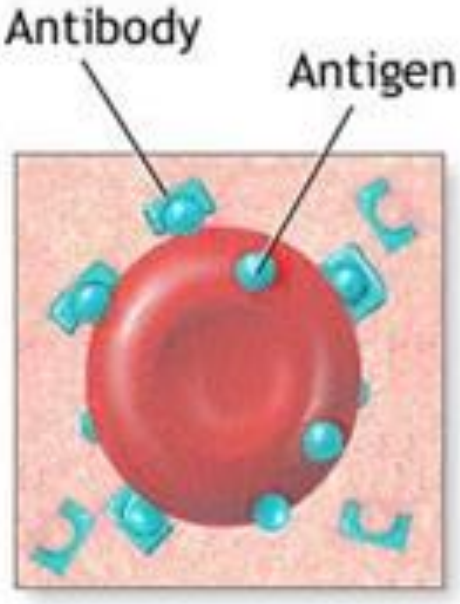
Ebola hemorrhagic fever



An antibody is a protein produced by the immune system in response to the presence of an antigen

Overview

Ebola hemorrhagic fever is a severe and often deadly illness that can occur in humans and in primates (monkeys, gorillas).Ebola hemorrhagic fever has made worldwide news because of its destructive potential.

Symptoms

*Arthritis & Backache (low) & Diarrhea

*Fatigue & Headache & Malaise & Nausea

*Sore throat & Vomiting & Depression

*Bleeding from eyes, ears, and nose

*Bleeding from the mouth and rectum (gastrointestinal bleeding)

*Eye inflammation (conjunctivitis)

*Genital swelling (labia and scrotum)

*Increased feeling of pain in skin

*Rash over the entire body that often contains blood (hemorrhagic)

*Roof of mouth looks red

*Seizures, coma, delirium

Treatment

There is no known cure. Existing medicines that fight viruses (antivirals) do not work well against this virus. The patient is usually hospitalized and will most likely need intensive care. Supportive measures for shock include medications and fluids given through a vein. Bleeding problems may require transfusions of platelets or fresh blood.

Causes

Ebola hemorrhagic fever (Ebola fever) is caused by a virus belonging to the family called Filoviridae. Scientists have identified four types of the Ebola virus. Three have been reported to cause disease in humans: Ebola-Zaire virus; Ebola-Sudan virus; and the Ebola-Ivory virus. The human disease has so far been limited to parts of Africa. The disease has so far been limited to parts of Africa. A very small number of people in the United States who were infected with the fourth type of the virus, known as Ebola Reston, did not develop any signs of disease. The disease can be passed to humans from infected animals and animal materials. Ebola can also be spread between humans by close contact with infected bodily fluids or through infected needles in the hospital.

Tests & diagnosis

*Coma & Electrolytes

*Disseminated intravascular coagulation

*Tests of how well the blood will clot (coagulation studies)

*Tests to show whether someone has been exposed to the Ebola virus

There may be signs and symptoms of:

Prognosis

As many as 90% of patients die from the disease. Patients usually die from shock rather than blood loss.

Prevention

Avoid areas in which there are epidemics. Wear a gown, gloves, and mask around sick patients. These precautions will greatly decrease the risk of transmission.

Complications

Survivors may have unusual problems, such as hair loss and sensory changes.

When to contact a doctor

Call your health care provider if you have traveled to Africa (or if you know you have been exposed to Ebola fever) and you develop symptoms of the disorder. Early diagnosis and treatment may help improve the chances of survival.

VEGA RAPID RESPONSE EBOLA TEST

(Serum/Plasma/Whole Blood)

Instructions for Use ::

A rapid test for the qualitative detection o f Ebola in serum, plasma or whole blood.

For In vitro test use only.

Intended Use

The *VEGA* Ebola Test Device (Serum/Plasma/Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of Ebola Virus in Serum, Plasma or Whole Blood.

Summary

Ebola hemorrhagic fever (Ebola HF) is a severe, often fatal disease in humans and non human primates (monkeys, gorillas and chimpanzees) that has appeared sporadically. The virus is one of two members of a family of RNA viruses called the Filoviridae. There are four identified subtypes of Ebola virus. 90% of the outbreaks were caused by the EBOLA Zaire.

Principle

The VEGA Ebola Test Device (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of Ebola in whole blood, serum or plasma. The membrane is pre-coated with capture reagent on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-Ebola antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with capture reagent on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates 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.

Reagents

The test device contains anti-Ebola antibodies coated particles and anti-Ebola antibodies coated on the membrane.

Precautions

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

Storage & Stability

Store as packaged in the sealed pouch at 4-30 °C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. The buffer should be stored at 4-30 °C. **DO NOT FREEZE**. Do not use beyond the expiration date.

Materials:

Materials Provided:

Test Device with Pipette
Buffer
Instructions for Use

Materials Required but not Provided:

Specimen collection container
Centrifuge (for plasma only)
Timer

Specimen Collection & Preparation

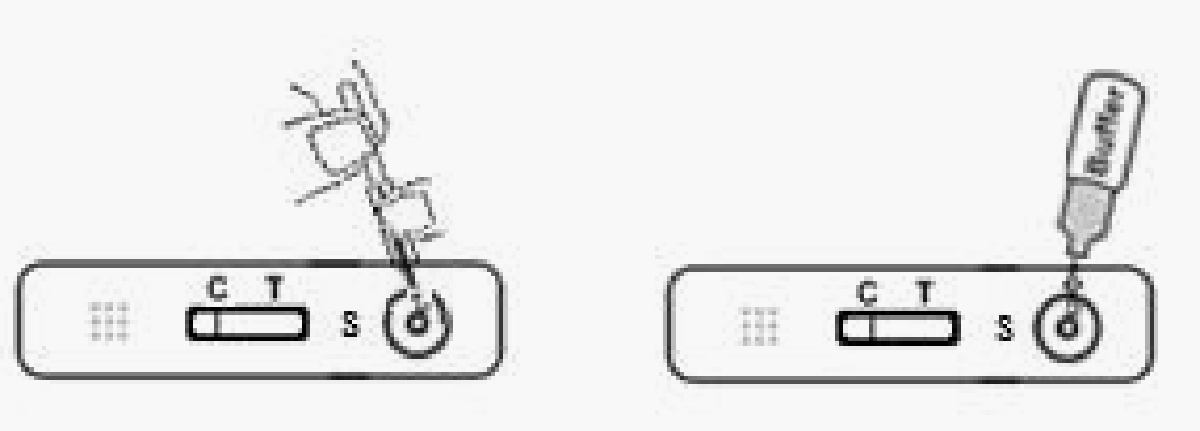
The *VEGA* Ebola Test Device (Serum/Plasma/Whole Blood) can be performed using Serum, Plasma or Whole Blood.
Separate the Serum or Plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.

OR

Use Whole Blood.
Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, serum or plasma 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 for transportation of etiologic agents.

Directions for Use:

Allow test device, buffer, Serum, Plasma or Whole Blood specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.



1) Remove the test device 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.)Place the test device on a clean and level surface. Transfer 75μl of Serum or Plasma or 50μl of Whole Blood to the sample well of the test Device window (S). Add 25μl or 1 drop of buffer to the test sample well (S) if you use Whole Blood and start the timer.

3) Wait for the red line(s) to appear. The test line should be read within 10 minutes. Do not interpret the results after 20 minutes.

Note: Low titers of Ebola might result in a faint line appearing in the test region (T) after a prolonged time. Do not interpret the result after 20 minutes

Interpretation of Results:

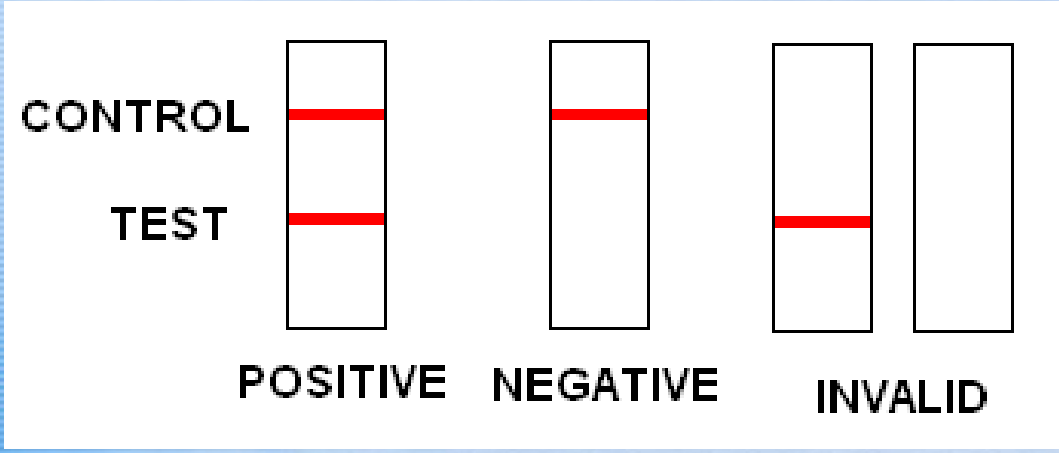
(Please refer to the illustration)

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

NEGATIVE: One red line appears in the control region (C). No apparent red or pink 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor

NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of Ebola antigen present in the specimen. However, neither the quantitative value nor the rate of increase in Ebola antigen can be determined by this qualitative test.



A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

Limitations

The *VEGA* Ebola Test Device (Serum/Plasma/Whole Blood)is for *In vitro* use only. The test should be used for the detection of Ebola antigen in Serum, Plasma or Whole Blood specimen.

The *VEGA* Ebola Test Device (Serum/Plasma/Whole Blood)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.

For confirmation, further analysis of the specimens should be performed, such as ELISA and/or western blot analysis. 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 follow-up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of Ebola infections.

Performance Characteristics

METHOD COMPARISON:Clinical evaluation was conducted comparing the results obtained using the *VEGA* Ebola Test Device (Serum/Plasma/Whole Blood)to approved Ebola ELISA assay test kits. The study included 201 specimens: both assays identified 131 negative, 70 Ebola positive results. The results demonstrated 100% overall agreement (for a percent concordance of ≥ 99%) of the *VEGA* Ebola Test Device (Serum/Plasma/Whole Blood) when compared to approved Ebola ELISA Test.

Reference Ebola ELISA Method

VEGA Method	Ebola Positive	Ebola Negative
	Positive	**Negative**
	70	**0**
	0	**131**

SENSITIVITY AND SPECIFICTITY:

The VEGA Ebola Test Device (Serum/Plasma/Whole Blood) demonstrated a sensitivity of 100% on Ebola samples and a specificity of 100%.

Bibliography

1)Lucht A, Grunow R, Mo¨ller P, Feldmann H, Becker S. Development, characterization and use of monoclonal antibodies for the detection
of Ebola virus. J Virol Methods 2003; 111:21–8.

2)Grolla A, Lucht A, Dick D, Strong JE, Feldmann H. Laboratory diagnosis of Ebola and Marburg hemorrhagic fever. Bull SocPatholExot 2005; 98:205–9.

3)Becker S, Feldmann H, Will C, Slenczka W. Evidence for occurrence of filovirus antibodies in humans and imported monkeys: do subclinical filovirus infections occur worldwide? Med MicrobiolImmunol 1992; 181:43–55.

4)World Health Organization. Outbreak(s) of Ebola haemorrhagic fever in the Republic of Congo, January–April 2003. WklyEpidemiol Rec2003; 78:285–9.

5) Hartmann H, Lu¨bbers B, Cararetto M, Bautsch W, Klos A, Ko¨hl J. Rapid quantification of C3a and C5a using a combination of chromatographic and immunoassay procedures. J Immunol Methods 1993; 166:35–44.

6) Ksiazek TG, Rollin PE, Jahrling PB, Johnson E, Dalgard DW, Peters CJ. Enzyme immunosorbent assay for Ebola virus antigens in tissues of infected primates. J ClinMicrobiol 1992; 30:947–50.

Manufactured by :
VEGA MEDICARE LIMITED
Plot # 85-89, EPIP,
Pashamylaram,
Medak Dist. 502307.A.P. INDIA.
E-mail: info@vegabiotech.com
www.vegabiotech.com