



## Introducing **Xpert® Ebola\***

### *Projected Release (CE-IVD) H2 2015:*

#### **Situation/Introduction**

- Ebola virus disease (EVD) outbreaks have occurred sporadically throughout West Africa for decades.
- Among the five Ebola virus species identified, Zaire Ebola virus has affected the widest geographic regions and is the cause of the 2014 West Africa outbreak.
- As of March 2015, over 24,000 individuals have been infected and over 10,000 have died as a result.<sup>1</sup>
- EVD has spread to countries in West Africa, Europe and United States.

#### **Unmet Need**

- Currently available rapid tests are not sensitive enough to confirm Ebola virus disease.<sup>2</sup>
- Rapid, accurate, and reliable determination of Ebola virus disease (EVD) maximizes medical decision making – enabling real-time testing during patient presentation.

#### **Preliminary Intended Use**

- Xpert Ebola is a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of RNA from the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in individuals with signs and symptoms of Ebola virus infection. Testing with Xpert Ebola should not be performed unless the individual meets clinical and epidemiological criteria for testing of suspected cases. Results are for the presumptive identification of Ebola Zaire virus. The definitive identification of Ebola Zaire virus infection requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reporting is required. The diagnosis of Ebola Zaire virus infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of the Ebola Zaire virus.

\* Product distribution outside the United States.

# Introducing **Xpert® Ebola\***

## **Cepheid Molecular Testing Delivers:**

- Consistent high quality results regardless of laboratory environments
- Quick and efficient identification of Ebola Zaire Viral RNA
- Critical information in making important isolation decisions to prevent further transmission and supports infection control efforts

## **Why GeneXpert®?**

- An on-demand, *actionable* result in about 90 minutes
- A qualitative diagnostic test for fast and accurate detection of Ebola Zaire Viral RNA
  - Multiple targets to ensure accurate coverage
- Improved workflow eliminates the need to wait for sample accumulation
- Less than 1 minute hands-on time
- Sample type: Whole Blood

## **Impact:**

- Fast and accurate detection of Ebola Zaire Virus, the cause of the 2014 outbreak
- On-demand capability with throughput and scalability suitable to a variety of testing environments
- One platform provides flexibility to perform a broad menu of easy to perform tests
- Can address changes in patient pathways and healthcare delivery costs

**Xpert Ebola: Cepheid's on-demand Xpert test will provide redundant target segments to ensure accurate & reliable detection of Ebola Zaire Viral RNA.**

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### **References:**

1. WHO. Ebola Situation Reports. 2015 Mar 18. Accessed Mar 2015. <http://apps.who.int/ebola/current-situation/ebola-situation-report-18-march-2015>
2. WHO. UPDATE on the WHO Emergency Quality Assessment Mechanism for in vitro diagnostics for Ebola virus disease. 2014 Nov 28. Accessed Mar 2015. [http://www.who.int/medicines/ebola-treatment/20141128\\_Ebola\\_Update.pdf](http://www.who.int/medicines/ebola-treatment/20141128_Ebola_Update.pdf)

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