

~~~~~ Certificate of Analysis ~~~~~

Product Code : 69202  
 Product Name : Mycoplasma gene Detection Kit “MycoFinder”  
 Lot No. : 19L990  
 Exp. Data : 2021/01/06

■ Contents of Analysis

| Contents            | Specimens                                                                                         | Standards                                                                                | Results  |
|---------------------|---------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|----------|
| Exterior            | Product's outer box                                                                               | There is no damage, blot, etc.<br>It is correctly labeled.                               | Conforms |
| Sensitivity         | DNA of 11 kinds of mycoplasma<br>(10 copies/Reaction)                                             | All targets are positive within 45 cycles.                                               | Conforms |
| Accuracy            | Negative Control                                                                                  | Amplification is not detected.                                                           | Conforms |
| Reproducibility     | Detection of 7 mycoplasma strains listed<br>in the Japanese Pharmacopoeia<br>(10 copies/Reaction) | All tests in triplicate are positive within 45<br>cycles about all targets.              | Conforms |
|                     | Detection of 4 mycoplasma strains listed<br>in the EU Pharmacopoeia etc.<br>(10 copies/Reaction)  | More than 1/3 of tests in triplicate are<br>positive within 45 cycles about all targets. | Conforms |
|                     | Negative Control                                                                                  | Amplification is not detected in triplicate.                                             | Conforms |
| Positive<br>Control | Untreated (1 piece)<br>(2000 copies/Reaction)                                                     | FAM, HEX and ROX are positive in 30±2<br>cycles.                                         | Conforms |
|                     | Acceleration aging (2 pieces or more)<br>(2000 copies/Reaction)                                   | FAM, HEX and ROX are positive in 30±2<br>cycles.                                         | Conforms |

■ Certification

This product was confirmed to satisfy the quality standards for shipping.

Inspection Data : 2020/01/09

Inspected by : Y. Tomaru • K. Satoh Sign : K. Satoh

18G-MC002

**Nihon Techno Service Co., Ltd.**

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## ■ Results of Quality Inspection

○ Reagent lot

Mycoplasma DNA : Japanese Pharmacopoeia : 180705  
 EU Pharmacopoeia etc. : 180705  
 Positive Control : 19L990

Detection Sensitivity (10 copies/rxn)

| Items                    | Cq    |       |       |         | RFU     |          |          |          |
|--------------------------|-------|-------|-------|---------|---------|----------|----------|----------|
|                          | 1     | 2     | 3     | Average | 1       | 2        | 3        | Average  |
| Acholeplasma laidlawii   | 36.70 | 36.40 | 35.82 | 36.30   | 3094.66 | 11026.18 | 5415.03  | 6511.95  |
| Mycoplasma arginini      | 35.78 | 35.39 | 36.15 | 35.77   | 8128.25 | 10208.39 | 8165.92  | 8834.19  |
| Mycoplasma fermentans    | 34.54 | 35.48 | 34.88 | 34.97   | 7923.71 | 8385.37  | 2666.05  | 6325.04  |
| Mycoplasma pneumoniae    | 34.89 | 35.28 | 34.45 | 34.87   | 6437.38 | 9469.65  | 4985.87  | 6964.30  |
| Mycoplasma orale         | 35.18 | 35.29 | 35.10 | 35.19   | 4997.39 | 6187.38  | 6226.08  | 5803.62  |
| Mycoplasma hyorhinis     | 34.91 | 34.90 | 34.84 | 34.89   | 5042.53 | 4911.38  | 5181.99  | 5045.30  |
| Mycoplasma salivarium    | 35.55 | 34.43 | 34.55 | 34.85   | 9041.67 | 7806.93  | 8864.43  | 8571.01  |
| Mycoplasma gallisepticum | 36.03 | 34.99 | 34.44 | 35.15   | 3745.86 | 5073.63  | 4621.48  | 4480.32  |
| Ureaplasma urealyticum   | 34.89 | 35.06 | 35.14 | 35.03   | 8268.32 | 10481.95 | 11446.99 | 10065.75 |
| Mycoplasma synoviae      | 35.91 | 35.28 | 34.97 | 35.39   | 4855.24 | 5172.18  | 7827.79  | 5951.74  |
| Spiroplasma citri        | 34.73 | 33.86 | 34.24 | 34.28   | 3647.61 | 3352.74  | 4715.05  | 3905.13  |
| Negative Control         | 0.00  | 0.00  | 0.00  | 0.00    | -1.21   | 11.16    | 1.29     | 3.75     |

Positive Control ( $2 \times 10^3$  copies/ $\mu$ l)

| Items                | Cq    |       |       | RFU      |         |         |
|----------------------|-------|-------|-------|----------|---------|---------|
|                      | FAM   | HEX   | ROX   | FAM      | HEX     | ROX     |
| Untreated            | 29.53 | 29.25 | 29.09 | 10789.79 | 3244.38 | 6689.31 |
| Acceleration treated | 29.74 | 29.45 | 29.29 | 10679.89 | 3479.02 | 7076.58 |
|                      | 29.36 | 29.32 | 29.16 | 8680.27  | 2862.00 | 5901.07 |
|                      | 29.63 | 29.62 | 29.57 | 8296.10  | 2835.18 | 5851.63 |

### Quality of qPCR Reaction System (Detection Sensitivity)

10 copies were detected for the entire standard DNAs of 7 mycoplasma strains listed on the 17 th revision Japanese Pharmacopoeia. Negative control was not detected.

### Quality of Positive Control

Both of untreated and acceleration aging tested positive control DNAs ( $2E + 03$  copies) were detected with Cq  $30 \pm 2$  as mycoplasma (FAM) and internal control (HEX, ROX).

\* All tests were performed with BIO-RAD CFX96.

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