HIV 1/2/O Rapid Test Cassette (Serum/Plasma) Package Insert

REF L031-10131	English

A rapid test for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1 type 2 and subtype O in serum or plasma
For professional in vitro diagnostic use only

INTENDED USE

ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Human Immunodeficiency Virus (HIV) type 1, type 2 and subtype O in serum or plasma.

SUMMARY

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virus is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoproteins are on the envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV 1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with high potential risk for developing AIDS. [1] HIV 2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.[2] Both HIV 1 and HIV 2 elicit immune response.[3] Detection of HIV antibodies in serum or plasma is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV.[4] Despite the differences in their biological characteristics, serological activities and genome sequences, HIV 1 and HIV 2 show strong antigenic cross-reactivity.[5,6] Most HIV 2 positive sera can be identified by using HIV 1 based serological tests.
ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV-1, HIV-2, and/or Subtype O in serum or plasma specimen. The test utilizes Gold conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1/2 /O in serum or plasma.

PRINCIPLE

ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV 1/2/O in serum or plasma. The membrane is pre-coated with recombinant HIV antigens including gp41, gp36 and HIV-O recombinant antigen. And the conjugate pad is treated with gold particles which are conjugated with gp41, gp36 and HIV-O recombinant antigen.. During testing, the serum or plasma specimen reacts with HIV antigen coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigen on the membrane in the test line region. If the specimen contains antibodies to HIV 1, HIV 2 and/or subtype O, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain HIV 1, HIV 2 and/or subtype O antibodies, a colored line will not appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use.
- Do not use the components beyond the expiration date.
- **DO NOT FREEZE.**

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND PREPARATION

- ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma) can be performed using serum or plasma.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test Cassettes
- Disposable specimen droppers
- Package insert

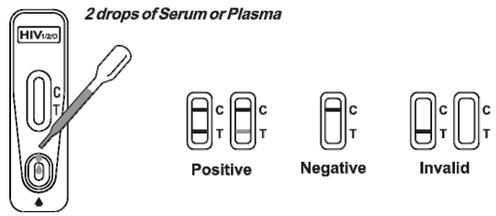
Materials Required But Not Provided

- Specimen collection containers
- Centrifuge
- Timer

DIRECTIONS FOR USE

Allow the test cassette, specimen to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 80 μL) to the "Sample Well" of the test cassette, start the timer. See illustration below.
3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE: * Two distinct colored lines appear. One line should be in the control region (C) and another line should be in the test region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HIV antibodies present in the specimen. Therefore, any shade of colored in the test region (T) should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).
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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
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.

LIMITATION

1. ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV in serum or plasma. Neither the quantitative value nor the rate of increase in HIV antibody concentration can be determined by this qualitative test.
2. This test will only indicate the presence of antibodies to HIV in the specimen and should not be used as the sole criteria for the diagnosis of HIV 1 and/or HIV 2 infection.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or Western Blot analysis.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. If the test result is negative and clinical symptoms persist, additional follow up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of HIV 1 and/or HIV 2 infection.

EXPECTED VALUES

ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial HIV EIA test. The correlation between these two systems is >99.0 %.

PERFORMANCE CHARACTERISTICS

Sensitivity

ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma) has been tested by anti-HIV 1 low titer performance panel, anti- HIV-2 low titer specimen and anti- HIV-1 subtype O low titer specimen. And it has also been compared with a leading commercial EIA HIV test on clinical specimens. The results show that ACON HIV 1/2/O Test Cassette (Serum/Plasma) is very sensitive to HIV 1, HIV 2 and/or subtype O antibodies.

Specificity

The specificity of the test is comparable to a leading commercial HIV EIA test. ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma) is highly specific for anti-HIV 1(including subtype O) and HIV 2 compared to a leading commercial HIV EIA test.

Method		EIA		Total Results
HIV 1/2/O Rapid Test Cassette	Results	Positive	Negative	
	Positive	114	0	114
	Negative	0	303	303
Total Results		114	303	417

Relative Sensitivity: >99.9% (96.82%-100%)* Relative Specificity: >99.9% (98.79%-100%)*
Overall Agreement: >99.0% (99.12%-100%)* *95% Confidence Interval

Precision

Intra Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of ACON HIV 1/2/O Rapid Test Cassette (Serum/Plasma) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

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Index of Symbols

	Manufacturer	Σ	Tests per kit	30°C / 2°C	Store between 2-30°C
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
LOT	Lot Number	REF	Catalog #		

***ACON* Laboratories, Inc.**
10125 Mesa Rim Road,
San Diego, CA 92121, USA

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