

# Study: More Than 1 in 3 Heater-Cooler Devices Contaminated

For 15% of samples, bacteria and fungi levels were off the charts

[Crystal Phend](#), June 15, 2017

Testing of heater-cooler units used in open heart surgery often turned up *Mycobacterium chimaera* -- an organism linked to fatal patient infections -- as well other bacteria and fungi, despite decontamination attempts.

Among samples sent to one specialty testing laboratory from 89 heater-cooler devices at 23 centers, 51% tested positive for nontuberculous mycobacteria and 37% were positive specifically for *M. chimaera*.

Four units were also colonized with *Legionella*, John Rihs, vice president of laboratory services at Special Pathogens Laboratory in Pittsburgh, reported at the [Association for Professionals in Infection Control and Epidemiology](#) meeting in Portland.

Of the 653 samples cultured from July 2015 through December 2016, 15% were so contaminated with bacteria and fungi, with heterotrophic plate counts up to five million CFU/mL, that initial results were uninterpretable.

The other species recovered from these units, such as *M. abscessus/chelonae* and *M. goodii*, have not been associated with disease in this setting, Rihs said in an interview (which was monitored by conference media relations).

"But if it's raining down *M. chimaera* over the surgical field, it's likely raining down those too," Rihs told *MedPage Today*, noting that such infections have

probably occurred without being connected to the devices.

Nontuberculous mycobacteria are ubiquitous in the environment and particularly endemic in plumbing but typically grow slowly, such that patients may not present with problems for years after the surgery during which infection occurred.

The problem with *M. chimaera* in heater-cooler units emerged in 2015 with case reports from Europe, subsequently found in many cases to be tied to the popular LiveNova/Sorin 3T devices that had been contaminated at the manufacturing plant during testing and shipped wet to hospitals around the world.

However, [all commercially-available heater-cooler devices](#) have had reports of contamination sent to the FDA through mandatory or voluntary reporting.

Once colonized and a biofilm forms, it's difficult to eradicate, Rihs noted.

Eleven of the units originally clear of *M. chimaera* became positive later in his study, and some decontaminated devices then tested positive again months later.

The [FDA has warned](#) against using contaminated 3T devices and suggested moving away from those manufactured before the source contamination was eradicated. But it didn't recommend testing all machines for *M. chimaera* because false negative rates are high.

Relatively few labs can do the water sample testing required, Rihs said. Still, given the high contamination rates, he called the FDA stance on routine testing "a little disturbing."

"The only way you're going to know these units are not colonized is to do routine testing," he said. And even with updated instructions for use and

cleaning to help reduce risk, "without monitoring these microbiologically, you'll never know if a break in [decontamination] technique has occurred."

Rihs disclosed no relevant relationships with industry.