



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY**

**I Background Information:**

**A 510(k) Number**

K242976

**B Applicant**

Medical Wire & Equipment Company (Bath) Ltd

**C Proprietary and Established Names**

Medical Wire Fecal Transwab Liquid Cary Blair Medium Collection and Transport Device

**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 make a substantial equivalence determination for the Medical Wire Fecal Transwab Liquid Cary Blair Medium Collection and Transport Device for the collection, transport and storage of fecal specimens for laboratory culture of bacteria.

**B Measurand:**

Not Applicable

**C Type of Test:**

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

### **III Intended Use/Indications for Use:**

#### **A Intended Use(s):**

See Indications for Use below.

#### **B Indication(s) for Use:**

The Medical Wire Fecal Transwab Liquid Cary Blair Medium Collection and Transport Device is intended to preserve the viability and infectivity of fecal specimens after their collection and during transport from the collection site to the testing laboratory. The product can be used to collect stool specimen directly from the patient, using the swab as a rectal swab. Alternatively, the swab can be used to take material from a previously collected stool specimen. Fecal Transwab specimens are processed using standard clinical laboratory operating procedures for microbiological specimens.

#### **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 Medical Wire Fecal Transwab Liquid (Cary Blair) Medium Collection and Transport Device (referred to as Fecal Transwab System below) 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 Cary Blair medium, co-packaged with a foam tip swab. The kit comes in four different configurations, 1) 2 mL of media in a 12mmX80mm vial without a swab, 2) 2mL of media in a 12mmX80mm vial with a foam tipped swab, 3) 2 mL of media in a 16mmX100mm vial without a swab, and 4) 2mL of media in a 16mmX100mm vial with a foam tipped swab.

#### **B Principle of Operation:**

The Transwab transport and preservation medium is a maintenance medium designed to maintain the viability of enteric pathogenic bacteria during transit to the testing laboratory. The Transwab Transport and Preservation Medium is comprised of the following:

- Potassium di-hydrogen phosphate
- Di-sodium hydrogen phosphate
- Sodium thioglycollate
- Sodium chloride
- Calcium chloride
- Deionized water

The foam tipped swab provided with the Transwab has a solid plastic shaft with a molded breakpoint site and is sterile.

**V Substantial Equivalence Information:**

**A Predicate Device Name(s):**

Copan FecalSwab Collection, Transport And Preservation System,

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

K142094

**C Comparison with Predicate(s):**

<b>Device &amp; Predicate Device(s):</b>	<u>Device: K242976</u>	Predicate: <u>K142094</u>
Device Trade Name	Medical Wire Fecal Transwab Liquid Cary Blair Medium Collection and Transport Device	Copan FecalSwab Collection, Transport and Preservation System
<b>General Device Characteristic Similarities</b>		
Intended Use/Indications For Use	The Medical Wire Fecal Transwab Liquid Cary Blair Medium Collection and Transport Device is intended to preserve the viability and infectivity of fecal specimens after their collection and during transport from the collection site to the testing laboratory. The product can be used to collect stool specimen directly from the patient, using the swab as a rectal swab. Alternatively, the swab can be used to take material from a previously collected stool specimen. Fecal Transwab specimens are processed using standard clinical laboratory operating procedures for microbiological specimens.	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.
Specimen Type	Stool specimen, rectal specimen	Same
Microorganisms supported	Enteric pathogenic bacteria	Same
Tube configuration	Conical tubes with screw caps	Same

Kit configuration comes with a swab	Swab included	Same
Media volume	2mL	Same
<b>General Device Characteristic Differences</b>		
Microorganisms tested	<i>Escherichia coli</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>Plesiomonas shigelloides</i> <i>Escherichia coli</i> O157:H7 <i>Clostridium difficile</i>	<i>Escherichia coli</i> <i>Escherichia coli</i> O157:H7 <i>Salmonella typhimurium</i> <i>Shigella sonnei</i> <i>Campylobacter jejuni</i> <i>Yersinia enterocolitica</i> <i>Vibrio parahaemolyticus</i> <i>Enterococcus faecalis</i> vancomycin resistant (VRE) <i>Clostridium difficile</i>
Medium formulation	Potassium di-hydrogen phosphate Di-sodium hydrogen phosphate Sodium thioglycollate Sodium chloride Calcium chloride Deionized water	Chloride salts Sodium salts Phosphate buffer L-Cysteine Agar Water
Shelf-life	24 months	15 months
Specific swab type	Foam tip	Flocked nylon tip

## VI Standards/Guidance Documents Referenced:

CLSI M40-A2 *Quality Control of Microbiological Transport Systems*

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

#### 1. Precision/Reproducibility:

N/A

#### 2. Linearity:

N/A

#### 3. Analytical Specificity/Interference:

N/A

#### 4. Assay Reportable Range:

N/A

## 5. Stability/Shelf-life

Shelf-life stability testing was performed using a real-time study design with seven lots of media. Media was evaluated for the following parameters: pH, Gram stain, fill volume, clarity, color, vial integrity and swab packaging integrity. Recovery of microorganisms from fecal matrix was assessed by the Roll Plate method and swab elution, as described in A.6 below. The data support stability for up to 24 months at room temperature.

## 6. Bacterial Recovery:

Bacterial recovery studies were performed using two methods, roll plate and swab elution, based on CLSI M40-A2 to determine recovery of viable enteric organisms. Dilutions of representative enteric pathogenic microorganisms were prepared in saline and mixed 1:5 with 50% negative clinical matrix (bulk negative clinical stool matrix was mixed 50:50 with saline to maintain consistency) prior to transfer into the media for each method.

Recovery of the following microorganisms from physiological saline was evaluated using both the roll plate and the swab elution method: *Campylobacter jejuni* ATCC 33291, *Enterococcus faecalis* ATCC 29212, *Escherichia coli* ATCC 25922, *Salmonella typhimurium* ATCC 14028, *Shigella sonnei* (flexneri) ATCC 12022, *Vibrio parahaemolyticus* ATCC 17802, *Yersinia enterocolitica* ATCC 9610, *Plesiomonas shigelloides* ATCC 14029, *Escherichia coli* O157:H7 ATCC 700728, and *Clostridium difficile* ATCC 9689.

For the roll plate method, 100 µL from each diluted organism inoculum was mixed with 500 µL of 50% negative clinical matrix. The mixture was then added directly to the Fecal Transwab 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 held at 2-8 °C for 0, 24, and 48 hours or at 20-25 °C for 0, 24 and 48 hours for all claimed organisms except *C. diff*. *C. diff* was held at both 2-8 °C and 20-25 °C for 0 and 24 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, as shown in **Table 1**. The acceptance criterion for roll plate recovery was an average CFU for the stored Fecal Transwab Systems that was within 200 CFUs of the time zero CFU in table 2.

**Table 1. Roll plate method recovery results using the Fecal Transwab System.**

Organism	Temperature	Time Point	Average CFU Count	Change from T <sub>0</sub>
<i>Vibrio parahaemolyticus</i>	N/A	T <sub>0</sub>	220	0
	2-8°C	24h	248	+28
		48h	276	+56
	20-25°C	24h	308	+88

Organism	Temperature	Time Point	Average CFU Count	Change from T <sub>0</sub>
<i>Enterococcus faecalis</i>		48h	395	+175
	N/A	T <sub>0</sub>	158	0
	2-8°C	24h	159	+1
		48h	150	-8
	20-25°C	24h	215	+67
		48h	275	+117
<i>Yersinia enterocolitica</i>	N/A	T <sub>0</sub>	225	0
	2-8°C	24h	205	-20
		48h	168	-67
	20-25°C	24h	225	0
		48h	236	+11
<i>Escherichia coli</i>	N/A	T <sub>0</sub>	218	0
	2-8°C	24h	207	-11
		48h	207	-11
	20-25°C	24h	350	+132
		48h	376	+158
<i>Salmonella typhimurium</i>	N/A	T <sub>0</sub>	218	0
	2-8°C	24h	214	-4
		48h	207	-11
	20-25°C	24h	355	-137
		48h	332	-114
<i>Campylobacter jejuni</i>	N/A	T <sub>0</sub>	222	0
	2-8°C	24h	161	-61
		48h	113	-109
	20-25°C	24h	89	-133
		48h	33	-189
<i>Plesiomonas shigelloides</i>	N/A	T <sub>0</sub>	198	0
	2-8°C	24h	189	-9
		48h	164	-34
	20-25°C	24h	198	-0
		48h	177	-21
<i>Shigella flexneri</i>	N/A	T <sub>0</sub>	186	0
	2-8°C	24h	184	-2
		48h	152	-34
	20-25°C	24h	177	-9
		48h	128	-56
<i>E. coli</i> 0157:H7	N/A	T <sub>0</sub>	228	0
	2-8°C	24h	317	+89
		48h	228	0
	20-25°C	24h	315	+87
		48h	459	+231
<i>Clostridium difficile</i>	N/A	T <sub>0</sub>	222	0
	2-8°C	24h	85	-137
	20-25°C	24h	32	-190

For the swab elution method, 100 µL from each dilution of inoculum was absorbed by each of three swabs from each of three lots of Fecal Transwab System. The swab was then added to the device tube. The inoculated tubes were held at 2-8 °C for 0, 24, and 48 hours or at 20-25 °C for 0, 24 and 48 hours for all claimed organisms except *C. diff*. *C. diff* was held at both 2-8 °C and 20-25 °C for 0 and 24 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, as shown in **Table 2**. The acceptance criterion for swab elution recovery was an average CFU for the stored Fecal Transwab Systems that was within 3 log<sub>10</sub> of the time zero CFU in table 2.

**Table 2. Swab elution recovery results using the Fecal Transwab System.**

Organism	Temperature	Time Point	Average CFU Count	Log <sub>10</sub> Count	Log Change from T <sub>0</sub>
<i>Vibrio parahaemolyticus</i>	N/A	T <sub>0</sub>	2.1×10 <sup>4</sup>	4.32	0.00
	2-8°C	24h	4.1×10 <sup>4</sup>	4.61	+0.29
		48h	3.5×10 <sup>4</sup>	4.54	+0.22
	20-25°C	24h	4.2×10 <sup>5</sup>	5.62	+1.30
		48h	3.5×10 <sup>4</sup>	4.54	+0.22
<i>Enterococcus faecalis</i>	N/A	T <sub>0</sub>	1.6 × 10 <sup>5</sup>	5.20	0.00
	2-8°C	24h	1.5×10 <sup>5</sup>	5.18	-0.02
		48h	1.1×10 <sup>5</sup>	5.04	-0.16
	20-25°C	24h	1.8×10 <sup>5</sup>	5.26	+0.06
		48h	1.7×10 <sup>5</sup>	5.23	+0.03
<i>Yersinia enterocolitica</i>	N/A	T <sub>0</sub>	1.1×10 <sup>5</sup>	5.04	0.00
	2-8°C	24h	1.3×10 <sup>5</sup>	5.11	+0.07
		48h	1.1×10 <sup>5</sup>	5.04	0.00
	20-25°C	24h	4.6×10 <sup>5</sup>	5.66	+0.62
		48h	1.7×10 <sup>6</sup>	6.23	+1.19
<i>Escherichia coli</i>	N/A	T <sub>0</sub>	2.3×10 <sup>5</sup>	5.36	0.00
	2-8°C	24h	1.3×10 <sup>5</sup>	5.11	-0.25
		48h	6.6×10 <sup>4</sup>	4.82	-0.54
	20-25°C	24h	5.0×10 <sup>5</sup>	5.70	+0.34
		48h	2.1×10 <sup>6</sup>	6.32	+0.96
<i>Salmonella typhimurium</i>	N/A	T <sub>0</sub>	6.1×10 <sup>5</sup>	5.79	0.00
	2-8°C	24h	5.9×10 <sup>5</sup>	5.77	-0.02
		48h	3.3×10 <sup>5</sup>	5.52	-0.27
	20-25°C	24h	6.6×10 <sup>5</sup>	5.82	+0.03
		48h	1.6×10 <sup>6</sup>	6.20	+0.41
<i>Campylobacter jejuni</i>	N/A	T <sub>0</sub>	3.7×10 <sup>5</sup>	5.57	0.00
	2-8°C	24h	4.1×10 <sup>5</sup>	5.61	+0.04
		48h	3.3×10 <sup>5</sup>	5.52	-0.05
	20-25°C	24h	9.2×10 <sup>4</sup>	4.96	-0.61
		48h	4.2×10 <sup>3</sup>	3.62	-1.95
<i>Plesiomonas shigelloides</i>	N/A	T <sub>0</sub>	2.2×10 <sup>5</sup>	5.34	0.00
	2-8°C	24h	1.9×10 <sup>5</sup>	5.28	-0.06
		48h	1.3×10 <sup>5</sup>	5.11	-0.23
	20-25°C	24h	1.1×10 <sup>5</sup>	5.04	-0.30
		48h	5.9×10 <sup>4</sup>	4.77	-0.57
<i>Shigella flexneri</i>	N/A	T <sub>0</sub>	1.8×10 <sup>5</sup>	5.26	0.00
	2-8°C	24h	1.4×10 <sup>5</sup>	5.15	-0.11
		48h	1.2×10 <sup>5</sup>	5.08	-0.18
	20-25°C	24h	1.3×10 <sup>5</sup>	5.11	-0.15
		48h	5.9×10 <sup>4</sup>	4.77	-0.49
<i>E. coli</i> 0157:H7	N/A	T <sub>0</sub>	1.5×10 <sup>5</sup>	5.18	0.00
	2-8°C	24h	1.5×10 <sup>5</sup>	5.18	0.00
		48h	8.2×10 <sup>4</sup>	4.91	-0.27
	20-25°C	24h	4.3×10 <sup>5</sup>	5.63	+0.45
		48h	7.4×10 <sup>5</sup>	5.87	+0.69
<i>Clostridium difficile</i>	N/A	T <sub>0</sub>	5.9×10 <sup>4</sup>	4.77	0.00

Organism	Temperature	Time Point	Average CFU Count	Log <sub>10</sub> Count	Log Change from T <sub>0</sub>
	2-8°C	24h	3.5×10 <sup>4</sup>	4.54	-0.23
	20-25°C	24h	4.2×10 <sup>2</sup>	2.62	-2.15

The data provided and summarized in tables 1 and 2 met the predefined acceptance criteria when stored at refrigeration (2-8 °C) and room temperature (20-25 °C) and tested at 24 and 48 hrs., except for *C. difficile* that demonstrated adequate recovery up to 24hrs.

7. Assay Cut-Off:

N/A

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

N/A

2. Matrix Comparison:

N/A

**C Clinical Studies:**

1. Clinical Sensitivity:

N/A

2. Clinical Specificity:

N/A

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

N/A

**D Clinical Cut-Off:**

N/A

**E Expected Values/Reference Range:**

N/A

**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.