510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K233534

B Applicant

Hardy Diagnostics

C Proprietary and Established Names

Viral Transport Medium

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 Hardy Diagnostics' Viral Transport Medium for collection and transport of viral organisms for standard laboratory culture and testing.

B Measurand:

Not applicable.

C Type of Test:

Non-propagating transport culture medium.

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
Hardy Diagnostics' Viral Transport Medium (VTM) is intended for the collection and transport of clinical specimens for the preservation of viral agents including, Influenza A, Influenza B, Adenovirus, and Echovirus from the collection site to the testing laboratory. Hardy Diagnostics' VTM is a culture-based media that is intended to be used for standard laboratory procedures of virus culture and diagnostic assays which utilize stable recoverable infectious viral particles.

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 Hardy Diagnostics Viral Transport Medium is a non-propagating transport media used for the collection and transport of clinical specimens suspected of containing viruses for viral culture and detection. The VTM consists of Hank's Balanced Salt Solution, a buffer to maintain a neutral pH, and fetal bovine serum, sucrose for specimen stabilization, along with Amphotericin B and Gentamicin Sulfate to inhibit bacterial and fungal growth. VTM also contains a pH indicator (phenol red) to provide a visual check on medium pH. The VTM appears translucent and light peach in color.

The Hardy Diagnostics Viral Transport Medium includes a polypropylene screw-cap tube with skirted conical bottom containing 3mL of transport medium. The product is supplied in multiple configurations described in table 1 below: tubes alone, or in a kit format with a swab.

Table 1. List of Configurations: Hardy Diagnostics' Viral Transport Medium

Catalog Number	Description	Quantity
R99	VTM, 16 × 100mm polypropylene tube, 3mL fill	20 tubes/box
R64BX	VTM, 13 × 80mm polypropylene tube, 3mL fill	100 tubes/box
TPV50	TransPRO VTM System, single 16×100mm polypropylene tube, 3mL fill with individually wrapped, sterile, mini-tip, flocked swab with 80mm breakpoint.	50 each/box

B Principle of Operation:
Clinical specimens are aseptically collected using swabs (polyester (Dacron), rayon, or flocked nylon) and shafts (plastic or flexible wire) that are non-toxic to viral agents. Swabs with a scored breakpoint at or less than 100 mm are recommended. The TransPRO Viral Transport Medium (VTM) System includes an individually wrapped, sterile, mini-tip flocked swab with an 80mm

breakpoint. After collection of specimens, cap is removed from the tube and swab is inserted into the media. The swab shaft is cut with scissors or broken off by bending the shaft at the scored breakpoint against the rim of the tube. The us swab shaft is required to be below the rim of the tube to facilitate proper cap closure of the tube. The tubes may then be stored or transported at the permissible temperature.

Hardy Diagnostics' VTM has the following ingredients.

- Hank's Balanced Salts Solution (HBSS)
- Bovine Serum Albumin
- Amphotericin B
- Gentamicin Sulfate
- L-Glutamic Acid
- Sucrose
- Phenol Red

HBBS, bovine albumin, and sucrose provide stabilization to the specimen. Gentamicin Sulfate and Amphotericin B inhibit bacterial and fungal contamination, respectively. Phenol red functions as a pH indicator.

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: K233534	Predicate: K042970
Device Trade Name	Hardy Diagnostics Viral Transport Medium	Copan Universal Transport Medium (UTM-RT) System
Device Product Code and Classification	JSM, Class 1	JSM, Class 1
General Device Characteristic Similarities		
Intended Use/Indications For Use	Hardy Diagnostics' Viral Transport Medium (VTM) is intended for the collection and transport of clinical specimens	Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimens

	for the preservation of viral agents including, Influenza A, Influenza B, Adenovirus, and Echovirus from the collection site to the testing laboratory. Hardy Diagnostics' VTM is a culture-based media that is intended to be used for standard laboratory procedures of virus culture and diagnostic assays that utilize stable recoverable infectious viral particles.	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.
Tube Material	Plastic Screw-Cap Tube	Same
pH	7.3 ± 0.2 at 25ºC	Same
Shelf-life	12 months or 365 days	Same
Storage Temperature	2-25ºC	Same
Single Use Device	Yes	Same
General Device Characteristic Differences		
Media Formulation	• Hank's Balanced Salts Solution (HBSS) • Bovine Serum Albumin • Amphotericin B • Gentamicin Sulfate • L-Glutamic Acid • Phenol Red • Sucrose	• Hank's Balanced Salts solution (HBSS) • Bovine Serum Albumin (BSA) • Vancomycin • Amphotericin B • Colistin • L-Glutamic Acid • L-Cysteine • HEPES Buffer • Phenol Red • Gelatin • Sucrose
Supported Strains	• Adenovirus • Echovirus • Influenza A • Influenza B	• Adenovirus • Cytomegalovirus • Echovirus Type 30 • Herpes Simplex Virus Type 1 • Herpes Simplex Virus Type 2 • Influenza A • Parainfluenza 3

		• Respiratory Syncytial Virus • Varicella Zoster Virus • *Chlamydia pneumoniae* • *Chlamydia trachomatis* • *Mycoplasma hominis* • *Mycoplasma pneumoniae* • *Ureaplasma urealyticum*

VI Standards/Guidance Documents Referenced:

Not applicable.

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:
To evaluate Shelf-life, real-time stability studies were conducted with Hardy Diagnostics' VTM lots in a real-time aging study at 2-8°C and 20-25°C. Three VTM lots were tested qualitatively for appearance (e.g., visual inspection for turbidity, precipitation, color, etc.), pH (acceptable range: 7.3 ± 0.2), fill volume (measured by weight), virus viability at every month from 0 to 12 months. All results met the study acceptance criteria and support a shelf-life stability of Hardy Diagnostics' VTM for up to 12 months at 2-25°C.

6. Detection Limit:

Performance Testing - Recovery Studies:

The performance of Hardy Diagnostics Viral Transport Medium (VTM) was evaluated for culture-based recovery of Influenza A, Influenza B, Echovirus, Adenovirus, and Respiratory Syncytial Virus (RSV). Pooled negative clinical matrix was spiked with known concentration of virus and then the contrived viral samples were transferred with swabs into subject VTM and held at 2-8°C and 20-25°C for 0, 24, and 48 hours. The viral recovery study was conducted with three variously aged lots of 3 ml VTM covering the claimed shelf-life. At the end of each time point media stored under each temperature range, an aliquot of incubated samples were serially diluted, and inoculated in triplicate into the susceptible host cell line. After 24-72 hours, Viral quantification was determined by microscopic observation of virus induced CPE to determine the fifty-percent tissue culture infective dose ($TCID_{50}$/mL) using the Reed-Muench method. Results were considered acceptable if the average viral recovery for each time point and storage condition demonstrate any percent changes within ±90% (i.e., 1 log change) from baseline (T=0).

Table 2 and Table 3 below exhibit the viral recovery performance of the Hardy Diagnostics Viral Transport Medium at 20-25°C and at 2-8°C respectively.

Table 2: Viral recovery performance of Hardy Diagnostics Viral Transport Medium at 20-25°C

Test Strain	Viral recovery ($TCID_{50}$/mL) at T=0 hr.	Percent changes in viral recovery from the baseline (T= 0 hr.) (-ve indicates reduction)	
		24 hrs.	48 hrs.
Influenza A	$2.12x10^3$	-92.24*	-59.76
Influenza B	$7.23x10^2$	-23.86	-3.45
Echovirus	$1.40x10^5$	-20.55	-25.23
Adenovirus	$1.92x10^3$	18.11	-7.71

* Considered acceptable because subsequent timepoints, i.e., 48 h time point showed < 90% increase.

Table 3: Viral recovery performance of Hardy Diagnostics Viral Transport Medium at 2-8°C

Test Strain	Viral recovery ($TCID_{50}$/mL) at T=0 hr.	Percent Changes in viral recovery from the baseline (T= 0 hr.) (-ve indicates reduction)	
		24 hrs.	48 hrs.
Influenza A	$1.32x10^3$	-5.98	-58.59
Influenza B	$8.05x10^2$	-36.32	-44.27
Echovirus	$1.27x10^5$	21.91	-3.98
Adenovirus	$1.47x10^3$	-20.19	23.11

The viral recovery study results support the recovery of the tested viruses for up to 48 hours from collection when samples are stored in the Hardy Diagnostics Viral Transport Medium at 2-8°C or at room temperature (20-25°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.