TOYO®

INSTRUCTION FOR USE
Anti-HIV 1/2 Test, WB/S/P
Anti-HIV (HIVab) Detection in
Whole Blood / Serum / Plasma

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: THIV02
Human Immunodeficiency Virus Antibody Cassette Test.

BACKGROUND INFORMATION
HIV/AIDS is the most devastating disease humankind has ever faced. HIV stands for human immunodeficiency virus, and is the virus that causes AIDS. HIV destroys certain blood cells that are crucial to the normal function of the immune system, which defends the body against illness. AIDS stands for Acquired Immunodeficiency Syndrome. It occurs when the immune system is weakened by HIV to the point where a person develops any number of diseases or cancers.
HIV infection is most commonly detected through the test of a sample of blood or oral fluid. If the blood or oral fluid sample contains HIV antibodies proteins the body produces to fight off the infection the person is HIV-positive. A rapid HIV test has recently been developed for use with oral fluid other than saliva, and can also be used on plasma specimens.
HIV does not survive well outside the body. Therefore, it cannot be transmitted through casual, everyday contact. Mosquitoes and other insects do not transmit HIV. HIV can be spread by sexual contact with an infected person, by sharing needles and/or syringes and/or other injecting equipment or, less commonly (and now very rarely in countries where blood is screened for HIV antibodies), through transfusions of infected blood or blood clotting factors.
Early laboratory diagnosis of primary human immunodeficiency virus (HIV) infection is based on the detection of viral RNA or p24 antigen in plasma or serum prior to antibody seroconversion. The diagnostic window of HIV infection may be reduced on average by 4 - 5 days by screening for p24 antigen.

INTENDED USE
Anti-HIV 1/2 Test is a rapid qualitative immunoassay for the detection of antibodies (IgG, IgA and IgM) generated against all subtypes of Human Immunodeficiency Virus Type 1 (HIV-1) (including Group O) and Type 2 (HIV-2) in human whole blood / serum / plasma.

REAGENTS
Recombinant HIV antigen, anti-HIV monoclonal antibody and recombinant HIV antigen conjugated with colloidal gold particles

METHOD
Anti-HIV 1/2 Test uses solid-phase immunochromatographic technology for the qualitative detection of anti-HIV in human whole blood / serum / plasma. The test is a two-site immunometric assay in which a combination of monoclonal antibodies and recombinant antigens are used to selectively detect anti-HIV in samples with a high degree of sensitivity. Recombinant HIV antigens (include gp120, gp41, gp36, p24) were immobilized on the test area "T" and anti-HIV monoclonal antibodies were immobilized on the control area "C" of the nitrocellulose membrane. Recombinant HIV antigens include gp120, gp41, gp36, p24 conjugated with colloidal gold particles, were dried on a conjugate pad. Sample is introduced from sampling pad. If there is anti-HIV in the sample, anti-HIV binds to the mobile recombinant HIV antigens conjugated with colloidal gold particles. Together they move to the test area "T". Anti-HIV molecules bind to the immobilized recombinant HIV antigens and as a result of this, anti-HIV molecules that have already bound to mobile recombinant HIV antigens (conjugated with colloidal gold particles) become immobilized in the test area "T" thus creating a visible colored signal due to the accumulation of colloidal gold particles in the test area "T" (a colored test line), indicating positive test result. If there is no anti-HIV in the sample then sample moves to the test area "T" together with unbound (free) recombinant HIV antigens conjugated with colloidal gold particles. Immobilized recombinant HIV antigens can not bind to mobilized recombinant HIV antigens conjugated with colloidal gold particles, therefore no visible colored signal in test area "T" (no colored test line) can be obtained, indicating negative test result. Regardless of anti-HIV content of the liquid sample, mobile recombinant HIV antigens conjugated with colloidal gold particles, bind to immobilized anti-HIV monoclonal antibodies while liquid sample is passing through the control area "C". Therefore accumulation of colloidal gold particles produces a visible colored signal in the control area "C" (a colored control line), indicating a valid test result. Colored line should be visible in the control area "C" in every case; if no visible colored line in control area "C", test result should be indicated as invalid.

PRECAUTIONS AND LIMITATIONS
1. For professional and *in vitro* diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. Use a new dropper for each sample.
6. The test device should be discarded in a proper biohazard container after testing.
7. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
8. Do not freeze and thaw the serum, plasma samples repeatedly. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.
9. Do not use turbid, hemolyzed samples. Turbid test samples should be centrifuged.
10. Hemolytic samples should not be used since they can lead to invalid or false results.
11. This test will indicate only the presence or absence of anti-HIV in the sample, and should not be used as the only basis for the diagnosis of HIV.

As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result.Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

STORAGE
Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

Kit components : Test cassettes, droppers, diluents (for whole blood samples only) and instructions for use.
Additional materials required but not provided : Sample collection tube, centrifuge and timer.
Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION
The test can be performed using whole blood, serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible.
For Whole Blood Samples: Test should be performed immediately with whole blood samples. Otherwise, whole blood samples should be stored at 2 - 8 °C with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation until they are being tested in a period of 2 days after collection.
For Serum Samples: Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum.(Centrifugation time & speed: 2300-2880 x g for ~ 10 min)
For Plasma Samples: Collect blood into a collection tube with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma.(Centrifugation time & speed: 2300-2880 x g for ~ 10 min)
Do not use turbid, hemolyzed samples. If the sample cannot be tested on the day of collection, store the serum, plasma samples in a refrigerator or freezer. Do not freeze and thaw the serum, plasma samples repeatedly. Do not freeze whole blood sample. Bring the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Turbid test samples should be centrifuged. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.

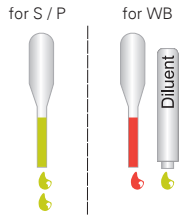
TEST PROCEDURE

1. Bring the tests and whole blood / serum / plasma samples to room temperature, Take the test out of its pouch.
2. **For Whole Blood Samples:** Draw whole blood into dropper and put 1 drop (30 μl) into the sample well of the cassette. Immediately after, 1 drop of diluent is added into the sample well and allowed to soak in.

   For Serum / Plasma Samples: Draw serum / plasma into dropper and put 2 drops (50 μl) into the sample well of the cassette. Do not use diluent for serum / plasma samples. Avoid the formation of any air bubbles.
3. Depending on the anti-HIV concentration in the sample, the test can react even in 5 minutes. Results should be read at 15 minutes as shown below. Do not interpret results beyond 20 minutes, results forming after 20 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

Negative: Only one colored line is visible in "C" area, indicating that HIV antibody does not exist.
Positive: Two colored lines are visible in "C" and "T" areas, indicating that HIV antibody exists.
Low concentration of HIV antibody may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid: No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.
Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

Anti-HIV 1/2 Test can detect antibodies (IgG, IgA and IgM) generated against all subtypes of Human Immunodeficiency Virus Type 1 (HIV-1) (including Group O) and Type 2 (HIV-2).

Sample Status	Sample Anti-HIV Status	S / P Sample Type			WB Sample Type		
		Study Number	Com. Assay	Result	Study Number	Com. Assay	Result
Positive samples (all available subtypes)	Positive	500	EIA	100 %	500	EIA	100 %
Blood donors	Negative	1058	EIA	100 %	1011	EIA	100 %
Clinical	Negative	250	EIA	100 %	210	EIA	100 %
Pregnant women	Negative	212	EIA	100 %	212	EIA	100 %
Rheumatoid Factor (RF)	Negative	150	EIA	100 %	150	EIA	100 %
Anti-HCV	Negative	20	EIA	100 %	10	EIA	100 %
Bilirubin	Negative	10	EIA	100 %	-	-	-
Hemoglobin	Negative	10	EIA	100 %	-	-	-
Triglycerides	Negative	10	EIA	100 %	-	-	-

Sensitivity and Specificity

For S/P samples; results of positive samples (500/500), Negative blood donors samples (1058/1058) and clinical samples (250/250) are used. Using these results; sensitivity, specificity, +predictive, - predictive values are calculated as;

Sensitivity: 100 % Specificity: 100 % + Predictive V: 100 % - Predictive V: 100 %

For WB samples; results of positive samples (500/500), Negative blood donors samples (1011/1011) and clinical samples (210/210) are used. Using these results; sensitivity, specificity, +predictive, - predictive values are calculated as;

Sensitivity: 100 % Specificity: 100 % + Predictive V: 100 % - Predictive V: 100 %

Seroconversion panels: 40 seroconversion panels for Türklab Anti-HIV 1/2 Test were conducted where EIA was the reference assay. All 40 seroconversions were properly detected by the Türklab Anti-HIV 1/2 Test which reacted positive with the appearance of a line at "C" area for the control and with another line at "T" area for the test sample. The predicate EIA assay also detected the seroconversion of all 40 panels. This evaluation indicates that Türklab Anti-HIV 1/2 Test has demonstrated an equivalent performance in the diagnostic sensitivity compared to the CE-marked EIA assay.

Cross Reactivity: Cross reactivity has been tested with below samples, no cross reactivity was found with the Anti-HIV 1/2 Test.
- Anti-HCV whole blood / serum / plasma samples, Anti-HCV positive control
- Whole blood / serum / plasma samples from pregnant women.

Interferences Following potentially interfering substances were tested with Anti-HIV 1/2 Test: Hemoglobin, Bilirubin, Triglycerides, Rheumatoid Factor (RF). No interference was observed. Hemolytic samples should not be used since they can lead to invalid or false results.

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TÜRKLAB let us diagnose

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CE 1434

Manufacturer
Consult instruction for use
Attention, see instruction for use
IVD *In vitro* diagnostic medical device
For single use only
Number of test
REF Catalog number
Storage temperature
LOT Lot number
Expiry date