HIV p24 Antigen Rapid Test (Whole Blood/Serum/Plasma) For professional use

ELISURE

IVD REF SIC-RDT-HIV24-202120

A rapid test for the diagnosis of Human Immunodeficiency Virus to detect p24 antigen to HIV type 1 qualitatively in Whole Blood, Serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The HIV p24 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of p24 antigen to Human Immunodeficiency Virus (HIV) type 1 in whole blood, serum or plasma to aid in the diagnosis of HIV infection.

SUMMARY

The HIV p24 antigen is a small piece of protein that is found on the capsule of the HIV virus. When a person is infected with HIV, these bits of protein can be found floating in the blood. The HIV p24 antigen rapid test is the test that detects these bits of protein. This test was first developed as a HIV screening test but rapidly ran out of favor due to the development of more advanced NAT tests.[1] The window period for p24 testing is also very small. This test alone is only accurate for between 3 and 6 weeks post exposure.[2] So it is a test with very limited applications unless combined with HIV antibody test. The presence of p24 antigen in the blood indicated a recent HIV infection.[3]

The HIV p24 Antigen Rapid Test is a rapid test to qualitatively detect the presence of p24 antigen to HIV 1 in whole blood, serum or plasma specimen. The test utilizes latex conjugate HIV p24 antibody to selectively detect p24 antigen to the HIV type 1 in whole blood, serum or plasma.

PRINCIPLES

The HIV p24 Antigen Rapid Test is a qualitative, membrane based immunoassay for the detection of p24 antigen to HIV type 1 in whole blood, serum or plasma. The membrane is pre-coated with mouse anti-HIV p24 antibody. During testing, the whole blood, serum or plasma specimen reacts with HIV p24 antibody coated particles in the test Cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with HIV p24 antibody on the membrane in the test line region. If the specimen contains p24 antigen to HIV type 1, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain p24 antigen to HIV type 1, 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.

MATERIALS

Materials provided

• Test cassettes • Droppers • Package insert • Buffer

Materials required but not provided

• Specimen collection containers • Timer • Centrifuge

WARNINGS AND 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 test Cassettes are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures 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 assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HIV p24 Antigen Rapid Test can be performed using Whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by **using a capillary tube:**
    - Touch the end of the capillary tube to the blood until filled to approximately 50 μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test Cassette.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. 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. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 local regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the coagulant tube for collecting the blood specimen.

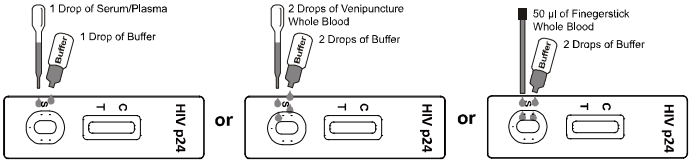
DIRECTIONS FOR USE

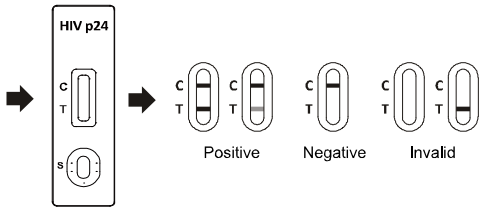
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test Cassette from the sealed pouch and use it as soon as possible.
2. Place the Cassette on a clean and level surface.

   For **Serum or Plasma** specimen:
   Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 25 μL) to the specimen area, then **add 1 drop of buffer** (approximately 40 μL),and start the timer, see illustration below.
   For **Venipuncture Whole Blood** specimen:
   Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 μL) to the specimen area, then **add 2 drops of buffer** (approximately 80 μL), and start the timer. See illustration above.
   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube **and transfer approximately 50 μL of fingerstick whole blood specimen** to the specimen area of test Cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer beyond 30 days after opening the vial.





INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HIV p24 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line 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. If the problem persists, discontinue using the test Cassette immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal quality control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this test Cassette; 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 HIV p24 Antigen Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of HIV p24 antigen in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in HIV p24 antigen can be determined by this qualitative test.
2. The HIV p24 Antigen Rapid Test will only indicate the presence of p24 antigen to HIV type 1 in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HIV infection.
5. The hematocrit of the whole blood should be between 25% and 65%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The HIV p24 Antigen Rapid Test has been compared to a leading commercial ELISA HIV test using clinical specimens. The results show that the relative sensitivity of the HIV p24 Antigen Rapid Test is 96.7% and the relative specificity is 99.3%.

Method		ELISA		Total Results
HIV p24 Antigen Rapid Test	Results	Positive	Negative	
	Positive	29	2	31
	Negative	1	298	299
Total Results		30	300	330

Relative sensitivity: 96.7% (95%CI*: 82.8%~99.9%);
Relative specificity: 99.3% (95%CI*: 97.6%~99.9%);
Accuracy: 99.1% (95%CI*: 97.4%~99.8%). *Confidence Intervals

Limitation of Detection

The minimum detection level is 1ng/ml for HIV p24 antigen.

Precision

Intra-Assay

Within-run precision has been determined by using 15 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 15 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the HIV p24 Rapid Test has been tested over a 3-day period

using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The HIV p24 Rapid Test has been tested by Anti-HAMA IgG, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-HCV IgG, anti-Syphilis IgG, anti-RF IgG, anti-MONO IgM, anti-*H.Pylori* IgG, anti-Rubella IgG, anti-Rubella IgM, anti-CMV IgG, anti-CMV IgM, anti-Toxo IgG, anti-Toxo IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to HIV negative and positive specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2 g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin: 1.1 g/dL
Bilirubin: 1 g/dL	Oxalic Acid: 600 mg/dL

None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAPHY

1. Blacklist of English teachers suspected of having AIDS pursued." This image of Randall L. Tobias is used in a Korean news article suggesting that foreign English teachers residing in Korea are at risk for AIDS. Accessed 16 Feb., 2010.
2. Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood". US Food and Drug Administration. Retrieved 12 October, 2013.
3. FDA Approves First Nucleic Acid Test (NAT) Systems to Screen Plasma for Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV).

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
IVD	*In vitro* diagnostic medical device		Use-by date
	Temperature limit	LOT	Batch code
	Do not use if package is damaged		Manufacturer
REF	Catalogue number		Do not re-use

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