

Certificate of Analysis

TaqMan® PreAmp Cells-to-CT™ Kit

Product No.	4387299
Lot No.	2693781
Date of Manufacture	2023-03-30
Expiration Date	2024-03-31
Product Description	The TaqMan® PreAmp Cells-to CT™ Kit enables lysis, reverse transcription, preamplification, and real-time PCR analysis of up to 100 gene expression targets from limited samples of mammalian cultured cells, without RNA purification.
Functional Testing	Each component is functionally tested by preparing lysates from a serial dilution of 10–10 ⁵ cultured cells and performing real-time RT-PCR targeting PPIA. Amplification signals are compared to those obtained from purified RNA from the same source. Result: Pass

TEST	SPECIFICATION	RESULT
Lysis Solution		
Activity Assay	Activity of Lysis Solution is tested.	Pass
Ionic Strength	Ionic strength is determined.	Pass
pH Assay	pH is determined.	Pass
Stop Solution		
Exonuclease Activity	A sample is incubated with labeled double-stranded DNA, followed by PAGE analysis.	Pass
Inhibition Assay	The ability of Stop Solution to inhibit Lysis Solution activity is tested.	Pass
Nonspecific Endonuclease Activity	A sample is incubated with supercoiled plasmid DNA and analyzed by agarose gel electrophoresis.	Pass
pH Assay	pH is determined.	Pass
RNase Activity	A sample is incubated with labeled RNA, followed by PAGE analysis.	Pass
DNase I		
Protease Activity	A sample is incubated with protease substrate and analyzed by fluorescence.	Pass
RNase Activity	A sample is incubated with labeled RNA, followed by PAGE analysis.	Pass
2X RT Buffer		
Cation Concentration	Cation concentrations are determined.	Pass
Exonuclease Activity	A sample is incubated with labeled double-stranded DNA, followed by PAGE analysis.	Pass
Nonspecific Endonuclease Activity	A sample is incubated with supercoiled plasmid DNA and analyzed by agarose gel electrophoresis.	Pass
pH Assay	pH is determined.	Pass

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RNase Activity	A sample is incubated with labeled RNA, followed by PAGE analysis.	Pass
RT-PCR Testing	2X RT Buffer is tested in two-step RT-PCR targeting an endogenous control gene using purified RNA.	Pass
20X RT Enzyme Mix		
Exonuclease Activity	A sample is incubated with labeled double-stranded DNA, followed by PAGE analysis.	Pass
Nonspecific Endonuclease Activity	A sample is incubated with supercoiled plasmid DNA and analyzed by agarose gel electrophoresis.	Pass
Protease Activity	A sample is incubated for with protease substrate and analyzed by fluorescence.	Pass
RNase Activity	A sample is incubated with labeled RNA, followed by PAGE analysis.	Pass
RT Activity Assay	Incorporation of [α - 32 P]dTTP into first strand cDNA during a reverse transcription reaction is measured.	Pass
RT-PCR testing	20X RT Enzyme Mix is tested in two-step RT-PCR targeting an endogenous control gene using purified RNA.	Pass
TaqMan® Gene Expression Master Mix		
AmpliTaq Gold® DNA Polymerase UP Activity	AmpliTaq Gold® DNA Polymerase Ultra-Pure (UP) activity is determined.	Pass
Bacterial DNA	A sample is tested for bacterial DNA.	Pass
dNTP Concentrations	Individual dNTP concentrations are measured.	Pass
DNase Activity	A sample is tested for DNase activity.	Pass
Mg ²⁺ Ion Concentration	A sample is tested for magnesium ion (Mg ²⁺) concentration.	Pass
pH Assay	pH is determined.	Pass
RNase Activity	A sample is tested for RNase activity.	Pass
ROX™ Passive Reference Fluorescence Assay	A sample is tested for ROX dye fluorescence.	Pass
Functional Testing	TaqMan® Gene Expression Master Mix is tested with simplex and duplex PCR targeting plasmid DNAs on an Applied Biosystems 7900HT Fast Real-Time PCR System. Functional testing data for this component is available by entering its part number and lot number at http://docs.appliedbiosystems.com/coasearch.taf .	Pass

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TaqMan® PreAmp Master Mix

MgCl ₂ Concentration	A sample is tested for MgCl ₂ concentration.	Pass
dNTP Concentrations	Individual dNTP concentrations are measured.	Pass
Functional Testing	TaqMan® PreAmp Master Mix is tested for functional performance on an Applied Biosystems 7900HT Fast Real-Time PCR System. The preamplification reaction is performed using a pool of 100 TaqMan® Gene Expression Assays. Preamplified versus unamplified cDNA is compared by analyzing the CT values of 21 of the targets contained in the 100-assay pool. Functional testing data for this component is available by entering its part number and lot number at http://docs.appliedbiosystems.com/coasearch.taf .	Pass

For Research Use Only. Not for use in diagnostic procedures.

ISO CERTIFICATION

This product is produced in accordance to Thermo Fisher Scientific Baltics UAB, a wholly owned subsidiary of Thermo Fisher Scientific Inc. (hereinafter Thermo Fisher) certified Quality Management (ISO 9001) and Environmental Management (ISO 14001) systems. Thermo Fisher Scientific Baltics UAB is also certified according to the standards ISO 13485 (Quality management system for IVD medical devices).

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