NEW ENGLAND BioLabs® Inc.

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New England Biolabs
Product Specification

Product Name:	*Q5® Reaction Buffer Pack*
Catalog #:	*B9027S*
Concentration:	*5X Concentrate*
Shelf Life:	*36 months*
Storage Temp:	*-20°C*
Composition (1X):	*Proprietary*
Specification Version:	*PS-B9027S v1.0*
Effective Date:	*20 Jun 2016*

Assay Name/Specification (minimum release criteria)
Endonuclease Activity (Nicking, Buffer) - A 50 µl reaction in 2X Q5® Reaction Buffer containing 1 µg of supercoiled PhiX174 DNA incubated for 4 hours at 37°C results in <10% conversion to the nicked form as determined by agarose gel electrophoresis.
Non-Specific DNase Activity (16 hour, Buffer) - A 50 µl reaction in 2X Q5® Reaction Buffer 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.
PCR Amplification (20 kb Lambda DNA, Buffer) - A 50 µl reaction in Q5® Reaction Buffer in the presence of 200 µM dNTPs and 1 µM primers containing 10 ng Lambda DNA with 1 unit of Q5® High-Fidelity DNA Polymerase for 22 cycles of PCR amplification results in the expected 20 kb product.
PCR Amplification (7 kb Human Genomic DNA, Buffer) - A 50 µl reaction in Q5® Reaction Buffer in the presence of 200 µM dNTPs and 0.5 µM primers containing 20 ng Human Genomic DNA with 1 unit of Q5® High-Fidelity DNA Polymerase for 30 cycles of PCR amplification results in the expected 7 kb product.
Phosphatase Activity (pNPP, Buffer) - A 200 µl reaction in 1M Diethanolamine @ pH 9.8 and 0.5 mM $MgCl_2$ containing 2.5 mM *p*-Nitrophenyl Phosphate (pNPP) and a minimum of 80 µl Q5® Reaction Buffer incubated for 4 hours at 37°C yields <0.0001 unit of alkaline phosphatase activity as determined by spectrophotometric analysis.
qPCR DNA Contamination (*E. coli* Genomic, Buffer) - A minimum of 1 µl of Q5® Reaction Buffer 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.

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

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Assay Name/Specification (minimum release criteria)
RNAse Activity Assay (4 Hour 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 Q5® Reaction Buffer 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.

Date 20 Jun 2016

Derek Robinson
Director of Quality Control

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ISO 13485 Registered Medical Devices