ThermoFisher SCIENTIFIC

Certificate of Analysis

TaqPath™ 1-Step Multiplex Master Mix (No ROX)

Product No: ☐ A28521 ☒ A28522 ☐ A28523

Quantity: ☐ 1 x 0.5 mL ☒ 5 x 1 mL ☐ 1 x 10 mL

Packaging Lot[1]: 2768450
Expiration Date: 04 July 2025
Storage: -30 to -10°C
Bulk Lot[2]: 2757325

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.

Analytical Methods

Parameter	QC method	Specification	Result
Magnesium ion (Mg^{2+}) concentration	High performance ion chromatography with the detection of conductivity signal is performed on the product and standards.	24.48 – 33.12 mM	Conforms
Potassium ion (K^{+}) concentration		170 – 230 mM	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
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 / 50 µL Reaction Volume	Conforms
pH	The pH value is measured at a temperature of 25 °C.	7.95 – 8.25	Conforms

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

Functional Tests

TaqPath™ 1-Step Multiplex Master Mix (No ROX) is tested for performance using a panel of two quadplex assay combinations and four simplex Gene Expressions assays. The first quadplex assay combination consists of four Gene Expression assays run with a serial dilution of human RNA.. The second quadplex assay combination consists of three Gene Expression assays coupled with an exogenous internal positive control (IPC) reagent. The second quadplex and four simplex reactions are run at one concentration of purified human RNA. Performance attributes evaluated include: PCR efficiency, R2 value, Ct Value, and Absolute Delta Ct between Quadplex and Simplex.

Quadplex 1	PCR Efficiency	R^2 Value	Result
Assay Hs00164924_m1	85% - 115%	≥ 0.95	Conforms
Assay Hs99999909_m1	85% - 115%	≥ 0.95	Conforms
Assay RNaseP	85% - 115%	≥ 0.95	Conforms
Assays GAPDH	85% - 115%	≥ 0.95	Conforms

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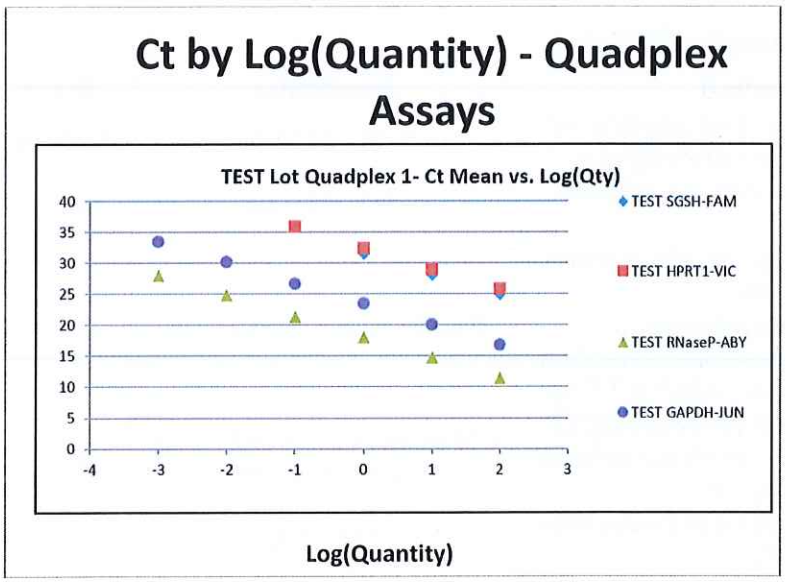
Quadplex 2	Average Ct Value	Ct Std. Dev.	Result
Assay Exogenous IPC (quadplex assay)	27.18 – 31.48	≤ 0.4	Conforms

Simplex	Absolute Delta Ct (Simplex vs Multiplex)	Result
Assay Hs00164924_m1	< 1.5	Conforms
Assay Hs99999909_m1	< 1.5	Conforms
Assay RNaseP	< 1.5	Conforms
Assays GAPDH	< 1.5	Conforms



Quality Signature: Ieva Lukoševičiūtė

Date: 13 September 2023

For Laboratory Use.

[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 Lot's to be filled by the same bulk Lot.