510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K211256

B Applicant

Wuxi Nest Biotechnology Co., Ltd.

C Proprietary and Established Names

Disposable Sampler Viral Transport Media

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JSM	Class I, reserved	21 CFR 866.2390 - Transport Culture Medium	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain substantial equivalence determination for the NEST Disposable Sampler (Viral Transport Media) device for the collection, transport, and storage of viral specimens for laboratory culture and downstream testing.

B Measurand:

Not Applicable

C Type of Test:

Non-propagating Transport Device with culture medium.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The NEST Disposable Sampler (Viral Transport Medium) is intended for the collection and transport of upper respiratory clinical specimens to the laboratory for standard diagnostic or identification techniques. The Viral Transport Medium can be used in the laboratory to perform culture, isolation and detection of upper respiratory viruses including Influenza A, Rhinovirus, and Respiratory Syncytial Virus (RSV).

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

None.

IV Device/System Characteristics:

A Device Description:

The Viral Transport Media is composed of media tube filled with VTM (Viral Transport Media), with or without swabs, depending on the kit configuration.

The Viral Transport Media is composed of Sodium chloride, Disodium hydrogen phosphate dodecahydrate, Potassium chloride, Potassium dihydrogen phosphate, Magnesium sulfate heptahydrate, glucose, HEPES, Sodium bicarbonate, Fluconazole, Gentamicin sulfate, Griseofulvin, Polymyxin sulfate, Sodium hydroxide, Calcium chloride, BSA, L-cysteine, and with or without Phenol red.

The preservation tube is made of medical-grade polypropylene materials. The pre filled VTM tubes are provided as 5 mL tubes filled with 2.5 mL VTM or 10 mL tubes filled with 3 mL VTM.

Both the 5mL and the 10mL size tubes filled with the volumes noted above are sold alone, kitted with either an oropharyngeal (OP) swab, a nasopharyngeal (NP)swabs or kitted with both OP and NP swabs. The OP and NP swabs are flocked nylon fiber with the swab shaft made of ABS (acrylonitrile butandiene styrene).

B Principle of Operation:

The Viral Transport Media consists of a universal transport medium that can sustain the viability of clinically important viruses. The media is intended to be used by trained health care professionals. The VTM contains proteins for stabilization, antibiotics to minimize bacterial and fungal growth, a buffer to maintain a neutral pH and a pH indicator (phenol red) which is optional.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Copan Universal Transport Medium (utm-rt) System

B Predicate 510(k) Number(s):
K042970

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K211256	Predicate: K042970
Device Trade Name	NEST Disposable Sampler Viral Transport Media	Copan universal transport medium (UTM-RT) system
General Device Characteristic Similarities		
Intended Use/Indications For Use	The NEST Disposable Sampler (Viral Transport Medium) is intended for the collection and transport of upper respiratory clinical specimens to the laboratory for standard diagnostic or identification techniques. The Viral Transport Medium can be used in the laboratory to perform culture, isolation and detection of upper respiratory viruses including Influenza A, Rhinovirus, and Respiratory Syncytial Virus (RSV).	Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasma or ureaplasma from the collection site to the testing laboratory. UTM-RT can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasma and ureaplasma culture.
Device Product Code and Classification	JSM, Class I	JSM, Class I
Shelf Life	12 months	12 months
pH	pH 7.3 ± 0.2 at 25ºC	pH 7.3 ± 0.2 at 25ºC
General Device Characteristic Differences		
Media formulation	HANK's Balanced Salts Solution, HEPES, Sodium bicarbonate, Fluconazole,	HANK's Balanced Salts, BSA, L-cysteine, gelatin, sucrose, L-glutamic acid, HEPES

	Gentamicin sulfate, Griseofulvin, Polymyxin sulfate, Phenol red, Sodium hydroxide, glucose, BSA and L-cysteine.	buffer, vancomycin, amphotericin B, colistin, phenol red
Vial Specification	5 mL vial: 2.5 mL VTM 10 mL vial: 3.0 mL VTM	1 mL UTM in 12x80 mm tube 3 mL UTM in 16x100 mm tube 10 mL UTM in 25x90 mm tube
Supported claims to perform culture, isolation and detection of:	Influenza A, Rhinovirus, and Respiratory Syncytial Virus (RSV)	chlamydiae, mycoplasma or ureaplasma and viruses
pH indicator	Optional	None

VI Standards/Guidance Documents Referenced:

1. ISO 10993-5(2009) Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

2. ISO 10993-10 (2010) Biological Evaluation of Medical Devices – Tests for irritation and skin sensitization.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Not Applicable

2. Linearity:

   Not Applicable

3. Analytical Specificity/Interference:

   Not Applicable

4. Assay Reportable Range:

   Not Applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Shelf-life: The shelf-life of the Viral Transport Media was determined in real-time to be 12 months when stored at 2-8ºC and 25 ± 3ºC. To assess the integrity of the kit, the following properties of the kit were assessed, at 5 replicates per timepoint, and had the following results. Three lots were assessed for the following categories:

a. The media was assessed for appearance. The Viral Transport Media remained a clear red color when assessed at 2-8ºC and 25 ± 3ºC at various time intervals out to 12 months.
b. pH was assessed using a pH meter to demonstrate that the Viral Transport Media maintain a pH between 7.3-7.5 when assessed at 2-8ºC and 25 ± 3ºC for 12 months.
c. Sterility was assessed by plating 100 µL of Viral Transport Media stored at 2-8ºC and 25 ± 3ºC at various time intervals out to 12 months, on PCA plates. The media showed no microbial growth at any of the time points tested.
d. The integrity of the antimicrobial components in the medium was assessed via a bacterial growth inhibition (bacteriostasis) study. The study demonstrated that media was bacteriostatic when the media was stored at 2-8ºC and 25 ± 3ºC for 12 months. The following organisms *E. coli, S. aureus, B. subtilis, C ablicans and A. niger*, were assessed and culture growth was determined to be inhibited through its claimed shelf life.

Sterilization:
The Viral Transport Media tube with media are not sold as sterile nor are they intended to be sterilized by the user. These vials are single use devices that do not require cleaning by the operator.

Swabs are sterilized in the final packaging using Irradiation Sterilization. Irradiation sterilization was performed using ISO 11137-1: 2015 and ISO 11137-2: 2016. A bioburden study was conducted, and it was determined that a 14.8 kGy dose of electron beam irradiation was required to reach a sterility assurance level of 10^{-6}.

6. Detection Limit:

Viral Recovery:
Culture-Based Viral Recovery Studies: Performance of the Viral Transport Media was evaluated for virus viability at different incubation times, temperatures, and 3 lots of media.

Viability Assay Layout. Strains of Respiratory syncytial virus Type A (RSV-A), Influenza A (A/PR/8/34 H1N1) virus, and Rhinovirus Type 16 (HRV-16) were used for media validation. Each virus was first mixed with nasopharyngeal matrix, transferred with the collection swab and then added to the Viral Transport Media to yield a final concentration of 10^5 $TCID_{50}$/mL. The mixtures were then incubated at 4°C and 25°C in triplicates. Aliquots of each replicate were recovered at 0, 24, or 48 hours and serially diluted. A 100 µL volume of each dilution was then inoculated in duplicate into the susceptible host cell line. Host cells (HEp-2 for RSV-A, MDCK for H1N1, and HeLa for HRV-16) were plated at a suitable density in microwell plates for 2-3 days prior to evaluation. The following controls were run: a viability control containing no virus to ensure mammalian cell integrity and absence of contamination; a virus control containing virus stock to ensure infectivity of virus; a cytotoxicity control containing VTM only to observe any cytotoxic effects from the VTM on the mammalian cells; and a recovery control containing virus in culture medium stored and tested under the same conditions as the test samples. Host cells and

diluted virus were incubated for 2-3 days, followed by fixation of the cells with Formalin for 1 hour and finally staining with methylene blue for 15 minutes. Viability was determined by assessing for plaque formation in triplicate for each time point tested. **Tables 1, 2, and 3** show the mean PFU/mL values for each virus tested at time 0 and different times and temperatures for viral recovery. The data supported the claim for storage times of 24 hours and 48 hours and temperatures of 4°C and 25°C.

Table 1: Viral recovery for Influenza A at various incubation times and tempearatures.

Test Virus	Test samples (lot #)	Test conditions	Mean Virus Titer ($x10^4$ PFU/mL)	Percent decrease (%)
Influenza A (A/PR/8/34 H1N1)	080921ES1	0h	83.4	-
		4ºC, 24h	70.5	15.47
		4ºC, 48h	61.3	26.50
		25ºC, 24h	66.4	20.38
		25ºC, 48h	44.7	46.40
	040121PS	0h	79.2	-
		4ºC, 24h	71.8	9.34
		4ºC, 48h	63.7	19.57
		25ºC, 24h	66.9	15.53
		25ºC, 48h	44.4	43.94
	101020E01	0h	92.3	-
		4ºC, 24h	79.1	14.30
		4ºC, 48h	73.5	20.37
		25ºC, 24h	74.3	19.50
		25ºC, 48h	60.2	34.78

Table 2: Viral recovery for Rhinovirus Type 16 at various incubation times and tempearatures.

Test Virus	Test samples (lot #)	Test conditions	Mean Virus Titer ($x10^4$ PFU/mL)	Percent decrease (%)
Rhinovirus Type 16 (HRV-16)	080921ES1	0h	231.7	-
		4ºC, 24h	213.8	7.73
		4ºC, 48h	204.5	11.74
		25ºC, 24h	168.5	27.28
		25ºC, 48h	124.7	46.18

	040121PS	0h	203.7	-
		4ºC, 24h	183.4	9.97
		4ºC, 48h	169.3	16.89
		25ºC, 24h	200.2	1.72
		25ºC, 48h	157.8	22.53
	101020E01	0h	176.5	-
		4ºC, 24h	169.8	3.80
		4ºC, 48h	154.3	12.58
		25ºC, 24h	114.0	35.41
		25ºC, 48h	93.8	46.86

Table 3: Viral recovery for Respiratory Syncytial Virus Type A at various incubation times and tempearatures.

Test Virus	Test samples (lot #)	Test conditions	Mean Virus Titer ($x10^4$ PFU/mL)	Percent decrease (%)
Respiratory Syncytial Virus Type A (RSV-A)	080921ES1	0h	26.8	-
		4ºC, 24h	22.0	17.91
		4ºC, 48h	20.0	25.37
		25ºC, 24h	23.2	13.43
		25ºC, 48h	21.0	21.64
	040121PS	0h	31.0	-
		4ºC, 24h	24.0	22.58
		4ºC, 48h	21.2	31.61
		25ºC, 24h	24.8	20.00
		25ºC, 48h	16.2	47.74
	101020E01	0h	33.5	-
		4ºC, 24h	26.3	21.49
		4ºC, 48h	25.7	23.28
		25ºC, 24h	23.8	28.96
		25ºC, 48h	26.7	20.30

Results of Viability Assay. The Viral Transport Media demonstrated virus viability of Flu A (H1N1), RSV, Rhinovirus for all replicates in all lots, incubation times, and storage

temperatures. The studies demonstrate that the VTM maintains the viability of all viruses tested for 48 hours at refrigerated (4°C) and room temperature (25°C).

7. Assay Cut-Off:

   Not Applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not Applicable

2. Matrix Comparison:

   Not Applicable

C Clinical Studies:

1. Clinical Sensitivity:

   Not Applicable

2. Clinical Specificity:

   Not Applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not Applicable

D Clinical Cut-Off:

Not Applicable

E Expected Values/Reference Range:

Not Applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.