

Certificate of Analysis

GUNSTER BIOTECH*~Best Choice for Life Sciences~***0.2ml qPCR 8-Strip Tubes (With Optical Caps)**

Product No. MB-Q200

(01)4711115650108

Lot No. 107039-250603

(11)250126

Expiry Date January 26, 2025

(17)300126

(10)107039-250603



TEST	SPECIFICATION	RESULT
USP Class VI Testing		
All material resin is tested, qualified, and shown to be non-toxic as established in the Standards USP Plastic Class VI.	-	Pass
RoHS 2011 / 65 / EU Testing		
All material resin is tested, qualified, and shown to be non-heavy metal as established in the RoHS 2011 / 65 / EU.	-	Pass
REACH (EC) No 1907/2006 & Non 240 SVHC & Non 2 SVHC		
All material resin is tested, qualified, and shown to be non SVHC (Substances of Very High Concern, candidate list is published on January 17, 2023 & February 17, 2023) and has followed REACH (EC) No 1907/2006 Regulation.	-	Pass
U.S. FDA 21 CFR 177.1520 3.2a Testing		
All material resin is tested, qualified, and shown to be in compliance with U.S. FDA CFR 21 177.1520 3.2a.	-	Pass
PCR Inhibitor-Free		
Tested by determine 10-fold serial dilution qPCR efficiency		
R ² of qPCR serial dilution	≥ 0.99	Pass
qPCR efficiency	90-110%	Pass
ATP-Free		
Tested by Luciferase assay method		
ATP	< 10 ⁻¹³ mg/μl	Pass
Non-Pyrogenic Testing		
Tested by LAL test, which according to USP33 <85>, <161>, and the guideline provided by FDA of the United States.		
Pyrogen	< 0.004 EU/ml	Pass
Human DNA Free		
Tested by Human specific-L1 sequence PCR detection		
Human DNA	< 0.5 pg/μl	Pass
DNase / RNase Free		
Tested by nuclease assay method		
Dnase	< 4*10 ⁻⁶ Kunitz units/μl	Pass
RNase	< 5*10 ⁻¹⁰ Kunitz units/μl	Pass
Quality Control Testing		
Visual Inspection	-	Pass
Functional Test	-	Pass
Evaporation Test	< 5%	Pass

For Research Use Only.

Manufactured in compliance with ISO 9001:2015 and ISO 13485:2016 certified quality management system.

MADE IN TAIWAN

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