WHO Emergency Use Assessment and Listing for EVD IVDs
PUBLIC REPORT

Product: STANDARD™ Q Ebola *Zaire* Ag
EUAL Number: EAE 0444-117-00

Abstract

In order to respond to the urgent need for quality-assured in vitro diagnostics in the event of Ebola Virus Disease (EVD) outbreak, WHO has established a WHO Emergency Quality Assessment Mechanism of In Vitro Diagnostics (IVDs) for EVD. It consists of review of any existing evidence of safety and performance; desktop review of selected manufacturing and quality management systems documentation and limited laboratory evaluation of the product.

STANDARD™ Q Ebola *Zaire* Ag with product code **05EZ10 (CE-marked version)** manufactured by **SD Biosensor Inc.** 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, Republic of Korea was listed as eligible for WHO procurement on 8 September 2015. This public report was amended on 20 February 2019 to reflect the inclusion of the latest Instructions for Use and an update to the product name.

Intended use: STANDARD Q Ebola *Zaire* Ag is a chromatographic immunoassay for the presumptive qualitative detection of Ebola *Zaire* virus disease in whole blood, plasma or serum from individuals with signs and symptoms of Ebola virus infection in affected areas in conjunction with relevant epidemiological risk factors. This assay is intended for professional use, only for an initial screening test.

Intended user: Professional use only.

Principle SD Q Line Ebola *Zaire* Ag test device has 4 pre-coated lines, “T1” (Test line 1), “T2” (Test line 2), “T3” (Test line 3) and “C” (Control line). Mouse monoclonal antibodies specific to Zaire Ebola virus glycoprotein (GP) and mouse monoclonal antibodies specific to Zaire Ebola virus nucleoprotein (NP) and mouse monoclonal antibodies specific to Zaire Ebola virus viral matrix protein(VP40) are on the test region (“T1”, “T2” and “T3”) separately. Mouse monoclonal antibodies specific to Zaire Ebola virus GP, NP and VP40 – colloid gold conjugate reacts with the Zaire Ebola virus in the specimen. They move along the membrane chromatographically to the test region (“T1”, “T2” and “T3”) and form a visible line as the antibody-antigen-antibody gold particle complex with high degree of sensitivity and specificity. Three test lines and control line in the result window are not visible before applying any specimen. The control line is used for procedural control and should always appear if the test procedure is performed correctly.

The STANDARD™ Q Ebola *Zaire* Ag kit contains sufficient reagents to process 25 specimens or quality control samples. The kit contains the following:

Components of STANDARD™ Q Ebola *Zaire* Ag kit	**25 Tests/Kit 05EZ10**
Test Device	25
Positive Control swab	1
Negative Control swab	1
Control swab extraction buffer (0.3ml/tube)	2
Disposable dropper	25
Disposal bag	25
Instructions for use:	1

Materials required but not provided:

Name
Timer or watch
Materials required for venipuncture whole blood specimen collection
Materials required to obtain a fingerstick whole blood specimen

Storage:
Store the test kit at 2 to 40°C. Do not freeze the kit components.
*Note: When kit is stored at refrigerator, all kit components must be brought to room temperature (15 to 40°C) minimum 30 minutes prior to use.

Background information

SD Biosensor Inc. submitted an expression of interest for WHO emergency quality assessment of **STANDARD™ Q Ebola *Zaire* Ag** on 9 February 2015.

1. Product dossier assessment

SD Bionsensor Inc., submitted documentation in support of safety and performance for **STANDARD™ Q Ebola *Zaire* Ag** as per the "Invitation to Manufacturers of Ebola Virus In Vitro Diagnostics to Submit an Expression of Interest (EOI) for Emergency Assessment by WHO".[1] The information submitted in the product application was reviewed by WHO staff and external experts (reviewers) appointed by WHO. The findings of the reviews were reported in accordance with "Emergency Quality Assessment Mechanism of In Vitro Diagnostics for Ebola Virus Protocol for the Review of Documentary Evidence of Safety, Quality and Performance" (document number WHO PQDx_0188 v0.2).

Safety and performance documentation assessment conclusion: acceptable.

[1] Invitation to manufacturers of Ebola virus in vitro diagnostics to submit an Expression of Interest (EOI) for emergency assessment by WHO. Accessed on 24 November 2014 at http://www.who.int/diagnostics_laboratory/141002_revised_invitation_to_mx_of_ebola_virus_diagnostics_rc.pdf?ua=1

2. Review of quality management documentation

To establish the eligibility for WHO procurement, SD Biosensor Inc. was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation, it was established that sufficient information was provided by SD Biosensor Inc. to fulfil the requirements described in the "Invitation to manufacturers of Ebola Virus In Vitro Diagnostics to submit an Expression of Interest (EOI) for Emergency Assessment by WHO".

Quality management documentation assessment conclusion: acceptable.

3. Laboratory evaluation

The **STANDARD™ Q Ebola *Zaire* Ag** kit was assessed in a blinded, cross-sectional study to aiming at determining the comparative performance of several antigen detection tests for EVD. The performance evaluation was conducted in two separate arms, one prospective, using fresh, whole blood specimens and a retrospective arm on a selected set of archived, de-identified plasma specimens. Results were compared to conventional molecular testing with RT-PCR using the RealStar Filovirus Screen RT-PCR Kit 1.0 (altona Diagnostics GmbH) as benchmark assay. The archived specimens were selected to reflect representative populations seen in 1) passive case-finding (i.e. EVD identified in symptomatic patients who have arrived at a treatment center) and 2) active case-finding (i.e. EVD identified in individuals actively sought by healthcare workers from among case contacts and other at-risk individuals in the field). There was no study-related follow-up and study results were not used for patient care.
Retrospective specimens were obtained from: EU Mobile Lab (Hastings), Nigeria Mobile Laboratory (Kambia), PHE Laboratories (Kerrytown, Port Loko, Makeni). Whole blood specimens were collected from the Public Health England (PHE) laboratory in Makeni, Sierra Leone.

A total of 446 initial patient specimens were selected, comprising 100 fresh whole blood specimens and 346 stored plasma specimens.

Performance of the STANDARD™ Q Ebola *Zaire* Ag kit when compared with the RealStar Filovirus Screen RT-PCR Kit 1.0 (altona Diagnostics GmbH):

	Number tested	Performance (95% CI)
Sensitivity on whole blood and plasma	126	84.9% (78.6–91.2)
Specificity on whole blood and plasma	289	99.7 % (99.1–100.0)

Laboratory evaluation conclusion: acceptable.

Scope and duration of procurement eligibility

The **STANDARD™ Q Ebola *Zaire* Ag** kit with product code **05EZ10** manufactured by SD Biosensor Inc. is considered to be eligible for WHO procurement. The assay may be used to test symptomatic individuals for EVD. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO prequalified.

As part of the on-going requirements for listing as eligible for WHO procurement, SD Biosensor Inc. must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality and performance requirements. SD Biosensor Inc. is required to notify WHO of any complaints, including adverse events related to the use of the product within 7 days. Furthermore, WHO will continue to monitor the performance of the assay in the field.

WHO reserves the right to rescind eligibility for WHO procurement, if additional information on the safety, quality and performance comes to WHO's attention during post-market surveillance activities.

Commitment to WHO

Participation in further WHO coordinated studies as requested.

Labelling

1. Instructions for Use

Quality approved by SD BIOSENSOR / For *In vitro* diagnostic use only

STANDARD Q
Ebola *Zaire* Ag

REF 05EZ10

STANDARD™ Q Ebola *Zaire* Ag

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

EXPLANATION OF THE TEST

[Principle] STANDARD Q Ebola *Zaire* Ag test device has 4 pre-coated lines, "T1"(Test line 1), "T2"(Test line 2), "T3"(Test line 3) and "C"(Control line). Mouse monoclonal antibodies specific to *Zaire* Ebola virus glycoprotein(GP) and mouse monoclonal antibodies specific to *Zaire* Ebola virus nucleoprotein(NP) and mouse monoclonal antibodies specific to *Zaire* Ebola virus viral matrix protein(VP40) are on the test region("T1", "T2" and "T3") separately. Mouse monoclonal antibodies specific to *Zaire* Ebola virus GP, NP and VP40 – colloid gold conjugate react with the *Zaire* Ebola virus in the specimen. They move along the membrane chromatographically to the test region("T1", "T2" and "T3") and form a visible line as the antibody- antigen-antibody gold particle complex with high degree of sensitivity and specificity. Three test lines and control line in the result window are not visible before applying any specimen. The control line is used for procedural control and should always appear if the test procedure is performed correctly.

[Intended Use] STANDARD Q Ebola *Zaire* Ag is a chromatographic immunoassay for the presumptive qualitative detection of Ebola *Zaire* virus disease in whole blood, plasma or serum from individuals with signs and symptoms of Ebola virus infection in affected areas in conjunction with relevant epidemiological risk factors. This assay is intended for professional use, only for an initial screening test.

MATERIALS PROVIDED / ACTIVE INGREDIENTS OF MAIN COMPONENTS

[STANDARD Q Ebola *Zaire* Ag includes]

No.	Materials	25 Tests/Kit
①	Test Device	25
②	Positive Control Swab	1
③	Negative Control Swab	1
④	Control swab extraction buffer (0.3ml/tube)	2
⑤	Disposable dropper	25
⑥	Disposal bag	25
⑦	Instructions for use	1

[Active ingredients of main components]

- 1 test device included; Gold conjugate (as main component): Mouse monoclonal anti-*Zaire* Ebola virus GP-conjugated gold colloid (OD10±2, 540nm, 7±1.4μl), Mouse monoclonal anti-*Zaire* Ebola virus NP-conjugated gold colloid (OD10±2, 540nm, 7±1.4μl), Mouse monoclonal anti-*Zaire* Ebola virus VP40-conjugated gold colloid (OD10±2, 540nm, 7±1.4μl) / Test Line "1" (as main component): Mouse monoclonal anti-*Zaire* Ebola virus GP (0.63± 0.13μg), Test Line "2" (as main component): Mouse monoclonal anti-*Zaire* Ebola virus NP (0.63±0.13μg), Test Line "3" (as main component): Mouse monoclonal anti-*Zaire* Ebola virus VP40 (0.63± 0.13μg) / Control Line (as main component): Mixture of Recombinant *Zaire* Ebola virus glycoprotein, nucleoprotein and matrix protein antigen (1.38±0.28μg), Nitrocellulose membrane (25±5 x 4.0±0.8mm), Conjugate pad (7±1.4 x 4.0±0.8mm), Sample pad (13±2.6 x 4.0±0.8mm), Absorbent pad (18±3.6 x 4.0±0.8mm)
- Ebola *Zaire* Ag Positive Control Swab : Recombinant *Zaire* Ebola GP Ag (0.5±0.1μg), Recombinant *Zaire* Ebola NP Ag (0.5±0.1μg), Recombinant *Zaire* Ebola virus VP40 Ag (0.5±0.1μg)
- Ebola *Zaire* Ag Negative Control swab : 1% BSA (q.s), 100 mM Tris buffer (q.s)
- Control swab extraction buffer : 100 mM Tris Buffer (0.3ml), Proclin 300 (q.s)

MATERIALS REQUIRED, BUT NOT PROVIDED

- Timer

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Store the test kit at 2 - 40°C. DO NOT FREEZE the kit components.
   *Note: When kit is stored at refrigerator, all kit components must be brought to room temperature (15 - 40°C) minimum 30 min prior to use.
2. Perform the test immediately after removing the test device from the foil pouch. Do not use reagents beyond the stated expiration date marked on the label.
3. The shelf life of the kit is as indicated on the outer package.
4. Do not use the test kit if the pouch is damaged or the seal is broken.
5. Silica gel in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the pouch should be discarded.
6. Do not store the test kit in direct sunlight.

WARNINGS

1. For *in vitro* diagnostic use only. Do not reuse test device.
2. The instructions must be followed exactly to get accurate results. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant[1].
6. Do not mix and interchange different specimens.
7. When used as directed, test kit reagents present no risk to the user.
8. Do not pipette by mouth.
9. Do not mix reagent of different lots.
10. Avoid contact with all specimens, used test device and potentially contaminated materials, because Ebola virus is highly contagious and spreads by direct contact with blood or other body fluids of an infected human.
11. Ebola *Zaire* Ag Positive Control swab is coated with mixture of recombinant *Zaire* Ebola virus protein. So it is not contagious.
12. Specimens should always be treated as infectious and/or biohazardous and sample and assay waste should be discarded according to local safety regulations.
13. Follow necessary precautions when handling specimens with this test. Use personal protective equipment (PPE) consistent with current guideline[2].

COLLECTION, STORAGE AND PRECAUTION OF SPECIMEN

[Whole blood]

- Collect the venous whole blood into the anticoagulant (such as heparin, EDTA and sodium citrate) tube.
- The capillary whole blood sample must be tested within one minute immediately after collection.

[Serum or Plasma]

- [Serum] Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood at 1,000g for 10 minutes to get serum specimen of supernatant.
- [Plasma] Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge (for 10 minutes at 1,000g) blood to get plasma specimen.
- If specimen is not tested immediately, it should be refrigerated at 2 - 8°C up to six days.
- For long term storage, store at -70°C. Avoid freeze-thaw cycles.
- If the serum or plasma specimens are kept in refrigerator or freezer, bring to room temperature (15 - 40°C) for 30 minutes prior to use.

[Precaution]

- Hemolyzed samples can lead to impair test results. If a specimen is found to be hemolyzed, do not use the specimen.
- Use separate disposable dropper for each specimen in order to avoid cross-contamination of specimens which could cause erroneous results.
- Discard alcohol swab if package is pierced or damaged.
- Serum or plasma specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified by centrifugation at 1,000g for 10min at 4°C prior to assaying.
- There is a possible risk of false positive results when capillary whole blood is used as a specimen type instead of venous whole blood.
- Inappropriate collection and handling for venous and capillary whole blood can produce incorrect results.

PREPARATION OF CONTROL

Insert each control swab(Positive(②) or Negative(③)) into the control swab extraction buffer(④) and swirl the swab for at least ten seconds. Remove the swab.

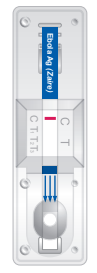
PROCEDURE OF THE TEST (REFER TO FIGURE ON BACK PAGE)

1. Allow all kit components and specimen to come to room temperature (15 - 40°C) before testing.
2. Remove the test device(①) from the foil pouch prior to use, and place it on a flat, dry surface.
   [Using a disposable dropper(⑤)] Apply 3 drops (about 100μL) of prepared control or specimen into the sample port vertically.
   Or, [Using a micropipette] Apply 100μL of prepared control or specimen into the sample port.
   *Caution: For specimen volume, the recommended volume (70 - 130μl) is needed to meet normal migration upon test run.
3. As the test begins to work, you will see purple color move across the result window in the center of the test device. Read the test result at 20-30 minutes. Do not read after 30 minutes.
4. After test is done, discard used test components into the disposal bag(⑥).

INTERPRETATION OF THE RESULTS (REFER TO FIGURE ON BACK PAGE)

[Negative result]

- A color appears on the control ("C") line only.

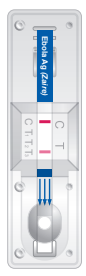


[Positive result]

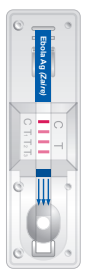
- ***Zaire* Ebola virus Glycoprotein(GP) Positive**
  The presence of two color lines ("C" and "T1") within the result window no matter which line appears first, indicates *Zaire* Ebola virus infection.
- ***Zaire* Ebola virus Nucleoprotein(NP) Positive**
  The presence of two color lines ("C" and "T2") within the result window no matter which line appears first, indicates *Zaire* Ebola virus infection.
- ***Zaire* Ebola virus Viral matrix protein(VP40) Positive**
  The presence of two color lines ("C" and "T3") within the result window no matter which line appears first, indicates *Zaire* Ebola virus infection.
- ***Zaire* Ebola virus GP, NP and VP40 Positive**
  The presence of four color lines ("C", "T1", "T2" and "T3") within the result window no matter which line appears first, indicates *Zaire* Ebola virus infection.

Zaire Ebola virus GP Positive

Zaire Ebola virus NP Positive



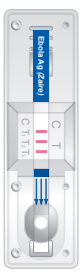
Zaire Ebola virus VP40 Positive



Zaire Ebola virus GP, NP and VP40 Positive

[Invalid result]

- If the control ("C") line color fails to appear, the result might be considered invalid. It is recommended that the specimen need to be retested.



LIMITATIONS OF THE TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. This test is limited to the detection of *Zaire* Ebola virus glycoprotein, nucleoprotein and viral matrix protein in the specimen. Detection of other species (Sudan, Bundibugyo, Taï Forest) of Ebola virus is not confirmed yet.
3. Incubation period of *Zaire* Ebola virus infection is 2 - 21 days after exposure to *Zaire* Ebola virus. For patients having shown symptoms for 3 days or less, or showing mild symptoms, the sample's viral load could be below the limit of detection. If the test result is negative and clinical symptoms are persistent, additional follow-up test using other clinical methods is recommended after 3 days from the first test. A negative result does not necessarily mean that there is no possibility of Ebola *Zaire* virus infection.
4. Test is useful as an initial screening test of *Zaire* Ebola virus diagnosis, but it should not be used as the sole criterion for the diagnosis of *Zaire* Ebola virus infection. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of *Zaire* Ebola virus infection.

INTERNAL QUALITY CONTROL

1. Internal Quality control : The test device has Test Lines and Control Line on the surface of the test device. All Test Lines and Control Line in the result window are not visible before applying any specimen. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.
2. External Quality control :
   (1) Control Procedures: Positive and Negative control swabs should be tested according to the [Preparation of Control] and [Procedure of the Test].
   (2) Specification
   - Ebola *Zaire* Ag Positive control swab should be interpreted as test line "1", "2" and "3" positive.
   - Ebola *Zaire* Ag Negative control swab should be interpreted as negative.

PERFORMANCE CHARACTERISTICS

1. Internal evaluation (Table-1)
   Limit of detection(LOD) of STANDARD Q Ebola *Zaire* Ag is 12.5 ng/ml for recombinant *Zaire* Ebola virus GP, 50ng/ml for recombinant *Zaire* Ebola virus NP and 50ng/ml for recombinant *Zaire* Ebola virus VP40.
2. Reproducibility has been demonstrated by studies (within-run, between-run and batch- to- batch) with in-house reference panels. All values were identical to reference panel acceptance criteria.
   Table-1. Limit of detection(LOD) of STANDARD Q Ebola *Zaire* Ag

Concentration of In-house reference panel	STANDARD Q Ebola *Zaire* Ag		
	Zaire Ebola virus GP	*Zaire* Ebola virus NP	*Zaire* Ebola virus VP40
1,000 ng/ml	Positive	Positive	Positive
500 ng/ml	Positive	Positive	Positive
250 ng/ml	Positive	Positive	Positive
125 ng/ml	Positive	Positive	Positive
62.5 ng/ml	Positive	Positive	Weak Positive
31.3 ng/ml	Weak Positive	Positive	Negative

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15.6 ng/ml	Negative	Positive	Negative
7.8 ng/ml	Negative	Weak Positive	Negative
3.9 ng/ml	Negative	Weak Positive	Negative
2.0 ng/ml	Negative	Negative	Negative

*** NOTE:** The hook effect may be occurred at the concentration of 25ug/ml above.

Table-2. Hook effect of STANDARD Q Ebola *Zaire* Ag

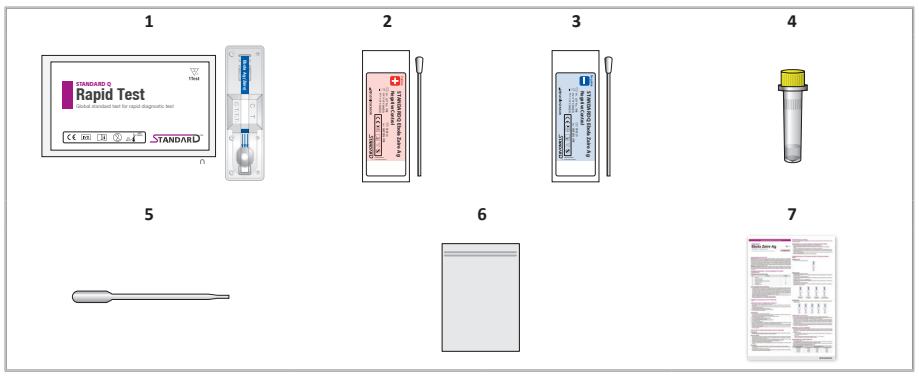
Concentration of antigen	Rec. GP 100μg/ml	Rec. GP 50μg/ml	Rec. GP 25μg/ml	Rec. GP 10μg/ml	Rec. GP 5μg/ml	Rec. GP 1μg/ml	Rec. GP 0.5μg/ml	Rec. GP 250μg/ml	Rec. GP 125μg/ml	Rec. GP 62.5μg/ml
***Zaire* Ebola virus GP**	2+	2+	3+	3+	3+	3+	2+	2+	1+	1+
Concentration of antigen	Rec. NP 100μg/ml	Rec. NP 50μg/ml	Rec. NP 25μg/ml	Rec. NP 10μg/ml	Rec. NP 5μg/ml	Rec. NP 1μg/ml	Rec. NP 0.5μg/ml	Rec. NP 250μg/ml	Rec. NP 125μg/ml	Rec. NP 62.5μg/ml
***Zaire* Ebola virus NP**	2+	2+	3+	3+	3+	3+	2+	2+	1+	1+
Concentration of antigen	Rec. VP40 100μg/ml	Rec. VP40 50μg/ml	Rec. VP40 25μg/ml	Rec. VP40 10μg/ml	Rec. VP40 5μg/ml	Rec. VP40 1μg/ml	Rec. VP40 0.5μg/ml	Rec. VP40 250μg/ml	Rec. VP40 125μg/ml	Rec. VP40 62.5μg/ml
***Zaire* Ebola virus VP40**	2+	2+	3+	3+	3+	3+	2+	2+	1+	1+

REFERENCES

Laboratory guidance for the diagnosis of Ebola Virus Disease in WHO 19/09/14

INTRODUCTION

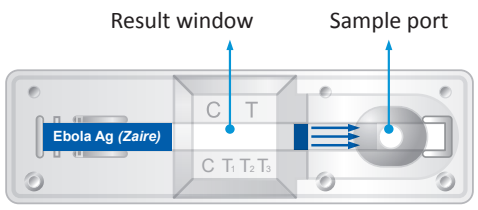
1. Now, open the package and look for the following:
   (1) Test Device
   (2) Positive Control Swab
   (3) Negative Control Swab
   (4) Control swab extraction buffer (0.3ml/tube)
   (5) Disposable dropper
   (6) Disposal bag
   (7) Instructions for use



2. First, read carefully the instruction on how to use the STANDARD Q Ebola *Zaire* Ag.
3. Next, look at the expiry date at the back of the foil pouch. Use another kit, if expiry date has passed.

/ Exp. Date : YYYY.MM.DD.

4. Open the foil pouch and look for the following:

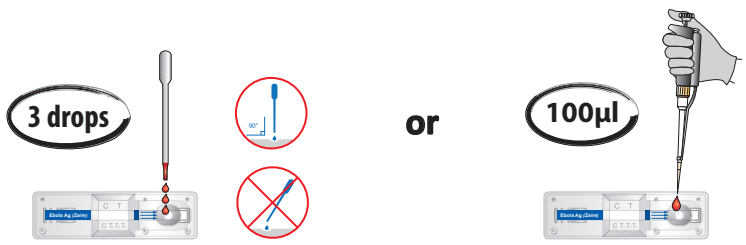


PREPARATION OF CONTROL

Insert each control swab (Positive or Negative) into the control swab extraction buffer and swirl the swab for at least ten seconds. Remove the swab.

TEST PROCEDURE

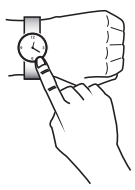
1. Add 3 drops (about 100μL) of specimen into the sample port.



Using a dropper

Using a micropipette

2. Read the test result at 20-30 minutes. Do not read after 30 minutes.

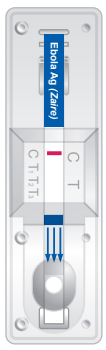


20-30min

INTERPRETATION OF THE RESULTS

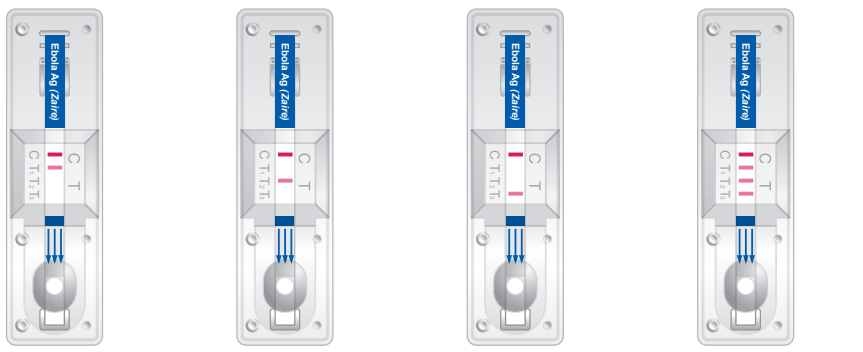
[Negative Result]

- One line “C” in result window.



[Positive result]

- GP Positive
  Two lines “C” and "T1" in result window.
- NP Positive
  Two lines “C” and "T2" in result window.
- VP40 Positive
  Two lines “C” and "T3" in result window.
- GP, NP and VP40 Positive
  Four lines “C”, “T1”, “T2” and “T3” in result window.



Zaire Ebola virus GP Positive

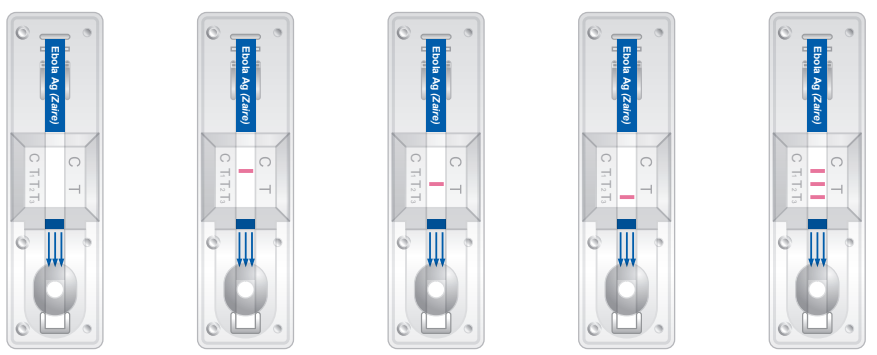
Zaire Ebola virus NP Positive

Zaire Ebola virus VP40 Positive

Zaire Ebola virus GP, NP and VP40 Positive

[Invalid Result]

- No control “C” line in result window.
- It is recommended that the specimen need to be retested.



BIBLIOGRAPHY

1. Centers for Disease Control and Prevention (CDC), Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
2. World Health Organization (WHO), Personal protective equipment for use in a filovirus disease outbreak - Rapid advice guideline

CE

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ISsue date: 2019.02