

## 一次性使用采样器（VTM）有效期延长声明

### Disposable sampler（VTM） validity extension statement

一次性使用采样器（VTM），通过 18 个月的实时老化数据监测和跟踪，进行了三个平行批次产品的性能研究测试，均符合产品质量标准。

现我司生产的一次性使用采样器（VTM），有效期 12 个月可以延长至 18 个月。

Through 18 months of real-time aging data monitoring and tracking, the performance of three parallel batches of VTM products were tested, and all of them met the product quality standards.

The validity period of the disposable sampler (VTM) produced by our company can be extended from 12 months to 18 months.

特此声明！

Hereby declare!

无锡耐思生命科技股份有限公司



2021 年 03 月 01 日

| VTM (Viral Transport Medium) |   |
|------------------------------|---|
| 202011                       | Disposable Sampler, 5 mL Vial with 2.5 mL VTM, with Individually Wrapped and Sterile Oropharyngeal Swab, 10 Vials/pk, 50 Vials + 50 Swabs/cs                |
| 202015                       | Disposable Sampler, 5 mL Vial with 2.5 mL VTM, with Individually Wrapped and Sterile Nasopharyngeal Swabs, 10 Vials/pk, 50 Vials + 50 Swabs/cs              |
| 202014                       | Disposable Sampler, 5 mL Vial with 2.5 mL VTM, with Individually Wrapped and Sterile Nasopharyngeal Swabs, 1 Vial + 1 NP Swab/pk, 50 pk/cs                  |
| 202016                       | Disposable Sampler, 10 mL Vial with 3 mL VTM, with Individually Wrapped and Sterile Oropharyngeal Swabs, 1 Vial + 1 Oral Swab/pk, 100 pk/cs                 |
| 202017                       | Disposable Sampler, 10 mL Vial with 3 mL VTM, with Individually Wrapped and Sterile Nasopharyngeal Swabs, 1 Vial + 1 NP Swab/pk, 100 pk/cs                  |
| 202019                       | Disposable Sampler, 5 mL Vial with 2.5 mL VTM, with Individually Wrapped and Sterile Oropharyngeal & Nasopharyngeal Swabs, 1 Vial + 1 NP Swab/pk, 100 pk/cs |
| 202018                       | Disposable Sampler, 10 mL Vial with 3 mL VTM, with Individually Wrapped and Sterile Oropharyngeal & Nasopharyngeal Swabs, 1 Vial + 1 NP Swab/pk, 100 pk/cs  |
| 202115                       | Disposable Sampler, 5 mL Vial with 2.5 mL VTM, 10 Vials/pk, 100 Vials/cs  |
| 202117                       | Disposable Sampler, 10 mL Vial with 3 mL VTM, 10 Vials/pk, 100 Vials/cs   |

|                       |         |   |                     |         |                              |
|-----------------------|---------|---|---------------------|---------|------------------------------|
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|                       | Email   | : info@nest-wuxi.com                                    |                     | Email   | : info@nestscientificusa.com |
|                       | Website | : www.cell-nest.com                                     |                     | Website | : www.nestscientificusa.com  |
|                       | Add     | : No.230, xida road, new district, Wuxi, Jiangsu, China |                     | Add     | : 3 Convery Blvd, Unit 600,  |
|                       |         |   |                     |         | Woodbridge NJ 07095, USA     |

## Reserved sample pooled analysis

| Name          | Disposable sampler                             |   | Date                | 2019-08-12          |           |
|---------------|--|---|---------------------|---------------------|-----------|
| Cat.No.       | 202015   |   | Lot                 | 081019P01           |           |
| specification | 10 vials/pk, 1 Swab/pk<br>50 vials+50 Swabs/cs |   | quantity            | 500 vials and swabs |           |
| No            | Test items and standards                       |   | observation results |                     |           |
|               |  |   | 6 months            | 12months            | 18months  |
| 1             | Appearance                                     | Clear liquid, red, no solid impurities  | Yes                 | Yes                 | Yes       |
| 2             | pH   | 7.1-7.5   | 7.36±0.03           | 7.34±0.03           | 7.41±0.05 |
| 3             | Quantity                                       | Not less than the indicated amount  | Yes                 | Yes                 | Yes       |
| 4             | Sterile  | Sterile   | Yes                 | Yes                 | Yes       |
| 5             | Sample Preservation Effect                     | Parainfluenza Virus 2 and Adenovirus were used to verify the preservation ability of NEST VTM. 2*LoD concentration of the virus samples were stored in NEST VTM at 2°C-8°C, and the PCR nucleic acid tests were performed at 48 h storage time. The test result should be positive. | Yes                 | Yes                 | Yes       |
| Note          |  |   |                     |                     |           |
| Conclusion    |  | The disposable sampler was stored for 18 months and the test results were qualified   |                     |                     |           |
| Operator      | 赵翔   | Date  | 2021.02.20          |                     |           |
| Review        | 张芹   | Date  | 2021.2.22           |                     |           |
| Approval      | 杨  | Date  | 2021.2.22           |                     |           |



## Reserved sample pooled analysis

| Name          | Disposable sampler                             |   | Date                | 2019-08-22          |           |
|---------------|--|---|---------------------|---------------------|-----------|
| Cat.No.       | 202015   |   | Lot                 | 082019P01           |           |
| specification | 10 vials/pk, 1 Swab/pk<br>50 vials+50 Swabs/cs |   | quantity            | 500 vials and swabs |           |
| No            | Test items and standards                       |   | observation results |                     |           |
|               |  |   | 6 months            | 12months            | 18months  |
| 1             | Appearance                                     | Clear liquid, red, no solid impurities  | Yes                 | Yes                 | Yes       |
| 2             | pH   | 7.1-7.5   | 7.35±0.04           | 7.31±0.02           | 7.40±0.04 |
| 3             | Quantity                                       | Not less than the indicated amount  | Yes                 | Yes                 | Yes       |
| 4             | Sterile  | Sterile   | Yes                 | Yes                 | Yes       |
| 5             | Sample Preservation Effect                     | Parainfluenza Virus 2 and Adenovirus were used to verify the preservation ability of NEST VTM. 2*LoD concentration of the virus samples were stored in NEST VTM at 2°C-8°C, and the PCR nucleic acid tests were performed at 48 h storage time. The test result should be positive. | Yes                 | Yes                 | Yes       |
| Note          |  |   |                     |                     |           |
| Conclusion    |  | The disposable sampler was stored for 18 months and the test results were qualified   |                     |                     |           |
| Operator      | 袁静   | Date  | 2021.02.25          |                     |           |
| Review        | 张芹   | Date  | 2021.2.26           |                     |           |
| Approval      | 杨  | Date  | 2021.2.26           |                     |           |



## Reserved sample pooled analysis

| Name          | Disposable sampler                             |   | Date                | 2019-08-25          |           |
|---------------|--|---|---------------------|---------------------|-----------|
| Cat.No.       | 202015   |   | Lot                 | 082319P01           |           |
| specification | 10 vials/pk, 1 Swab/pk<br>50 vials+50 Swabs/cs |   | quantity            | 500 vials and swabs |           |
| No            | Test items and standards                       |   | observation results |                     |           |
|               |  |   | 6 months            | 12months            | 18months  |
| 1             | Appearance                                     | Clear liquid, red, no solid impurities  | Yes                 | Yes                 | Yes       |
| 2             | pH   | 7.1-7.5   | 7.29±0.03           | 7.34±0.03           | 7.36±0.02 |
| 3             | Quantity                                       | Not less than the indicated amount  | Yes                 | Yes                 | Yes       |
| 4             | Sterile  | Sterile   | Yes                 | Yes                 | Yes       |
| 5             | Sample Preservation Effect                     | Parainfluenza Virus 2 and Adenovirus were used to verify the preservation ability of NEST VTM. 2*LoD concentration of the virus samples were stored in NEST VTM at 2°C-8°C, and the PCR nucleic acid tests were performed at 48 h storage time. The test result should be positive. | Yes                 | Yes                 | Yes       |
| Note          |  |   |                     |                     |           |
| Conclusion    |  | The disposable sampler was stored for 18 months and the test results were qualified   |                     |                     |           |
| Operator      | 赵静   | Date  | 2021.02.26          |                     |           |
| Review        | 张芳   | Date  | 2021.3.1            |                     |           |
| Approval      | 杨  | Date  | 2021.3.1            |                     |           |

