Ebola Rapid Test Kit
(Colloidal gold method)

INTENDED USE

Ebola Rapid Test Kit(Colloidal gold method) is intended for the qualitative detection of ebola antigens from Nose swabs. This test is intended to be used as an aid in the diagnosis of ebola.

This test is for in-vitro diagnostic use only.

SUMMARY

Ebola virus is mainly transmitted through blood, saliva, sweat and secretion of patients, and the incubation period of infection is 2-21 days. All the infected patients had high fever, headache, sore throat, weakness and muscle pain. Then there's vomiting, abdominal pain, diarrhea. Within two weeks after the onset of the disease, the virus overflowed, leading to internal and external bleeding, blood coagulation, necrotic blood quickly spread to all organs of the body, patients eventually appear oral, nasal and anal bleeding and other symptoms, patients can die within 24 hours.
In about 1500 confirmed Ebola cases, the mortality rate is as high as 88%

PRINCIPLE

The monoclonal antibody of anti-ebola virus core protein was pre-fixed on the strip, and another monoclonal antibody of anti-ebola virus core antigen was labeled on the colloidal gold, and the sandwich immunological detection method of double antibody was established.In the test process, if there is ebola virus in the sample, the specific antigen antibody reaction occurs and the positive result occurs;If there is no ebola, there is no reaction and a negative result.

MATERIAL

Material provided

1. 20 Individual sealed pouches, each containing:
   - Test device
   - Desiccant pouch
2. 2 Extraction Buffer vial:0.01 M Phosphate buffered saline (PBS) and 0.02% sodium azide.
3. 20 extraction tube
4. 20 swab
5. 1 Leaflet with instructions for use.

Material Required But Not Provided

- Timer

SPECIMEN COLLECTION AND STORAGE

Please use the swab provided in this product for sampling. Before collecting nasal and throat secretions, loosen the cover of the diluent bottle and take 400ul (about 13 drops of bubble free diluent) into a plastic test tube.

Note: when taking the diluent from the diluent bottle, discard the first drop and drop 13 drops of diluent into the plastic test tube from the second drop.Please use the swab provided in this product for sampling.Before collecting nasal and throat secretions, loosen the cover of the diluent bottle and take 400ul (about 13 drops of bubble free diluent) into a plastic test tube.Note: when taking the diluent from the diluent bottle, discard the first drop and drop 13 drops of diluent into the plastic test tube from the second drop.
When collecting the nasal secretion, insert the swab into the part with the most secretions in the nostril, gently shake the swab, and push it toward the nasal cavity until the turbinate bone (about 2.5cm in the nasa cavity), and gently shake the swab on the inner wall of the nasal cavity to take out.
When collecting the swab, insert the swab into the part with the most saliva in the throat, gently shake the swab on the inner wall of the throat, and take out the swab after sufficient samples are dipped.
Put the swab containing the sample into the diluent of the plastic test tube, squeeze the sample fully with your fingers for one minute, so that the sample is fully dissolved in the diluent. After the swab is taken out as far as possible, the liquid in the plastic tube is taken as the sample to be tested, and the upper cover of the plastic test tube shall be covered, and the test shall be carried out immediately. If it is not detected for a long time, it needs 2℃~8℃ of refrigeration,The storage time of samples shall not exceed 3 days.

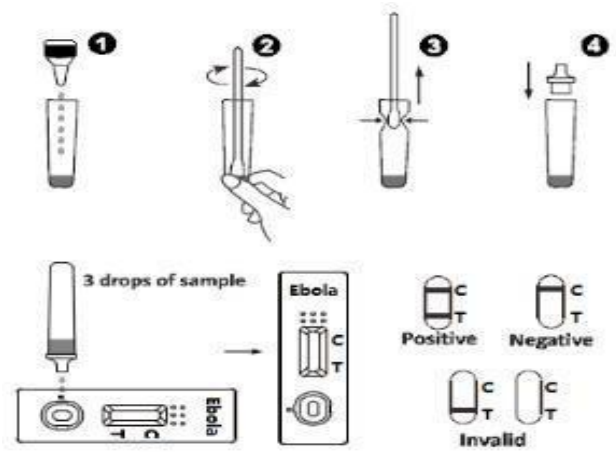
PRECAUTIONS

1.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4.Bring all reagents to room temperature (2℃-30℃） before use.
5.Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the Precautions for prevention of transmission of HIV, HBV and other blood-bome pathogens.
8.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9.Dispose of all specimens and materials used to perform the test as biohazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The testing results should be read within 5-15 minutes . Read result after 20 minutes may give erroneous results.

TEST PROCEDURE

1.Before testing, test cassette and sample should be restored to room temperature .
2.Open the aluminum foil package, take out the test cassette and place it on the horizontal table.
3. Reverse the plastic tube containing the treated sample and add 3 drops (about 90ul) into the sample hole(s) of the test kit. Count for 15 minutes and observe the results. Please note that the result is invalid after 30 minutes.

Window “C” is the control line, “T” is the test line.



INTERPRETATION OF RESULTS

Positive: a distinct red colored band appears on test line regions, in addition to a red line on the control line region. This indicates the presence of ebola in the sample.

Negative： the control line is the only visible line in the reagent cassette . The results do not exclude infection. If symptoms persist, a new sample should be taken from the patient within 3-5 days and retested.

Invalid test results： if the control line does not appear in the test bar, the test result is invalid regardless of whether there are other visible lines in the test bar. Retest with a new reagent cassette.

Noted:The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. But the substances level can not be determined by this qualitative test.

Insufficient specimen volume, incorrect operation procedure,or performing expired tests are the most likely reasons for control band failure.

LIMITATIONS OF THE TEST

1. This product is only used for preliminary screening of in vitro diagnosis. Please do not use it as a confirmation reagent. The positive results must be confirmed in combination of clinical symptoms and other tests.

2. Due to methodological or antigen specificity, testing the same sample with reagents from different manufacturers may result in different test results. Therefore, the results obtained by testing with different reagents should not be directly compared with each other to avoid incorrect medical interpretation. It is recommended that the laboratory indicate the characteristics of the reagents used in the test report issued to the clinician.

3.Reagents should be kept sealed and kept away from moisture. The reagents and the samples stored at low temperature should be equilibrated to room temperature before use.

4.Please follow the general guidelines for biosecurity in microbiology and biomedical laboratories.

5.The wastes including the used reagents and all samples are potentially infected, please dispose of them as infectious medical wastes.

INDEX OF SYMBOLS

	See instruction for use		Tests per kit		Manufacturing
IVD	For *in vitro* diagnostic use only		Expiry date		Do not reuse
2°C 30°C	Store between 2 ~ 30℃	LOT	Batch number	REF	Catalog #
	Keep away from sunlight		Keep dry	EC REP	Authorized Representative

our company is certified by ISO quality system