



Health service testing of heater cooler units used in cardiac surgery

Revised December 2017

Following the initial round(s) of microbiological testing of water samples from heater cooler units undertaken by Victorian hospitals in 2016, a regular testing schedule was implemented, commencing in 2017. This document describes the schedule and details of the testing and sampling processes.

Testing Schedule

Hospitals are advised to conduct three monthly testing of water samples from all heater cooler units in use in accordance with the schedule below. Each hospital will be required to submit water samples to Victoria's Public Health Laboratory, the Microbiological Diagnostic Unit (MDU), to test for non-tuberculous mycobacteria and for a heterotrophic plate count (HPC) to assess water quality.

Month	Test no.	Health services
January	1	Alfred Health, Monash Health, St Vincent's Health, Cabrini Private, Knox Private, St John of God Geelong
February	1	Austin Health, the Royal Children's Hospital, Epworth Eastern, Melbourne Private, St Vincent's Private, Warringal Private
March	1	Barwon Health, the Royal Melbourne Hospital, Epworth Richmond, Peninsula Private, the Valley Private
April	2	Alfred Health, Monash Health, St Vincent's Health, Cabrini Private, Knox Private, St John of God Geelong
May	2	Austin Health, the Royal Children's Hospital, Epworth Eastern, Melbourne Private, St Vincent's Private, Warringal Private

June	2	Barwon Health, the Royal Melbourne Hospital, Epworth Richmond, Peninsula Private, the Valley Private
July	3	Alfred Health, Monash Health, St Vincent's Health, Cabrini Private, Knox Private, St John of God Geelong
August	3	Austin Health, the Royal Children's Hospital, Epworth Eastern, Melbourne Private, St Vincent's Private, Warringal Private
September	3	Barwon Health, the Royal Melbourne Hospital, Epworth Richmond, Peninsula Private, the Valley Private
October	4	Alfred Health, Monash Health, St Vincent's Health, Cabrini Private, Knox Private, St John of God Geelong
November	4	Austin Health, the Royal Children's Hospital, Epworth Eastern, Melbourne Private, St Vincent's Private, Warringal Private
December	4	Barwon Health, the Royal Melbourne Hospital, Epworth Richmond, Peninsula Private, the Valley Private

Sampling and testing

The two tests undertaken on heater cooler unit water samples are:

1. Mycobacteria cultures (results available in approximately 8-9 weeks) to test for the presence of *Mycobacterium chimaera* and other non-tuberculous mycobacteria, and
2. A heterotrophic plate count (HPC, results available in 3-5 days) as a surrogate measure of cleanliness/overall water quality.

Frequency of testing

Until further notice, the department is continuing to advise hospitals to undertake testing of all heater cooler units in use at their facility every three months, according to the schedule outlined in this document. If it is your hospital's designated month for testing, this can be conducted on any day during the designated month. Some hospitals with more than one heater cooler unit have advised a preference for staggering the testing of their units by up to a month. These hospitals may wish to therefore use the sampling schedule as a prompt to commence their testing.

The frequency of testing is based on national recommendations by the Therapeutic Goods Administration and the Australian Commission on Safety and Quality in Health Care.

Sampling procedure

The sampling procedure recommended is that described by Public Health England, with key points as follows:

- Units should be connected and running for at least five minutes before water samples are taken
- Ideally sampling should take place just prior to the machine undergoing its disinfection cycle
- Water should be sampled from both the 'patient' circuit and the 'cardioplegia' circuit
- Sample volume of 100 mL (ie, 100 mL from each circuit)
- If not processed immediately, water should be stored between 2°C and 8°C for up to 24 hours.

Labelling

Ensure that samples are correctly labelled, including date, hospital name, heater cooler unit serial number, sample site (ie, which circuit) and details of a designated point of contact for results.

Where hospitals use/operate multiple heater cooler units, it is important that the serial number of each heater cooler unit being tested is included on the label.

Furthermore, where a private perfusion services provider is submitting heater cooler unit water samples, please ensure that the health service where the heater cooler unit is being used is included on the label and not just the name of the service provider.

These measures will avoid any confusion and assist with maintaining accurate and up to date statewide records on heater cooler unit testing history.

Responding to test results

If the results test positive for *Mycobacterium chimaera* or other non-tuberculous mycobacteria:

- do not use the heater cooler unit
- report positive results to the department, the TGA and the manufacturer as soon as possible
- contact the manufacturer as soon as possible to discuss decontamination. LivaNova Australia Pty Ltd provides a decontamination service for Sorin heater cooler units that are less than seven years old. Note that this may be a lengthy process depending on the manufacturer's workload constraints. Follow up testing of samples from decontaminated heater cooler units are currently subject to an 8 week wait for confirmation of negative mycobacterial cultures.
- access a backup or loan heater cooler unit if possible.

If the results are negative for mycobacteria but the heterotrophic plate count (HPC) is high:

- disinfect the heater cooler unit prior to further use and re-test as per the manufacturer's instructions
- seek advice from the manufacturer on dealing with persistently high HPC results.
- the department does not have a specific recommendation regarding maximum allowable HPC measurements. However, Public Health England's advice may be considered a useful point of reference, with maximum colony counts set at 100/mL at 22°C and 20/mL at 37°C. (Note that MDU conduct HPC measurements at 37°C)

All microbiological test results from MDU (ie, for *Mycobacterium chimaera* and HPC) are to be reported to the department until further notice, regardless of whether these are positive or negative. At this time, the department does not require results of any additional HPC tests undertaken by local health service laboratories.

It is advised that health services develop a local contingency plan for the ongoing provision of cardiac surgery in the event of a positive test result for *Mycobacterium chimaera*. This may include sourcing a back-up or loan heater cooler unit and/or working with other health services. If you think the provision of cardiac surgery at your health service will be affected, please contact the department. The department will provide further information on system level contingency plans if and when required.

Costs

The cost of testing by MDU is anticipated to be \$230 per sample. LivaNova Australia Pty Ltd is currently charging health services \$6,400 to decontaminate affected Sorin heater cooler units.

Contacts

Safer Care Victoria

Jonathan Prescott, Manager, Clinical Safety & Monitoring
Ph: (03) 9096 7258, email: jonathan.prescott@safercare.vic.gov.au

Sampling and testing inquiries

Microbiological Diagnostic Unit Public Health Laboratory,
University of Melbourne, Parkville VIC
Ph: (03) 8344 5701

References

Australian Commission on Safety and Quality in Health Care, February 2017. National Infection Control Guidance Non-tuberculous Mycobacterium associated with heater-cooler devices.

<https://www.safetyandquality.gov.au/publications/national-infection-control-guidance-for-non-tuberculous-mycobacterium-associated-with-heater-cooler-devices/>

Public Health England, updated November 2017. Mycobacterial Infections Associated with Heater Cooler Units.
<https://www.gov.uk/government/collections/mycobacterial-infections-associated-with-heater-cooler-units>

Therapeutic Goods Administration, updated November 2017. Infections associated with heater cooler devices.
<https://www.tga.gov.au/alert/infections-associated-heater-cooler-devices>

Investigations are ongoing and this guidance may be revised. Updates will be available at: <https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/infection-prevention/healthcare-associated-infection>