

## Section IV. Guidance Documents

### Chapter IV. Naturally Occurring Pathogens

#### Appendix A – Tube Code Table for Validation and Verification

| Appendix A:   |                           | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|---------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                           | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2                  | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                           | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass           |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (0,0,1)   | 0.0001, 0.00001, 0.000001 | 10  | 2                       | 0.01            | 0.1             |
| (0,0,2)   | 0.0001, 0.00001, 0.000001 | 9   | 3                       | 0.01            | 0.1             |
| (0,1,0)   | 0.0001, 0.00001, 0.000001 | 10  | 2                       | 0.01            | 0.1             |
| (0,1,1)   | 0.0001, 0.00001, 0.000001 | 9   | 3                       | 0.01            | 0.1             |
| (0,2,0)   | 0.0001, 0.00001, 0.000001 | 9   | 3                       | 0.01            | 0.1             |
| (0,2,1)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (0,3,0)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (1,0,0)   | 0.0001, 0.00001, 0.000001 | 6   | 5                       | 0.1             | 1               |
| (1,0,1)   | 0.0001, 0.00001, 0.000001 | 9   | 3                       | 0.01            | 0.1             |
| (1,0,2)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (1,1,0)   | 0.0001, 0.00001, 0.000001 | 9   | 3                       | 0.01            | 0.1             |
| (1,1,1)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (1,1,2)   | 0.0001, 0.00001, 0.000001 | 10  | 1                       | 0.001           | 0.01            |
| (1,2,0)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (1,2,1)   | 0.0001, 0.00001, 0.000001 | 10  | 1                       | 0.001           | 0.01            |
| (1,3,0)   | 0.0001, 0.00001, 0.000001 | 10  | 1                       | 0.001           | 0.01            |
| (1,3,1)   | 0.0001, 0.00001, 0.000001 | 8   | 1                       | 0.001           | 0.01            |
| (1,4,0)   | 0.0001, 0.00001, 0.000001 | 8   | 1                       | 0.001           | 0.01            |
| (2,0,0)   | 0.0001, 0.00001, 0.000001 | 5   | 2                       | 0.01            | 0.1             |
| (2,0,1)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (2,0,2)   | 0.0001, 0.00001, 0.000001 | 10  | 1                       | 0.001           | 0.01            |
| (2,1,0)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (2,1,1)   | 0.0001, 0.00001, 0.000001 | 10  | 1                       | 0.001           | 0.01            |
| (2,1,2)   | 0.0001, 0.00001, 0.000001 | 10  | 6                       | 0.01            | 0.1             |
| (2,2,0)   | 0.0001, 0.00001, 0.000001 | 7   | 4                       | 0.01            | 0.1             |
| (2,2,1)   | 0.0001, 0.00001, 0.000001 | 10  | 6                       | 0.01            | 0.1             |
| (2,2,2)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (2,3,0)   | 0.0001, 0.00001, 0.000001 | 8   | 5                       | 0.01            | 0.1             |
| (2,3,1)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (2,4,0)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |

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| Appendix A:   |                           | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|---------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                           | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2                  | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                           | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass           |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (2,4,1)   | 0.0001, 0.00001, 0.000001 | 7   | 0                       | 0.0001          | 0.001           |
| (2,5,0)   | 0.0001, 0.00001, 0.000001 | 7   | 0                       | 0.0001          | 0.001           |
| (3,0,0)   | 0.0001, 0.00001, 0.000001 | 6   | 3                       | 0.01            | 0.1             |
| (3,0,1)   | 0.0001, 0.00001, 0.000001 | 9   | 5                       | 0.01            | 0.1             |
| (3,0,2)   | 0.0001, 0.00001, 0.000001 | 10  | 0                       | 0.0001          | 0.001           |
| (3,1,0)   | 0.0001, 0.00001, 0.000001 | 9   | 5                       | 0.01            | 0.1             |
| (3,1,1)   | 0.0001, 0.00001, 0.000001 | 10  | 0                       | 0.0001          | 0.001           |
| (3,1,2)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (3,2,0)   | 0.0001, 0.00001, 0.000001 | 10  | 0                       | 0.0001          | 0.001           |
| (3,2,1)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (3,2,2)   | 0.0001, 0.00001, 0.000001 | 8   | 6                       | 0.01            | 0.1             |
| (3,3,0)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (3,3,1)   | 0.0001, 0.00001, 0.000001 | 8   | 6                       | 0.01            | 0.1             |
| (3,3,2)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (3,4,0)   | 0.0001, 0.00001, 0.000001 | 8   | 6                       | 0.01            | 0.1             |
| (3,4,1)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (3,5,0)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (4,0,0)   | 0.0001, 0.00001, 0.000001 | 8   | 1                       | 0.001           | 0.01            |
| (4,0,1)   | 0.0001, 0.00001, 0.000001 | 9   | 0                       | 0.0001          | 0.001           |
| (4,0,2)   | 0.0001, 0.00001, 0.000001 | 10  | 7                       | 0.01            | 0.1             |
| (4,1,0)   | 0.0001, 0.00001, 0.000001 | 9   | 0                       | 0.0001          | 0.001           |
| (4,1,1)   | 0.0001, 0.00001, 0.000001 | 10  | 7                       | 0.01            | 0.1             |
| (4,1,2)   | 0.0001, 0.00001, 0.000001 | 5   | 4                       | 0.01            | 0.1             |
| (4,2,0)   | 0.0001, 0.00001, 0.000001 | 10  | 7                       | 0.01            | 0.1             |
| (4,2,2)   | 0.001, 0.0001, 0.00001    | 10  | 2                       | 0.01            | 0.1             |
| (4,3,0)   | 0.0001, 0.00001, 0.000001 | 5   | 4                       | 0.01            | 0.1             |
| (4,3,1)   | 0.001, 0.0001, 0.00001    | 10  | 8                       | 0.1             | 1               |
| (4,3,2)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (4,4,0)   | 0.001, 0.0001, 0.00001    | 10  | 8                       | 0.1             | 1               |
| (4,4,1)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (4,5,0)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (4,5,1)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (4,6,0)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (5,0,0)   | 0.0001, 0.00001, 0.000001 | 9   | 6                       | 0.01            | 0.1             |
| (5,0,1)   | 0.0001, 0.00001, 0.000001 | 7   | 0                       | 0.0001          | 0.001           |
| (5,0,2)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (5,0,3)   | 0.001, 0.0001, 0.00001    | 5   | 0                       | 0.001           | 0.01            |
| (5,1,0)   | 0.0001, 0.00001, 0.000001 | 7   | 0                       | 0.0001          | 0.001           |
| (5,1,1)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (5,1,2)   | 0.001, 0.0001, 0.00001    | 5   | 0                       | 0.001           | 0.01            |

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| Appendix A:   |                           | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|---------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                           | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2                  | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                           | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass           |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (5,1,3)   | 0.001, 0.0001, 0.00001    | 8   | 7                       | 0.1             | 1               |
| (5,2,0)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (5,2,1)   | 0.001, 0.0001, 0.00001    | 5   | 0                       | 0.001           | 0.01            |
| (5,2,2)   | 0.001, 0.0001, 0.00001    | 8   | 7                       | 0.1             | 1               |
| (5,3,0)   | 0.001, 0.0001, 0.00001    | 5   | 0                       | 0.001           | 0.01            |
| (5,3,1)   | 0.001, 0.0001, 0.00001    | 8   | 7                       | 0.1             | 1               |
| (5,3,2)   | 0.001, 0.0001, 0.00001    | 9   | 8                       | 0.1             | 1               |
| (5,4,0)   | 0.001, 0.0001, 0.00001    | 8   | 7                       | 0.1             | 1               |
| (5,4,1)   | 0.001, 0.0001, 0.00001    | 9   | 8                       | 0.1             | 1               |
| (5,4,2)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (5,5,0)   | 0.001, 0.0001, 0.00001    | 9   | 8                       | 0.1             | 1               |
| (5,5,1)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (5,6,0)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (6,0,0)   | 0.0001, 0.00001, 0.000001 | 5   | 4                       | 0.01            | 0.1             |
| (6,0,1)   | 0.001, 0.0001, 0.00001    | 10  | 2                       | 0.01            | 0.1             |
| (6,0,2)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (6,0,3)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (6,1,0)   | 0.001, 0.0001, 0.00001    | 10  | 2                       | 0.01            | 0.1             |
| (6,1,1)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (6,1,2)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (6,1,3)   | 0.001, 0.0001, 0.00001    | 10  | 9                       | 0.1             | 1               |
| (6,2,0)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (6,2,1)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (6,2,2)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (6,2,3)   | 0.001, 0.0001, 0.00001    | 10  | 3                       | 0.01            | 0.1             |
| (6,3,0)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (6,3,1)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (6,3,2)   | 0.001, 0.0001, 0.00001    | 10  | 3                       | 0.01            | 0.1             |
| (6,4,0)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (6,4,1)   | 0.001, 0.0001, 0.00001    | 10  | 3                       | 0.01            | 0.1             |
| (6,4,2)   | 0.001, 0.0001, 0.00001    | 6   | 2                       | 0.01            | 0.1             |
| (6,5,0)   | 0.001, 0.0001, 0.00001    | 10  | 3                       | 0.01            | 0.1             |
| (6,5,1)   | 0.001, 0.0001, 0.00001    | 6   | 2                       | 0.01            | 0.1             |
| (6,5,2)   | 0.001, 0.0001, 0.00001    | 9   | 3                       | 0.01            | 0.1             |
| (6,6,0)   | 0.001, 0.0001, 0.00001    | 6   | 2                       | 0.01            | 0.1             |
| (6,6,1)   | 0.001, 0.0001, 0.00001    | 9   | 3                       | 0.01            | 0.1             |
| (6,7,0)   | 0.001, 0.0001, 0.00001    | 9   | 3                       | 0.01            | 0.1             |
| (7,0,0)   | 0.001, 0.0001, 0.00001    | 5   | 0                       | 0.001           | 0.01            |
| (7,0,1)   | 0.001, 0.0001, 0.00001    | 8   | 7                       | 0.1             | 1               |
| (7,0,2)   | 0.001, 0.0001, 0.00001    | 10  | 9                       | 0.1             | 1               |

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|---|------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                        | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2               | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                        | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass        |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (7,0,3)   | 0.001, 0.0001, 0.00001 | 7   | 2                       | 0.01            | 0.1             |
| (7,1,0)   | 0.001, 0.0001, 0.00001 | 8   | 7                       | 0.1             | 1               |
| (7,1,1)   | 0.001, 0.0001, 0.00001 | 10  | 9                       | 0.1             | 1               |
| (7,1,2)   | 0.001, 0.0001, 0.00001 | 7   | 2                       | 0.01            | 0.1             |
| (7,1,3)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (7,2,0)   | 0.001, 0.0001, 0.00001 | 10  | 9                       | 0.1             | 1               |
| (7,2,1)   | 0.001, 0.0001, 0.00001 | 10  | 3                       | 0.01            | 0.1             |
| (7,2,2)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (7,2,3)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (7,3,0)   | 0.001, 0.0001, 0.00001 | 10  | 3                       | 0.01            | 0.1             |
| (7,3,1)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (7,3,2)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (7,3,3)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (7,4,0)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (7,4,1)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (7,4,2)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (7,4,3)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (7,5,0)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (7,5,1)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (7,5,2)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (7,6,0)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (7,6,1)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (7,6,2)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (7,7,0)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (7,7,1)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (8,0,0)   | 0.001, 0.0001, 0.00001 | 9   | 8                       | 0.1             | 1               |
| (8,0,1)   | 0.001, 0.0001, 0.00001 | 7   | 2                       | 0.01            | 0.1             |
| (8,0,2)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (8,0,3)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (8,1,0)   | 0.001, 0.0001, 0.00001 | 7   | 2                       | 0.01            | 0.1             |
| (8,1,1)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (8,1,2)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (8,1,3)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (8,2,0)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (8,2,1)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (8,2,2)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (8,2,3)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (8,3,0)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (8,3,1)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (8,3,2)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |

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| Appendix A:   |                        | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                        | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2               | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                        | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass        |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (8,3,3)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (8,4,0)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (8,4,1)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (8,4,2)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (8,4,3)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (8,5,0)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (8,5,1)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (8,5,2)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (8,5,3)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (8,6,0)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (8,6,1)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (8,6,2)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (8,7,0)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (8,7,1)   | 0.001, 0.0001, 0.00001 | 8   | 4                       | 0.01            | 0.1             |
| (8,7,2)   | 0.001, 0.0001, 0.00001 | 10  | 5                       | 0.01            | 0.1             |
| (8,8,0)   | 0.001, 0.0001, 0.00001 | 8   | 4                       | 0.01            | 0.1             |
| (8,8,1)   | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (9,0,0)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (9,0,1)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (9,0,2)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (9,0,3)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (9,1,0)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (9,1,1)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (9,1,2)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (9,1,3)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (9,1,4)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (9,2,0)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (9,2,1)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (9,2,2)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (9,2,3)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (9,2,4)   | 0.001, 0.0001, 0.00001 | 10  | 5                       | 0.01            | 0.1             |
| (9,3,0)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (9,3,1)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (9,3,2)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (9,3,3)   | 0.001, 0.0001, 0.00001 | 10  | 5                       | 0.01            | 0.1             |
| (9,3,4)   | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (9,4,0)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (9,4,1)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (9,4,2)   | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (9,4,3)   | 0.001, 0.0001, 0.00001 | 7   | 4                       | 0.01            | 0.1             |

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| Appendix A:   |                        | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                        | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2               | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                        | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass        |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (9,4,4)   | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (9,5,0)   | 0.001, 0.0001, 0.00001 | 8   | 4                       | 0.01            | 0.1             |
| (9,5,1)   | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (9,5,2)   | 0.001, 0.0001, 0.00001 | 7   | 4                       | 0.01            | 0.1             |
| (9,5,3)   | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (9,5,4)   | 0.001, 0.0001, 0.00001 | 10  | 0                       | 0.0001          | 0.001           |
| (9,6,0)   | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (9,6,1)   | 0.001, 0.0001, 0.00001 | 9   | 5                       | 0.01            | 0.1             |
| (9,6,2)   | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (9,6,3)   | 0.001, 0.0001, 0.00001 | 10  | 0                       | 0.0001          | 0.001           |
| (9,7,0)   | 0.001, 0.0001, 0.00001 | 9   | 5                       | 0.01            | 0.1             |
| (9,7,1)   | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (9,7,2)   | 0.001, 0.0001, 0.00001 | 6   | 4                       | 0.01            | 0.1             |
| (9,7,3)   | 0.001, 0.0001, 0.00001 | 9   | 6                       | 0.01            | 0.1             |
| (9,8,0)   | 0.001, 0.0001, 0.00001 | 10  | 6                       | 0.01            | 0.1             |
| (9,8,1)   | 0.001, 0.0001, 0.00001 | 7   | 1                       | 0.001           | 0.01            |
| (9,8,2)   | 0.001, 0.0001, 0.00001 | 8   | 0                       | 0.0001          | 0.001           |
| (9,8,3)   | 0.001, 0.0001, 0.00001 | 10  | 7                       | 0.01            | 0.1             |
| (9,9,0)   | 0.001, 0.0001, 0.00001 | 9   | 0                       | 0.0001          | 0.001           |
| (9,9,1)   | 0.001, 0.0001, 0.00001 | 8   | 0                       | 0.0001          | 0.001           |
| (9,9,2)   | 0.001, 0.0001, 0.00001 | 7   | 0                       | 0.0001          | 0.001           |
| (10,0,0)  | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (10,0,1)  | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (10,0,2)  | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (10,0,3)  | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (10,1,0)  | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (10,1,1)  | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (10,1,2)  | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (10,1,3)  | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (10,1,4)  | 0.001, 0.0001, 0.00001 | 10  | 0                       | 0.0001          | 0.001           |
| (10,2,0)  | 0.001, 0.0001, 0.00001 | 8   | 4                       | 0.01            | 0.1             |
| (10,2,1)  | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (10,2,2)  | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (10,2,3)  | 0.001, 0.0001, 0.00001 | 6   | 4                       | 0.01            | 0.1             |
| (10,2,4)  | 0.001, 0.0001, 0.00001 | 8   | 0                       | 0.0001          | 0.001           |
| (10,3,0)  | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (10,3,1)  | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (10,3,2)  | 0.001, 0.0001, 0.00001 | 9   | 0                       | 0.0001          | 0.001           |
| (10,3,3)  | 0.001, 0.0001, 0.00001 | 7   | 5                       | 0.01            | 0.1             |
| (10,3,4)  | 0.001, 0.0001, 0.00001 | 5   | 4                       | 0.01            | 0.1             |

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| Appendix A:   |                        | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                        | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2               | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                        | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass        |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (10,3,5)  | 0.001, 0.0001, 0.00001 | 6   | 0                       | 0.0001          | 0.001           |
| (10,4,0)  | 0.001, 0.0001, 0.00001 | 10  | 6                       | 0.01            | 0.1             |
| (10,4,1)  | 0.001, 0.0001, 0.00001 | 9   | 0                       | 0.0001          | 0.001           |
| (10,4,2)  | 0.001, 0.0001, 0.00001 | 7   | 0                       | 0.0001          | 0.001           |
| (10,4,3)  | 0.001, 0.0001, 0.00001 | 5   | 4                       | 0.01            | 0.1             |
| (10,4,4)  | 0.001, 0.0001, 0.00001 | 6   | 5                       | 0.01            | 0.1             |
| (10,4,5)  | 0.01, 0.001, 0.0001    | 7   | 6                       | 0.1             | 1               |
| (10,5,0)  | 0.001, 0.0001, 0.00001 | 8   | 0                       | 0.0001          | 0.001           |
| (10,5,1)  | 0.001, 0.0001, 0.00001 | 7   | 0                       | 0.0001          | 0.001           |
| (10,5,2)  | 0.001, 0.0001, 0.00001 | 6   | 0                       | 0.0001          | 0.001           |
| (10,5,3)  | 0.01, 0.001, 0.0001    | 5   | 0                       | 0.001           | 0.01            |
| (10,5,4)  | 0.01, 0.001, 0.0001    | 8   | 7                       | 0.1             | 1               |
| (10,5,5)  | 0.01, 0.001, 0.0001    | 9   | 8                       | 0.1             | 1               |
| (10,5,6)  | 0.01, 0.001, 0.0001    | 7   | 2                       | 0.01            | 0.1             |
| (10,6,0)  | 0.001, 0.0001, 0.00001 | 5   | 4                       | 0.01            | 0.1             |
| (10,6,1)  | 0.01, 0.001, 0.0001    | 6   | 5                       | 0.1             | 1               |
| (10,6,2)  | 0.01, 0.001, 0.0001    | 7   | 6                       | 0.1             | 1               |
| (10,6,3)  | 0.01, 0.001, 0.0001    | 9   | 8                       | 0.1             | 1               |
| (10,6,4)  | 0.01, 0.001, 0.0001    | 7   | 2                       | 0.01            | 0.1             |
| (10,6,5)  | 0.01, 0.001, 0.0001    | 10  | 3                       | 0.01            | 0.1             |
| (10,6,6)  | 0.01, 0.001, 0.0001    | 6   | 2                       | 0.01            | 0.1             |
| (10,7,0)  | 0.01, 0.001, 0.0001    | 5   | 0                       | 0.001           | 0.01            |
| (10,7,1)  | 0.01, 0.001, 0.0001    | 8   | 2                       | 0.01            | 0.1             |
| (10,7,2)  | 0.01, 0.001, 0.0001    | 10  | 9                       | 0.1             | 1               |
| (10,7,3)  | 0.01, 0.001, 0.0001    | 10  | 3                       | 0.01            | 0.1             |
| (10,7,4)  | 0.01, 0.001, 0.0001    | 6   | 2                       | 0.01            | 0.1             |
| (10,7,5)  | 0.01, 0.001, 0.0001    | 9   | 3                       | 0.01            | 0.1             |
| (10,7,6)  | 0.01, 0.001, 0.0001    | 8   | 3                       | 0.01            | 0.1             |
| (10,7,7)  | 0.01, 0.001, 0.0001    | 10  | 4                       | 0.01            | 0.1             |
| (10,8,0)  | 0.01, 0.001, 0.0001    | 9   | 8                       | 0.1             | 1               |
| (10,8,1)  | 0.01, 0.001, 0.0001    | 10  | 3                       | 0.01            | 0.1             |
| (10,8,2)  | 0.01, 0.001, 0.0001    | 6   | 2                       | 0.01            | 0.1             |
| (10,8,3)  | 0.01, 0.001, 0.0001    | 5   | 2                       | 0.01            | 0.1             |
| (10,8,4)  | 0.01, 0.001, 0.0001    | 8   | 3                       | 0.01            | 0.1             |
| (10,8,5)  | 0.01, 0.001, 0.0001    | 10  | 4                       | 0.01            | 0.1             |
| (10,8,6)  | 0.01, 0.001, 0.0001    | 9   | 4                       | 0.01            | 0.1             |
| (10,8,7)  | 0.01, 0.001, 0.0001    | 6   | 3                       | 0.01            | 0.1             |
| (10,8,8)  | 0.01, 0.001, 0.0001    | 8   | 4                       | 0.01            | 0.1             |
| (10,9,0)  | 0.01, 0.001, 0.0001    | 6   | 2                       | 0.01            | 0.1             |
| (10,9,1)  | 0.01, 0.001, 0.0001    | 5   | 2                       | 0.01            | 0.1             |

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| Appendix A:   |                           | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|---------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                           | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2                  | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                           | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass           |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (10,9,2)  | 0.01, 0.001, 0.0001       | 8   | 3                       | 0.01            | 0.1             |
| (10,9,3)  | 0.01, 0.001, 0.0001       | 7   | 3                       | 0.01            | 0.1             |
| (10,9,4)  | 0.01, 0.001, 0.0001       | 6   | 3                       | 0.01            | 0.1             |
| (10,9,5)  | 0.01, 0.001, 0.0001       | 8   | 4                       | 0.01            | 0.1             |
| (10,9,6)  | 0.01, 0.001, 0.0001       | 10  | 1                       | 0.001           | 0.01            |
| (10,9,7)  | 0.01, 0.001, 0.0001       | 8   | 1                       | 0.001           | 0.01            |
| (10,9,8)  | 0.01, 0.001, 0.0001       | 10  | 0                       | 0.0001          | 0.001           |
| (10,9,9)  | 0.01, 0.001, 0.0001       | 8   | 0                       | 0.0001          | 0.001           |
| (10,10,0)   | 0.01, 0.001, 0.0001       | 10  | 4                       | 0.01            | 0.1             |
| (10,10,1)   | 0.01, 0.001, 0.0001       | 9   | 4                       | 0.01            | 0.1             |
| (10,10,2)   | 0.01, 0.001, 0.0001       | 8   | 4                       | 0.01            | 0.1             |
| (10,10,3)   | 0.01, 0.001, 0.0001       | 9   | 5                       | 0.01            | 0.1             |
| (10,10,4)   | 0.01, 0.001, 0.0001       | 6   | 4                       | 0.01            | 0.1             |
| (10,10,5)   | 0.01, 0.001, 0.0001       | 7   | 0                       | 0.0001          | 0.001           |
| (10,10,6)   | 0.10, 0.01, 0.001         | 10  | 2                       | 0.01            | 0.1             |
| (10,10,7)   | 0.10, 0.01, 0.001         | 8   | 2                       | 0.01            | 0.1             |
| (10,10,8)   | 0.10, 0.01, 0.001         | 10  | 3                       | 0.01            | 0.1             |
| (10,10,9)   | 0.10, 0.01, 0.001         | 8   | 3                       | 0.01            | 0.1             |
| (0,0,1)   | 0.0001, 0.00001, 0.000001 | 10  | 2                       | 0.01            | 0.1             |
| (0,0,2)   | 0.0001, 0.00001, 0.000001 | 9   | 3                       | 0.01            | 0.1             |
| (0,1,0)   | 0.0001, 0.00001, 0.000001 | 10  | 2                       | 0.01            | 0.1             |
| (0,1,1)   | 0.0001, 0.00001, 0.000001 | 9   | 3                       | 0.01            | 0.1             |
| (0,2,0)   | 0.0001, 0.00001, 0.000001 | 9   | 3                       | 0.01            | 0.1             |
| (0,2,1)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (0,3,0)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (1,0,0)   | 0.0001, 0.00001, 0.000001 | 6   | 5                       | 0.1             | 1               |
| (1,0,1)   | 0.0001, 0.00001, 0.000001 | 9   | 3                       | 0.01            | 0.1             |
| (1,0,2)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (1,1,0)   | 0.0001, 0.00001, 0.000001 | 9   | 3                       | 0.01            | 0.1             |
| (1,1,1)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (1,1,2)   | 0.0001, 0.00001, 0.000001 | 10  | 1                       | 0.001           | 0.01            |
| (1,2,0)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (1,2,1)   | 0.0001, 0.00001, 0.000001 | 10  | 1                       | 0.001           | 0.01            |
| (1,3,0)   | 0.0001, 0.00001, 0.000001 | 10  | 1                       | 0.001           | 0.01            |
| (1,3,1)   | 0.0001, 0.00001, 0.000001 | 8   | 1                       | 0.001           | 0.01            |
| (1,4,0)   | 0.0001, 0.00001, 0.000001 | 8   | 1                       | 0.001           | 0.01            |
| (2,0,0)   | 0.0001, 0.00001, 0.000001 | 5   | 2                       | 0.01            | 0.1             |
| (2,0,1)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |
| (2,0,2)   | 0.0001, 0.00001, 0.000001 | 10  | 1                       | 0.001           | 0.01            |
| (2,1,0)   | 0.0001, 0.00001, 0.000001 | 9   | 4                       | 0.01            | 0.1             |



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| Appendix A:   |                           | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|---------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                           | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2                  | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                           | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass           |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (2,1,1)   | 0.0001, 0.00001, 0.000001 | 10  | 1                       | 0.001           | 0.01            |
| (2,1,2)   | 0.0001, 0.00001, 0.000001 | 10  | 6                       | 0.01            | 0.1             |
| (2,2,0)   | 0.0001, 0.00001, 0.000001 | 7   | 4                       | 0.01            | 0.1             |
| (2,2,1)   | 0.0001, 0.00001, 0.000001 | 10  | 6                       | 0.01            | 0.1             |
| (2,2,2)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (2,3,0)   | 0.0001, 0.00001, 0.000001 | 8   | 5                       | 0.01            | 0.1             |
| (2,3,1)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (2,4,0)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (2,4,1)   | 0.0001, 0.00001, 0.000001 | 7   | 0                       | 0.0001          | 0.001           |
| (2,5,0)   | 0.0001, 0.00001, 0.000001 | 7   | 0                       | 0.0001          | 0.001           |
| (3,0,0)   | 0.0001, 0.00001, 0.000001 | 6   | 3                       | 0.01            | 0.1             |
| (3,0,1)   | 0.0001, 0.00001, 0.000001 | 9   | 5                       | 0.01            | 0.1             |
| (3,0,2)   | 0.0001, 0.00001, 0.000001 | 10  | 0                       | 0.0001          | 0.001           |
| (3,1,0)   | 0.0001, 0.00001, 0.000001 | 9   | 5                       | 0.01            | 0.1             |
| (3,1,1)   | 0.0001, 0.00001, 0.000001 | 10  | 0                       | 0.0001          | 0.001           |
| (3,1,2)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (3,2,0)   | 0.0001, 0.00001, 0.000001 | 10  | 0                       | 0.0001          | 0.001           |
| (3,2,1)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (3,2,2)   | 0.0001, 0.00001, 0.000001 | 8   | 6                       | 0.01            | 0.1             |
| (3,3,0)   | 0.0001, 0.00001, 0.000001 | 8   | 0                       | 0.0001          | 0.001           |
| (3,3,1)   | 0.0001, 0.00001, 0.000001 | 8   | 6                       | 0.01            | 0.1             |
| (3,3,2)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (3,4,0)   | 0.0001, 0.00001, 0.000001 | 8   | 6                       | 0.01            | 0.1             |
| (3,4,1)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (3,5,0)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (4,0,0)   | 0.0001, 0.00001, 0.000001 | 8   | 1                       | 0.001           | 0.01            |
| (4,0,1)   | 0.0001, 0.00001, 0.000001 | 9   | 0                       | 0.0001          | 0.001           |
| (4,0,2)   | 0.0001, 0.00001, 0.000001 | 10  | 7                       | 0.01            | 0.1             |
| (4,1,0)   | 0.0001, 0.00001, 0.000001 | 9   | 0                       | 0.0001          | 0.001           |
| (4,1,1)   | 0.0001, 0.00001, 0.000001 | 10  | 7                       | 0.01            | 0.1             |
| (4,1,2)   | 0.0001, 0.00001, 0.000001 | 5   | 4                       | 0.01            | 0.1             |
| (4,2,0)   | 0.0001, 0.00001, 0.000001 | 10  | 7                       | 0.01            | 0.1             |
| (4,2,2)   | 0.001, 0.0001, 0.00001    | 10  | 2                       | 0.01            | 0.1             |
| (4,3,0)   | 0.0001, 0.00001, 0.000001 | 5   | 4                       | 0.01            | 0.1             |
| (4,3,1)   | 0.001, 0.0001, 0.00001    | 10  | 8                       | 0.1             | 1               |
| (4,3,2)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (4,4,0)   | 0.001, 0.0001, 0.00001    | 10  | 8                       | 0.1             | 1               |
| (4,4,1)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (4,5,0)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (4,5,1)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |

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| Appendix A:   |                           | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|---------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                           | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2                  | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                           | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass           |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (4,6,0)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (5,0,0)   | 0.0001, 0.00001, 0.000001 | 9   | 6                       | 0.01            | 0.1             |
| (5,0,1)   | 0.0001, 0.00001, 0.000001 | 7   | 0                       | 0.0001          | 0.001           |
| (5,0,2)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (5,0,3)   | 0.001, 0.0001, 0.00001    | 5   | 0                       | 0.001           | 0.01            |
| (5,1,0)   | 0.0001, 0.00001, 0.000001 | 7   | 0                       | 0.0001          | 0.001           |
| (5,1,1)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (5,1,2)   | 0.001, 0.0001, 0.00001    | 5   | 0                       | 0.001           | 0.01            |
| (5,1,3)   | 0.001, 0.0001, 0.00001    | 8   | 7                       | 0.1             | 1               |
| (5,2,0)   | 0.0001, 0.00001, 0.000001 | 6   | 0                       | 0.0001          | 0.001           |
| (5,2,1)   | 0.001, 0.0001, 0.00001    | 5   | 0                       | 0.001           | 0.01            |
| (5,2,2)   | 0.001, 0.0001, 0.00001    | 8   | 7                       | 0.1             | 1               |
| (5,3,0)   | 0.001, 0.0001, 0.00001    | 5   | 0                       | 0.001           | 0.01            |
| (5,3,1)   | 0.001, 0.0001, 0.00001    | 8   | 7                       | 0.1             | 1               |
| (5,3,2)   | 0.001, 0.0001, 0.00001    | 9   | 8                       | 0.1             | 1               |
| (5,4,0)   | 0.001, 0.0001, 0.00001    | 8   | 7                       | 0.1             | 1               |
| (5,4,1)   | 0.001, 0.0001, 0.00001    | 9   | 8                       | 0.1             | 1               |
| (5,4,2)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (5,5,0)   | 0.001, 0.0001, 0.00001    | 9   | 8                       | 0.1             | 1               |
| (5,5,1)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (5,6,0)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (6,0,0)   | 0.0001, 0.00001, 0.000001 | 5   | 4                       | 0.01            | 0.1             |
| (6,0,1)   | 0.001, 0.0001, 0.00001    | 10  | 2                       | 0.01            | 0.1             |
| (6,0,2)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (6,0,3)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (6,1,0)   | 0.001, 0.0001, 0.00001    | 10  | 2                       | 0.01            | 0.1             |
| (6,1,1)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (6,1,2)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (6,1,3)   | 0.001, 0.0001, 0.00001    | 10  | 9                       | 0.1             | 1               |
| (6,2,0)   | 0.001, 0.0001, 0.00001    | 7   | 6                       | 0.1             | 1               |
| (6,2,1)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (6,2,2)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (6,2,3)   | 0.001, 0.0001, 0.00001    | 10  | 3                       | 0.01            | 0.1             |
| (6,3,0)   | 0.001, 0.0001, 0.00001    | 8   | 2                       | 0.01            | 0.1             |
| (6,3,1)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (6,3,2)   | 0.001, 0.0001, 0.00001    | 10  | 3                       | 0.01            | 0.1             |
| (6,4,0)   | 0.001, 0.0001, 0.00001    | 7   | 2                       | 0.01            | 0.1             |
| (6,4,1)   | 0.001, 0.0001, 0.00001    | 10  | 3                       | 0.01            | 0.1             |
| (6,4,2)   | 0.001, 0.0001, 0.00001    | 6   | 2                       | 0.01            | 0.1             |
| (6,5,0)   | 0.001, 0.0001, 0.00001    | 10  | 3                       | 0.01            | 0.1             |

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2011 Revision**

| Appendix A:   |                        | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                        | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2               | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                        | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass        |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (6,5,1)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (6,5,2)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (6,6,0)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (6,6,1)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (6,7,0)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (7,0,0)   | 0.001, 0.0001, 0.00001 | 5   | 0                       | 0.001           | 0.01            |
| (7,0,1)   | 0.001, 0.0001, 0.00001 | 8   | 7                       | 0.1             | 1               |
| (7,0,2)   | 0.001, 0.0001, 0.00001 | 10  | 9                       | 0.1             | 1               |
| (7,0,3)   | 0.001, 0.0001, 0.00001 | 7   | 2                       | 0.01            | 0.1             |
| (7,1,0)   | 0.001, 0.0001, 0.00001 | 8   | 7                       | 0.1             | 1               |
| (7,1,1)   | 0.001, 0.0001, 0.00001 | 10  | 9                       | 0.1             | 1               |
| (7,1,2)   | 0.001, 0.0001, 0.00001 | 7   | 2                       | 0.01            | 0.1             |
| (7,1,3)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (7,2,0)   | 0.001, 0.0001, 0.00001 | 10  | 9                       | 0.1             | 1               |
| (7,2,1)   | 0.001, 0.0001, 0.00001 | 10  | 3                       | 0.01            | 0.1             |
| (7,2,2)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (7,2,3)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (7,3,0)   | 0.001, 0.0001, 0.00001 | 10  | 3                       | 0.01            | 0.1             |
| (7,3,1)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (7,3,2)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (7,3,3)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (7,4,0)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (7,4,1)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (7,4,2)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (7,4,3)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (7,5,0)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (7,5,1)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (7,5,2)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (7,6,0)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (7,6,1)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (7,6,2)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (7,7,0)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (7,7,1)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (8,0,0)   | 0.001, 0.0001, 0.00001 | 9   | 8                       | 0.1             | 1               |
| (8,0,1)   | 0.001, 0.0001, 0.00001 | 7   | 2                       | 0.01            | 0.1             |
| (8,0,2)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (8,0,3)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (8,1,0)   | 0.001, 0.0001, 0.00001 | 7   | 2                       | 0.01            | 0.1             |
| (8,1,1)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (8,1,2)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |

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2011 Revision**

| Appendix A:   |                        | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                        | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2               | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                        | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass        |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (8,1,3)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (8,2,0)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (8,2,1)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (8,2,2)   | 0.001, 0.0001, 0.00001 | 5   | 2                       | 0.01            | 0.1             |
| (8,2,3)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (8,3,0)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (8,3,1)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (8,3,2)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (8,3,3)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (8,4,0)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (8,4,1)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (8,4,2)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (8,4,3)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (8,5,0)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (8,5,1)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (8,5,2)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (8,5,3)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (8,6,0)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (8,6,1)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (8,6,2)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (8,7,0)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (8,7,1)   | 0.001, 0.0001, 0.00001 | 8   | 4                       | 0.01            | 0.1             |
| (8,7,2)   | 0.001, 0.0001, 0.00001 | 10  | 5                       | 0.01            | 0.1             |
| (8,8,0)   | 0.001, 0.0001, 0.00001 | 8   | 4                       | 0.01            | 0.1             |
| (8,8,1)   | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (9,0,0)   | 0.001, 0.0001, 0.00001 | 6   | 2                       | 0.01            | 0.1             |
| (9,0,1)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (9,0,2)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (9,0,3)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (9,1,0)   | 0.001, 0.0001, 0.00001 | 9   | 3                       | 0.01            | 0.1             |
| (9,1,1)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (9,1,2)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (9,1,3)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (9,1,4)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (9,2,0)   | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (9,2,1)   | 0.001, 0.0001, 0.00001 | 10  | 4                       | 0.01            | 0.1             |
| (9,2,2)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (9,2,3)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (9,2,4)   | 0.001, 0.0001, 0.00001 | 10  | 5                       | 0.01            | 0.1             |
| (9,3,0)   | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |

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| Appendix A:   |                        | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                        | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2               | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                        | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass        |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (9,3,1)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (9,3,2)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (9,3,3)   | 0.001, 0.0001, 0.00001 | 10  | 5                       | 0.01            | 0.1             |
| (9,3,4)   | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (9,4,0)   | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (9,4,1)   | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (9,4,2)   | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (9,4,3)   | 0.001, 0.0001, 0.00001 | 7   | 4                       | 0.01            | 0.1             |
| (9,4,4)   | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (9,5,0)   | 0.001, 0.0001, 0.00001 | 8   | 4                       | 0.01            | 0.1             |
| (9,5,1)   | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (9,5,2)   | 0.001, 0.0001, 0.00001 | 7   | 4                       | 0.01            | 0.1             |
| (9,5,3)   | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (9,5,4)   | 0.001, 0.0001, 0.00001 | 10  | 0                       | 0.0001          | 0.001           |
| (9,6,0)   | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (9,6,1)   | 0.001, 0.0001, 0.00001 | 9   | 5                       | 0.01            | 0.1             |
| (9,6,2)   | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (9,6,3)   | 0.001, 0.0001, 0.00001 | 10  | 0                       | 0.0001          | 0.001           |
| (9,7,0)   | 0.001, 0.0001, 0.00001 | 9   | 5                       | 0.01            | 0.1             |
| (9,7,1)   | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (9,7,2)   | 0.001, 0.0001, 0.00001 | 6   | 4                       | 0.01            | 0.1             |
| (9,7,3)   | 0.001, 0.0001, 0.00001 | 9   | 6                       | 0.01            | 0.1             |
| (9,8,0)   | 0.001, 0.0001, 0.00001 | 10  | 6                       | 0.01            | 0.1             |
| (9,8,1)   | 0.001, 0.0001, 0.00001 | 7   | 1                       | 0.001           | 0.01            |
| (9,8,2)   | 0.001, 0.0001, 0.00001 | 8   | 0                       | 0.0001          | 0.001           |
| (9,8,3)   | 0.001, 0.0001, 0.00001 | 10  | 7                       | 0.01            | 0.1             |
| (9,9,0)   | 0.001, 0.0001, 0.00001 | 9   | 0                       | 0.0001          | 0.001           |
| (9,9,1)   | 0.001, 0.0001, 0.00001 | 8   | 0                       | 0.0001          | 0.001           |
| (9,9,2)   | 0.001, 0.0001, 0.00001 | 7   | 0                       | 0.0001          | 0.001           |
| (10,0,0)  | 0.001, 0.0001, 0.00001 | 8   | 3                       | 0.01            | 0.1             |
| (10,0,1)  | 0.001, 0.0001, 0.00001 | 7   | 3                       | 0.01            | 0.1             |
| (10,0,2)  | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (10,0,3)  | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (10,1,0)  | 0.001, 0.0001, 0.00001 | 9   | 4                       | 0.01            | 0.1             |
| (10,1,1)  | 0.001, 0.0001, 0.00001 | 6   | 3                       | 0.01            | 0.1             |
| (10,1,2)  | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (10,1,3)  | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (10,1,4)  | 0.001, 0.0001, 0.00001 | 10  | 0                       | 0.0001          | 0.001           |
| (10,2,0)  | 0.001, 0.0001, 0.00001 | 8   | 4                       | 0.01            | 0.1             |
| (10,2,1)  | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |

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| Appendix A:   |                        | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|------------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                        | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2               | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                        | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass        |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (10,2,2)  | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (10,2,3)  | 0.001, 0.0001, 0.00001 | 6   | 4                       | 0.01            | 0.1             |
| (10,2,4)  | 0.001, 0.0001, 0.00001 | 8   | 0                       | 0.0001          | 0.001           |
| (10,3,0)  | 0.001, 0.0001, 0.00001 | 10  | 1                       | 0.001           | 0.01            |
| (10,3,1)  | 0.001, 0.0001, 0.00001 | 8   | 1                       | 0.001           | 0.01            |
| (10,3,2)  | 0.001, 0.0001, 0.00001 | 9   | 0                       | 0.0001          | 0.001           |
| (10,3,3)  | 0.001, 0.0001, 0.00001 | 7   | 5                       | 0.01            | 0.1             |
| (10,3,4)  | 0.001, 0.0001, 0.00001 | 5   | 4                       | 0.01            | 0.1             |
| (10,3,5)  | 0.001, 0.0001, 0.00001 | 6   | 0                       | 0.0001          | 0.001           |
| (10,4,0)  | 0.001, 0.0001, 0.00001 | 10  | 6                       | 0.01            | 0.1             |
| (10,4,1)  | 0.001, 0.0001, 0.00001 | 9   | 0                       | 0.0001          | 0.001           |
| (10,4,2)  | 0.001, 0.0001, 0.00001 | 7   | 0                       | 0.0001          | 0.001           |
| (10,4,3)  | 0.001, 0.0001, 0.00001 | 5   | 4                       | 0.01            | 0.1             |
| (10,4,4)  | 0.001, 0.0001, 0.00001 | 6   | 5                       | 0.01            | 0.1             |
| (10,4,5)  | 0.01, 0.001, 0.0001    | 7   | 6                       | 0.1             | 1               |
| (10,5,0)  | 0.001, 0.0001, 0.00001 | 8   | 0                       | 0.0001          | 0.001           |
| (10,5,1)  | 0.001, 0.0001, 0.00001 | 7   | 0                       | 0.0001          | 0.001           |
| (10,5,2)  | 0.001, 0.0001, 0.00001 | 6   | 0                       | 0.0001          | 0.001           |
| (10,5,3)  | 0.01, 0.001, 0.0001    | 5   | 0                       | 0.001           | 0.01            |
| (10,5,4)  | 0.01, 0.001, 0.0001    | 8   | 7                       | 0.1             | 1               |
| (10,5,5)  | 0.01, 0.001, 0.0001    | 9   | 8                       | 0.1             | 1               |
| (10,5,6)  | 0.01, 0.001, 0.0001    | 7   | 2                       | 0.01            | 0.1             |
| (10,6,0)  | 0.001, 0.0001, 0.00001 | 5   | 4                       | 0.01            | 0.1             |
| (10,6,1)  | 0.01, 0.001, 0.0001    | 6   | 5                       | 0.1             | 1               |
| (10,6,2)  | 0.01, 0.001, 0.0001    | 7   | 6                       | 0.1             | 1               |
| (10,6,3)  | 0.01, 0.001, 0.0001    | 9   | 8                       | 0.1             | 1               |
| (10,6,4)  | 0.01, 0.001, 0.0001    | 7   | 2                       | 0.01            | 0.1             |
| (10,6,5)  | 0.01, 0.001, 0.0001    | 10  | 3                       | 0.01            | 0.1             |
| (10,6,6)  | 0.01, 0.001, 0.0001    | 6   | 2                       | 0.01            | 0.1             |
| (10,7,0)  | 0.01, 0.001, 0.0001    | 5   | 0                       | 0.001           | 0.01            |
| (10,7,1)  | 0.01, 0.001, 0.0001    | 8   | 2                       | 0.01            | 0.1             |
| (10,7,2)  | 0.01, 0.001, 0.0001    | 10  | 9                       | 0.1             | 1               |
| (10,7,3)  | 0.01, 0.001, 0.0001    | 10  | 3                       | 0.01            | 0.1             |
| (10,7,4)  | 0.01, 0.001, 0.0001    | 6   | 2                       | 0.01            | 0.1             |
| (10,7,5)  | 0.01, 0.001, 0.0001    | 9   | 3                       | 0.01            | 0.1             |
| (10,7,6)  | 0.01, 0.001, 0.0001    | 8   | 3                       | 0.01            | 0.1             |
| (10,7,7)  | 0.01, 0.001, 0.0001    | 10  | 4                       | 0.01            | 0.1             |
| (10,8,0)  | 0.01, 0.001, 0.0001    | 9   | 8                       | 0.1             | 1               |
| (10,8,1)  | 0.01, 0.001, 0.0001    | 10  | 3                       | 0.01            | 0.1             |
| (10,8,2)  | 0.01, 0.001, 0.0001    | 6   | 2                       | 0.01            | 0.1             |

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| Appendix A:   |                     | Tube Code Table for Validation and Verification |                         |                 |                 |
|---|---------------------|---|-------------------------|-----------------|-----------------|
| Initial Pre-Process <i>V.p. Density</i> Measurement |                     | Post-Process <i>V.p. Density</i> Measurement    |                         |                 |                 |
| Column 1  | Column 2            | Column 3  | Column 4                | Column 5        | Column 6        |
| Before: 10 tubes, 3 dilutions                       |                     | After: 1 dilution;<br>total tubes               | Allowed                 | 2 log reduction | 3 log reduction |
| Tube Codes  | Homogenate Mass     |   | Positive (turbid) tubes | Homogenate Mass | Homogenate Mass |
| (10,8,3)  | 0.01, 0.001, 0.0001 | 5   | 2                       | 0.01            | 0.1             |
| (10,8,4)  | 0.01, 0.001, 0.0001 | 8   | 3                       | 0.01            | 0.1             |
| (10,8,5)  | 0.01, 0.001, 0.0001 | 10  | 4                       | 0.01            | 0.1             |
| (10,8,6)  | 0.01, 0.001, 0.0001 | 9   | 4                       | 0.01            | 0.1             |
| (10,8,7)  | 0.01, 0.001, 0.0001 | 6   | 3                       | 0.01            | 0.1             |
| (10,8,8)  | 0.01, 0.001, 0.0001 | 8   | 4                       | 0.01            | 0.1             |
| (10,9,0)  | 0.01, 0.001, 0.0001 | 6   | 2                       | 0.01            | 0.1             |
| (10,9,1)  | 0.01, 0.001, 0.0001 | 5   | 2                       | 0.01            | 0.1             |
| (10,9,2)  | 0.01, 0.001, 0.0001 | 8   | 3                       | 0.01            | 0.1             |
| (10,9,3)  | 0.01, 0.001, 0.0001 | 7   | 3                       | 0.01            | 0.1             |
| (10,9,4)  | 0.01, 0.001, 0.0001 | 6   | 3                       | 0.01            | 0.1             |
| (10,9,5)  | 0.01, 0.001, 0.0001 | 8   | 4                       | 0.01            | 0.1             |
| (10,9,6)  | 0.01, 0.001, 0.0001 | 10  | 1                       | 0.001           | 0.01            |
| (10,9,7)  | 0.01, 0.001, 0.0001 | 8   | 1                       | 0.001           | 0.01            |
| (10,9,8)  | 0.01, 0.001, 0.0001 | 10  | 0                       | 0.0001          | 0.001           |
| (10,9,9)  | 0.01, 0.001, 0.0001 | 8   | 0                       | 0.0001          | 0.001           |
| (10,10,0)   | 0.01, 0.001, 0.0001 | 10  | 4                       | 0.01            | 0.1             |
| (10,10,1)   | 0.01, 0.001, 0.0001 | 9   | 4                       | 0.01            | 0.1             |
| (10,10,2)   | 0.01, 0.001, 0.0001 | 8   | 4                       | 0.01            | 0.1             |
| (10,10,3)   | 0.01, 0.001, 0.0001 | 9   | 5                       | 0.01            | 0.1             |
| (10,10,4)   | 0.01, 0.001, 0.0001 | 6   | 4                       | 0.01            | 0.1             |
| (10,10,5)   | 0.01, 0.001, 0.0001 | 7   | 0                       | 0.0001          | 0.001           |
| (10,10,6)   | 0.10, 0.01, 0.001   | 10  | 2                       | 0.01            | 0.1             |
| (10,10,7)   | 0.10, 0.01, 0.001   | 8   | 2                       | 0.01            | 0.1             |
| (10,10,8)   | 0.10, 0.01, 0.001   | 10  | 3                       | 0.01            | 0.1             |
| (10,10,9)   | 0.10, 0.01, 0.001   | 8   | 3                       | 0.01            | 0.1             |