



Certificate of Analysis

COA No: CA_XBE-0002

Version: 03

IMMOLASE™ DNA Polymerase

Suitable for Research and further Manufacturing Use as an IVD component

Storage Conditions: -20°C

Lot number: IM-718204A

Expiry date: May 2020

Quality Control Parameters

Analysis	Specification	Result
Activity	Quantitative PCR analysis amplifying 1 gene from a dilution series of enzyme under standard conditions. Cq and melting profiles must be consistent for the test and reference sample with 0.5+/- Cq variance.	Passed
Sensitivity	Quantitative PCR analysis amplifying 1 gene from a dilution series of mouse cDNA under standard conditions. Cq and melting profiles must be consistent for the test and reference sample with 0.5+/- Cq variance. A 3Kb fragment is amplified with a dilution series of Lambda DNA, using standard conditions and 30 cycles. Single distinct bands were observed with agarose gel electrophoresis (ethidium stained).	Passed
Heat activation	A 125bp fragment is amplified with a dilution series of enzyme, using 4 heat activation times and 30 cycles. Single distinct bands were observed, at the appropriate activation time, with agarose gel electrophoresis (ethidium stained).	Passed
DNA contamination	Quantitative PCR analysis with no template. Presence of <i>E. coli</i> and mouse genomic DNA checked. Test sample must amplify in line with a reference sample.	Passed
DNase contamination	Incubation of a 1Kb double stranded DNA fragment. Incubation for 4 hours at 37°C with dilution series of DNase I. Analysed by agarose gel electrophoresis. Test sample must show less degradation than the limit of detection 2.5×10^{-3} U DNase.	Passed

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 <small>A Medtronic Life Sciences Company</small>	<h2>Certificate of Analysis</h2>	COA No: CA XBB-0002
		Version: 03

<h1>ImmoBuffer</h1> Suitable for Research and further Manufacturing Use as an IVD component	Storage Conditions:	-20°C
	Lot number:	IB-718104A
	Expiry date:	May 2020

Quality Control Parameters

Analysis	Specification	Result
Functional	Fragment of size 800bp was amplified with a dilution series of IMMOLASE™, using standard conditions and 30 cycles. Single distinct bands were observed with agarose gel electrophoresis (ethidium stained).	Passed
DNA contamination	Quantitative PCR analysis with no template. Presence of <i>E. coli</i> and mouse genomic DNA checked. Test sample must amplify in line with a reference sample.	Passed
DNase contamination	Incubation of a 1Kb double stranded DNA fragment. Incubation for 4 hours at 37°C with dilution series of DNase I. Analysed by agarose gel electrophoresis. Test sample must show less degradation than the limit of detection 2.5×10^{-3} U DNase.	Passed

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 <small>A Medtronic Life Sciences Company</small>	Certificate of Analysis	COA No: CA_XBB-0014
		Version: 03

<h2>MgCl₂ Solution, 50mM</h2> <p>Suitable for Research and further Manufacturing Use as an IVD component</p>	Storage Conditions:	-20°C
	Lot number:	MG-717111A
	Expiry date:	May 2020

Quality Control Parameters

Analysis	Specification	Result
Functional	Fragments of sizes 800bp and 3000bp are amplified with a dilution series of BIOTAQ™ DNA Polymerase, using standard conditions and 30 cycles. Single distinct bands were observed with agarose gel electrophoresis (ethidium stained).	Passed
DNA contamination	Quantitative PCR analysis with no template. Presence of <i>E. coli</i> and mouse genomic DNA checked. Test sample must amplify in line with a reference sample.	Passed
DNase contamination	Incubation of a 1Kb double stranded DNA fragment. Incubation for 4 hours at 37°C with dilution series of DNase I. Analysed by agarose gel electrophoresis. Test sample must show less degradation than the limit of detection 2.5×10^{-3} U DNase.	Passed

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