band. If another color band appears in the down section of the window, this band is the test band.

### A. NEGATIVE RESULTS:

The presence of only one purple color band ("C" band) within the window indicates a negative result.



### B. POSITIVE RESULTS:

- Positive for HIV1: two bands are appeared in the test line 1 (T1) and control line (C).
- Positive for HIV2: two bands are appeared in the test line 2 (T2) and control line (C).
- Three bands are appeared in the test line 1, 2, and control line, it shall be suggested to do sample dilution and re-testing process. The re-test result is true. If the re-test result still showed three bands, the result is positive for HIV1 and HIV2.



### C. INVALID RESULTS:

If no band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen should be re-tested using a new test kit.



## PERFORMANCE CHARACTERISTICS

Multi-site studies were performed using a total of 2,555 specimens. Each specimen was tested with Asan Easy Test<sup>®</sup> HIV1/2 and HIV RNA detection by RT-PCR. The results are summarized in the following tables.

n= 2,555		HIV RNA detection by RT-PCR		Total
		Positive	Negative	
Asan Easy Test <sup>®</sup> HIV1/2	Positive	540	5	545
	Negative	0	2,010	2,010
Total		540	2,015	2,555

※ Relative Sensitivity :100%, Relative Specificity :99.75%

※ Detection limit : 1.0 s/CO

## STORAGE AND EXPIRATION

1. Asan Easy Test HIV1/2 should be stored between 2~30°C (35.6~86 °F)
2. Expiration date of this kit is 24 months after its manufacture date.

## LIMITATIONS OF THE TEST

Asan Easy Test<sup>®</sup> HIV1/2 is designed for primary screening test of antibodies against HIV-1 or HIV-2 virus. Although this kit can provide fast and easy way to get a result, the testing can alone be used to be diagnose AIDS and also the testing do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.



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