510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K232357

B Applicant

Copan Italia S.p.A.

C Proprietary and Established Names

Copan Universal Transport Medium (UTM-RT) System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JSM, LIO	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 Copan Universal Transport Medium (UTM-RT) for a new Intended Use claim of stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing respiratory viruses' nucleic acids (to add on to the existing Intended Use of the previously cleared device) under the same device name.

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:

Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimen 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.

UTM-RT is intended for the stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing respiratory viruses' nucleic acids. UTM-RT is intended for use with compatible molecular assays.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

Do not freeze specimens intended to be processed for nucleic acids investigations. Stability of nucleic acids when frozen in UTM-RT has not been evaluated and validated.

D Special Instrument Requirements:

Not Applicable

IV Device/System Characteristics:

A Device Description:

The candidate device, Copan UTM-RT, is provided in a screw capped, conical bottom, polypropylene tube filled with 3mL of UTM-RT transport medium. Copan UTM-RT is supplied in either of two (2) configurations, namely, medium tube alone in a paper-film peel pouch (bulk configuration), or medium tube accompanied by sterile flocked swab in a peel pouch for specimen collection (kit configuration). In the kit configuration, the flocked swab is available in three (3) shapes—i.e., regular, minitip, and minitip flexible —that are suitable for specimen collection from various sites on patient, including the upper respiratory cavity. Further, the medium tube for both the swab configurations above can be provided with or without glass beads inside. The medium tube with beads will be distinguished from tube without beads by the wording "with beads" written in the product description on tube and external labels, as well as in other labeling materials.

The screw cap of the UTM-RT medium tube has a unique internal molded design that is able to capture a swab shaft when the shaft is broken off into the tube and cap is closed. The flocked specimen collection swab (provided sterile in a paper-peel pouch with UTM-RT medium in the kit configuration) has a tip flocked with nylon fiber and a solid plastic shaft with a molded breaking point. The nylon flocked swab along with its plastic shaft is the only component that may come in transient (typically < 1 minute) contact with patient tissue (e.g., mucosal surfaces) during use in specimen collection. After the specimen is collected, the swab shaft is broken off at the breaking point such that the swab with the collected specimen remains within the medium tube.

B Principle of Operation:

The UTM-RT medium is designed to maintain the integrity and viability of viruses, chlamydiae, mycoplasma, or ureaplasma and the integrity of nucleic acids for upper respiratory viruses.

Composition of the UTM-RT medium:

Modified Hank's Balanced Salts	HEPES Buffer 1M
Bovine Serum Albumin	Vancomycin
L-Cysteine Hydrochloride	Amphotericin B
Sodium Bicarbonate	Colistin
Gelatin	Phenol Red
Sucrose	Distilled Water
L-Glutamic Acid	

Specimens preserved in UTM-RT transport media are suitable for testing with subsequent culture procedure (all clinical specimens) or molecular amplification (limited to upper respiratory clinical specimens suspected of containing nucleic acids from respiratory viruses).

V Substantial Equivalence Information:

A Predicate Device Name(s):
Merit Medical Systems Cultura Collection and Transport System

B Predicate 510(k) Number(s):
K201674

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device (K232357)	Predicate (K201674)
Device Trade Name	Copan Universal Transport Medium (UTM-RT) System	Merit Medical Systems Cultura Collection and Transport System
Manufacturer	Copan Italia S.p.A.	Merit Medical Systems, Inc.
General Device Characteristic Similarities		
Intended Use/Indications For Use	Copan Universal Transport Medium (UTM-RT) System is intended for the collection and transport of clinical specimen 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. UTM-RT is intended for the stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing respiratory viruses' nucleic acids. UTM-RT is intended for use with compatible molecular assays.	The Merit Cultura Collection and Transport System is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic/identification techniques. The Merit Cultura Collection and Transport System is a culture-based media that can be used for upper respiratory viral diagnostic assays including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus.

Device & Predicate Device(s):	Device (K232357)	Predicate (K201674)
Tube and cap material	Plastic	Same
Swab material	Various flocked nylon applicators on a plastic shaft with break point	Same
Media Volume	3 mL	Same
Single use device	Yes	Same
Principle of operation	Culture-based medium for maintenance of target microorganism viability and integrity. The specimen can be tested with culture- based technique and/or with PCR-based technique.	Same
General Device Characteristic Differences		
Shelf-life	18 months	12 months
Media list of ingredients	Hank's Balanced Salt Solution, bovine serum albumin, L-cysteine, gelatin, L-glutamic acid, HEPES buffer, phenol red, sucrose, vancomycin, amphotericin B and colistin	Hank's Balanced Salt Solution (HBSS), Fetal Bovine Serum (FBS), D-glucose, Phenol Red, Gentamicin sulfate and Amphotericin B
Specimen transport conditions and storage time	Up to 96 hours at 2–25°C.	Up to 120 hours at 2–25°C.

VI Standards/Guidance Documents Referenced:

Not applicable to the current studies.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility; Linearity; Analytical Specificity/Interference; Assay Reportable Range; Traceability; Expected Values (Controls, Calibrators, or Methods); Assay Cut-off:

   Not Applicable

2. Stability/Shelf life:

   The previously cleared device (K042970) has a shelf-life of 18-months. For the candidate device, no changes were made to the manufacturing of the UTM-RT transport medium or kit components, and no extension of the shelf-life was claimed. The existing shelf-life stability validation data from the original clearance remains appropriate to support an 18-month shelf life claim for the candidate device.

3. Detection Limit:

Performance Testing – Culture Recovery Studies:

Performance of the Copan Universal Transport Medium (UTM-RT) System was evaluated by culture-based recovery studies for viral and bacterial test strains under and the results were deemed acceptable during the clearance of the original device, K042970. Since the medium tube (container), UTM-RT media composition, and other kit components remain unchanged, and no extension of the specimen stability is being claimed, a new set of performance evaluation for specimen stability via culture recovery is not required for the current candidate device (K232357).

Performance Testing – Nucleic Acid Stability Studies:

To support the new intended use claim, *"UTM-RT is intended for the stabilization and transportation of an unprocessed upper respiratory clinical specimen suspected of containing respiratory viruses' nucleic acids. UTM-RT is intended for use with compatible molecular assays"*, the sponsor conducted fresh studies to determine the LoD of molecular detection of three (3) representative target viral nucleic acids—namely, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV)—followed by specimen stability studies in the candidate transport medium system. These stability studies, performed both in cold (2–8ºC) and at room temperature (22–28ºC), utilized variously aged lots (as available) of UTM-RT provided in medium tubes with and without glass beads as shown below in **Table 1**.

Table 1: ***Use of UTM-RT media lots in stability studies***

UTM-RT	Number of lots used (as available)	Lot age designation	Lot age (in months from production) at testing
With Beads	Four (4)	New	1–4.2
	Two (2)	Middle-Aged	12.9–13.5
	Nine (9)	Old / Expired	20.3–22.7
Without Beads	Three (3)	New	0.8–1.4
	Three (3)	Middle-Aged	11.1–13.3
	Three (3)	Old / Expired	18.7–19.6

Further, the LoD and stability studies with the candidate device were performed in an artificial nasopharyngeal/nasal (referred to as "NPS/NS") fluid matrix. This simulated matrix was previously qualified as an appropriate matrix when used with Copan UTM/VTM since this was shown to be equivalent to clinical nasopharyngeal and anterior nasal matrices in Sample Matrix and Transport Media Equivalency studies performed to support clearance of the Cepheid *Xpert Xpress CoV-2/Flu/RSV plus* Assay (K231481). Therefore, the use of the same simulated matrix to support this transport medium candidate device was deemed appropriate, and the studies were designed and conducted accordingly.

As shown in the following summary **Tables 2–4**, the freshly performed stability tests with representative viral targets (as indicated above) demonstrated specimen stability for up to 96 hours during storage and/or transport at a temperature range of 2–25ºC in UTM-RT tubes with or without glass beads. Samples were tested using a compatible, representative, FDA-cleared molecular assay (i.e., Cepheid *Xpert Xpress CoV-2/Flu/RSV plus* Assay in combination with GeneXpert Dx) following the molecular assay's package insert. The cycle threshold (Ct) values were used to assess performance and calculate the difference in Ct values (ΔCt) at tested time

points relative to baseline (Time 0). Results were considered acceptable if a ΔCt < 3 was observed. Additionally, these studies established acceptable performance of the candidate device for UTM-RT medium aged up to 18 months by incorporating lots of different ages at the time of testing.

Table 2: ***Overall stability data for Influenza A1/A2 virus in lots of UTM-RT per specimen storage time and temperature, all tests PASSED preset acceptance criteria (ΔCt < 3).***

Virus	Beads	Lot age of UTM-RT at testing	UTM-RT lot	Time point	ΔCt* (average Time x – T_0) at 22–28°C storage	ΔCt* (average Time x – T_0) at 2–8°C storage
Flu A1	YES	New	2400409 LAB	72 hrs.	0.6	-0.4
				96 hrs.	0.6	0.4
			2319013	72 hrs.	0.6	-0.1
				96 hrs.	0.4	0.7
			2318982	72 hrs.	0.6	0.5
				96 hrs.	0.8	0.5
			2317477	72 hrs.	0.3	0.3
				96 hrs.	0.9	0.7
		Middle-Aged	2301907	72 hrs.	-0.2	0
				96 hrs.	0.3	0.2
			2301790	72 hrs.	0.9	0.5
				96 hrs.	0.9	0.5
		Old / Expired	2211427	72 hrs.	0.2	0.2
				96 hrs.	0.5	0.1
			2211110	72 hrs.	0.6	0.1
				96 hrs.	0.5	0.3
			2207355	72 hrs.	0.1	0.1
				96 hrs.	0.4	0
	NO	New	B400273	72 hrs.	0.9	0.5
				96 hrs.	0.8	0.8
			B400416	72 hrs.	0.7	0.4
				96 hrs.	0.8	0.6
			B400266	72 hrs.	1	0.5
				96 hrs.	1	0.8
		Middle-Aged	B300767	72 hrs.	0.7	0.4
				96 hrs.	1.4	0.9
			B302525	72 hrs.	0.3	0
				96 hrs.	0.7	0.2
			B302734	72 hrs.	0.7	0.6
				96 hrs.	1.1	0.8
		Old / Expired	B203103	72 hrs.	0.5	0.4
				96 hrs.	0.6	0.3
			B203226	72 hrs.	0.5	-0.1
				96 hrs.	0.6	0.4
			B203262	72 hrs.	0.3	0.1
				96 hrs.	0.4	0
	YES	New		72 hrs.	0.5	-0.3

Virus	Beads	Lot age of UTM-RT at testing	UTM-RT lot	Time point	ΔCt* (average Time x – T_0) at 22–28°C storage	ΔCt* (average Time x – T_0) at 2–8°C storage
Flu A2			2400409 LAB	96 hrs.	0.4	0.5
			2319013	72 hrs.	0.4	0.1
				96 hrs.	0.3	0.6
			2318982	72 hrs.	0.5	0.7
				96 hrs.	0.6	0.7
			2317477	72 hrs.	0.2	0.2
				96 hrs.	0.6	0.7
		Middle-Aged	2301907	72 hrs.	-0.1	0.1
				96 hrs.	0.3	0.2
			2301790	72 hrs.	0.7	0.4
				96 hrs.	0.8	0.5
		Old / Expired	2211427	72 hrs.	0.2	0.3
				96 hrs.	0.5	0.2
			2211110	72 hrs.	0.6	0.3
				96 hrs.	0.6	0.4
			2207355	72 hrs.	0.2	0.3
				96 hrs.	0.6	0.2
	NO	New	B400273	72 hrs.	0.7	0.3
				96 hrs.	0.6	0.8
			B400416	72 hrs.	0.5	0.3
				96 hrs.	0.8	0.7
			B400266	72 hrs.	0.7	0.4
				96 hrs.	0.7	0.6
		Middle-Aged	B300767	72 hrs.	0.5	0.4
				96 hrs.	1.1	0.8
			B302525	72 hrs.	0.2	0.1
				96 hrs.	0.5	0.3
			B302734	72 hrs.	0.6	0.6
				96 hrs.	1	0.8
		Old / Expired	B203103	72 hrs.	0.3	0.4
				96 hrs.	0.5	0.4
			B203226	72 hrs.	0.6	-0.1
				96 hrs.	0.7	0.6
			B203262	72 hrs.	0.3	0
				96 hrs.	0.3	0

Note: *The average Ct value is calculated for each time point X hrs. (Time $_X$) starting with time 0 (T_0) and the difference (ΔCt) at each Time $_X$ is then estimated relative to the average Ct at T_0, i.e., (Time $_X$ – T_0), as indicated by the Asterisk (*).*

Table 3: ***Overall stability data for Influenza B virus in lots of UTM-RT per specimen storage time and temperature, all tests PASSED preset acceptance criteria (ΔCt < 3).***

Virus	Beads	Lot age of UTM-RT at testing	UTM-RT lot	Time point	ΔCt* (average Time X – T_0) at 22–28°C storage	ΔCt* (average Time X – T_0) at 2–8°C storage
Flu B	YES	New	2400409 LAB	72 hrs.	-1.2	-0.8
				96 hrs.	-0.5	-0.6
			2319013	72 hrs.	1	-0.4
				96 hrs.	1	0.1
			2318982	72 hrs.	0.4	0.4
				96 hrs.	1	0
			2317477	72 hrs.	0.1	-0.2
				96 hrs.	0.8	-0.4
		Middle-Aged	2301907	72 hrs.	0	-0.4
				96 hrs.	0	0.2
			2301790	72 hrs.	0	-0.5
				96 hrs.	-0.8	-0.4
		Old / Expired	2211429	72 hrs.	0.4	-0.6
				96 hrs.	-0.4	-1
			2212455	72 hrs.	-0.2	-0.8
				96 hrs.	-0.1	-1
			2208203	72 hrs.	0.5	0.2
				96 hrs.	0.2	-0.1
	NO	New	B400273	72 hrs.	1.1	0.3
				96 hrs.	1	-0.2
			B400416	72 hrs.	0	0.3
				96 hrs.	-0.2	-0.1
			B400266	72 hrs.	0.8	0.3
				96 hrs.	-0.4	0
		Middle-Aged	B300767	72 hrs.	0.8	-0.1
				96 hrs.	0.8	0.4
			B302525	72 hrs.	0.3	-0.6
				96 hrs.	0.2	-0.6
			B302734	72 hrs.	1	0.5
				96 hrs.	0	-0.4
		Old / Expired	B203103	72 hrs.	0.4	0
				96 hrs.	0.1	0.1
			B203226	72 hrs.	0.3	-0.1
				96 hrs.	-0.8	-0.5
			B203262	72 hrs.	1.1	0.1
				96 hrs.	0.1	-0.3

Note: *The average Ct value is calculated for each time point X hrs. (Time $_X$) starting with time 0 (T_0) and the difference (ΔCt) at each Time $_X$ is then estimated relative to the average Ct at T_0, i.e., (Time $_X$ – T_0), as indicated by the Asterisk (*).*

Table 4: ***Overall stability data for Respiratory Syncytial virus (RSV) in lots of UTM-RT per specimen storage time and temperature, all tests PASSED preset acceptance criteria (ΔCt < 3).***

Virus	Beads	Lot age of UTM-RT at testing	UTM-RT lot	Time point	ΔCt* (average Time X – T_0) at 22–28°C storage	ΔCt* (average Time X – T_0) at 2–8°C storage
RSV	YES	New	2400409 LAB	72 hrs.	0.2	-0.1
				96 hrs.	0.2	-0.4
			2319013	72 hrs.	0.4	0.2
				96 hrs.	0.1	0.2
			2318982	72 hrs.	-0.3	0
				96 hrs.	0.1	-0.2
			2317477	72 hrs.	0.5	0.3
				96 hrs.	0.6	0.2
		Middle-Aged	2301907	72 hrs.	0.4	0.4
				96 hrs.	0.4	0.4
			2301790	72 hrs.	-0.1	0
				96 hrs.	0.1	-0.3
		Old / Expired	2211426	72 hrs.	0.6	0.1
				96 hrs.	0.5	0.2
			2212454	72 hrs.	0.4	0.1
				96 hrs.	0.2	0.1
			2208079	72 hrs.	0.2	0
				96 hrs.	-0.1	-0.3
	NO	New	B400273	72 hrs.	-0.2	0
				96 hrs.	0.2	-0.2
			B400416	72 hrs.	-0.2	0
				96 hrs.	0	-0.3
			B400266	72 hrs.	0.1	0.1
				96 hrs.	0.2	0
		Middle-Aged	B300767	72 hrs.	-0.1	0
				96 hrs.	-0.1	0
			B302525	72 hrs.	0.3	-0.1
				96 hrs.	0.5	0.4
			B302734	72 hrs.	-0.1	0.3
				96 hrs.	0	0.1
		Old / Expired	B203103	72 hrs.	-0.2	-0.3
				96 hrs.	-0.1	-0.2
			B203226	72 hrs.	0.9	1.1
				96 hrs.	1.1	1
			B203262	72 hrs.	0.2	0.1
				96 hrs.	0.4	0.4

Note: *The average Ct value is calculated for each time point X hrs. (Time $_X$) starting with time 0 (T_0) and the difference (ΔCt) at each Time $_X$ is then estimated relative to the average Ct at T_0, i.e., (Time $_X$ – T_0), as indicated by the Asterisk (*).*

Of note, the performance parameters established in these studies pertain exclusively to the newly introduced claim of stability of respiratory viral nucleic acids in the candidate medium

for subsequent testing in a compatible molecular assay. Especially, frozen storage of specimens in UTM-RT at or below −70ºC for testing with a molecular assay has not been validated and is not recommended. However, it is acceptable to store specimens in UTM-RT at or below −70ºC for subsequent processing using virus, chlamydiae, mycoplasma, and ureaplasma culture, as was previously cleared (K042970). This distinction is noted in device labeling.

B Comparison Studies:

Method Comparison with Predicate Device; Matrix Comparison:

Not Applicable

C Clinical Studies:

Clinical Sensitivity; Clinical Specificity; Other Clinical Supportive Data (if applicable):

Not Applicable

D Clinical Cut-Off:

Not Applicable

E Expected Values/Reference Range:

Not Applicable

VIII Proposed Labeling:

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

IX Conclusion:

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