

Ebola Antigen Rapid Test Kit

Instructions For Use

PRODUCT NAME

Ebola Antigen Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

This kit is intended for use with venipuncture whole blood and fingerstick whole blood specimens as an aid in diagnosis of EVD in patients suspected of and with signs or symptoms consistent with EVD who have epidemiological risk factor(s) for Ebolavirus exposure (e.g., contact with a known or suspected case, travel to a geographic location at a time when Ebolavirus transmission was known or suspected to have occurred). It is intended for professional in vitro diagnostic use. The results obtained should not be the sole determinant for clinical decision.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Ebola hemorrhagic fever is a severe, often-fatal disease in humans and nonhuman primates that has appeared sporadically since its initial recognition in 1976. Ebola virus is one of three genera of the family of RNA viruses called the Filoviridae. There are four species of Ebola virus affecting humans: Bundibugyo virus (BDBV), Sudan virus (SUDV), Tai Forest virus (TAFV), and Ebola virus (EBOV) strains. The presence of Ebola virus antigens indicate that the individual may be currently infected and capable of transmitting the virus.

Ebola Antigen Rapid Test Kit is a qualitative membrane-based immunoassay for the detection of Ebola Antigen in human venipuncture whole blood and fingerstick whole blood specimens. The test device consists of: 1) a burgundy-colored conjugate pad containing anti-Ebola antibody conjugated with colloid gold, 2) a nitrocellulose membrane strip containing test line (T) and a control line (C). The test line (T) is pre-coated with another anti-Ebola antibody, and the control line (C) is pre-coated with goat anti mouse IgG. 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. If the specimen contains sufficient Ebola Antigen, a colored line(s) will appear in the test line region (T). Absence of test line 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

Each kit contains:

1. Test Devices: 25 pieces test devices individually pouched.
2. Wash Buffer Solution: 3 ml in dropper bottle.
3. Droppers: 25 pieces droppers of 10 ul.
4. Instructions For Use: 1 copy attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and / or protective clothing
- Micropipette
- Lancets (for fingertip whole blood only)

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121 °C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of wash buffer, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The Kit should be stored between 2-30°C and the shelf life is 24 months.
2. The Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

Applicable samples: Venipuncture whole blood and fingerstick whole blood specimens.

1. Collect Venipuncture whole blood : Using standard venous phlebotomy procedures collect a whole blood sample using a tube containing EDTA (lavender top) anticoagulant. If the specimens are not tested at the time of collection, the specimen may be stored at 2°C - 30°C (36°F - 86°F) for up to 24 hours.
2. Collect fingerstick whole blood: Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Using a sterile lancet, puncture the skin just off the center of the finger pad and perpendicular to the fingerprint ridges. Apply slight pressure beside the point of the puncture. Avoid aggressive squeezing of the finger to make it bleed. Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form. Whole blood collected by finger stick should be tested immediately.
3. Do not freeze whole blood specimens.

QUALITY CONTROL

An internal procedural control is included in the test, a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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.

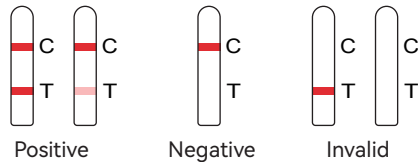
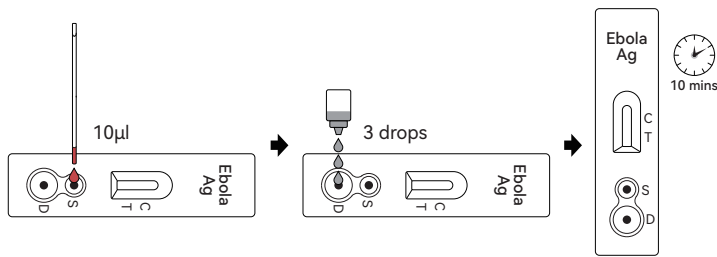
TEST PROCEDURE

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

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. Using a dropper: Hold the dropper vertically, draw the sample up to the dropper's scale line, and transfer the sample to the sample well of the test cassette (approximately 10ul), then add three drops of buffer (approximately 90ul) to the buffer well and start the timer. Avoid trapping air bubbles in the sample well.

Using a micropipette: Hold the micropipette vertically, draw the sample (10 μ l) and transfer the sample to the sample well of the test cassette, then add three drops of buffer (approximately 90 μ l) to the buffer well and start the timer. Avoid trapping air bubbles in the sample well.

- Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that Ebola antigen has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the Ebola antigen has been detected and the result is positive.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is a detection line, and the test shall be conducted again.

LIMITATIONS

- The kit is for in vitro diagnostic use only. The test should be used for the detection of Ebola antigen in whole blood specimens only. Neither the quantitative value nor the rate of increase in Ebola antigen concentration can be determined by this qualitative test.
- The kit will only indicate the presence of Ebola antigen in the specimen and should not be used as the sole criteria for the diagnosis of Ebola infection.
- As with all diagnostic tests, 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 Ebola infection.

PERFORMANCE CHARACTERISTICS

Interfering Substances

The following potential interfering substances have been tested using The kit and no interference was observed:

Substance	Tested Concentration
Bilirubin	25 mg/dL
HAMA	2464ng/mL
Hemoglobin	20 g/dL
Cholesterol	13 mmol/L
Acetylsalicylic Acid	3.62 mmol/L
Salicylic Acid	4.34 mmol/L
Ibuprofen	2425 μ mol/L
Acetaminophen	1324 μ mol/L
Rifampin	78.1 μ mol/L
Amoxicillin	206 μ mol/L
Tetracycline	34 μ mol/L
Erythromycin	81.6 μ mol/L
Biotin	3.6 μ g/mL

INDEX OF SYMBOL

	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
	Temperature limit		Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks		

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