



## Certificate of Analysis

COA No: CA\_XBE-0002

Version: 04

# IMMOLASE™ DNA Polymerase

Suitable for Research and further Manufacturing Use as an IVD component

Kit Lot No: BIO-21047\_PL350-B066710

Storage Conditions: -20°C

Component Lot No: IM-819101A

Expiry date: February 2021

## 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 $\pm 0.5$ 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 $\pm 0.5$ 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 $2.5 \times 10^{-3}$ U DNase.	Passed

Authorised by Christopher Weatherall

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## Certificate of Analysis

COA No: CA XBB-0002

Version: 04

### ImmoBuffer

Suitable for Research and further Manufacturing Use as an IVD component

Kit Lot No:	BIO-21047_PL350-B066710
Storage Conditions:	-20°C
Component Lot No:	IB-819101A
Expiry date:	February 2021

### 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 $2.5 \times 10^{-3}$ U DNase.	Passed

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## Certificate of Analysis

COA No: CA\_XBB-0014

Version: 04

### MgCl<sub>2</sub> Solution, 50mM

Suitable for Research and further Manufacturing Use as an IVD component

Kit Lot No:	BIO-21047_PL350-B066710
Storage Conditions:	-20°C
Component Lot No:	MG-2031.005
Expiry date:	February 2021

### 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 $2.5 \times 10^{-3}$ U DNase.	Passed

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