

## 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

## Reserved sample pooled analysis

Name	Disposable sampler	Date	2019-08-12		
Cat.No.	202015	Lot	081019P01		
specification	10 vials/pk, 1 Swab/pk 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℃-8℃, 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	赵辉	Date	2021.02.20		
Review	张芹	Date	2021.2.22		
Approval	张芹	Date	2021.2.22		



## Reserved sample pooled analysis

Name	Disposable sampler	Date	2019-08-22		
Cat.No.	202015	Lot	Q82019P01		
specification	10 vials/pk, 1 Swab/pk 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℃-8℃, 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	2021.02.25		
Review	张芳	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 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℃-8℃, 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		

