	Certificate of Analysis	CA_XBE-0063-2
		Version: 01

Low DNA Taq HS 10 U/μL Suitable for Research and further Manufacturing Use as an IVD component	Catalog No:	MDX010
	Lot No:	EN015-B071520
	Shipping / Storage Conditions:	-20°C
	Component Lot No:	IM-919106A
	Expiry date:	July 2021

Quality Control Parameters

Heat-activated, thermostable DNA polymerase suited to amplification of bacterial and fungal DNA

Analysis	Specification	Result
Activity	<p>Quantitative PCR analysis amplifying 1 gene from a dilution series of enzyme under standard conditions.</p> <p><u>Pass Criteria:</u></p> <p>Cq and melting profiles must be consistent for the test and reference sample with ± 0.5 Cq variance.</p>	Passed
Sensitivity by qPCR	<p>Quantitative PCR analysis amplifying 1 gene from a dilution series of mouse cDNA under standard conditions.</p> <p><u>Pass Criteria:</u></p> <p>Cq and melting profiles must be consistent for the test and reference sample with ± 0.5 Cq variance.</p>	Passed
Sensitivity by Endpoint PCR	<p>A 3Kb fragment is amplified with a dilution series of Lambda DNA, using standard conditions and 30 cycles.</p> <p><u>Pass Criteria:</u></p> <p>Single distinct bands were observed with agarose gel electrophoresis (ethidium stained). Test sample must amplify in line with a reference sample.</p>	Passed
Heat activation	<p>A 125bp fragment is amplified with a dilution series of enzyme, using 4 heat activation times and 30 cycles.</p> <p><u>Pass Criteria:</u></p> <p>Single distinct bands were observed, at the appropriate activation time, with agarose gel electrophoresis (ethidium stained). Test sample must amplify in line with a reference sample.</p>	Passed

United Kingdom
Headquarters UK

info.uk@bioline.com
Tel: +44 (0)20 8830 5300
Fax: +44 (0)20 8452 2822

USA

info@meridianlifescience.com
Tel: +1 901.382.8716
Fax: +1 901.382.0027

Germany

info.de@bioline.com
Tel: +49 (0)3371 60222 00
Fax: +49 (0)3371 60222 01

France

info.fr@bioline.com
Tel: +33 (0)1 42 56 04 40
Fax: +33 (0)9 70 06 62 10

Australia

info.aust@bioline.com
Tel: +61 (0)2 9209 4180
Fax: +61 (0)2 9209 4763

	Certificate of Analysis	CA_XBE-0063-2
		Version: 01

DNA contamination	<p>Quantitative PCR analysis with no template. Presence of <i>E. coli</i> and mouse genomic DNA checked.</p> <p><u>Pass Criteria:</u></p> <p>Test sample must amplify in line with a reference sample.</p>	Passed
DNase contamination	<p>DNase contamination is measured as DNA substrate degradation against a DNase I dilution series by agarose gel electrophoresis.</p> <p>Limit of detection: 6.25×10^{-4} KU DNase I.</p> <p><u>Pass Criteria:</u></p> <p>No detectable degradation.</p>	Passed

Authorised by Christopher Weatherall



United Kingdom
Headquarters UK

info.uk@bioline.com
Tel: +44 (0)20 8830 5300
Fax: +44 (0)20 8452 2822

USA

info@meridianlifescience.com
Tel: +1 901.382.8716
Fax: +1 901.382.0027

Germany


info.de@bioline.com
Tel: +49 (0)3371 60222 00
Fax: +49 (0)3371 60222 01

France

info.fr@bioline.com
Tel: +33 (0)1 42 56 04 40
Fax: +33 (0)9 70 06 62 10

Australia

info.aust@bioline.com
Tel: +61 (0)2 9209 4180
Fax: +61 (0)2 9209 4763

	Certificate of Analysis	COA No: CA XBB-0002-2
		Version: 01

Low DNA Reaction Buffer, 10x Suitable for Research and further Manufacturing Use as an IVD component	Catalog No:	MDX010
	Lot No:	EN015-B071520
	Shipping / Storage Conditions:	-20°C
	Component Lot No:	IB-919106A
	Expiry date:	July 2021

Quality Control Parameters

Low DNA Reaction Buffer 10x is a combination of the latest advances in buffer chemistry together with enhancers and stabilizers at optimal concentrations. It has been designed for use with Low DNA Taq HS making it ideal for PCR of low-copy bacterial targets to avoid false-positive amplification, such as in water testing

Analysis	Specification	Result
Functional	Fragment of size 800bp was amplified with a dilution series of Low DNA Taq, 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

Authorised by Christopher Weatherall



United Kingdom
Headquarters UK

info.uk@bioline.com
Tel: +44 (0)20 8830 5300
Fax: +44 (0)20 8452 2822

USA

info@meridianlifescience.com
Tel: +1 901.382.8716
Fax: +1 901.382.0027

Germany


info.de@bioline.com
Tel: +49 (0)3371 60222 00
Fax: +49 (0)3371 60222 01

France

info.fr@bioline.com
Tel: +33 (0)1 42 56 04 40
Fax: +33 (0)9 70 06 62 10

Australia

info.aust@bioline.com
Tel: +61 (0)2 9209 4180
Fax: +61 (0)2 9209 4763

	Certificate of Analysis	COA No: CA_XBB-0014
		Version: 05

MgCl₂ Solution, 50mM Suitable for Research and further Manufacturing Use as an IVD component	Catalog No:	MDX010
	Lot No:	EN015-B071520
	Shipping / Storage Conditions:	-20°C
	Component Lot No:	MG-2031.006
	Expiry date:	July 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 2.5×10^{-3} U DNase.	Passed

Authorised by Christopher Weatherall



United Kingdom
Headquarters UK

info.uk@bioline.com
Tel: +44 (0)20 8830 5300
Fax: +44 (0)20 8452 2822

USA

info@meridianlifescience.com
Tel: +1 901.382.8716
Fax: +1 901.382.0027

Germany

info.de@bioline.com
Tel: +49 (0)3371 60222 00
Fax: +49 (0)3371 60222 01

France

info.fr@bioline.com
Tel: +33 (0)1 42 56 04 40
Fax: +33 (0)9 70 06 62 10

Australia

info.aust@bioline.com
Tel: +61 (0)2 9209 4180
Fax: +61 (0)2 9209 4763