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New England Biolabs
Product Specification

Product Name:	*Isothermal Amplification Buffer Pack*
Catalog #:	*B0537S*
Concentration:	*10X Concentrate*
Shelf Life:	*36 months*
Storage Temp:	*-20°C*
Composition (1X):	*20 mM Tris-HCl, 50 mM KCl, 10 mM $(NH_4)_2SO_4$, 2 mM $MgSO_4$, 0.1 % Tween® 20, (pH 8.8 @ 25°C)*
Specification Version:	*PS-B0537S v2.0*
Effective Date:	*12 Feb 2020*

Assay Name/Specification (minimum release criteria)
Endonuclease Activity (Nicking, Buffer) - A 50 µl reaction in 2X Isothermal Amplification 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 Isothermal Amplification Buffer containing 1 µg of T3 or T7 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.
pH (buffers/solutions) - The pH of 10X Isothermal Amplification Buffer is between pH 8.7 and 8.9 at 25°C.
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 40 µl Isothermal Amplification 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 Isothermal Amplification 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.
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 Isothermal Amplification 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 12 Feb 2020

Derek Robinson
Director, Quality Control

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