

## New England Biolabs Product Specification

*Product Name:* SARS-CoV-2 Rapid Colorimetric LAMP Assay Kit  
*Catalog #:* E2019S  
*Kit Components:* WarmStart<sup>®</sup> Colorimetric LAMP 2X Master Mix with UDG (M1804)  
SARS-CoV-2 Positive Control (N gene) DNA (N2117)  
Internal Control LAMP Primer Mix (rActin) (S0164)  
SARS-CoV-2 LAMP Primer Mix (N/E) (S1883)  
Nuclease-free Water (B1502)  
Guanidine Hydrochloride Solution (B2619)

*Shelf Life:* 6 months  
*Storage Temp:* -20°C  
*Specification Version:* PS-E2019S v1.0  
*Effective Date:* 07 Jul 2020

### Assay Name/Specification (minimum release criteria)

**Functional Testing (RT-LAMP, SARS-CoV-2)** - SARS-CoV-2 Rapid Colorimetric LAMP Assay Kit is functionally tested and compared to a previous kit lot using human total RNA and human total RNA spiked with synthetic SARS-COV-2 RNA in a 30-minute colorimetric LAMP assay at 65°C. Prior to isothermal incubation, all assembled reactions must be pink. Following incubation, internal control reactions containing human total RNA with and without SARS-CoV-2 RNA and SARS-CoV-2 Positive Control reactions must result in a color change indicating positive detection while reactions that lack template remain pink. SARS-CoV-2 reactions containing human total RNA spiked with SARS-CoV-2 RNA must result in a color change indicating positive detection observable down to 50 copies while reactions that lack template remain pink.

\* **Individual Product Component Note** - Standard Quality Control Tests are performed for each component included in SARS-CoV-2 Rapid Colorimetric LAMP Assay Kit and meet the designated specifications.

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Date 07 Jul 2020

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