BioAssay+
Making Rapid Tests Smarter

Windsor, Canada, www.immunoassay.ca

Ebola Zaire IgM/IgG rapid test cassette Assay+

Early detection of ebola zaire IgM and IgG in serum or plasma for *in vitro* diagnostic use

Introduction

Ebola virus, specie Zaire causes highly mortality by hemorrhagic fever, resulting in the death of 50 to 90% within days. Ebola has a 2 to 21 day incubation period. The current diagnostic method is by PCR and ELISA test. Ebola rapid test detects specific ebola IgM and IgG antibody , occurring 2 to 4 days after the infection and 5 to day infection and after recovery, respectively. Compared to other tests, ebola rapid test is more convenient with low cost, it can be performed in field, mobile hospital and laboratory.

Safty measure:

Ebola antibody test must be manipulated in a biosafety Level 4 facility, personal protection and specimen deposit have to follow WHO or local health authority guidline .

Assay principle

The recombinant ebola-Z antigens are used in the test, Serum or plasma from ebola infection is loaded to the device, the specific ebola antibodies in specimen will bind to gold-conjugated ebola antigens forming antibody – colloid gold-antigen complex. While the complex migrates along nitrocellulose membrane, the complex is captured on the test lines coated with anti-human IgG or IgM causing a pink to deep pink band at the IgG or IgM test line. The signal intensity is variable depending on the amount of specific antibody present in specimen. A red control line should always develop over control line indicating the proper performance.

This test device has been tested by WHO ebola panel and widely tested in Africa, the sensitivity up to 90%, 95% for its specifity.

Kit Components

Each test kit contains:
1. A pouch
2. Pouch contains one cassette test device
3. One 10 ul plastic pipette
4. Each 25 tests with one 3 ml dropper bottle with assay buffer

Stability and Storage Conditions

Dengue IgG/IgM test kit is stable at room temperature between 10-28'C for one and half year in the unopened pouches.

DO NOT FREEZE the kit or expose to temperature extremes.

General Precautions

- The test is for *In Vitro* diagnosis only.
- Appropriate infection control and handling procedures should be followed – do not smoke, eat or drink in the area where the test is to be performed. Use protective clothing and gloves when handling samples and when performing the test.
- Do not pipette any samples or reagents by mouth.
- All materials should be considered as potentially infectious. To disinfect, either autoclave materials at 121.5'C for 1 hour or treat with Sodium hyprochlorite (1 percent solution).
- Do not use test beyond the expiration date indicated.

Sample Collection

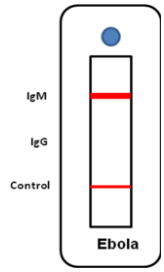
Serum or plasma is used for this device. The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8'C after collection for up to 3 days. If testing can not be done within 3 days, serum can be stored frozen at –20'C or colder.

Test Procedure

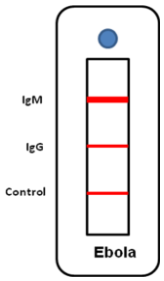
1. Remove test cards from the pouches before your test, lay over a clean flat surface.
2. In case, the tested samples are in frozen status, the sample has to be sit in room temperature to completely thawing, and mixed well for test.
3. Add 10ul serum or plasma to the well over the test card using included pipette.
4. Follow adding sample, add two or three drops assay buffer from the dropper bottle.
5. Results are then read 15 to 30 minutes, make sure control line is always positive.

Reading test results

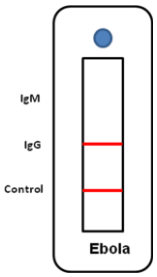
1. Ebola IgM positive



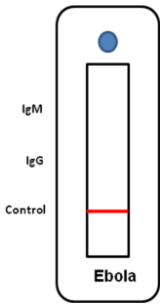
2. Ebola IgM or IgG/IgM positive



3. Ebola IgG positive



4. Ebola test negative



PLEASE NOTE: When reading this test, a clear visible line over IgG or IgM area of the card within the prescribed time limit indicates a positive result.

4. Indeterminate

Control line should appear always If test line is positive or negative. without positive control line, it is recommended that a fresh device be used and the test repeated carefully following the directions of the product insert.

5. Quality Control:

A known positive and negative control should be run to insure proper performance. All control tests should be handled in the same manner as patient samples.

Result analysis:

1. Early ebola IgM: positive or weak positive without ebola IgG between 2 to 5 days of symptom may indicate an early stage of ebola infection;

2. Positive dengue IgM and IgG may occur after 4 to 5 days after symptom;

3. Strong dengue IgG without ebola IgM may indicate late stage infection, or recovery patients.

Limitation of the Test

This instruction should be followed carefully and performed properly.

Ebola IgM/IgG test is designed to detect antibodies against ebola virus in serum or plasma. Testing of any other body fluids has not been validated and may not yield appropriate results.

For samples that test positive by ebola IgM/IgG test, more specific confirmatory testing may be done. A clinical evaluation of the patient's situation and history should also be made before a final diagnosis is established.