



CERTIFICATE OF ANALYSIS

Certified Reference Material

Assay: EUA Assay Ebola Zaire (EZ1)

Description: 100X Positive Control, Frozen, 10 reactions per tube.

Lot Number: 300513-01S 150714

Period of Validity: Expires July 2016

Certified Property Values:

Test	Specifications	Results
Ct Value	Ct value produced is within expected range	PASS
	All positive control replicates produced a Ct value	PASS
Identification	Positive control detected in specific real-time PCR assay	PASS
Homogeneity	Positive control is sufficiently homogeneous	PASS

Certification Analytical Method:

Real-time Reverse Transcriptase PCR on the Applied Biosystems 7500 Fast Dx platform was used to validate the certification values of CRM. Homogeneity was established by evaluating a minimum of 80 samples of the reference material in its final sellable state by a minimum of two technicians on two separate days with two instruments if available. Protocols have been followed to insure the certified value represents the true value. NMRC cannot be held responsible for changes that happen during storage of the positive control at the customer's location.

Intended Use:

CRM is to be used for *in vitro* diagnostic use only under EUA for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) on specified instruments in individuals in affected areas with signs and symptoms of Ebola virus infection or who are at risk for exposure or may have been exposed to the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in conjunction with epidemiological risk factors.

Instructions for Use:

Refer to instruction booklet for details regarding proper use and storage conditions.

Hazards: CRM is considered non-hazardous. MSDS is available upon request.

For Information Only: CRM produced an average Ct value of 19.71 ± 0.54 with a range of 19.16 to 21.15. Analysis parameters included a manual Ct threshold of $1E5$ and a manual baseline with a start cycle of 3 and an end cycle of 15.

EUA Assay Ebola Zaire (EZ1) 100X positive control 300513-01S 150714 has been certified for use on 21 July 2014 by Joan Gebhardt, Head, PCR Production Facility.



Naval Medical Research Center PCR Production Facility
Biological Defense Research Directorate
8400 Research Plaza
Fort Detrick, MD 21702