

CERTIFICATE OF ANALYSIS

TaqPath™ DuraPlex™ 1-Step RT-qPCR Master Mix (No ROX)

Product No: ☐ A58669 ☒ A58670 ☐ A58671
 Quantity: ☐ 1 x 0.5 mL ☒ 5 x 1 mL ☐ 1 x 10 mL
 Packaging Lot¹: 2924713
 Expiry Date: 05-10-2025 (DD-MM-YYYY)
 Storage: -20 ± 5 °C
 Bulk Lot²: 2821690

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

QUALITY CONTROL

Analytical Methods	Parameter	Method Description	Requirement	Result
	Magnesium ion (Mg ²⁺) concentration	High Performance Ion Chromatography (HPIC) with the detection of conductivity signal is performed on the product and standards.	23.8 – 32.2 mM	Conforms
	Potassium ion concentration (K ⁺)		110 – 149 mM	Conforms
	<i>E. coli</i> DNA level	<i>E. coli</i> DNA levels are quantified via qPCR utilizing a standard curve with four replicates for each point.	≤ 10 copies of <i>E. coli</i> DNA/50µL reaction	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.	Samples have ≤ 44.0 pg / 5 µL	Conforms
	pH	The pH value is measured at a temperature of 25 °C.	8.28 – 8.58	Conforms

Note: Enzyme bulk is tested for activity and E.coli DNA level

Functional QC Test

TaqPath™ DuraPlex™ 1-Step RT-qPCR Master Mix (No ROX) is tested for performance using a panel of 5-plex assay. Reactions are performed on a serial dilution of RNA template. Performance attributes evaluated include PCR efficiency, R², and absolute CT value.

Quadplex	PCR Efficiency	R ² Value	Ct Value	Result
Target 1 – FAM	85% - 115%	≥ 0.98	11.00 – 14.00	Conforms
Target 2 – VIC	85% - 115%	≥ 0.98	11.60 – 14.60	Conforms
Target 3 – ABY	85% - 115%	≥ 0.98	11.00 – 14.00	Conforms
Target 4 – Cy5	85% - 115%	≥ 0.98	10.80 – 14.30	Conforms
Target 5 – JUN	85% - 115%	≥ 0.98	11.00 – 14.20	Conforms



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

For Laboratory Use

Quality authorized by QC:

Audronė Lakštauskienė



Date: 2024-03-06

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

² 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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