

# 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!





#### ISO9001 & ISO13485 & FDA

VTM (Vir	al 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
202013	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
202014	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
202010	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
202017	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
202019	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
202018	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

Tel Email Website 0510-6878 8698 / 6878 8718 info@nest-wuxi.com www.cell-nest.com Add

No.230, xida road, new district, Wuxi, Jiangsu, China

Tel Email Website Add

+1-732-381-0268 info@nestscientificusa.com www.nestscientificusa.com 3 Convery Blvd, Unit 600, Woodbridge NJ 07095, USA © Wuxi NEST Biotechnology Co., Ltd.



### Reserved sample pooled analysis

Name		Disposable sampler		Date		2019-08-12	
Cat.No.		202015		Lot	ot 081019P		D19P01
specification		10 vials/pk, 1 Swab/pk 50 vials+50 Swabs/cs		quant	ity	500 vials and sw	
				observation results			
No		Test items and standards			hs	12months	18months
1	Appearance	Clear liquid, red, no solid impurit	ties Yes			Yes	Yes
2	рН	7.1-7.5	7.36		.03	7.34±0.03	$7.41 \pm 0.05$
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 Adenoviru used to verify the preservation abilit NEST VTM. 2*LoD concentration of t virus samples were stored in NEST V 2°C-8°C, and the PCR nucleic acid te were performed at 48 h storage time test result should be positive.	y of the TM at	Yes		Yes	Yes
	Note			OEC	TION	SPECI	•
Conclusion		he disposable sampler was stored for 18 months and the test results were qualified					
Operator		友-昭	Date		021.02.20		
Review		友好 张芊	Date		wy. 2.22		
Approval		- FOR	Da	ite		2021. 2.23	



### Reserved sample pooled analysis

Name		Disposable sampler		Date	2019	2019-08-22	
Cat.No.		202015		Lot	082	082019P01	
specification		10 vials/pk, 1 Swab/pk 50 vials+50 Swabs/cs		quantity	500 vials	500 vials and swabs	
				observation results			
No		Test items and standards		6 months	12months	18months	
1	Appearance	Clear liquid, red, no solid impuri	ties	Yes	Yes	Yes	
2	рН	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 Adenoviruused to verify the preservation ability NEST VTM. 2*LoD concentration of virus samples were stored in NEST V 2°C-8°C, and the PCR nucleic acid to were performed at 48 h storage time test result should be positive.	preservation ability of concentration of the re stored in NEST VTM at PCR nucleic acid tests at 48 h storage time. The		Yes	Yes	
Note				DECTION SPECIA			
Conclusion		The disposable sampler was stored for 18 months and the text text to the way of the sample of the sa					
Operator		龙形	Date		2021.02.75		
Review		张芳	Da	ite	w21. 2.76		
Approval		trak	Da	ite	2021.2.26		



## Reserved sample pooled analysis

Name		Disposable sampler		Date	2019	2019-08-25	
Cat.No.		202015		Lot	082	082319P01	
specification		10 vials/pk, 1 Swab/pk 50 vials+50 Swabs/cs		quantity	500 vials	500 vials and swabs	
				observation results			
No	Test items and standards			6 months	12months	18months	
1	Appearance	Clear liquid, red, no solid impuri	iquid, red, no solid impurities		Yes	Yes	
2	рН	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	used to verify the preservation ability NEST VTM. 2*LoD concentration of virus samples were stored in NEST V 2°C-8°C, and the PCR nucleic acid to	rainfluenza Virus 2 and Adenovirus were ed to verify the preservation ability of ST VTM. 2*LoD concentration of the us samples were stored in NEST VTM at C-8°C, and the PCR nucleic acid tests are performed at 48 h storage time. The st result should be positive.		Yes	Yes	
	Note				CTION SPEC		
Conclusion		The disposable sampler was stored for 18 months and the test results were quadried 质检专用章					
Operator		支新	Date		2021.02.26		
Review		张芳	Da	ite	2021. 3·)		
Approval		- stool	Da	ite	221.3.1		