

ReEBOV® Antigen Rapid Test Kit (Ebola Virus VP40 Matrix Protein Detection)

For Research Use Only

Not For Use In Diagnostic Procedures

PRINCIPLE OF THE TEST

The Ebola virus (EBOV) encodes seven proteins, including the VP40 matrix protein (i.e. VP40 antigen). Advanced protein chemistry techniques have been used to develop non-infectious, recombinant EBOV VP40 antigen. Affinity purified caprine polyclonal antibody has been developed using the recombinant EBOV VP40 antigen to detect the presence of the native EBOV VP40 antigen in the serum, plasma or whole blood of suspected Ebola Virus Disease (EVD) patients.

The ReEBOV® Antigen Rapid Test is performed as a dipstick immunoassay. Sample consisting of serum, plasma or whole blood (finger stick or venous collection) is added to the Sample Pad. Inserting the dipstick into a test tube containing the Sample Buffer initiates the flow of sample through the reagent pads and across the nitrocellulose membrane. The EBOV VP40 specific antibody is striped onto nitrocellulose membrane in order to capture EBOV VP40 antigen. The EBOV VP40 specific antibody is also conjugated to gold nanoparticles and deposited in one of the rapid test reagent pads. As the assay develops, the EBOV VP40 antigen present in the sample forms immune-complexes with the anti-EBOV VP40 antibody - gold nanoparticles. As the VP40 antigen bound gold nanoparticles are captured by Test Line, the deposition of the gold nanoparticles generates a pink to red signal which corresponds to the concentration of EBOV VP40 antigen present in the sample. Excess gold nanoparticles are captured by the Control Line, indicating a valid result. Visual interpretation is made between 15 to 25 minutes signal development time. Refer to the Visual Aid section.

REAGENTS

Store at 2–8°C. Do Not Freeze.



Each ReEBOV® Antigen Rapid Test Kit contains the following reagents

- 2 x 25 ReEBOV® Antigen Rapid Test Dipsticks in resealable foil pouches with desiccant
- 2 x 7mL Sample Buffer Dropper Bottles
- 2 x 0.25mL Negative Control (negative human serum, lyophilized)
- 2 x 0.25mL Positive Control (recombinant VP40 spiked in negative human serum, lyophilized)
- 1 each Instruction for Use and Visual Aid

WARNINGS AND PRECAUTIONS

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Ebola Virus is classified as NIAID Category A Priority Pathogen. Handling of infectious blood and serum requires advanced biocontainment (BSL-4) facilities. Use of this product in BSL -1, -2 or -3 facilities is not recommended. If advanced biocontainment facilities are not available the use of all possible universal precautions is highly recommended including safety goggles and/or face shields, masks or respiratory equipment, disposable gowning, boots and gloves. Decontamination equipment and solutions should be readily available. Biohazardous wastes should be autoclaved and/or incinerated.

1. The ReEBOV[®] Antigen Rapid Test controls are prepared with pooled negative human serum (Negative Control). The Positive Control is negative human serum to which recombinant EBOV VP40 antigen has been added.
2. Human source material used to prepare the Calibrators and Controls included in this kit have been tested and shown to be negative for antibodies to HBsAg, HCV, and HIV 1 & 2 by FDA required tests. All human blood derivatives, including patient samples, should be handled as potentially infectious material.
3. Do not pipette by mouth.
4. Do not smoke, eat, or drink in areas where specimens or kit reagents are handled.
Certain components are labeled with the following: Irritating to eyes (R 36). Avoid contact with skin and eyes (S 24/25). In case of contact with eyes, rinse immediately with plenty of water and seek medical advice (S 26). If swallowed, seek medical advice immediately and show container or label (S 46).
Warning  . Biological Risk .

SPECIMEN COLLECTION AND PREPARATION

Whole Blood from fingerstick or collected in EDTA or Citrate Vacutainers can be tested using the ReEBOV[®] Antigen Rapid Test dipsticks. Serum, EDTA plasma, or citrate plasma (3.2%) can also be tested with the ReEBOV[®] Antigen Rapid Test dipsticks.

For serum samples, collect blood by venipuncture and allow to clot for at least 30 minutes then separate the serum by centrifugation at 1500g for 10 minutes. Do not use hemolyzed, icteric, or lipemic serum as these conditions may cause aberrant test results. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

If using EDTA or citrated plasma, blood should be collected by venipuncture and the plasma separated from the cells immediately by centrifugation at 1500g for 10 minutes. The supernatant must be carefully removed after centrifugation to avoid contamination with platelets. Repeating the centrifugation and separation steps may be advisable to minimize platelet contamination.

INSTRUCTIONS FOR USE

Materials Provided:

ReEBOV[®] Antigen Rapid Test; see “Reagents” for a complete listing.

Materials Required But Not Provided:

- Precision pipettors capable of delivering between 10 µL and 250 µL, with appropriate tips
- Laboratory-grade water
- Test tubes with caps
- In austere testing conditions: disposable gloves, gowning, safety goggles, face shields, respiratory masks; and boots that can be decontaminated
- Safety lancets

Procedural Notes

- Bring serum or plasma samples and kit reagents to ambient temperature (18-30°C) and mix well before using; avoid foaming. Return all unused samples and reagents to refrigerated storage as soon as possible.
- Visual interpretation of assay results must be conducted within 15-25 minutes signal development time.
- Incubation temperatures above or below normal room temperature (18-30°C) may contribute to inaccurate results.
- Do not use kit components beyond the expiration date.

- Do not mix kit components from different kit lot numbers.

Assay Procedure – ReEBOV® Antigen Rapid Test Dipsticks For Whole Blood

(See Visual Instruction Aid for fingerstick on page 5)

Remove appropriate amount of dipsticks for testing the required whole blood samples.

1. Add 4 drops of Sample Buffer to an appropriate size test tube or vial (not included).
2. If performing fingerstick using safety lancet (not included), allow full drop of blood to develop.
3. Transfer 1 drop (30µL) of blood onto the open area of the Sample Pad.
4. Insert the ReEBOV® Antigen Rapid Test dipsticks (arrows down) into tubes containing the Sample Buffer. Replace the tube caps. **DO NOT** shake, agitate, or invert test tubes during rapid test signal development.
5. Allow the ReEBOV® Antigen Rapid Test to develop for 15-25min before performing a visual interpretation.

Assay Procedure – ReEBOV® Antigen Rapid Test for Serum or Plasma

Remove appropriate amount of dipsticks for testing the required serum samples.

1. Add 4 drops of Sample Buffer to an appropriate size test tube or vial (not included).
2. Transfer 30 µL of Serum or Plasma onto the open area of the Sample Pad.
3. Insert the ReEBOV® Antigen Rapid Test dipsticks (arrows down) into tubes containing the Sample Buffer. Replace the tube caps. **DO NOT** shake, agitate, or invert test tubes during rapid test signal development.
4. Allow the ReEBOV® Antigen Rapid Test to develop for 15-25 min before performing a visual interpretation.

Assay Procedure – ReEBOV® Antigen Rapid Test for Negative or Positive Control

Remove appropriate amount of dipsticks for testing one Negative Control, one Positive Control.

1. Reconstitute one Lyophilized Negative Control and one Lyophilized Positive Control each with 0.250 mL of laboratory-grade water for minimum of 5 minutes at ambient temperature.
2. Add 4 drops of Sample Buffer to an appropriate size test tube or vial (not included).
3. For Positive and Negative Controls, add 30 µL to the open area of Sample Pad.
4. Insert the ReEBOV® Antigen Rapid Test dipsticks (arrows down) into tubes containing the Sample Buffer. Replace the tube caps. **DO NOT** shake, agitate, or invert test tubes during rapid test signal development.
5. Allow the ReEBOV® Antigen Rapid Test to develop for 15-25 min before performing a visual interpretation.

Results Interpretation – Refer to included Visual Aid on page 5.

1. The ReEBOV® Antigen Rapid Test results should be compared to the Visual Aids included to assist with the interpretation of the results. For a positive patient result on the ReEBOV® Antigen Rapid Test, a pink to red line should form across the Test Line.
2. For a negative patient result no line should be detected across the Test Line.
3. If available, a permanent record should be made by digital photography.

QUALITY CONTROL – Refer to included Visual Aid on page 5.

1. The ReEBOV® Antigen Rapid Test should form a red line across the Control Line indicating the dipstick is performing properly.
2. Failure of the Control Line to develop constitutes an invalid result and requires retesting.
3. The appearance of pink to red background, streaks or spots in the Test or Control Line area may be due to improper flow of reagents and constitutes an invalid result and requires retesting.
4. The development of partial width or variable intensity Test Line does not constitute an invalid result but retesting may be considered

LIMITATIONS OF THE TEST – RESEARCH USE ONLY – Not for use in diagnostic procedures.

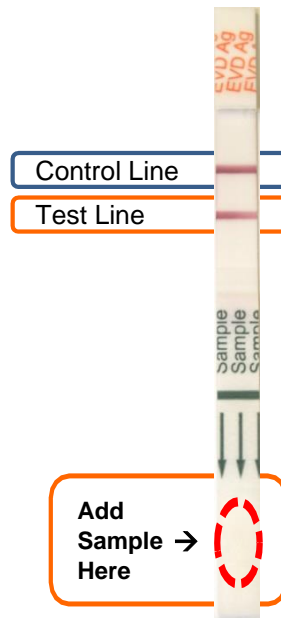
The ReEBOV[®] Antigen Rapid Test detects the presence of EBOV VP40 antigen in suspected patient serum, plasma, and whole blood. Ongoing studies indicate that circulating EBOV VP40 antigen may be absent or undetectable if the patient has progressed to their humoral immune response and anti-EBOV VP40 antibody titers may have developed.

A negative ReEBOV[®] Antigen Rapid Test result does not eliminate the possibility that the suspected EVD patient is EBOV antibody positive. Performance characteristics of this test have not been established.

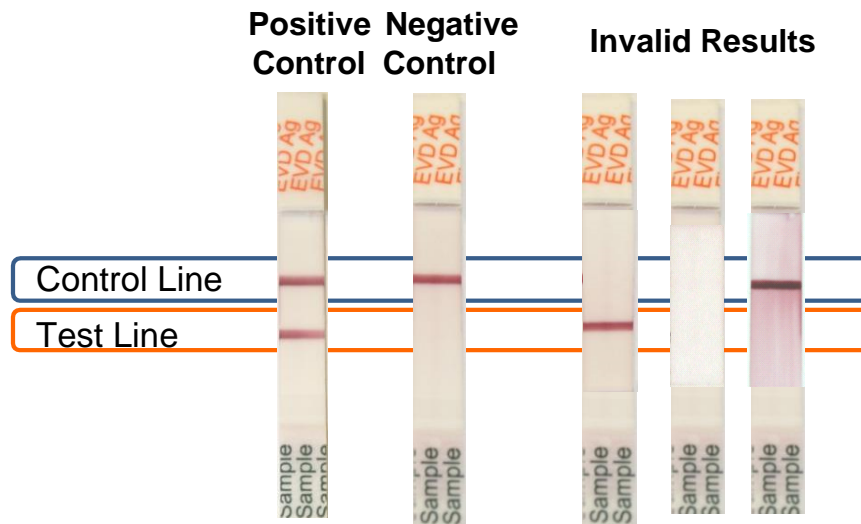
No interference was observed for Bilirubin, HAMA, Quinidine Gluconate, Acetaminophen, or Intralipids at all levels tested. Hemoglobin did cause false-negatives at the 20 g/dL (= 200 mg/mL) or higher while Rheumatoid Factor did cause a false-positive signal from 117 to 2000 IU/mL but previous results indicate that it is a non-interferent at 60 IU/mL and below. Combined results of Interfering Substances testing demonstrate that only higher levels of Hemoglobin and Rheumatoid Factor (>60IU/mL) cause false-negative or false-positive results, respectively. Excessive levels of Hemoglobin and Bilirubin in clinical samples is listed as a limitation for the assay due to interference with signal development or results interpretation due to elevated background.

Visual Aid

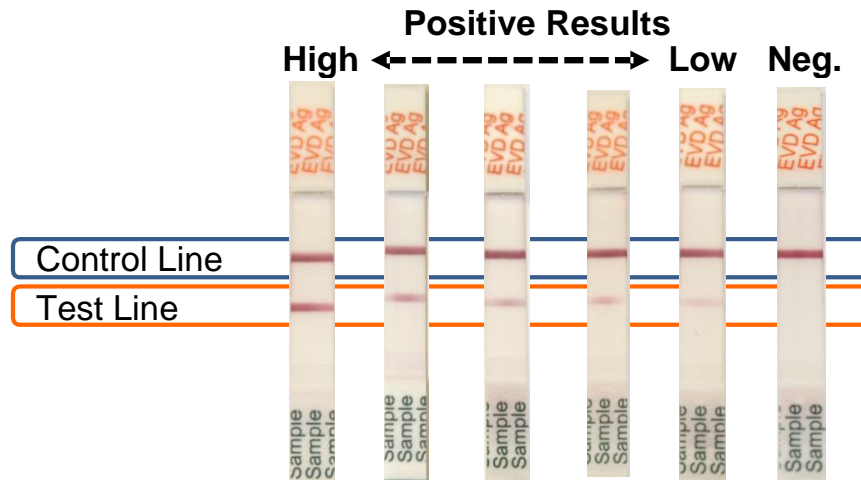
Rapid Test Dipstick



Quality Control

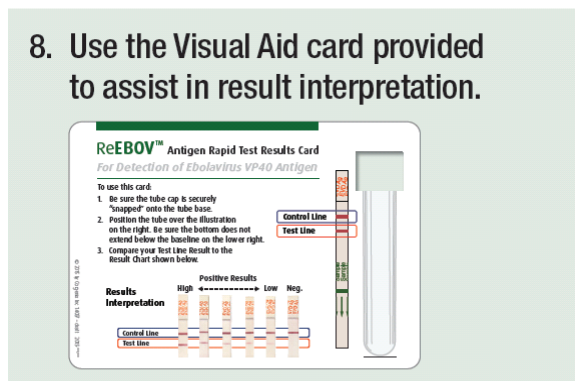
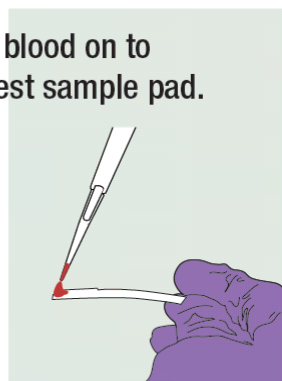
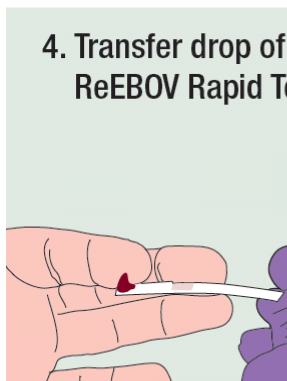
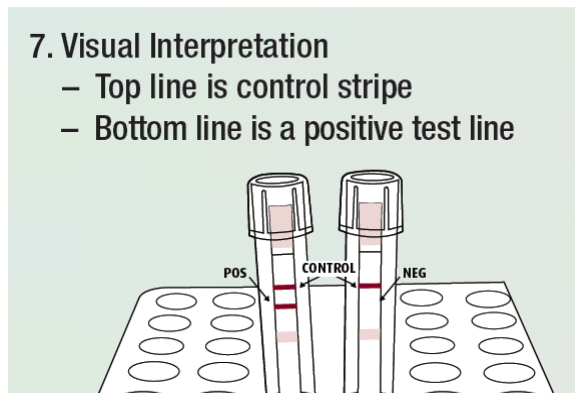
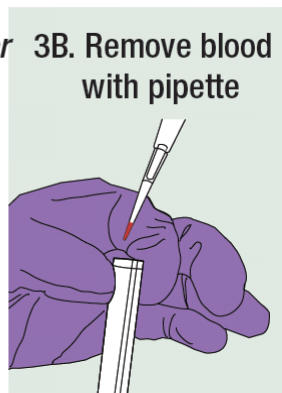
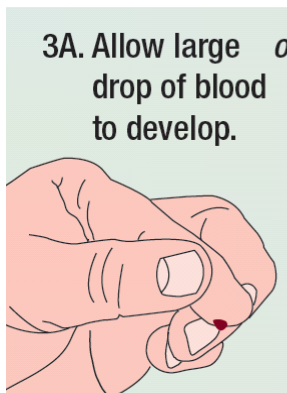
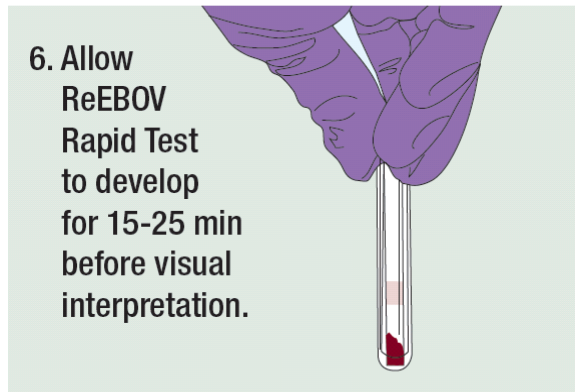
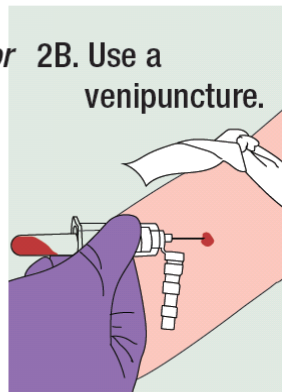
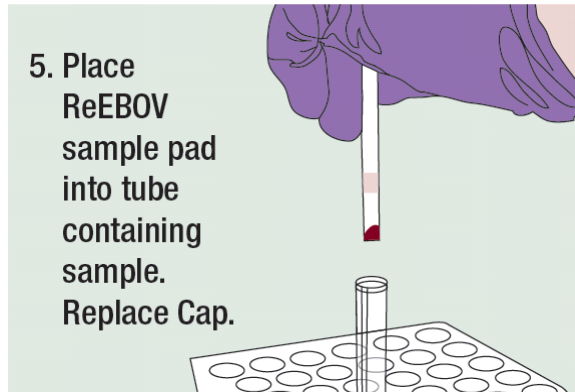
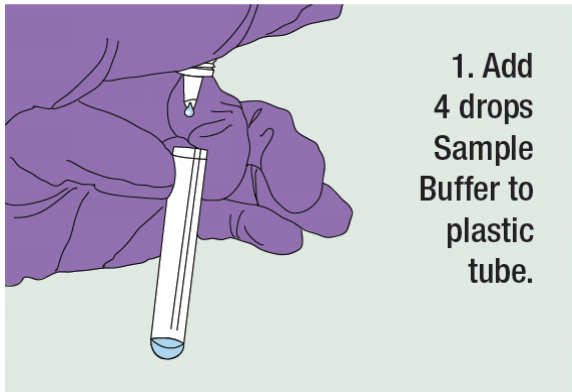


Results Interpretation











ReEBOV™ Antigen Rapid Test Instructions

For Detection of Ebolavirus VP40 Antigen



Symbol Legend

							
Batch Code	Use by/ Expiry Date	Temperature Limitations	Warning	Catalog Number	Manufacturer	Consult Instructions for Use (Package Insert)	Biological Risk

Warranty

This product is warranted to perform as described in this package insert. Zalgen Labs, LLC disclaims any implied warranty of merchantability or fitness for a particular use, and in no event shall Zalgen Labs, LLC be liable for consequential damage.

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