

New England Biolabs Certificate of Analysis

Product Name: SARS-CoV-2 Positive Control (N gene)
 Catalog Number: N2117S
 Packaging Lot Number: 10097754
 Expiration Date: 01/2023
 Storage Temperature: -20°C
 Storage Conditions: Proprietary
 Specification Version: PS-N2117S v2.0

SARS-CoV-2 Positive Control (N gene) Component List			
NEB Part Number	Component Description	Lot Number	Individual QC Result
N2117SVIAL	SARS-CoV-2 Positive Control (N gene)	10094222	Pass

Assay Name/Specification	Lot # 10097754
<p>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 ΔCq 10 between the sample and no template controls.</p>	Pass
<p>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.</p>	Pass
<p>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.</p>	Pass
<p>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.</p>	Pass
<p>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</p>	Pass

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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.	

This product has been tested and shown to be in compliance with all specifications.

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Christie Vazquez
Production Scientist
15 Jun 2021



Michael Tonello
Packaging Quality Control Inspector
15 Jun 2021