

**CERTIFICATE OF ANALYSIS**

**A52702                      TaqPath™ BactoPure™ Microbial Detection Master Mix**

Quantity:                      50 mL  
 Packaging Lot<sup>1</sup>:              2820004  
 Expiry Date:                27-08-2025 (DD-MM-YYYY)  
 Storage:                      at 5 ± 3 °C  
 Bulk Lot<sup>2</sup>:                    2790454

Manufactured according to current good manufacturing practices (cGMP) and is subjected to a panel of quality control tests to ensure the highest level of performance and lot-to-lot consistency.

**QUALITY CONTROL**

	Parameter	Method Description	Requirement	Result
<b>Analytical Methods</b>	Deoxynucleotide triphosphate (dNTP) concentrations (individually measured)	The amount of 2'-deoxynucleotide triphosphates is quantitated by High Performance Liquid Chromatography (HPLC).	dATP: 0.42 – 0.58 mM dCTP: 0.42 – 0.58 mM dGTP: 0.21 – 0.29 mM Modified dGTP: 0.21 – 0.29 mM dUTP: 0.85 – 1.15 mM	Conforms
	Magnesium ion (Mg <sup>2+</sup> ) concentration	High Performance Ion Chromatography (HPIC) with the detection of conductivity signal is performed on the product and standards.	9.35 – 12.65 mM	Conforms
	Potassium ion concentration (K <sup>+</sup> )		85 – 115 mM.	Conforms
	RNase level	RNase levels are measured using a modified RNA oligonucleotide possessing a quencher and fluorescent label that emits a fluorescent signal when cleaved by RNase.	≤0.570 pg/5µL	Conforms
	DNase level	DNase levels are measured using a modified DNA oligonucleotide possessing a quencher and fluorescent label that emits a fluorescent signal when cleaved by DNase.	≤70.0 pg/5µL	Conforms
	pH	The pH value is measured at a temperature of 25 °C.	7.85 – 8.15	Conforms



	Parameter	Method Description	Requirement	Result
Functional Tests	Standard Curve Analysis	qPCR efficiency, R <sup>2</sup> , and absolute Ct values are obtained utilizing serial dilutions of control human DNA on both Simplex and Multiplex assays.	R <sup>2</sup> Simplex VIC ≥ 0.980 R <sup>2</sup> Simplex FAM ≥ 0.980 R <sup>2</sup> Multiplex VIC ≥ 0.980 R <sup>2</sup> Multiplex FAM ≥ 0.980  Efficiency Simplex VIC: 85.0% ≤ Eff. ≤ 115.0% Efficiency Simplex FAM: 85.0% ≤ Eff. ≤ 115.0% Efficiency Multiplex VIC: 85.0% ≤ Eff. ≤ 115.0% Efficiency Multiplex FAM: 85.0% ≤ Eff. ≤ 115.0%  ▲ Ct (Simplex-Multiplex) ≤ 1.00	Conforms
	DNA Background	Screened for DNA background with assays targeting Pan-Bacteria, Pan-Fungal, Pan-Eukaryotic, Pan-Vertebrae, and antibiotic resistance genes (ARG) sequences. The positive control (PC), Exogenous internal positive control (IPC), and no template control (NTC) are evaluated to fall within the required range per assay tested.	Avg. NTC Ct of four technical replicates ≥ 38  Avg. PC Value of four technical replicates fall within the required range.  Exogenous IPC Ct of four technical replicates fall within 26.40 – 28.41	Conforms

Functional QC Test				
Assay Type	PCR efficiency	NTC Ct ≥ 36	R <sup>2</sup> value	Absolute Delta Ct (Simplex vs Multiplex)
Assay RNaseP	Conforms	Conforms	Conforms	Conforms
Assay Tert	Conforms	Conforms	Conforms	

Background Target	Assay ID	Average PC Values	Average NTC Ct ≥ 38
ARG	APNKXMX	Conforms	Conforms
	APRR7V	Conforms	Conforms
	APRWKTT	Conforms	Conforms
	KAN*	Conforms	Conforms
Pan-Vertebrae	APT2FDP	Conforms	Conforms
Pan-Bacteria	Ba04230899_s1	Conforms	Conforms
	Ba04930791_s1	Conforms	Conforms
	APU69XM	Conforms	Conforms
Pan-Eukaryotic	Hs03003631-g1	Conforms	Conforms
Pan-Fungal	18S-R*	Conforms	Conforms

\*These assays are custom ordered.

For Laboratory Use.

Quality authorized by QC: Audronė Lakštauskienė

Date: 2023-10-04

<sup>1</sup> Packaging Lot is the unique lot # assigned to the packing event of the vials into the product boxes.

<sup>2</sup> Bulk lot is the unique lot # assigned to the production lot prior to filling. Note: It is possible for different packing lots to be filled by the same bulk lot.



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