Clinical Laboratory Testing for *Mycobacterium chimaera* (Updated 1/24/17)

On October 13, 2016 the CDC released a Health Alert Network (HAN00397) regarding the potential contamination of heater-cooler devices [Stöckert 3T heater-cooler, LivaNova PLC] used during cardiac surgery with *Mycobacterium chimaera*. Health departments are being asked to communicate with healthcare facilities that perform cardiac surgery using heater-cooler devices about the risk of *M. chimaera* infection associated with these devices and to be prepared to assist with further investigations.

Public Health Laboratories may have already received inquiries on the best approaches for testing for *M. chimaera.* From the laboratory perspective, identification of *M. chimaera* can be quite difficult. *M. chimaera* is part of the *Mycobacterium avium* complex (MAC) and is very similar to *M. intracellulare* with only a single nucleotide difference in 16s rDNA (base pair difference between *M. intracellulare* T450C and *M. chimaera*).[1, 2]

Environmental, water and air sampling and monitoring is challenging due to issues with specimen collection and the possibility of false negatives. Laboratories should refer to information provided by the manufacturer of the heater-cooler units and FDA for appropriate monitoring.

Methods to Identify *M. chimaera*

Commonly used identification methods for *Mycobacterium* such as HPLC, MALDI-TOF[3] and Accuprobe[4] are able to identify to the *M. avium* complex level or to the species level *M. avium* or *M. intracellulare* but they are unable to identify *M. chimaera*. Those commonly used method can be used to perform the initial identification but then suspect cases that are positive for the *M. avium* complex or *M. intracellulare* would need to be triaged to a sequencing based method, which is currently the only method that can discriminate between *M. chimaera and M. intracellulare.* Of note, there are several different sequencing methods published (see the references below) including 16s rDNA, *rpoB*, internal transcribed spacer (ITS) or whole genome sequencing (WGS) to distinguish between the two species.

Resources for laboratories interested in performing their own sequencing:

Wallace RJ, et al. Absence of *Mycobacterium intracellulare* and presence of *Mycobacterium chimaera* in household water and biofilm samples of patients in the United States with *Mycobacterium avium* complex respiratory disease. J Clin Micro. 2013. Jun;51(6):1747-52. Available at: https://www.ncbi.nlm.nih.gov/pubmed/23536397

Bills ND, et al. Molecular identification of *Mycobacterium chimaera* as a cause of infection in a patient with chronic obstructive pulmonary disease. 2009. Diagn Microbiol Infect Dis. Mar;63(3)292-5. Available at: https://www.ncbi.nlm.nih.gov/pubmed/19216940

Hasan NA, et al. Complete Genome Sequence of Mycobacterium chimaera Strain AH16. 2016 (Genome Announcements; Accepted).

Resources for laboratories interested in using a reference laboratory:

If your laboratory is interested in using a reference laboratory we suggest you contact your local or state public health laboratory to assist you in identifying a laboratory that utilizes a methodology sufficient to identify *M. chimaera* specifically.

FDA Resources

Update: *Mycobacterium chimaera* infections associated with LivaNova PLC (formerly Sorin Group Deutschland GmBH) Stöckert 3T Heater-Cooler System: FDA Safety Communication. October 13, 2016. Washington, DC: US Department of Health and Human Services, Food and Drug Administration; 2016. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm

Nontuberculous mycobacterium (NTM) infections associated with heater-cooler devices (HCD) during cardiothoracic surgery. Gaithersburg, MD: FDA Circulatory System Devices Panel of the Medical Devices Advisory Committee; June 2–3, 2016. Available at: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm485091.htm

CDC Resources

Perkins KM, et al. Notes from the Field: Mycobacterium chimaera Contamination of Heater-Cooler Devices Used in Cardiac Surgery — United States. 2016. MMWR 65(40):1117-8. Available at: https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w

Non-tuberculous Mycobacterium (NTM) Infections and Heater-Cooler Devices: Interim Practical Guidance: Updated October 27, 2016. Available at: http://www.cdc.gov/HAI/pdfs/outbreaks/CDC-Notice-Heater-Cooler-Units-final-clean.pdf

Interim Guide for the Identification of Possible Cases of Nontuberculous Mycobacterium Infections Associated with Exposure to Heater-Cooler Units. May 13, 2016. Available at: http://www.cdc.gov/hai/pdfs/outbreaks/Guide-for-Case-Finding.pdf

Contaminated Heater-Cooler Devices. Available at: https://www.cdc.gov/hai/outbreaks/heater-cooler.html

References

1. Schweickert B, et al. Occurrence and clinical relevance of Mycobacterium chimaera sp. nov., Germany. Emerg Infect Dis. 2008.14:1443–1446. Available at: https://www.ncbi.nlm.nih.gov/pubmed/18760016
2. Tortoli E, et al. Proposal to elevate the genetic variant MAC-A, included in the Mycobacterium avium complex, to species rank as Mycobacterium chimaera sp. nov. Int J Syst Evol Microbiol 2004. 54:1277–1285. Available at: https://www.ncbi.nlm.nih.gov/pubmed/15280303
3. Buckwalter SP et al. Evaluation of Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry for Identification of Mycobacterium species, Nocardia species, and Other Aerobic Actinomycetes. J Clin Microbiol. 2016 Feb;54(2):376-84. Available at: http://jcm.asm.org/content/54/2/376.full.pdf
4. Tortoli E, et al. Commercial DNA probes for mycobacteria incorrectly identify a number of less frequently encountered species. 2010. J Clin Microbiol. Jan;48(1):307-10. Available at: https://www.ncbi.nlm.nih.gov/pubmed/19906898

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