WHO Emergency Use Assessment and Listing for EVD IVDs
PUBLIC REPORT

Product: SD Q Line Ebola Zaire Ag
Number: EA 0021-020-00

Abstract

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

SD Q Line Ebola Zaire Ag with product code 05EZ10 manufactured by SD Biosensor Inc. (Republic of Korea) was listed as eligible for WHO procurement on 8 September 2015.

SD Q Line Ebola Zaire Ag
Method: 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 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: SD Q Line Ebola Zaire Ag is a chromatographic immunoassay for the presumptive 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.

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

- Ebola Zaire Ag Test Device: 25
- Ebola Zaire Ag Positive Control swab: 1
- Ebola Zaire Ag Negative Control swab: 1
Materials required but not provided:
- Timer

Storage:
Store the test kit at 1 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 (15~40°C) minimum 30 min prior to use.

Background information

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

1. Product dossier assessment
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.

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 SD Q Line Ebola Zaire Ag 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 SD Q Line Ebola Zaire Ag when compared with the RealStar Filovirus Screen RT-PCR Kit 1.0 (altona Diagnostics GmbH):**

- Sensitivity on whole blood and plasma (n=126) 84.9% (95% CI) (78.6–91.2)
- Specificity on whole blood and plasma (n=289) 99.7 % (95% CI) (99.1–100.0)

Laboratory evaluation conclusion: acceptable.

**Scope and duration of procurement eligibility**

The **SD Q Line Ebola Zaire Ag** 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.