

## New England Biolabs Product Specification

*Product Name:* SARS-CoV-2 Positive Control (N gene)  
*Catalog #:* N2117B  
*Shelf Life:* 24 months  
*Storage Temp:* -20°C  
*Storage Conditions:* Proprietary  
*Specification Version:* PS-N2117B v1.0  
*Effective Date:* 15 Jun 2021

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

**A260/A280 Assay** - The ratio of UV absorption of SARS-CoV-2 Positive Control (N gene) at 260 and 280 nm is between 1.8 and 2.0.

**DNA Concentration (qPCR, Control DNA)** - SARS-CoV-2 Positive Control (N gene) is quantified using qPCR. Triplicate, 20 µl reactions are run on SARS-CoV-2 Positive Control (N gene), six DNA standards, and no template controls for 40 cycles of PCR amplification, resulting in a standard curve with a calculated PCR efficiency of 90-110% and R2 value  $\geq 0.99$ , and a  $\Delta Cq > 10$  between the sample and no template controls. For each new lot tested, the difference in Cq between the new lot and the standard 3 is  $< 1$  Cq. For each new lot tested, the difference in Cq between the new lot and the control lot is  $< 1$  Cq.

**Non-Specific DNase Activity (DNA, 16 hour)** - A 50 µl reaction in 1X NEBuffer 2 containing 5 µg of SARS-CoV-2 Positive Control (N gene) incubated for 16 hours at 37°C results in a DNA pattern free of detectable nuclease degradation as determined by agarose gel electrophoresis.

**Restriction Digest (Linearization)** - A 50 µl reaction in CutSmart® Buffer containing 5 µg of SARS-CoV-2 Positive Control (N gene) and 20 units of XhoI incubated for 1 hour at 37°C produces  $> 95\%$  linearization resulting in a single band of approximately 4021 bp as determined by agarose gel electrophoresis.

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