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# Certificate of Analysis

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

Product No: ☐ A28521 ☒ A28522 ☐ A28523

Quantity: ☐ 1x0.5mL ☒ 5x1mL ☐ 1x10mL

Packaging Lot[1]: 2548342

Expiration Date: 2024-09-30

Storage: -30 to -10°C

Bulk Lot[2]: 2552594

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 ≤ 44.0pg/5µL | 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

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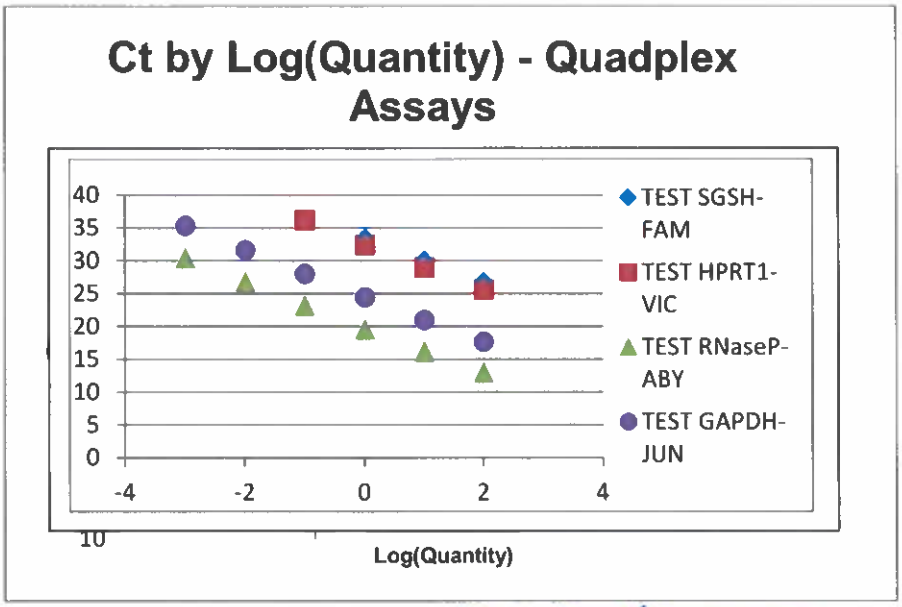
simplex reactions are run at one concentration of purified human RNA. Performance attributes evaluated include: PCR efficiency, R2 value, Ct Value, and Absolute Delta Ct between Quadplex and Simplex.

| 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 |

| 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:** Elton Todd

**Date:** 25 Apr 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 lots to be filled by the same bulk lot.