

490, rue de la Couronne, Québec (Québec) G1K 9A9

Téléphone : (418) 654-INRS (4677)  
 Télécopieur : (418) 654-2525  
 Courriel : Communications

**Medical Systems**

Company Name

60 Dundas Street East, Suite 104

Address

Mississauga / Ontario / L5A 1W0

City Province Postal Code

(905) 270-9645 / (905) 270-6993 / Mr. Stephen Romaniuk

Telephone / Fax / Client

**Medical Valves**

Product

220200K to 220200P / 246S10

Lot # / Purchase Order

03-26-02 / S / 04-23-02

Received Quantity Processed

5747

Analysis #

**Analyses Microbiologiques**

- 8110 Mesophilic aerobic bacteria enumeration
- 8488 Staph, aureus coagulase pos. enumeration
- 8654 Fecal coliforms detection, E. coli
- 8014 Total coliforms detection MPN
- 8838 Yeast and mold enumeration
- 8922 Bacterial identification
- 8351 Anaerobic bacteria enumeration
- 8768 Fecat streptococcus enumeration
- 8054 Pseudomonas detection
- 8658 Yeast and mold identification
- 8615 Listeria monocyrogenes detection
- 8888 Microbial challenge of medical valves

**Results**


Note: Results are only valid for material as received in our laboratories.

April 30, 2002

Chantal Thibault

Guy McSween

Service de Microbiologic Appliquee de  
DINRS-IAF

## Objective

To assess the risk of viral contamination from patient's blood during radiological studies and the integrity of the one-way valve in the prevention of back flow of potentially contaminated solutions into sterile multiple-use intravenous contrast solution.

## Material and Method

1. This test was performed in addition to test #5557 of December 2001. The study apparatus was modified, introducing a syringe sampling site upstream from the one-way valve instead of a three-way valve. Also as a modification from previous protocol, tubing down stream from the one way valve was not filled with the phage suspension but with the sterile saline.
2. Test procedures were performed to assess biologic characteristics of the checked valves as described in the protocol developed by the department of Medical Engineering at the Toronto Hospital and described in Health Canada's Communicable Disease Report – Volume 22-4.15 February 1996.
3. Valves were assembled, sterilised and provided by Medicis Medical Supplies Inc. Product was described as Medical Systems 3 Gang Manifold 3G3234 and lot number of the 5 items were 220200-K, L, M, N & P.
4. Bags of 250ml sterile 0.9% sodium chloride injection solution were from Baxter, lot WOK21B3, exp. May 02.
5. Test was performed using a staphylococcal bacteriophage (Group II, page 55). This bacteriophage and the host bacteria *Staphylococcus aureus* 27696 were obtained from American Type Culture Collection (ATCC). The phage was propagated and titrated using ATCC procedures.
6. Upstream and down stream from the one-way valve, the system was filled with sterile 0.9% saline.
7. Bacteriophage contained in a 60ml syringe came in contact with the sterile saline introduced in the manifold (see annexed figure, protocol provided by Medical Systems and prepared by investigators Riley, Wobeser and Yao).
8. The mixture was allowed to equilibrate in the manifold system over 1 hour, with one millilitre sample taken upstream from the one-way valve with no pressure and three others collected at the same site after a 1 minute pressure at 20 minute intervals.
9. Pressure of 10 psi was applied at the syringe plunger by depressing the plunger by 10 cc with the syringe containing 30cc of liquid and 20 cc of air.
10. Aliquots of 1 ml were obtained from the syringe sampling valve just proximal to the one-way valve. To obtain these samples, it was necessary to open the incoming upstream saline solution since all the system was closed and tubes were not compressible.
11. Fluid samples were dropped onto 5 propagating lawn of the fresh *Staphylococcus aureus* strain, and the plates were ready for lysis after an overnight incubation at 37 degrees Celsius.

12. Positive samples were obtained before and after all the pressure challenge experiments to ensure viability of the bacteriophage and the estimate its population throughout the entire period of the testing.

13. Negative samples containing only the bacteria lawn were also produced and purity of the bacterial strain was also assessed by streaking on agar plate.

## Results

**Table 1.** Plage forming units of phage upstream the one-way valve.

Time (min) / pressure #	211100A	21100B	211100C	211100E	211100F
0 / 0	<1/ml	<1/ml	<1/ml	<1/ml	<1/ml
20 / 1	<1/ml	<1/ml	<1/ml	<1/ml	<1/ml
40 / 2	<1/ml	<1/ml	<1/ml	<1/ml	<1/ml
60 / 3	<1/ml	<1/ml	<1/ml	<1/ml	<1/ml

**Table 3.** Plage forming units of phase in positive and negative controls

	Before Challenge	After Challenge
Page / ml solution	$1.4 \times 10^{16}$	$1.0 \times 10^{10}$
Negative Control	<1/ml	<1/ml

April 30, 2002

Chantal Thibault

---

Guy McSween

---

Service de Microbiologie Appliquée de  
DINRS-IAF