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FDA permits to market first rapid Ebola virus antigens diagnostic test

11 October 2019 | News

The OraQuick Ebola Rapid Antigen Test is the first rapid diagnostic test the FDA has allowed to be marketed in the U.S. for the Ebola Virus Disease (EVD)



The U.S. Food and Drug Administration allowed marketing of a rapid diagnostic test (RDT) to detect Ebola virus antigens (proteins) in human blood from certain living individuals and samples from certain recently deceased individuals suspected to have died from Ebola (cadaveric oral fluid). The OraQuick Ebola Rapid Antigen Test is the first rapid diagnostic test the FDA has allowed to be marketed in the U.S. for the Ebola Virus Disease (EVD). The test provides a rapid, presumptive diagnosis that must be confirmed.

"Today's marketing authorization provides another important tool in the effort to fight Ebola, which continues to be a priority of the U.S. Government, especially as we work with our partners, including the World Health Organization, to help address the current Ebola outbreak in the Democratic Republic of Congo (DRC)," said Acting FDA Commissioner Ned Sharpless, M.D. "The current outbreak in the DRC has already killed thousands and the outbreaks in West Africa that began in 2014 tragically killed more than 11,000. Investigational vaccines and therapeutics have shown promising results, but one of the most important tools in stopping these outbreaks is quickly diagnosing patients and supporting safe and dignified burials. This marketing authorization may provide additional assurances to health care professionals seeking to use these types of rapid diagnostics. The ability to use this test to promptly make a presumptive Ebola diagnosis could help providers to more quickly isolate patients and begin treatments that can be potentially life-saving. Additionally, this device could be used to support safe and dignified burials while helping to reduce the risk of transmission during those burials."

The FDA has authorized a number of diagnostic tests for EVD under the EUA pathway to assist with the public health response. Today's marketing authorization of the first EVD presumptive rapid diagnostic test for Ebola virus antigens through the De Novo review pathway reflects the ongoing collaboration between the U.S. Government and test developers to gather additional data on EUA products.

For the OraQuick Ebola Test submission, the FDA reviewed data from multiple clinical studies of blood samples and cadaveric oral fluid from the 2014 West African outbreak and from a variety of analytical studies. Based on these data, the FDA determined that general and special controls were necessary to provide a reasonable assurance of the safety and effectiveness of the OraQuick Ebola Test when intended to identify antigens associated with Ebola virus in blood from symptomatic patients and oral fluid of cadavers.

The OraQuick Ebola Test was reviewed under the De Novo premarket review pathway, a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this marketing authorization, the FDA is establishing criteria, called special controls, that determine the requirements for demonstrating accuracy, reliability and effectiveness of tests intended to identify Ebola virus antigens. These special controls, when met along with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

The OraQuick Ebola Test was granted Breakthrough Device designation, meaning the FDA provided intensive interaction and guidance to the company on efficient device development, to expedite evidence generation and the agency's review of the device. To qualify for such designation, a device must provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition, and meet one of the following criteria: the device must represent a breakthrough technology; there must be no approved or cleared alternatives; the device must offer significant advantages over existing approved or cleared alternatives; or the availability of the device is in the best interest of patients.

The FDA granted marketing authorization of the OraQuick Ebola Test to OraSure Technologies, Inc.