

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

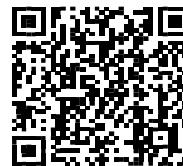
Lot No. 107043

(11)250119

Expiry Date January 19, 2025

(17)300119

(10)107043



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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