

COA No: CA\_XBE-0070

Version: 02

## High Conc. Glycerol–Free *Bst* 100U/μL

Catalog No:	MDX018
Lot No:	EM115-B123020
Storage Conditions:	-20°C
Component Lot No:	223111A
Expiry date:	December 2025

Suitable for Research and further Manufacturing Use

### **Quality Control Parameters**

#### Lyophilization-compatible Bst DNA polymerase for isothermal applications

Analysis	Specification	Result
Functional	Activity is measured as DNA polymerase units by Rolling Circle Amplification against a reference <i>Bst</i> DNA polymerase standard curve. <u>Pass Criteria</u> : Activity must be ≥100 U/μL	Passed
DNA contamination	DNA contamination is measured by quantitative PCR on <i>E. coli</i> and mouse genomic DNA specific targets. <u>Pass Criteria</u> : Amplification traces must overlay with the negative control.	Passed
DNase contamination	DNase contamination is measured as DNA substrate degradation against a DNase I dilution series by agarose gel electrophoresis. Limit of detection: 6.25 x 10 <sup>-4</sup> KU DNase I. <u>Pass Criteria</u> : No detectable degradation.	Passed
RNase contamination	RNase contamination is measured by quantitative PCR against RNase standards. Limit of detection: 9.7 x 10 <sup>-3</sup> ng/μL RNase. <u>Pass Criteria</u> : No detectable degradation.	Passed

QA / QC Representative:

Andrew Galeeba-M

Date: 18<sup>th</sup> December 2023

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# BST Reaction Buffer, 10x

For research or further manufacturing use only

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### **Quality Control Parameters**

Analysis	Specification	Result
Functional	TTR (time-to-result) values obtained by Loop mediated amplification reaction of Test Sample vs Reference sample must be within 1.5 minutes	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 concordance with control sample.	Passed
DNase contamination Incubation of a 1 Kb 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 exhibit less degradation than the limit of detection 2.5 x 10 <sup>-3</sup> U DNase.		Passed

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### **Enzyme Dilution Buffer, 10x**

For research or further manufacturing use only

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#### **Quality Control Parameters**

Enzyme Dilution Buffer is a Triton-free Glycerol-free 10x buffer used for the dilution of Taq antibody or reverse transcriptase.

Analysis	Specification	Result
	A 3Kb fragment was amplified with a dilution series of Enzyme Dilution Buffer, using standard conditions and 30 cycles.	
Functional	A 3Kb fragment was amplified with a dilution series of <i>Taq polymerase</i> , using standard conditions and 30 cycles.	Passed
	Single distinct bands were observed with agarose gel electrophoresis (ethidium stained).	
Glycerol determination	Glycerol content is < 0.2% determined by spectrophotometric analysis and comparison to a standard curve.	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 6.25 x $10^{-4}$ KU/µL.	Passed
RNase contamination	Quantitative PCR analysis with high and low RNase standards. Test sample must show less RNase activity than the limit of detection: $9.7x10^{-3}$ ng/µl RNase.	Passed

QA / QC Representative:

Andrew Galeeba-M

Date: 18<sup>th</sup> December 2023

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