HIV Ag/Ab Tri-line Rapid Test

(Whole Blood/Serum/Plasma)

A rapid test for the qualitative detection of human immunodeficiency virus type 1 (HIV-1) p24 antigen, human immunodeficiency virus type 1 antibody and type 2 antibody in human whole blood, serum, or plasma specimens.
For professional in vitro diagnostic use only.
Please read the package insert carefully before using.

【SPECIFICATION】

1 Test/Kit, 2 Tests/Kit, 5 Tests/Kit, 7 Tests/Kit, 10 Tests/Kit, 20 Tests/Kit, 25 Tests/Kit, 40 Tests/Kit

【INTENDED USE】

The iCARE HIV Ag/Ab Tri-line Rapid Test is a tri-line, serological, lateral flow chromatographic immunoassay for the simultaneous and qualitative detection of human immunodeficiency virus type 1 (HIV-1) p24 antigen, human immunodeficiency virus type 1 antibody and type 2 antibody in human whole blood, serum, or plasma specimens to aid in the diagnosis of infection with HIV. The test only provides preliminary analysis results but not critical diagnosis criteria. Any reactive specimen with the iCARE HIV Ag/Ab Tri-line Rapid Test must be analyzed and confirmed with alternative testing method(s) and clinical findings. The test is intended for healthcare professional use. Applications of the test including, screening test for sex transmitted diseases (STD's) among high-risk group of people, regular health examinations, and field screen test for blood bank.

【SUMMARY】

Human Immunodeficiency Virus type-1 (HIV-1) and type-2 (HIV-2) are enveloped single strand RNA virus that cause acquired immunodeficiency syndrome (AIDS). Current data indicate that the HIV is transmitted through sexual contact, exposure to blood (including sharing contaminated needle and syringe) or certain blood products or from an infected mother to her child during the prenatal period. People with increased risk of HIV infection include intravenous drug users, homosexuals, and hemophiliacs. The presence of HIV-1 p24 antigen indicates fresh infection with HIV-1 virus, and presence of antibodies to HIV- 1/HIV-2 indicates previous exposures to HIV-1/HIV-2 virus.

The iCARE HIV Ag/Ab Tri-line Rapid Test utilizes anti-HIV-1 p24 antibody and recombinant HIV antigen immobilized on a membrane to detect HIV-1 p24 antigen, HIV type 1 and HIV type 2 antibodies qualitatively and selectively in human whole blood, serum, or plasma specimens.

【TEST PRINCIPLE】

The iCARE HIV Ag/Ab Tri-line Rapid Test is a qualitative membrane-based immunoassay for the detection of HIV-1 p24 antigen, HIV type 1 and HIV type 2 antibody in human whole blood, serum, or plasma specimens. The test device consists of: 1) a burgundy-colored pad containing colloidal gold particles coated with recombinant HIV-1 antigen gp41/120, recombinant HIV-2 antigen gp36, and colloidal gold particles coated with monoclonal anti-HIV-1 p24 antibody and 2) a nitrocellulose membrane strip containing two test lines (Ab line and Ag line) and a control line (C). The Ab line is coated with recombinant HIV-1 antigen gp41/120 and recombinant HIV-2 antigen gp36 for the detection of HIV type 1 and HIV type 2 antibodies, and the Ag line is coated with monoclonal anti-HIV-1 p24 antibody for the detection of HIV-1 p24 antigen. When an adequate volume of specimen is added to the specimen well(S) of the device, the specimen migrates by capillary action across the device and interacts with the immobilized antigens respectively. If the specimen contains HIV type 1 and/or HIV type 2 antibodies, a colored line will appear in the Ab line region. If the specimen contains HIV-1 p24 antigen, a colored line will appear in the Ag line region. Absence of any test lines (Ab and Ag) suggests a negative result. An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control lines, regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test device.

【MATERIALS PROVIDED】

- Test device individually foil pouched with a desiccant
- Sample diluent
- Dropper
- Package insert

【MATERIALS REQUIRED BUT NOT PROVIDED】

Timer, Positive control, Negative control, Specimen collection containers

【WARNINGS AND PRECAUTIONS】

1. For *in vitro* diagnostic use only. Do not reuse the test.
2. Do not freeze the test kit or its components.
3. These instructions must be carefully read and strictly followed by a trained healthcare professional to achieve accurate results. All users should read the instructions before performing test.
4. The test is only for the detection of HIV-1 p24 antigen, HIV-1 and/or HIV-2 antibodies, not for any other viruses or pathogens.
5. Inadequate or inappropriate specimen collection, storage, and transportation are likely to result in false negative test results.
6. Do not use hemolyzed blood specimens for testing.
7. Do not eat, drink or smoke in the area where handling specimens or performing the test.
8. Do not use the test kit beyond its expiration date.
9. Do not mix components from different kit lots.
10. Leave test device sealed in its foil pouch until just before use. Do not use the test device if the pouch is damaged or the seal is broken.
11. To avoid contamination or inaccurate test result, do not touch the reaction area of test device when performing the test.
12. Wear appropriate personal protection equipment and gloves when performing the test, collecting and handling patient specimens.

13. Dispose of all used test devices and potentially contaminated materials in a biohazard container as if they were infectious waste and dispose according to applicable local laws and regulations.

【STORAGE AND STABILITY】

1. The test kit should be stored either at room temperature or refrigerated (2-30°C), away from direct sunlight. Do not freeze the kit or expose the kit to temperatures over 30°C.
2. The shelf life of the kit is as indicated on the outer package (24 months from date of manufacture).
3. This test kit is stable until the expiration date marked on the outer package and foil pouch. Ensure all test components are at room temperature (15-30°C) before use.
4. Perform the test immediately after taking out the test device from the foil pouch.

【SAMPLE COLLECTION AND PREPARATION】

Consider any materials of human origin as infectious and handle them using standard biosafety procedures. The test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma specimens. Follow standard laboratory procedures to collect specimens.

Plasma/Serum

1. Collect blood specimen into collection tube containing EDTA, citrate or heparin for plasma or collection tube containing no anticoagulants for serum by venipuncture.
2. To make plasma specimen, centrifuge collected specimens and carefully withdraw the plasma into a new pre-labeled tube.
3. To make serum specimen, allow blood to clot, then centrifuge collected specimens and carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2-8°C if not tested immediately. Specimens can be stored at 2-8°C for up to 3 days, and should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles (no more than 3 times). Prior to testing, equilibrate frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity so as to avoid interference on result interpretation.

Whole Blood

Collect whole blood by either fingertip puncture or by venipuncture into collection tube containing EDTA, citrate or heparin for plasma. Do not use any hemolyzed blood for testing.

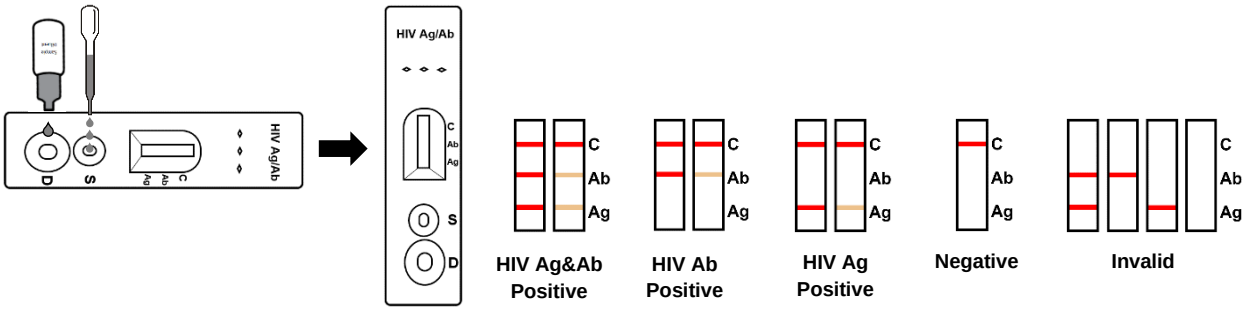
Do not freeze a whole blood specimen, otherwise the red blood cell will break, which may cause hemolysis. Whole blood specimens should be stored in refrigeration (2-8°C) if not tested immediately. The specimens must be tested within 24 hours after collection.

【TEST PREPARATION】

Before testing, open the package and equilibrate the test device, sample diluent, specimens and/or controls to room temperature, and shake the sample diluent gently before use. The most suitable temperature condition to perform the test is room temperature (15-30°C). If the test kit is stored at room temperature, it can be opened and used immediately.

【TEST PROCEDURES】

1. Take out the test device from sealed foil pouch and place on a dry, clean and level surface.
2. Be sure to label the device with specimen's ID number.
3. Fill the pipette dropper with the specimen. Hold the dropper vertically and transfer 3 drops of whole blood/serum/plasma specimen (approximately 30 µL) into the specimen well (S) making sure that there are no air bubbles. Then add one drop of sample diluent (approximately 30-40 µL) to the diluent well (D) immediately. See illustration below.
4. Start the timer.
5. Wait for the colored line(s) to appear. Read test results at 15 minutes. Do not interpret the result after 20 minutes.



【INTERPRETATION OF TEST RESULTS】

(Please refer to the illustrations above)

POSITIVE: Two or three lines appear. One colored line should be in the control line region (C) and another apparent colored line(s) should be in the test line region (Ab and/or Ag).

NOTE: The intensity of the color in the test line region will vary depending on the concentration of HIV-1 p24 antigen, HIV-1 and/or HIV-2 antibodies present in the specimen. Therefore, the presence of any test line, no matter how faint, within the designated observation time, indicates a positive result.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region.

INVALID: Control line fails to appear. 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, stop using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

1. **Internal Control:** An internal quality control is included in the test, in the form of a colored line appearing in the control line region (C), indicating that the test is functional, and proper and sufficient volume of specimen has been applied to enable migration through the test and control line, regardless of whether there is a test line or not. If the control line (C) does not appear within the testing time, test result is invalid and the test should be repeated with a new test device.
2. **External Control**: Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The test is only used for the qualitative detection of HIV-1 p24 antigen, and HIV-1 and/or HIV-2 antibodies in human whole blood, serum, or plasma specimens by healthcare professionals. The intensity of the test line does not have a linear correlation with the antigen or antibody level in the specimen.
2. The test does not indicate the level of HIV-1 p24 antigen, and HIV-1 and/or HIV-2 antibodies in the specimens or the rate of increase in antigen or antibodies, and should not be used as the sole criteria for the diagnosis of HIV infection.
3. A negative result indicates that HIV-1 p24 antigen, and HIV-1 and/or HIV-2 antibodies are not present in the specimen. However, a negative test result at any time does not preclude the possibility of exposure to or infection with HIV.
4. A negative result may occur if the level of HIV-1 p24 antigen, and HIV-1 and/or HIV-2 antibodies present in the specimen are below the detection limits of the assay or the HIV antigens and antibodies that are detected are not present during the stage of disease when a sample is collected.
5. A positive result using the iCARE HIV Ag/Ab Tri-line Rapid Test suggests the presence of HIV-1 p24 antigen and/or HIV-1/HIV-2 antibodies in the sample and the positive test result should be interpreted as preliminary positive for HIV-1 p24 antigen and/or HIV-1/HIV-2 antibodies. Positive test results must be confirmed by additional testing.
6. An individual who has HIV-1 p24 antigen and/or HIV-1/HIV-2 antibodies is presumed to be infected with the virus, however, an individual who has participated in an HIV vaccine study and has tested negative result with HIV-1 p24 antigen may develop antibodies to the vaccine and may or may not be infected with HIV.
7. This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 12 years of age.
8. Specimen collected from an individual infected with HIV-1 and/or HIV-2 who is receiving highly active antiretroviral therapy (HAART) may result in a false negative result.
9. If the test result is negative and clinical symptoms persist, additional testing using alternative clinical methods is recommended.
10. Test results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

【PERFORMANCE CHARACTERISTIC】

1. Clinical Performance

The iCARE HIV Ag/Ab Tri-line Rapid Test has been correctly identified specimens of a performance panel and has been evaluated with a reference commercial HIV Ag/Ab ELISA assay using clinical specimens. Test results are presented in the table below.

Clinical performance compared to ELISA: HIV 1/HIV-2 Antibodies

iCARE HIV Ag/Ab Tri-line Rapid Test	ELISA		
	Positive	**Negative**	**Total**
Positive	399	1	400
Negative	1	919	920
Total	400	920	1320

Sensitivity (Positive Percent Agreement): 99.75% = 399/400 (95% CI: 98.60%~99.96%)
Specificity (Negative Percent Agreement): 99.89% = 919/920 (95% CI: 99.39%~99.98%)
Accuracy (Overall Percent Agreement): 99.84% = (399+919)/1320 (95% CI: 99.45%~99.96%)

Clinical performance compared to ELISA: HIV-1 p24 Antigen

iCARE HIV Ag/Ab Tri-line Rapid Test	ELISA		
	Positive	**Positive**	**Total**
Positive	365	1	366
Negative	1	859	860
Total	366	860	1226

Sensitivity (Positive Percent Agreement): 99.72% = 365/366 (95% CI: 98.47%~99.95%)
Specificity (Negative Percent Agreement): 99.88% = 859/860 (95% CI: 99.34%~99.98%)
Accuracy (Overall Percent Agreement): 99.83% = (365+859)/1226 (95% CI: 99.41%~99.96%)

2. HIV-1 p24 Antigen Analytical Sensitivity

The analytical sensitivity of the iCARE HIV Ag/Ab Tri-line Rapid Test for HIV-1 p24 antigen in serum was evaluated and determined to be 2 IU/mL.

3. Cross-reactivity

No cross-reactivity was observed by testing the following positive specimens respectively: HAMA, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, H. pylori, MONO, CMV, Rubella and TOXO.

4. Interference

The following potentially interfering substances were added to HIV negative and positive specimens. Test results demonstrate that performance of the iCARE HIV Ag/Ab Tri-line Rapid Test was not affected by the listed potentially interfering substances at the concentrations tested.

Acetaminophen	20 mg/dl	Caffeine	20 mg/dl
Ascorbic acid	20 mg/dl	Creatinine	200 mg/dl
Acetylsalicylic acid	20 mg/dl	Gentistic acid	20 mg/dl
Albumin	10.5 g/dl	Hemoglobin	1000 mg/dl
Bilirubin	1,000 mg/dl	Oxilic acid	600 mg/dl
Cholesterol	800 mg/dl	Triglycerides	1,600 mg/dl

【REFERENCES】

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7. J.N. Wasserheit. Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases, Sexually Transmitted Diseases 1992; 19:61-77.

【INDEX OF SYMBOLS】

	Consult instruction for use	IVD	For *in vitro* diagnostic use only	REF	Catalog number		Temperature limit
LOT	Lot number		Use by		Do not reuse		Contains sufficient for <X> tests
	Keep dry		Manufacturer		Date of manufacture		Keep away from sunlight
	Do not use if package is damaged						

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