Ebola rapid diagnostic test receives FDA EUA, 10/15

OraSure Technologies received FDA Emergency Use Authorization for its OraQuick Ebola Rapid Antigen Test, which is designed to detect viral antigens in fingerstick and venous whole blood from patients presenting with signs and symptoms of Ebola infection in conjunction with epidemiological risk factors. The test is authorized only for the detection of Ebola Zaire virus. Positive results may be read as soon as they appear and have been observed as early as four minutes. Negative results have to be read at 30 minutes. The test can be used at ambient temperatures (up to 40°C, or 104°F), is easy to use with only two operational steps and a simple visual read, and does not require instrumentation. Additionally, the test is shelf stable in a wide range of storage conditions.

The test uses the OraQuick technology platform, which is the same technology used in the company's rapid HIV and HCV antibody test kits. It has not been cleared or approved by the FDA.

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