

#### **Certificate of Analysis**

COA No: CA\_XBE-0071

Version: 02

## **Bst DNA Polymerase**

Suitable for Research and further Manufacturing Use

Catalog No:	MDX012
Lot No:	EM112-B336130
Storage Conditions:	-20°C
Component Lot No:	525104B
Expiry date:	May 2027

### **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> polymerase standard curve.  Pass Criteria:  Activity must be 10 U/μL ±20%	Passed
DNA contamination	DNA contamination is measured by quantitative PCR on <i>E. coli</i> and mouse genomic DNA specific targets.  Pass Criteria: 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.  Pass Criteria: No detectable degradation.	Passed
RNase contamination	RNase contamination is measured by quantitative PCR against RNase standards. Limit of detection: $9.7 \times 10^{-3}$ ng/ $\mu$ L RNase. Pass Criteria: No detectable degradation.	Passed

QA / QC Representative:

7.121

Jan Rahnenführer

Date: 15<sup>th</sup> April 2025

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### **Certificate of Analysis**

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Version: 02

## **BST Reaction Buffer, 10x**

For research or further manufacturing use only

Catalog No:	MDX012
Lot No:	EM112-B336130
Storage Conditions:	-20°C
Component Lot No:	425104B
Expiry date:	May 2027

### **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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#### **Certificate of Analysis**

COA No: CA\_BDB-0032

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Version: v02

# **Enzyme Dilution Buffer, 1x**

For research or further manufacturing use only

Catalog No:	MDX012
Lot No:	EM112-B336130
Storage Conditions:	-20°C
Lot number:	425104B
Expiry date:	May 2027

### **Quality Control Parameters**

Enzyme Dilution Buffer is a Triton-free 1x 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).	
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/ $\mu$ L.	Passed

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