AG- HIV Ag+Ab RAPID TEST KIT

INSTRUCTION FOR USE

AstraGene - HIV Ag+Ab Rapid test kit is a rapid chromatographic immunoassay for the qualitative detection of HIV type 1 antibody, type 2 antibody and type 1 P24 antigen in whole blood, serum or plasma specimen to aid in the diagnosis of HIV infection.

PRINCIPLE

AstraGene - HIV Ag+Ab Rapid test kit is a qualitative membrane-based immunoassay for the detection:

HIV 1.2

The HIV 1.2 Rapid Test is a qualitative, membrane-based immunoassay for the detection of antibodies to HIV 1.2 in whole blood, serum or plasma. The membrane is pre-coated with recombinant HIV antigens. During testing, the whole blood, serum or plasma specimen reacts with HIV antigens coated particles in the test Cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigens on the membrane in the test line region. If the specimen contains antibodies to HIV 1 and/or HIV 2, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain HIV 1 and/or HIV 2 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.

HIV p24

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. working.

PACKAGE CONTENTS

Description	1 test	10 tests
Test Cassette with desiccant	1	10
Buffer	1× 100uL	1×1mL
Dropper	1	10
Instructions for use	1	1
Catalogue Number	AG/RTK/HIVAgAb/21/02	AG/RTK/HIVAgAb/21/01

MATERIAL REQUIRED (BUT NOT PROVIDED)

- Micropipette
- Anti- coagulant tube
- Protective gloves
- Timer
- Biohazard Container.

STORAGE &STABILITY

- All reagents are ready to use as supplied. Store unused test device unopened at 2-30°C. If stored at 2- 8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures over 30°C

SPECIMEN COLLECTION & PREPARATION

- AstraGene - HIV **Ag+Ab** Rapid test kit can be performed using whole blood (from venipuncture or fingerstick), serum or plasma specimen.
- 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 uL. 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.
- EDTAK2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the coagulant tube for collecting the blood specimen.

PROCEDURE

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

1. Bring the pouch to room temperature before opening it. 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 uL) to the specimen area of test Cassette, then add 1 drop of buffer (approximately 40 uL),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 uL) to the specimen area of test Cassette, then add 2 drops of buffer (approximately 80 uL), and start the timer. See illustration below.

For Fingerstick Whole Blood specimen:

To use a capillary tube: Fill the capillary tube and transfer approximately 50 uL of fingerstick whole blood specimen to the specimen area of test

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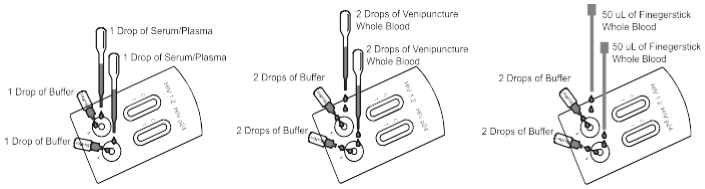
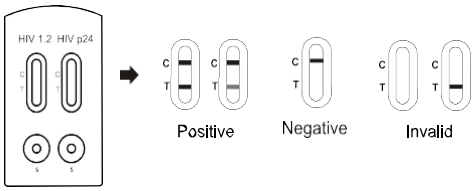
Cassette, then add 2 drops of buffer(approximately 80 uL), and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the results after 20 minutes.
Note: It is suggested not to use the buffer, beyond 30 days after opening the vial.



RESULT INTERPRETATION



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 type 1 antibody, type 2 antibody or HIV type1 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.

SENSITIVITY AND SPECIFICITY

- **HIV1.2:**
  Relative Sensitivity: >99.9% (95%CI*: 97.3%-100%);Relatively Specificity: 99.9% (95%CI*: 99.4%-100%); Accuracy: 99.9% (95%CI*: 99.5%-100%). *Confidence Intervals
- **HIVp24:**
  Relative sensitivity: 80.0% (95%CI*: 61.4%~92.3%); Relative specificity: 99.3% (95%CI*: 97.6%~99.9%); Accuracy: 97.6% (95%CI*: 95.3%~98.9%). *Confidence Intervals

LIMITATION OF THE PROCEDURE

- AstraGene - HIV **Ag+Ab** Rapid test kit is for in vitro diagnostic use only. The test should be used for the detection of HIV type 1 antibody, HIV type 2 antibody and HIV type 1 P24 antigen in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in HIV type 1 antibody, HIV type 2 antibody and HIV type 1 P24 antigen can be determined by this qualitative test.
- AstraGene - HIV **Ag+Ab** Rapid test kit will only indicate the presence of HIV type 1 antibody, HIV type 2 antibody and HIV type 1 P24 antigen in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
- As with all rapid test cassettes, all results must be interpreted together with other clinical information available to the physician.
- 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.
- The hematocrit of the whole blood should be between 25% and 65%.

WARNING AND PRECAUTION

- For in vitro diagnostic use only. Do not reuse. Do not use the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch. Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay. Wash hands thoroughly after finishing the tests.
- Do not eat, drink, or smoke in the area where the specimens or kits are being handled. Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national, or regional regulations. Keep out of children's reach.

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SYMBOLS

Do not use if package is damaged | Manufacturer | Batch Code

CE mark of Conformity | Refer to the instructions | ISO 13485:2016 | GMP

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