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 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 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