

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM**

A. 510(k) Number:

k142094

B. Purpose for Submission:

To provide data and information to support a substantial equivalence determination for the Copan FecalSwab Collection, Transport and Preservation System for the collection of rectal swab and fecal specimens and the preservation of enteric pathogenic bacteria present in those specimens.

C. Measurand:

Not applicable.

D. Type of Test:

Culture media system for the collection, transport, and preservation of rectal swab and fecal specimens.

E. Applicant:

Copan Italia S.p.A.

F. Proprietary and Established Names:

Copan FecalSwab Collection, Transport and Preservation System

G. Regulatory Information:

1. Regulation section:

21 CFR 866.2390; Transport culture medium

2. Classification:

Class I

3. Product code:

JSM: Culture media, non-propagating transport

LIO: Device, specimen collection

4. Panel:

Microbiology (83)

H. Intended Use:

1. Intended use:

The Copan FecalSwab Collection, Transport and Preservation System is intended for the collection of rectal swab and fecal specimens and to preserve the viability of enteric pathogenic bacteria during transport from the collection site to the testing laboratory. In the laboratory, FecalSwab specimens are processed using standard clinical laboratory operating procedures for culture.

2. Indication for use:

The Copan FecalSwab Collection, Transport and Preservation System is intended for the collection of rectal swab and fecal specimens and to preserve the viability of enteric pathogenic bacteria during transport from the collection site to the testing laboratory. In the laboratory, FecalSwab specimens are processed using standard clinical laboratory operating procedures for culture.

3. Special conditions for use statements:

For in vitro diagnostic use only.

For prescription use only.

4. Special instrument requirements:

None.

I. Device Description:

The Copan FecalSwab Collection, Transport and Preservation System (FecalSwab) is supplied in a collection kit format. Each collection kit consists of a package containing a plastic screw-cap tube with conical shaped bottom filled with 2 ml of transport and preservation medium and a specimen collection swab that has a tip flocked with soft nylon fiber.

The FecalSwab transport and preservation medium is a maintenance medium designed to maintain the viability of enteric pathogenic bacteria during transit to the testing laboratory.

The FecalSwab Transport and Preservation Medium is comprised of the following:

- Chloride salts
- Sodium salts
- Phosphate buffer
- L-Cysteine
- Agar
- Water

The nylon flocked specimen collection swabs provided with the Copan FecalSwab Collection, Transport and Preservation System have a solid plastic shaft with a molded breakpoint site and are sterile.

J. Substantial Equivalence Information:

1. Predicate device name:

Copan Venturi Transystem Cary-Blair Medium

2. Predicate 510(k) number:

k946286

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	Copan FecalSwab Collection, Transport and Preservation System (k142094)	Copan Venturi Transystem Cary-Blair Medium (k946286)
Product Code	JSM, LIO	JSM
Intended Use	<p>The Copan FecalSwab Collection, Transport and Preservation System is intended for the collection of rectal swab and fecal specimens and to preserve the viability of enteric pathogenic bacteria during transport from the collection site to the testing laboratory.</p> <p>In the laboratory, FecalSwab specimens are processed using standard clinical laboratory operating procedures for culture.</p>	<p>Copan Venturi Transystem Cary-Blair Medium product (132C) is a sterile ready-to-use system intended for the safe collection, transport, and preservation of clinical specimens for bacteriological examination. Product 132C is supplied with a plastic applicator swab. The Venturi Transystem with Cary-Blair Transport Medium is recommended for the collection and transport of fecal and rectal swab samples for the investigation of enteric pathogenic bacteria.</p>

Similarities		
Item	Device	Predicate
	Copan FecalSwab Collection, Transport and Preservation System (k142094)	Copan Venturi Transystem Cary-Blair Medium (k946286)
Product Configuration	Film-film peel-pouch containing 1 tube and 1 swab	Same
pH of Medium	6.90 – 7.50	Same
Storage Temperature	5-25 °C	Same
Container	Tube; Plastic	Same
Collection tool	Swab	Same
Swab Shaft	Plastic	Same
Biocompatible	Yes	Same
Sterility	Gamma Radiation – SAL 10-6	Same

Differences		
Item	Device	Predicate
	Copan FecalSwab Collection, Transport and Preservation System (k142094)	Copan Venturi Transystem Cary-Blair Medium (k946286)
Medium Formulation	Chloride salts Sodium salts Phosphate buffer L-Cysteine Agar Water	Sodium chloride Calcium chloride Disodium hydrogen phosphate Sodium thioglycolate Agar Water
Performance	Viability of target micro-organisms up to 72 hours at 2 – 8 °C and up to 48 hours at 20 – 25 °C. For <i>C. difficile</i> , up to 48 hours at 2 – 8 °C and up to 24 hours at 20 – 25 °C.	Viability of target micro-organisms up to 48 hours at room temperature.
Medium State	Semi-solid	Solid
Medium Volume	2 ml	5 ml
Swab Tip	Flocked nylon	Viscose
Shelf Life	15 months	20 months

Differences		
Item	Device	Predicate
	Copan FecalSwab Collection, Transport and Preservation System (k142094)	Copan Venturi Transystem Cary-Blair Medium (k946286)
Microorganisms tested	<i>Escherichia coli</i> <i>Escherichia coli O157:H7</i> <i>Salmonella typhimurium</i> <i>Shigella sonnei</i> <i>Campylobacter jejuni</i> <i>Yersinia enterocolitica</i> <i>Vibrio parahaemolyticus</i> <i>Enterococcus faecalis</i> <i>vancomycin resistant (VRE)</i> <i>Clostridium difficile</i>	<i>Escherichia coli</i> <i>Shigella flexneri</i> <i>Campylobacter jejuni</i> <i>Yersinia enterocolitica</i>

K. Standard/Guidance Documents Referenced:

Not applicable.

L. Test Principle:

Not applicable.

M. Performance Characteristics:

1. Analytical performance:

Recovery:

Bacterial recovery studies were performed using two methods based on CLSI M40-A2 to determine recovery of viable enteric organisms. Dilutions of representative enteric pathogenic microorganisms were prepared in physiological saline and used as inoculum.

For Method 1, 100 µL from each dilution of inoculum was added directly to the FecalSwab tube. For each inoculum concentration, one tube from each of three device lots was inoculated for each temperature / time storage condition. The inoculated tubes were stored at 2 – 8 °C for 0, 6, 24, 48 and 72 hours or at 20 – 25 °C for 0, 6, 24 and 48 hours. After storage, 100 µL from each device was transferred to each of three plates of appropriate culture medium and spread across the surface using a sterile spreader. The inoculated plates were incubated under appropriate conditions. Manual colony counts were performed. Plate counts from dilutions generating 25 – 250 colony forming units (CFU) were considered valid for determining the organism concentration. The average CFU from the nine plates (three plates per lot x three lots) for each temperature / time storage condition was compared to the CFU at time zero.

For Method 2, 100 µL from each dilution of inoculum was absorbed by each of three swabs from each of three lots of Copan FecalSwab System. The swab was then added to the device tube. The inoculated tubes were stored at 2 – 8 °C for 0, 6, 24, 48 and 72 hours or at 20 – 25 °C for 0, 6, 24 and 48 hours. After storage, the swab was removed from the device and used to streak a plate of the appropriate culture medium. The inoculated plates were incubated for 24 hours under appropriate conditions. Manual colony counts were performed. Plate counts from dilutions generating 25 – 250 CFU were considered valid. The average CFU from nine plates (three plates per lot x three lots) for each time / temperature storage condition was compared to the CFU at time zero.

The acceptance criterion for Method 1 and Method 2 was an average CFU for the stored FecalSwab Systems that was within 2 log₁₀ of the time zero CFU.

Recovery of the following microorganisms from physiological saline was evaluated:

<i>Escherichia coli</i>	ATCC 25922
<i>Escherichia coli</i> O157:H7	ATCC 700728 *
<i>Salmonella typhimurium</i>	ATCC 14028
<i>Shigella sonnei</i>	ATCC 12022
<i>Clostridium difficile</i>	ATCC 9689 *
<i>Vibrio parahaemolyticus</i>	ATCC 17802
<i>Enterococcus faecalis vancomycin resistant (VRE)</i>	ATCC 51299
<i>Yersinia enterocolitica</i>	ATCC 9610
<i>Campylobacter jejuni</i>	ATCC 33291

* Tested using Method 2 only.

Results met the acceptance criteria for each microorganism and each time / temperature storage condition with both Method 1 and Method 2, except for *C. difficile* which demonstrated acceptable recovery after 24 hours when stored at 20 – 25 °C and after 48 hours when stored at 2 – 8 °C. *Escherichia coli* O157:H7 and *Clostridium difficile* were tested with Method 2 only.

Method 1. Recovery Results after Inoculation with Microorganism Diluted in Physiological Saline. The average CFU/mL was calculated using results from the inoculum dilution that produced counts of 25 – 250 colonies / plate.

Organism	Hold Temp.	Average CFU/mL recovered (n = 9)					Log reduction (-) or log increase (+) ^a
		Time 0 hrs	Time 6 hrs	Time 24 hrs	Time 48 hrs	Time 72 hrs	
<i>E. coli</i>	2-8 °C	1640	1487	1157	821	608	-0.43
	20-25 °C	1640	1747	13200	33500	NA	1.31
<i>S. typhimurium</i>	2-8 °C	2200	1813	1780	2017	1667	-0.12
	20-25 °C	2200	5010	22000	166000	NA	1.88
<i>S. sonnei</i>	2-8 °C	2223	1853	2173	1963	1787	-0.09
	20-25 °C	2223	5143	23100	180000	NA	1.91
<i>V. parahaemolyticus</i>	2-8 °C	2197	1357	1970	1647	1423	-0.19
	20-25 °C	2197	8953	22567	176667	NA	1.91

Organism	Hold Temp.	Average CFU/mL recovered (n = 9)					Log reduction (-) or log increase (+) ^a
		Time 0 hrs	Time 6 hrs	Time 24 hrs	Time 48 hrs	Time 72 hrs	
<i>E. faecalis</i> (VRE)	2-8 °C	2023	1717	1767	1547	1363	-0.17
	20-25 °C	2023	1950	4553	34900	NA	1.24
<i>Y. enterocolitica</i>	2-8 °C	1583	1473	1470	1410	1440	-0.04
	20-25 °C	1583	5933	17533	104333	NA	1.82
<i>C. jejuni</i>	2-8 °C	2190	2060	1463	478	180	-1.09
	20-25 °C	2190	1787	1463	57	NA	-1.58

^a at time 72 hrs for 2 - 8 °C hold temperature or at time 48 hrs for 20 – 25 °C hold temperature

NA – not applicable; devices held at 20 – 25 °C were not tested at 72 hours.

Method 2. Recovery Results after Inoculation with Microorganism Diluted in Physiological Saline. The average CFU/swab was calculated using results from the inoculum dilution that produced counts of 25 – 250 colonies / plate.

Organism	Hold Temp.	Average CFU/swab recovered (n = 9)					Log reduction (-) or log increase (+) ^a
		Time 0 hrs	Time 6 hrs	Time 24 hrs	Time 48 hrs	Time 72 hrs	
<i>E. coli</i>	2-8 °C	107	112	85	83	73	-0.17
	20-25 °C	107	135	1323	5723	NA	1.73
<i>E. coli</i> O157:H7	2-8 °C	90	101	104	107	104	0.06
	20-25 °C	90	128	257	4117	NA	1.66
<i>S. typhimurium</i>	2-8 °C	138	141	159	158	97	-0.15
	20-25 °C	138	584	2273	9723	NA	1.85
<i>S. sonnei</i>	2-8 °C	127	126	42	146	116	-0.04
	20-25 °C	127	476	1910	9667	NA	1.88
<i>C. difficile</i>	2-8 °C	44	23	6	1	*	-1.85**
	20-25 °C	44	18	1	*	NA	-1.92**
<i>V. parahaemolyticus</i>	2-8 °C	200	178	176	168	154	-0.11
	20-25 °C	200	222	1623	15833	NA	1.90
<i>E. faecalis</i> (VRE)	2-8 °C	168	167	152	438	116	-0.16
	20-25 °C	168	170	439	2260	NA	1.13
<i>Y. enterocolitica</i>	2-8 °C	117	114	112	109	104	-0.05
	20-25 °C	117	172	1243	9777	NA	1.92
<i>C. jejuni</i>	2-8 °C	214	166	133	86	34	-0.80
	20-25 °C	214	168	58	4	NA	-1.70

^a at time 72 hrs for 2 - 8 °C hold temperature or at time 48 hrs for 20 – 25 °C hold

NA – not applicable; devices held at 20 – 25 °C were not tested at 72 hours.

* Result did not meet the acceptance criterion. A limitation was added to the package insert for recovery of *C. difficile* after up to 48 hours of hold time at 2 - 8 °C and up to 24 of hold time at 20 – 25 °C.

** Log difference at Time 48 hours for hold at 2 – 8 °C and at Time 24 hours for hold at 20 – 25 °C.

Recovery was also evaluated using representative pathogenic enteric microorganisms spiked into a solution of fecal matrix and tested with Method 2 as described above. To prepare the fecal matrix, stools from three healthy volunteers were pooled and added to

PBS in sufficient quantity to ensure that the final matrix contained at least 30% stool. Testing was performed as described for Method 2 above. Appropriate selective media were used to allow differentiation of the test microorganisms from the normal flora found in stool samples.

The acceptance criterion for recovery from fecal matrix was an average CFU for the stored FecalSwab Systems that was within 2 log₁₀ of the time zero CFU.

Recovery of the following microorganisms from fecal matrix was evaluated:

Escherichia coli O157:H7 ATCC 700728
Salmonella typhimurium ATCC 14028
Vibrio parahaemolyticus ATCC 17802

Results met the acceptance criterion for each microorganism and each time / temperature storage condition. Results for recovery of microorganisms from a fecal matrix are shown in the following table.

Method 2 Recovery Results for after Inoculation with Microorganism Diluted in Fecal Matrix. The average CFU/swab was calculated using results from the inoculum dilution that produced counts of 25 – 250 colonies / plate.

Organism	Hold Temp.	Average CFU/swab recovered (n = 9)					Log reduction (-) or log increase (+) ^a
		Time 0 hrs	Time 6 hrs	Time 24 hrs	Time 48 hrs	Time 72 hrs	
<i>E.coli</i> O157:H7	2-8 °C	123	137	138	153	160	0.11
	20-25 °C	123	134	748	7537	NA	1.79
<i>S. typhimurium</i>	2-8 °C	95	105	120	132	143	0.18
	20-25 °C	95	117	651	6380	NA	1.83
<i>V. parahaemolyticus</i>	2-8 °C	111	121	129	126	136	0.09
	20-25 °C	111	134	1141	7357	NA	1.82

^a at time 72 hrs for 2 - 8 °C hold temperature or at time 48 hrs for 20 – 25 °C hold
 NA – not applicable; devices held at 20 – 25 °C were not tested at 72 hours.

Overgrowth:

No overgrowth limit is defined by CLSI M40-A2 for devices held at room temperature (20-25 °C) because most commercial transport media cannot control for it. The capacity of the Copan FecalSwab System to inhibit overgrowth of normal flora found in stool specimens was evaluated using the procedure described for Method 2 above. A solution of *Pseudomonas aeruginosa* was prepared in physiological saline and used to inoculate three FecalSwab tubes from each of six lots. The inoculated tubes were stored at 2 – 8 °C for 0, 24, or 48 hours. After storage, the swab was removed and used to streak the surface of a nonselective culture plate.

The acceptance criterion was ≤ 1 log₁₀ increase in CFU, relative to time zero, after storage of the FecalSwab tubes at 2 – 8 °C for 48 hours.

All FecalSwab tubes met the acceptance criterion, showing less than a 1 log increase in CFU, relative to time zero, for swabs stored at 2 – 8 °C for 48 hours.

Bio-Burden:

Testing was performed in accordance with M40-A2. Ten FecalSwab kits from each of three lots were included in the testing.

The acceptance criterion was ≤ 2 bacteria in 10 microscopic fields examined for each slide. All 10 of the FecalSwab kits from each of the three lots met the acceptance criterion of less than or equal to two bacteria in 10 microscopic fields.

a. Precision/Reproducibility:

Not applicable.

b. Linearity/assay reportable range:

Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Shelf-life testing was performed at months 1, 8 and 16 after storage at 2 – 6 °C or 28 – 32 °C. Three lots of the Copan FecalSwab Collection, Transport and Preservation System were included in the study. Stability was evaluated by testing for:

- pH

Acceptance criterion: pH must remain within the target range of 6.90 – 7.50

- Bacterial recovery of *Escherichia coli*, *Salmonella typhimurium* and *Shigella sonnei*. After storage under the designated conditions, the devices were inoculated and held at 2 – 8 °C or 20 – 25 °C prior to plating. The inoculation and plating methods described for Method 1 and Method 2 above were included in the study.

Acceptance criterion: the average CFU must remain within $2 \log_{10}$ of the initial time zero CFU.

Results of the shelf life testing:

- The target pH range for the medium of 6.90 – 7.50 was maintained for all devices at each time point.
- The acceptance criterion of average CFU remaining within $2 \log_{10}$ of the initial microorganism CFU was met for all bacterial strains and each test condition.

These data demonstrate the ability of the Copan FecalSwab System to maintain pH

and bacterial viability under the intended use conditions and support the shelf life claim of 15 months from the date of manufacture.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Not applicable.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison is not applicable for a bacterial transport medium. The device itself does not provide a result that can be used in making a clinical decision.

Bench testing studies were performed to determine the ability of the Copan FecalSwab Collection, Transport and Preservation System to maintain viability of different strains of pathogenic enteric bacteria. Results of these studies demonstrated recovery of bacteria within the acceptance criteria recommended in CLSI M40-A2. Refer to [Analytical Performance](#) in Section M.1 above.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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