510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K220908

B Applicant

Ensol Biosciences Inc.

C Proprietary and Established Names

Ensol EnTM Specimen Collection and Transport System

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 EnTM Collection and Transport System 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

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Ensol EnTM Collection and Transport System is intended for the collection and transportation of clinical samples containing upper respiratory viruses including Influenza A, Human Coronavirus 229E, and Respiratory Syncytial Virus (RSV) from the collection site to the testing laboratory to be used with standard diagnostic/identification techniques that utilize stable recoverable infectious viral particles.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

IV Device/System Characteristics:

A Device Description:

The EnTM Collection and Transport System medium consists of a polypropylene conical tube filled with 2 ml of the transport medium (pale brown to red color medium solution), affixed with a polyethylene screw cap. The bottom part of the tube has a self-standing shape. Tubes are provided in a paper rack. The media tubes can be provided with one or two kinds of sterile specimen collection swabs, one for oropharyngeal (OP) oral use and the other nasopharyngeal (NP) for nasal use. The swab shaft is polystyrene with a breaking point, and the swab tip is flocked nylon fibers. The media is provided in two different configurations with and without the sterile peel pouch containing swabs as shown below:

Cat No.	Tube with VTM	Swab	Packaging
ES-TM-01	2 mL of VTM solution in 16 x 105 mm conical shape bottom screw-cap tube	One applicator NP swab with flocked nylon fiber tip with breaking point One applicator throat swab with flocked nylon fiber tip with breaking point Both swabs packaged together in a sterilized peel pouch	50 tubes with culture medium per box 50ea, NP swabs 50ea. OP swabs
ES-TM-02	2 mL of VTM solution in 16 x 105 mm conical shape bottom screw-cap tube	No swabs	50 tubes with culture medium per box

B Principle of Operation:

The EnTM Collection and Transport System is an osmotically balanced and buffered medium that contains Hank's balanced salt solution. Also, the medium contains a pH indicator, a protein stabilizer, sucrose as a preservative and antibiotics to prevent contamination from bacteria or fungi. The EnTM Collection and Transport System is used to safely collect and transport upper

respiratory viruses from collection sites to the testing laboratories. It is intended to be used by health care professionals.

After collecting a specimen using the swab, the swab is placed into the uncapped polypropylene tube filled with 2 mL of the transport medium, the swab shaft is broken off at the breakpoint by hand and the tube is capped closed. The swab specimen can be stored in the collection medium for up to 48 hours at 4°C. The swab specimen is ready for use in diagnostic to determine the presence of a target pathogen. Sample collection is performed by health care professionals.

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: K220908	Predicate: K042970
Device Trade Name	Ensol EnTM Collection and Transport System	Copan Universal Transport Medium (UTM-RT) System
Device Product Code and Classification	JSM	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Ensol EnTM Collection and Transport System is intended for the collection and transportation of clinical samples containing upper respiratory viruses including Influenza A, Human Coronavirus 229E, and Respiratory Syncytial Virus (RSV) from the collection site to the testing laboratory to be used with standard diagnostic/identification techniques that utilize stable recoverable infectious viral particles.	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.

Tube material	Polypropylene Plastic	Same
Shelf Life	12 months	Same
General Device Characteristic Differences		
Ingredients	Modified Hank's Balanced Salts with calcium and magnesium ions Sucrose Bovine serum albumin HEPES Gelatin L-Cysteine L-Glutamic acid Gentamicin sulfate Amphotericin B Vancomycin Colistin sulfate salt Phenol Red sodium salt	Hank's Balanced Salts, Sucrose, Bovine serum albumin, HEPES Buffer Gelatin L-Cysteine L-Glutamic acid Amphotericin B Vancomycin Colistin Phenol Red
Device Storage Temperature	25°C	2 - 25°C
Specimen Storage	48 hours when stored at 4°C.	48 hours at 2 - 25°C
Supported strains	Influenza A, Human Coronavirus 229E, Respiratory Syncytial Virus (RSV)	Adenovirus, Cytomegalovirus Echovirus Type 30, Herpes Simplex Virus Type 1, Herpes Simplex Virus Type 2, Influenza A, Parainfluenza 3, Respiratory Syncytial Virus, *Chlamydia pneumoniae,* *Chlamydia trachomatis,* *Mycoplasma hominis*

VI Standards/Guidance Documents Referenced:

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 stability: The shelf life for the EnTM Collection and Transport System was determined to be 12 months from the date of manufacture when stored at temperatures 25°C. The shelf life of the EnTM Collection and Transport Medium was evaluated using real-time aging performance test.

   Physical Stability: Physical stability was evaluated by Appearance, UV spectrum analysis (Scan: absorbance at 250-800 nm), and pH measurement at time points T = 0, 6, and 12 months using three lots stored at 25°C. The appearance was evaluated by inspecting visually to examine for a red and clear solution (translucent with no turbidity). Appearance results were acceptable for all lots at all storage times. To detect any physical changes in the media, UV Spectrum analysis was conducted by setting the wavelength range to 250-800 nm (scan). The UV spectrum scanning analysis for 250-800 nm produced similar results for all lots at all storage times. Absorbance at 290 nm was also measured for any physical changes and results showed no changes and produced similar results for all lots at all storage times. For pH measurement study, all the transport media demonstrated pH level within 7.4±1 for all lots at all storage times.

   Sterility test: The EnTM Collection and Transport System is not claimed to be sterile nor is it intended to be sterilized by the end user. To reduce contamination, the screw-cap tube is sterilized by irradiation with a maximum dose of 40 kGy using the E-beam irradiation process. A check for possible contamination was conducted by transferring transport media to growth medium Thioglycolate and incubated 35ºC for 3 days, and in Tryptic Soy Broth at 25ºC for 5 days and examined for growth turbidity. No bacterial or fungal proliferation was detected at either condition tested.

   No testing was performed at lower than 25ºC. Even though additional testing was conducted at higher temperatures (40ºC), the data was not required, and no claim was granted but the data supported stability at 12 months. The shelf-life study report supports the stability of the EnTM Collection and Transport System at room temperature 25°C for 12 months.

6. Detection Limit:

Viral Recovery:

Culture-Based Viral Recovery Study: Performance of the EnTM Collection and Transport System media was evaluated for virus viability at refrigerated temperatures (4 °C). Three lots of VTM with newly manufactured, middle-aged lot and close to expiry lots were used to evaluate viral recovery (ENTM-22001, ENTM-22003, and ENTM-23001). Influenza A (California/07/2009 H1N1, NCCP 42467), Human coronavirus 229E (Zeptometrix 0810229CF), and Human respiratory syncytial virus type A (type A strain Long, ATCC VR-26) were used for the viral recovery study. Each virus was diluted in pooled negative nasopharyngeal matrix transferred to the collection swab and then added to the Viral Transport Media. Aliquots of each replicate were stored at 4°C for 0, 24, and 48 hours. Host cells (MDCK for Influenza A, MRC-5 for Human coronavirus, and HEp-2 for Human respiratory syncytial virus type A) were plated for 1 day. At each timepoint the viral samples from EnTM were serially diluted and inoculated onto the host cell-line and cultured in a 96 well plate. The plates were incubated at 37°C and viral CPE was observed after 4-5 days. Viral titer was determined by the Reed-Muench method calculation of $TCID_{50}$ (50% tissue culture infective dose).

Results were considered acceptable if the average viral titer demonstrates any percent changes within ±90% (i.e.,1 log change). The results are presented in the Table 1. Any changes in the viral titer in the timepoints was shown as percent changes and negative percent change indicates reduction.

Table 1: Recovery of Viruses at 4˚C storage.

Test Virus	Lot	Average Virus Titer ($TCID_{50}$/mL)			Percent Changes (0 to 24 hrs.) *	Percent Changes (0 to 48 hrs.) *
		0 hr.	24 hrs.	48 hrs.		
Influenza A	ENTM-22001	3.58E+07	6.49E+06	9.07E+06	-81.84%	-74.64%
	ENTM-22003	2.80E+07	1.07E+07	1.33E+07	-61.70%	-52.53%
	ENTM-23001	3.34E+07	1.35E+07	6.04E+06	-59.53%	-81.89%
Human Coronavirus 229E	ENTM-22001	1.11E+04	1.16E+04	1.18E+04	3.73%	5.58%
	ENTM-22003	1.93E+04	2.36E+04	8.04E+03	22.25%	-58.41%
	ENTM-23001	1.14E+04	1.08E+04	8.87E+03	-5.69%	-22.36%
Respiratory Syncytial Virus	ENTM-22001	7.20E+05	5.20E+05	6.65E+05	-27.73%	-7.66%
	ENTM-22003	8.71E+05	4.05E+05	7.02E+05	-53.47%	-19.43%
	ENTM-23001	1.06E+06	3.72E+05	5.82E+05	-64.99%	-45.26%

*-ve indicates decline.

EnTM Collection and Transport System media demonstrated the recovery of viruses at 4˚C storage when evaluated for 48 hrs. in all replicates of tested viral strains (Influenza A, Human Coronavirus 229E, and Respiratory Syncytial Virus). All the results appear acceptable and support specimen transport for up to 48 hours when stored at 4˚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):

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.