

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

**A. 510(k) Number:**

K150887

**B. Purpose for Submission:**

To make a substantial equivalence determination for the Medical Chemical Corporation (MCC) Para-Fix C&S Medium transport system for the collection and transport of clinical specimens containing enteric bacteria from the clinic to the laboratory for bacteriological examination and culture.

**C. Measurand:**

Not applicable

**D. Type of Test:**

Collection and transport culture media system

**E. Applicant:**

Medical Chemical Corporation

**F. Proprietary and Established Names:**

MCC Para-Fix C&S Medium

**G. Regulatory Information:**

1. Regulation section:

21 CFR 866.2390 – Transport culture medium.

2. Classification:

Class I (general controls)

3. Product code:

JSM - Culture Media, non-propagating transport media

LIO: Device, Specimen Collection

4. Panel:

Microbiology (83)

**H. Intended Use:**

1. Intended use(s):

Para-Fix C&S Medium provides a method for collecting and preserving fecal specimens for the culture of intestinal enteric bacteria. Because the medium is capable of maintaining the bacteria for 96 hours, immediate transportation and processing of the specimen is not necessary.

2. Indication(s) for use:

Para-Fix C&S Medium provides a method for collecting and preserving fecal specimens for the culture of intestinal enteric bacteria. Because the medium is capable of maintaining the bacteria for 96 hours, immediate transportation and processing of the specimen is not necessary.

3. Special conditions for use statement(s):

For in vitro diagnostic use only

For prescription use only

4. Special instrument requirements:

None

**I. Device Description:**

Para-Fix C&S medium is supplied in a 30 mL vial that contains 15 ml of medium. The lid has a built in sample collection spoon. The C&S medium is a non-nutritive, buffered, isotonic solution with a pH indicator added. The medium also contains agar and sodium thioglycolate to maintain a low oxygen tension for the preservation of anaerobic species. The phenol red indicator will turn yellow when the solution is acidic and the conditions are not optimal for recovery of the intended organisms. The transport vial is intended to transport common enteric parasites found in the stool of infected patients. The kit does not include a swab.

Para-Fix C&S medium contains the following components:

- Disodium phosphate
- Phenol Red
- Agar
- Sodium Thioglycolate
- Calcium Chloride
- Distilled water

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Meridian Para-Pak (C&S)
2. Predicate 510(k) number(s):  
K792712
3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>MCC Para-Fix C&amp;S K150887</b>	<b>Meridian Para-Pak C&amp;S K792712</b>
Intended use	Para-Fix C&S Medium provides a method for collecting and preserving fecal specimens for the culture of intestinal enteric bacteria. Because the medium is capable of maintaining the bacteria for 96 hours, immediate transportation and processing of the specimen is not necessary.	The Para-Pak (C&S) System provides a standardized procedure for the routine collection, transportation, preservation, and culture of stool specimens for bacterial enteric pathogens. It is designed for easy collection of specimens by individuals not trained in microbiological techniques and affords an excellent means of minimizing the adverse effects of delay in specimen transportation.
Sample types	Fecal collection	Same
Sample transport	Vial with built in spoon	Same

<b>Differences</b>		
<b>Item</b>	<b>MCC Para-Fix C&amp;S K150887</b>	<b>Meridian Para-Pak C&amp;S K792712</b>
Medium composition	No glycerol or NaCl in the medium, medium contains agar at 0.15% (w/v)	C&S medium contains glycerol NaCl and no agar

<b>Differences</b>		
<b>Item</b>	<b>MCC Para-Fix C&amp;S K150887</b>	<b>Meridian Para-Pak C&amp;S K792712</b>
Specimen stability	2-8°C and 20-25°C, up to 96 hrs	Specimens must not be refrigerated, up to 72 hrs

**K. Standard/Guidance Document Referenced (if applicable):**

Quality Control of Microbiological Transport Systems; Approved Standard, M40-A2 (2014), Clinical and Laboratory Standards Institute (CLSI), Wayne, PA.

**L. Test Principle:**

Not applicable.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

The performance characteristics of Para-Fix C&S transport vials were determined by spiking enteric organisms prepared either in Para-Fix C&S transport medium or in clinically negative fecal matrix/Para-Fix C&S transport medium. Swab Elution and Roll-Plate methods were used in accordance with the CLSI M40-A2 document to determine recovery of viable enteric organisms. Initially, ten (10) enteric organisms in Para-Fix C&S transport medium were tested using only the Swab Elution method. Subsequently, as an additional challenge, further evaluation of the transport device was also performed using three (3) representative organisms, which were tested in fecal matrix/Para-Fix C&S transport medium using both the Swab Elution and Roll-Plate methods.

The 10 organisms listed below were added directly to Para-Fix C&S Medium and tested by the Swab Elution Method:

<i>Enterococcus faecalis</i>	ATCC 29212
<i>Escherichia coli</i>	ATCC 8739
<i>Shigella dysenteriae</i>	ATCC 9361
<i>Pseudomonas aeruginosa</i>	ATCC 9027
<i>Salmonella enterica</i>	ATCC 10708
<i>Vibrio parahaemolyticus</i>	ATCC 17802
<i>Clostridium difficile</i>	ATCC 9689
<i>Campylobacter jejuni</i>	ATCC 33291
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Bacillus subtilis</i>	ATCC 6633

The following 3 challenge organisms were spiked into clinically negative fecal matrix/Para-Fix C&S Medium and tested by the Roll-Plate and Swab Elution Methods:

*Escherichia coli* O157 ATCC 43894  
*Salmonella enterica* ATCC 10708  
*Vibrio parahaemolyticus* ATCC 17802

Acceptance criteria for recovery of bacteria as recommended in the CLSI document M40-A2 were applied. No over growth limit is defined by CLSI M40-A2 at room temperature (20-25°C) for the Swab Elution or Roll-Plate Methods because most commercial transport media cannot control for it.

Manual colony counts were conducted for the Roll-Plate Method and the Swab Elution Method at the four time intervals (0hr, 72hr, 96hr and 120hr) for the representative organisms. The averages from 3 vials plated in duplicate, (n=6) were used to generate plate counts and assess recovery and viability of organisms.

Swab Elution Method:

The results of the Swab Elution Method studies are presented in Table 1 for all enteric organisms in Para-Fix C&S transport medium and in Table 2 for the three (3) representative challenge enteric organisms in a mixture of Para-Fix C&S transport medium and fecal matrix. The results demonstrate that the Para-Fix C&S Medium is able to support and maintain acceptable viability of all organisms up to 96 hours when taken from pure culture and up to 120 hours when spiked into fecal matrix, at both room temperature (20-25°C) and under refrigerated (2-8°C) conditions. Acceptability is based on the acceptance criteria set forth in CLSI M40-A2. For viability in the Swab Elution Method to be considered acceptable, there shall be no more than a  $3 \log_{10}$  ( $1 \times 10^3$  +/- 10%) decline in CFU between the zero-time CFU count and the CFU counts for the predetermined end time point. This was demonstrated for all organisms tested.

Roll-Plate Method for Challenge Organisms:

The results of the Roll-Plate Method study are presented in Table 3 below for the three (3) representative challenge enteric organisms. The results demonstrate that the Para-Fix C&S Medium is able to maintain acceptable viability for all organisms up to 120 hours at room temperature (20-25°C) and under refrigerated (2-8°C) conditions based on the acceptance criteria set forth in CLSI M40-A2. For the transport system to demonstrate acceptable viability by the Roll-Plate method,  $\geq 5$  CFU should be recovered following the specified maintenance time from the specific dilution that yielded time-zero plate counts closest to 300 CFU.

**Table 1. Enteric Organism Recovery Results for Para-Fix C&S Medium Using Swab Elution Method.**

Organism*	Hold Temperature	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 96 hrs	T=96 hrs Log reduction (-) or Log increase (+)
<i>Escherichia coli</i>	2-8°C	1.6 X 10 <sup>7</sup>	5.1 X 10 <sup>7</sup>	0.51
	20-25°C	2.1 X 10 <sup>7</sup>	2.5 X 10 <sup>6</sup>	1.09
<i>Staphylococcus aureus</i>	2-8°C	1.6 X 10 <sup>7</sup>	1.4 X 10 <sup>7</sup>	-0.04
	20-25°C	1.5 X 10 <sup>7</sup>	2.4 X 10 <sup>7</sup>	0.20
<i>Pseudomonas aeruginosa</i>	2-8°C	8.1 X 10 <sup>6</sup>	6.2 X 10 <sup>6</sup>	-0.12
	20-25°C	9.2 X 10 <sup>6</sup>	2.0 X 10 <sup>6</sup>	1.34
<i>Salmonella enterica</i>	2-8°C	6.1 X 10 <sup>7</sup>	5.8 X 10 <sup>7</sup>	-0.02
	20-25°C	5.6 X 10 <sup>7</sup>	2.1 X 10 <sup>6</sup>	0.57
<i>Bacillus subtilis</i>	2-8°C	3.6 X 10 <sup>6</sup>	4.0 X 10 <sup>6</sup>	0.04
	20-25°C	4.6 X 10 <sup>6</sup>	1.6 X 10 <sup>7</sup>	0.54
<i>Vibrio parahaemolyticus</i>	2-8°C	9.8 X 10 <sup>6</sup>	8.9 X 10 <sup>6</sup>	-0.04
	20-25°C	9.8 X 10 <sup>6</sup>	8.8 X 10 <sup>6</sup>	-0.05
<i>Clostridium difficile</i>	2-8°C	1.2 X 10 <sup>7</sup>	1.0 X 10 <sup>7</sup>	-0.06
	20-25°C	1.1 X 10 <sup>7</sup>	9.5 X 10 <sup>6</sup>	-0.06
<i>Campylobacter jejuni</i>	2-8°C	5.8 X 10 <sup>7</sup>	5.0 X 10 <sup>7</sup>	-0.07
	20-25°C	4.0 X 10 <sup>7</sup>	3.5 X 10 <sup>7</sup>	-0.06
<i>Enterococcus faecalis</i>	2-8°C	2.3 X 10 <sup>7</sup>	2.1 X 10 <sup>7</sup>	-0.04
	20-25°C	2.2 X 10 <sup>7</sup>	1.8 X 10 <sup>7</sup>	-0.10
<i>Shigella dysenteriae</i>	2-8°C	2.2 X 10 <sup>7</sup>	1.4 X 10 <sup>7</sup>	-0.19
	20-25°C	2.4 X 10 <sup>7</sup>	5.1 X 10 <sup>6</sup>	-0.68

\*0.5 McFarland microorganism suspension diluted with C&S medium at 1:15

**Table 2. Representative Challenge Enteric Organism Recovery Results for Para-Fix C&S Medium Using the Swab Elution Method.**

Organism*	Hold Temperature	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 72 hrs	Average CFU's Recovered: Time 96 hrs	Average CFU's Recovered: Time 120 hrs	T=120 hrs Log reduction (-) or Log increase (+)
<i>Salmonella enterica</i>	2-8°C	2.7 X 10 <sup>2</sup>	2.9 X 10 <sup>2</sup>	3.0 X 10 <sup>2</sup>	2.0 X 10 <sup>2</sup>	-0.13
	20-25°C	3.2 X 10 <sup>2</sup>	**	**	**	N/A
<i>Vibrio parahaemolyticus</i>	2-8°C	2.2 X 10 <sup>2</sup>	1.6 X 10 <sup>2</sup>	6.3 X 10 <sup>2</sup>	6.8 X 10 <sup>2</sup>	+0.49
	20-25°C	2.5 X 10 <sup>2</sup>	**	**	**	N/A
<i>Escherichia coli</i>	2-8°C	1.6 X 10 <sup>2</sup>	8.9 X 10 <sup>1</sup>	1.3 X 10 <sup>2</sup>	9.4 X 10 <sup>1</sup>	-0.23
	20-25°C	1.0 X 10 <sup>2</sup>	6.8 X 10 <sup>2</sup>	5.4 X 10 <sup>2</sup>	7.6 X 10 <sup>2</sup>	+0.88

\*0.5 McFarland microorganism suspension diluted with fecal matrix and C&S medium at 1:2000

\*\* Too numerous to count

**Table 3. Representative Enteric Challenge Organism Recovery Results for Para-Fix C&S Medium using the Roll-Plate Method.**

Organism*	Hold Temperature	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 72 hrs	Average CFU's Recovered: Time 96 hrs	Average CFU's Recovered: Time 120 hrs	T=120 hrs Log reduction (-) or Log increase (+)
<i>Salmonella enterica</i>	2-8°C	190	192	162	97	-0.29
	20-25°C <sup>a</sup>	64	**	**	**	N/A
<i>Vibrio parahaemolyticus</i>	2-8°C	220	160	63	68	-0.51
	20-25°C	130	**	**	**	N/A
<i>Escherichia coli</i>	2-8°C	110	48	83	71	-0.19
	20-25°C	70	**	**	**	N/A

\* 0.5 McFarland microorganism suspension diluted with fecal matrix and C&S medium to 2x10<sup>4</sup> unless noted,

<sup>a</sup>diluted 2 X 10<sup>5</sup>

\*\* Too numerous to count

## Overgrowth Evaluation:

No over growth limit is defined by CLSI M40-A2 at room temperature (20-25°C) for the Swab Elution or Roll-Plate Methods because most commercial transport media cannot control for it. Para-Fix C&S is no different; overgrowth at room temperature (20-25°C) was recorded as Too Numerous To Count (TNTC) for the studies conducted with fecal matrix.

*a. Precision/Reproducibility:*

Not applicable.

*b. Linearity/assay reportable range:*

Not applicable.

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

**Shelf life:** The shelf life for Para-Fix C&S vials is 18 months after the date of manufacture. The stability tests were performed on 3 lots of Para-Fix C&S Medium up to 18 months of storage.

**pH Stability:** The pH value of Para-Fix C&S Medium up to 18 months of storage was 7.08 to 7.83.

**Sterilization:** Para-Fix C&S Medium vials are not sold as sterile, nor are they intended to be sterilized by the user. These vials are single use devices that do not require cleaning by the operator. Although there is no sterility claim, the manufacturing process includes treatment of finished vials in a steam chamber for 30 minutes to eliminate bioburden.

*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 done to determine the ability of Para-Fix C&S Medium to maintain viability of different strains of intestinal enteric bacteria with and without fecal matrix. Para-Fix C&S Medium showed recovery of representative bacteria from fecal matrix within the acceptance criteria recommended in CLSI-M40-A2 and similar to the predicate device. (See above under Performance Characteristics).

*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 it 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.