

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

A. 510(k) Number: K082472

B. Purpose for Submission: Initial Premarket Notification

C. Measurand: Preservation of viability and infectivity of viral specimens for viral culture

D. Type of Device: Transport and Culture Medium Devices

E. Applicant: Medical Wire & Equipment Company (Bath) Ltd.

F. Proprietary and Established Names: Virocult[®] Virus Collection and Transport System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LIO [Device, Specimen Collection]	Class I	Microbiological specimen collection and transport device 21 CFR 866.2900	Microbiology (83)

H. Intended Use:

Medical Wire & Equipment Virocult[®] Virus Collection and Transport System is intended to preserve the viability and infectivity of viral specimens for viral culture after their collection and during transport from the collection site to the testing laboratory. Virocult specimens are processed using standard clinical laboratory operating procedures for viral and cell culture.

3) Special conditions for use statement(s): For Prescription Use Only

4) Special instrument requirements: No special instruments are required for the device

I. Device Description: Each Virocult[®] device comprises a sterile peel pouch containing a rayon-tipped swab used to collect the sample and a tube containing an open cell polyurethane pad soaked with Virocult[®] virus transport medium. After sampling, the swab applicator is placed inside the tube, where the bud is bathed with the liquid from the foam pad.

Virocult[®] medium consists of a phosphate-buffered balanced salt solution, glucose, lactalbumin hydrolysate to stabilise the virus particles, and antibiotics to inhibit the growth of other microorganisms that may be present in the clinical specimen.

J. Substantial Equivalence Information:

a) Predicate device name (s):

Becton Dickinson Viral Culturette™
Copan Viral Transystem™

b) Predicate K numbers (s):

K800832

K001780

Technological characteristics and substantial equivalence

Medical Wire & Equipment's Virocult® products are substantially equivalent in design, intended use, and overall function to other FDA cleared commercially distributed products used for the collection and transport of viruses. Specifically Virocult® products are equivalent to the Becton Dickinson Viral Culturette (K800832), and the Copan Viral Transystem (K001780).

Medical Wire & Equipment's Virocult® device is a sterile, single use device intended for use in the collection, transport, and preservation of microbial specimens for viral culture. The candidate and predicate devices are equivalent in design and function in that single applicators are used for collection of the specimen and the swab applicator is then inserted into a tube containing medium for transport and preservation. Virocult® is are offered in a collection kit formats with specimen collection swabs.

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

1. CLSI. 'Quality Control of Microbiological Transport Systems'; *Approved Standard M40-A*. CLSI (formerly NCCLS) document M40-A [ISBN 1-56238-520-8]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.
2. Reed, L. J., and H. Muench. 1938. *A simple method of estimating fifty percent endpoints*. Am. J. Hyg. **27**:493-497.

L. Test Principle: Virocult® tubes contain a liquid medium to keep the specimen moist, and to maintain any viruses in a viable condition until they can be investigated at the laboratory by viral culture. The liquid medium consists of a balanced salt solution for maintaining osmotic pressure within physiological limits and phosphate buffers to stabilize the pH of the medium. The phosphate-buffered balanced salt solution contains glucose, lactalbumin hydrolysate to stabilize the virus particles, and antibiotics to inhibit the growth of other microorganisms that may be present in the clinical specimen.

M. Performance Characteristics (if/when applicable): The studies were conducted to evaluate the performance characteristics of the Medical Wire Virocult® using pure laboratory virus strains spiked onto a swab.

Recovery Studies: Virocult virus transport swabs were tested in accordance with CLSI (NCCLS) 'Quality Control of Microbiological Transport Systems; Approved Standard M40-A (2003). Known concentrations of Herpes simplex virus type 2 (HSV 2) and Adenovirus type 3 were inoculated, in triplicate, into the Virocult[®] swabs of different lot numbers and expiration dates and held at 22°C and 4°C. The swabs were sampled every day for four days (24 to 96 hours as per the standard). The results showed the Virocult device maintains the viability of virus as set out in the standard.

Hep-2 and A549 cell lines used routinely in the laboratory were utilised as the cell lines to support the growth of Adenovirus and HSV 2. Fresh working lots of a low passage number (<15) were split into tube cultures to have a confluent monolayer after 24 hours. Adenovirus type 3, ATCC VR-3 and HSV 2, ATCC VR-734 were obtained from the American Type Culture Collection and used to assess the performance of the swabs.

Methods: The viruses were inoculated into a flask containing a confluent monolayer of Hep-2 for Adenovirus 3 and A549 for HSV 2. Once the most of the monolayer showed CPE, the virus was harvested and stored for use as the stock suspension of virus. Stock suspensions of Adenovirus 3 and HSV type 2 were serially diluted using 10-fold dilutions and, in triplicate, inoculated into fresh Hep-2 and A549 tube cultures. Once CPE was obtained, the inoculum for 50,000 TCID/ml was calculated as originally described by Reed and Muench (1938, Am. J. Hyg. **27**:493-497). For both viruses this was calculated to be 0.3 ml of stock suspension. The swabs were inoculated, in triplicate, with 0.3 ml of stock suspension of virus, mixed thoroughly with the medium in the device and held at either 4°C or 22°C. On each appropriate day, 0.2 ml was withdrawn, inoculated into the appropriate tube culture and observed for CPE. The tubes were removed once ++++ CPE (100%) was observed. To compare using a much lower virus titer, the procedure was also carried out using an inoculum of stock virus into the swabs of 10,000 TCID/ml.

Results: The studies showed that Virocult allowed the recovery of viable Adenovirus Type 3 and HSV 2 viruses for at least 96 hours after inoculation at both 4°C and 22°C. Adenovirus Type 3 and HSV 2 had viral titers of 50,000 and 10,000 TCID/ml. respectively. Stability studies were performed on Medical Wire & Equipment's Virocult[®] products to support performance for a 12-month expiration date. Recovery testing, pH testing, toxicity testing and visual inspection were performed which demonstrated the stability of Medical Wire & Equipment's Virocult[®] over its 12 month shelf life.

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.