

Interim guidance on the use of rapid Ebola antigen detection tests

31 March 2015

Objective

To provide interim guidance to Ministries of Health and other organizations on the potential use of available rapid Ebola antigen-detection tests.

Background

Early identification of patients suspected to have Ebola virus disease is important for patient management and transmission interruption.

The laboratory diagnostic tests that are currently used in the field are based on detection of the Ebola virus nucleic acids by a method known as PCR – polymerase chain reaction. These tests are complex, require electricity, level 3 or 4 biosafety laboratories and specialized equipment and trained manpower. PCR remains the recommended and most accurate test for laboratory diagnosis of Ebola. In order to reach more remote settings, however, simpler laboratory tests will be needed.

Recently, several rapid tests that detect antigens produced by the Ebola virus have been developed in a format similar to pregnancy tests or malaria rapid tests. Though still requiring specific attention to biosafety, such rapid tests for antigen detection could have significant advantages in terms of simplicity, portability and low cost, but are likely to have less predictable performance than PCR, be more susceptible to reader error, and be less able to detect low concentrations of virus or the presence of virus in oral swabs.

Through its Emergency Use Assessment and Listing Procedure (EUAL), WHO has recently listed the ReEBOV™ Antigen Rapid Test Kit (Corgenix) for potential use during the current epidemic [on the basis of evidence of quality manufacturing, capacity to supply and documented and verified performance characteristics]. A limited WHO evaluation of ReEBOV™ Antigen Rapid Test Kit using fresh and frozen blood samples showed a sensitivity of 91.8% (95% CI: 84.5-96.8) and specificity of 84.6% (95% CI: 78.8-89.4) in comparison with the RealStar® Filovirus Screen RT-PCR Kit 1.0 (WHO-listed benchmark assay). There are additional clinical studies that have found better and worse performance than the WHO study, likely due to differences in the populations tested and the reference methods used. The guidance given below takes all the available data into account.

WHO is currently working with the Foundation for Innovative New Diagnostics (FIND) and other partners to assess additional rapid assays for potential use in the current or future Ebola outbreaks. If these tests being studied show substantially different performance than the ReEBOV™ Antigen Rapid Test Kit, this current guidance may require modification.

This interim guidance is intended to provide Ministries of Health and other organizations information on the potential role for rapid diagnostic tests detecting Ebola antigen for outbreak response and control.

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Interim technical guidance based on the currently available information

Overall guidance for current epidemic

Where PCR is available, rapid tests for detection of Ebola antigens should not be used in the routine diagnostic management of Ebola virus disease at the current stage of this outbreak. However there may be special situations where a rapid antigen test that has reasonable sensitivity in patients with high concentrations of Ebola virus in the blood may be beneficial.

Special settings where rapid antigen detection for Ebola may be beneficial

1. *In the investigation of suspected Ebola outbreaks in remote settings where PCR tests are not immediately available.*

Both positive and negative results obtained with rapid antigen detection tests must be confirmed using PCR. In the case where one or more patients in a suspect cluster are positive by the antigen-detection test, while awaiting confirmatory testing, action can be taken to a) isolate test-positive patients, b) repeat daily testing on patients who are initially test-negative but remain symptomatic, c) mobilize transport of samples for confirmatory testing and initiate outbreak-management procedures.

2. *In settings where the number of cases and suspects arriving for triage and care cannot be managed with the existing health staff and laboratory facilities.*

The use of a rapid antigen detection test would allow rapid isolation and care of those with the highest risk. In such a setting an antigen-detection test for Ebola, even with imperfect sensitivity, might be used to identify those patients with the most severe disease and the greatest likelihood to transmit the infection. Confirmatory testing using PCR would still need to be performed on all suspects, regardless of the results of their rapid test.

Example situations where rapid antigen detection tests should NOT be used

- Individual case management – including for establishing definitive diagnosis or making therapeutic decisions
- Certification of Ebola virus-free status prior to medical care for other illnesses
- Release of Ebola patients from Ebola Treatment Centers
- Pooled blood samples for community-based testing
- Testing blood before transfusion
- Active case finding without confirmatory PCR
- Any setting where action (quarantine, referral, care) based on results is not possible
- Airport screening

Caveats for use

- Only trained staff should perform testing and result interpretation
- Full Personal Protective Equipment is necessary for blood sampling and inoculated test strips should be treated as a biohazard unless the test strip comes with an inactivation buffer documented to be effective (see <http://who.int/csr/resources/publications/ebola/blood-collect-en.pdf>)
- Instructions for Use provided by the manufacturer should be followed carefully, including, taking note that the recommended specimen types are used; that specimens are used, stored and transported as instructed; that the test kit is stored as stated and appropriate controls are used.
- The social impact of reporting testing results for Ebola virus disease, especially with a non-confirmatory assay such as the antigen detection tests, should be carefully considered.
- A system for post market surveillance of test performance should be established in collaboration with WHO. To provide interim guidance to Ministries of Health and other organizations on the potential use of available rapid Ebola antigen-detection tests.

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