



Epidemiology Section
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
1600 Clifton Rd., MS A35
Atlanta, GA 30333

CDC test results of VapoTherm gas transfer cartridges and VapoTherm 2000i respiratory therapy device.

Matthew J. Arduino, Dr.P.H., Lead Microbiologist, Environmental and Applied Microbiology Section, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention

Introduction:

This report summarizes the results of microbiological testing completed at the CDC of unopened VapoTherm gas-transfer cartridges and of a VapoTherm machine that was subject to the newly developed disinfection protocol. This summary includes all information available as of September 1, 2006.

Methods: Testing of unopened cartridges

CDC has now tested 26 unopened VapoTherm high-flow and low-flow gas transfer cartridges from 13 different lots. This includes samples from lots where other un-opened cartridges had grown *Ralstonia* in tests done at other facilities. All cartridges have been cultured using one or more of the following methods:

1. Twenty –six unopened cartridges were cultured by introducing sterile phosphate buffered rinse solution, water, tryptic soy broth or Dey-Engley neutralizing broth into one air port and collecting the eluent from the other end. Eluents were then cultured using a membrane filtration method.
2. Three cartridges from one lot were cultured by introducing tryptic soy broth into one air port then capping both air ports to leave fluid in cartridges. The cartridges subjected to this test were from a lot where other un-opened cartridges were reportedly contaminated with *Ralstonia mannitolytica*. These cartridges were then agitated at room temperature for 7 days, after which the fluid was removed and cultured using a membrane filtration method.
3. One cartridge from a lot where other un-opened cartridges had grown *R. mannitolytica* was subjected to an additional test where sterile tubing was connected to the air-ports and sterile water was circulated through the cartridge for 28 days. The fluid was then removed and cultured using a membrane filtration method.

Results:

CDC has not recovered any gram-negative organisms, including *Ralstonia* species from any of the un-opened VapoTherm gas transfer cartridges. Cultures of one cartridge grew a small number of *Bacillus* species that most likely represented extrinsic contamination.



Epidemiology Section
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
1600 Clifton Rd., MS A35
Atlanta, GA 30333

The contamination may have occurred during necessary manipulation to fill the cartridges with nutrient broth and cap the ends.

Methods: Vapotherm 2000i Water Circuit Testing

Reprocessing of a previously contaminated machine with 200 ppm liquid chlorine dioxide by a hospital in Philadelphia failed to eradicate *Ralstonia* spp. The machine was subsequently disinfected with a new protocol utilizing 1000 ppm liquid chlorine dioxide by Vapotherm, Inc. and sent to CDC for bioburden testing. The machine was set-up to run using the by-pass tubing provided by Vapotherm in place of the cartridge. Our understanding is that this set up allows water to run through the entire fluid path of the machine. The machine was run at 37° for 30 days. Samples of the circulating water were obtained on days: 0, 3, 7, 14, 21 and 30 and were cultured using the membrane filtration method. Thirty days was chosen as the end-point as it is the maximum duration that a Vapotherm machine may be in use without reprocessing.

Results:

Ralstonia was not recovered from the samples of the water circulating through the machine. *Methylobacterium* was recovered from 0, 3, and 7 day samples at low levels (<10 CFU/mL); no bacteria, (including *Methylobacterium* species) were recovered after day 7.

Methods: Vapotherm 2000i Air Circuit Testing

Following the 30 days of continuous operation with the by-pass tubing, the machine was disinfected by CDC staff using the companies recommended routine reprocessing protocol with the Control III disinfectant (quaternary ammonium compound). A previously unused filter cartridge was placed in the machine and patient tubing, minus the nasal cannula, was connected to the machine. The distal end of the tubing was placed into a sterile container, the machine was turned on and vapor was collected for culture. Samples of vapor were obtained on days: 0, 7, 14, 21 and 30 and were cultured using the membrane filtration method.

Results

Samples of the vapor cultured from the machine following routine disinfection yielded no microorganisms in any sample.

Interpretation:

Cartridge testing: CDC has not recovered gram-negative organisms, including *Ralstonia*, from any of the 26 un-opened cartridges that were tested using a variety of methods that should have detected even very low levels of organisms. It must be noted that we have tested a very small number of cartridges compared to the overall number of cartridges produced and hence our results cannot definitively exclude the possibility of intermittent intrinsic contamination of the cartridges.



Epidemiology Section
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
1600 Clifton Rd., MS A35
Atlanta, GA 30333

Machine testing: The machine sent to CDC for testing was known to be contaminated with *Ralstonia*. *Ralstonia* was recovered from this machine after it had been treated with 200 ppm of liquid chlorine dioxide in a culture obtained at a hospital and sent to CDC for processing. After treatment with 1000 ppm of liquid chlorine dioxide, *Ralstonia* was not recovered from the device after 30 days of continuous operation at CDC. We recovered *Methylobacterium* in low concentrations from cultures taken earlier in the 30 day monitoring period at CDC. *Methylobacterium* is a pink pigmented gram-negative organism commonly found in water, and occasionally may be found in the healthcare setting. *Methylobacterium* was not found in previous cultures of this machine. The significance of this finding is not known. Following routine disinfection, no microorganisms were recovered from cultures of the vapor condensate collected during a 30 day period of continuous operation of the unit.

The results of this testing must also be extrapolated with caution as this test was performed once on only one machine and follow-up data is only available for 60 days.