Ebola Virus (EBOV) Real Time RT-PCR Kit User Manual

For In Vitro Diagnostic Use Only

1. Intended Use

Ebola Virus (EBOV) real time RT-PCR kit is used for the detection of EBOV in serum (non-heparin anticoagulant), body fluid, or urine sample by using the real time PCR systems.

2. Principle of Real-Time PCR

The principle of the real-time detection is based on the fluorogenic 5’ nucleotide assay. During the PCR reaction, the DNA polymerase cleaves the probe at the 5’ end and separates the reporter dye from the quencher dye only when the probe hybridizes to the target DNA. This cleavage results in the fluorescent signal generated by the cleaved reporter dye, which is monitored real-time by the PCR detection system. The PCR cycle at which an increase in the fluorescence signal is detected is mainly proportional to the amount of the specific PCR product. Monitoring the fluorescence intensities in real-time allows the detection of the accumulating product without having to re-open the reaction tube after the amplification.

3. Product Description

Ebola is the virus Eboavirus (EBOV), a viral genus, and the disease Ebola hemorrhagic fever (EHF), a viral hemorrhagic fever (VHF). The virus is named after the Ebola River Valley in the Democratic Republic of the Congo (formerly Zaïre), which is near the site of the first recognized outbreak in 1976 at a mission hospital run by Flemish nuns. It remained largely obscure until 1989 when several widely publicized outbreaks occurred among monkeys in the United States. The virus interferes with the endothelial cells lining the interior surface of blood vessels and causes coagulation. As the blood vessel walls become damaged and destroyed, the platelets are unable to coagulate, patients succumb to hypovolemic shock. Ebola is transmitted through bodily fluids, while contact with contaminated virus is sufficient to cause infection.

4. Kit Contents

The following sample results are possible:

- **Positive Control (quantitative assay)**
  - Input each concentration of standard controls at the end of run, and a standard curve will be formed.
  - The calibration for quantitative detection: Input each concentration of standard controls at the end of run, a standard curve will be automatically formed.

- **Blank**
  - The 5µl Master Mix with microproppets in sterile filter tips to each real time PCR reaction plate/tubes. Separately add 5µl RNA sample, positive and negative controls to different reaction plate/tubes. Immediately close the plate/tubes to avoid contamination.

- **Input standard**
  - When the number of samples is dozens or even hundreds of times greater than elution volume by some concentrating method, it can be much higher.