

New England Biolabs Product Specification

Product Name: SARS-CoV-2 Positive Control (N gene)
Catalog #: N2117S
Shelf Life: 24 months
Storage Temp: -20°C
Storage Conditions: Proprietary
Specification Version: PS-N2117S v2.0
Effective Date: 11 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 ≥ 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.

Functional Testing (qPCR, SARS-CoV-2) - SARS-CoV-2 Positive Control (N gene) is functionally tested and compared to a previous lot in a multiplex qPCR assay that detects the 2019-nCoV_N1 target and the 2019-nCoV_N2 target. 2 µl of the SARS-CoV-2 Positive Control (N gene) is measured in triplicate in 20 µl reactions resulting in a $\Delta Cq < 1$ for each target compared to a previous lot and a $\Delta Cq > 10$ between the sample and no template controls.

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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Date 11 Jun 2021

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