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New England Biolabs
Certificate of Analysis

Product Name:	*WarmStart® Colorimetric LAMP 2X Master Mix (DNA & RNA)*
Catalog #:	*M1800S/L*
Concentration:	*2X Concentrate*
Lot #:	*0091708*
Assay Date:	*08/2017*
Expiration Date:	*8/2018*
Storage Temp:	*-20°C*
Composition (1X):	*Proprietary*
Specification Version:	*PS-M1800S/L v1.0*
Effective Date:	*17 Aug 2017*

Assay Name/Specification (minimum release criteria)	**Lot #0091708**
Functional Testing (LAMP, Master Mix) - A 25 µl reaction with 1X WarmStart® Colorimetric LAMP Master Mix (DNA & RNA) in the presence of 1X LAMP Primers containing 10 ng genomic DNA and 1X LAMP fluorescent dye results in a threshold time of ≤ 15 minutes as determined by fluorescent detection.	**Pass**
Functional Testing (RT-LAMP, Master Mix) - A 25 µl reaction with 1X WarmStart® Colorimetric LAMP Master Mix (DNA & RNA) in the presence of 1X LAMP Primers containing 10 ng of genomic RNA and 1X LAMP fluorescent dye results in a threshold time of ≤ 15 minutes as determined by fluorescent detection.	**Pass**
Non-Specific DNase Activity (16 hour, Buffer) - A 50 µl reaction in 1X WarmStart® Colorimetric LAMP Master Mix (DNA & RNA) containing 1 µg of T3 DNA in addition to a reaction containing Lambda-HindIII DNA incubated for 16 hours at 37°C results in a DNA pattern free of detectable nuclease degradation as determined by agarose gel electrophoresis.	**Pass**
qPCR DNA Contamination (*E. coli* Genomic) - A minimum of 1 µl of WarmStart® Colorimetric LAMP Master Mix (DNA & RNA) is screened for the presence of *E. coli* genomic DNA using SYBR® Green qPCR with primers specific for the *E. coli* 16S rRNA locus. Results are quantified using a standard curve generated from purified *E. coli* genomic DNA. The measured level of *E. coli* genomic DNA contamination is ≤ 1 *E. coli* genome.	**Pass**
RNase Activity (Extended Digestion) - A 10 µl reaction in NEBuffer 4 containing 40 ng of a 300 base single-stranded RNA and a minimum of 1 µl of WarmStart® Colorimetric LAMP 2X Master Mix (DNA & RNA) is incubated at 37°C. After incubation for 4 hours, >90% of the substrate RNA remains intact as determined by gel electrophoresis using fluorescent detection.	**Pass**

Authorized by
Lynne Apone
17 Aug 2017

Inspected by
Tony Spear-Alfonso
07 Sep 2017

nqa ISO 9001 Registered Quality Management
nqa ISO 14001 Registered Environmental Management
nqa ISO 13485 Registered Medical Devices