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## CERTIFICATE OF ANALYSIS

**A52705** **TaqPath™ BactoPure™ Microbial Detection Master Mix No ROX**

Quantity: 5 x 1 mL

Packaging Lot[1]: 2812516

Expiry Date: 21-08-2025 (DD-MM-YYYY)

Storage: at 5 ± 3 °C

Bulk Lot[2]: 2788591

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 |
|---|---|---|---|---|
| **Analytical Methods** | 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<br>dCTP: 0.42 – 0.58 mM<br>dGTP: 0.21 – 0.29 mM<br>Modified dGTP: 0.21 – 0.29 mM<br>dUTP: 0.85 – 1.15 mM | Conforms |
| | Magnesium ion ($Mg^{2+}$) 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 ($K^{+}$) | | 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 |

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| | Parameter | Method Description | Requirement | Result |
|---|---|---|---|---|
| **Functional Tests** | Standard Curve Analysis | qPCR efficiency, $R^2$, and absolute Ct values are obtained utilizing serial dilutions of control human DNA on both Simplex and Multiplex assays. | $R^2$ Simplex VIC ≥ 0.980<br>$R^2$ Simplex FAM ≥ 0.980<br>$R^2$ Multiplex VIC ≥ 0.980<br>$R^2$ Multiplex FAM ≥ 0.980<br>Efficiency Simplex VIC: 85.0% ≤ Eff. ≤ 115.0%<br>Efficiency Simplex FAM: 85.0% ≤ Eff. ≤ 115.0%<br>Efficiency Multiplex VIC: 85.0% ≤ Eff. ≤ 115.0%<br>Efficiency Multiplex FAM: 85.0% ≤ Eff. ≤ 115.0%<br>▲Ct (Simplex-Multiplex) ≤1.00 | Conforms |
| | DNA Background | Screened for DNA contamination 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<br>Avg. PC Value of four technical replicates fall within the required range.<br>Exogenous IPC Ct of four technical replicates fall within 26.07 – 30.04 | Conforms |

| Functional QC Test | | | | |
|---|---|---|---|---|
| **Assay Type** | **PCR efficiency** | **NTC Ct ≥ 36** | **$R^2$ 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 |
| | APPRR7V | 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: 2023-09-28

[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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