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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 Lot[1]: 2952844

Expiry Date: 05-10-2025 (DD-MM-YYYY)

Storage: -20 ± 5 °C

Bulk Lot[2]: 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

	Parameter	Method Description	Requirement	Result
Analytical Methods	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
	E. coli DNA level	*E. coli* DNA levels are quantified via qPCR utilizing a standard curve with four replicates for each point.	≤ 10 copies of *E. coli* 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, R^2, 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

Thermo Fisher Scientific Baltics UAB
V. A. Graiciuno 8, Vilnius, LT-02241 Lithuania
Phone +370 700 55131
www.thermoscientific.com
For inquiries, contact us at cofarequests@thermofisher.com

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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: 2024-04-09

[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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